Sueño – Sleep Habits in HCHS

Reading Center Procedures

Version 4.0
March 20, 2014

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A. RECEIVING FILES FROM FIELD SITES

Zipped files received from field sites should be unzipped and organized within the Sueño database (\\Rfa01\bwh-sleepepi\projects\src\sueno). It is important that all files received be carefully labeled according to the procedure below. Confirm that sites have properly labeled all files (original zipped file, Actigraphy file and Daily Sleep Log) with the same subject ID and contact occasion. If this is not the case, delete the received files and ask sites to resend the zipped file with proper labeling.

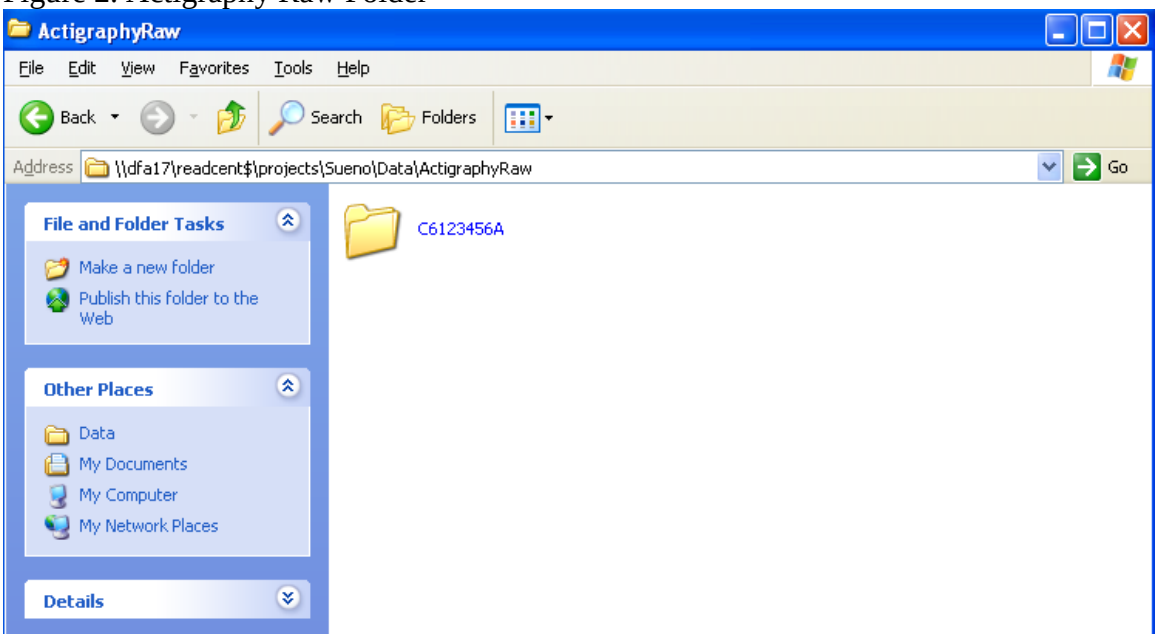
1. **Receiving Files:** Zipped files labeled with a subject ID number will be sent from Field Sites to the Reading Center.
    a. Open the folder labeled **Sueño > Data > Incoming**
    b. New zipped files will appear in the Incoming folder twice daily (noon and 11:00pm).
2. **Unzipping Files:**
    a. Make sure a copy of WinRAR, WinZip or another zipping program has been downloaded.
    b. Double click on the zipped file in order to open the file in a zipping program.
    c. Click on the **Extract to** icon. Click **OK**. Enter the encryption password **sueno321** and click **OK**. Unzipped contents should appear in the **Incoming folder**.

Figure 1. Unzipping Files

    d. The extracted Actigraphy file and the Daily Sleep Log should be placed in a folder labeled with the subject ID and the contact occasion (A or B) and this folder should be moved to the **ActigraphyRaw** folder. The zipped file should be moved to the **ActigraphyZipFiles** folder (see below).

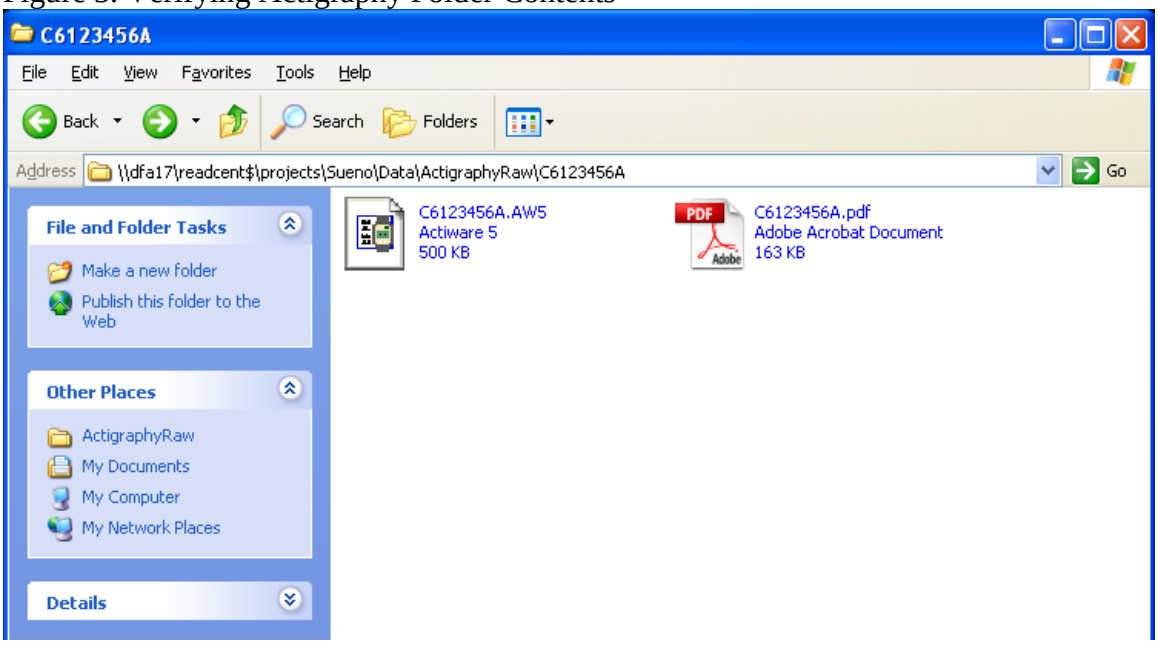
ActigraphyRaw Folder: This folder should contain a folder labeled with the subject ID and contact occasion (ex: C6123456A).

Figure 2. Actigraphy Raw Folder



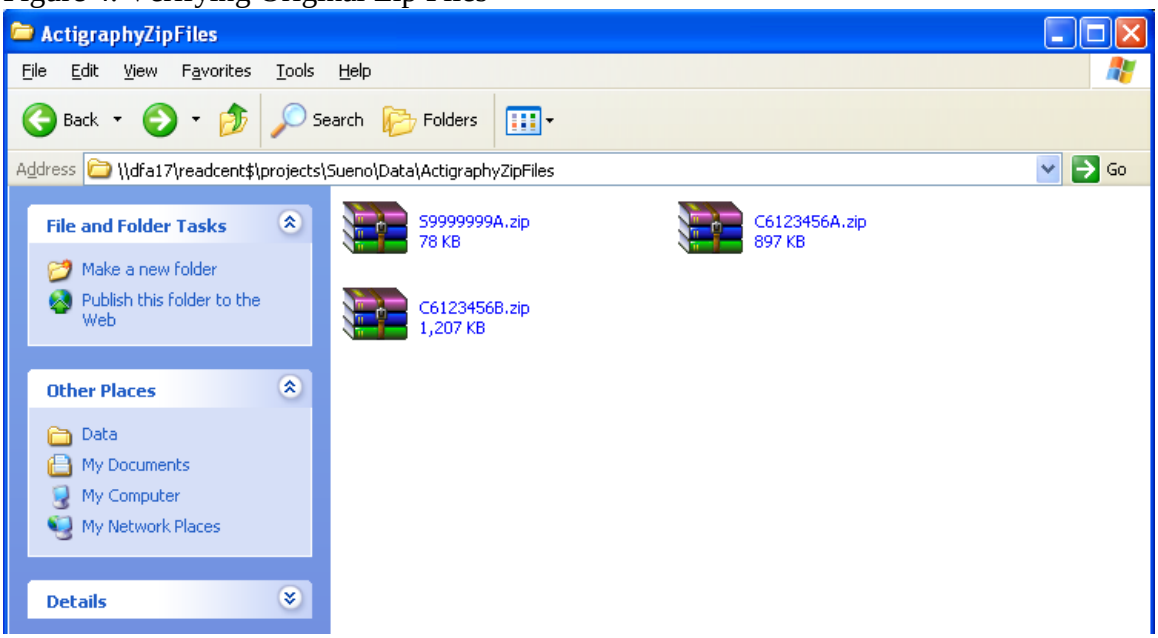
Subject ID + Contact Occasion Folder: This folder, within the ActigraphyRaw folder, should contain an .AW5 file (Actigraphy file) containing the actogram along with a scanned copy of the Daily Sleep Log.

Figure 3. Verifying Actigraphy Folder Contents



ActigraphyZipFiles Folder: This folder should contain the original zipped file received.

Figure 4. Verifying Original Zip Files



3. **Verify Match:**
    a. Each subject is given an ID that begins with the capitalized first letter of the site name followed by 7 digits (example: C6123456). The first letter should be B, C, M, or S (B: Bronx, C: Chicago, M: Miami, S: San Diego). Confirm that the files for the actogram and the Daily Sleep Log are labeled with the same subject ID and contact occasion.
    b. If files are not in this format (same subject ID and contact occasion), delete files and ask the field site to resend files clearly labeled with the same subject ID and contact occasion.
    c. If a subject failed to return a Daily Sleep Log or the log was left blank by the subject, there should be a blank Daily Sleep Log present. Encourage the Field Site staff to enter the participant ID, contact occasion and dates in the allotted portion of every page in the Daily Sleep Log.
    d. If there is no Daily Sleep Log present, delete files and contact the field site from which the zipped file was sent. Ask the site to resubmit the zipped file with both an actogram and a Daily Sleep Log. ***Do not*** assume that the absence of a Daily Sleep Log means the subject left the log blank.

B. QUALITY CHECK

The aim of this check is to quickly determine whether participants need to be contacted for a repeat study. Open the participant's Actigraphy file and adjust settings in order to determine whether the received Actigraphy file is of sufficient quality. Insufficient quality Actigraphy files are those that have **fewer than 5 days of valid data** either because there were fewer than 5 days recorded or because there were fewer than 5 included days after considering the exclusion criteria below (see B.2.a). A **day** is defined on the actogram based on the pre-set "Actogram Start Hour" under the "Analysis" menu, normally from 12:00:00 pm to 11:59:30 am. If the file is

determined to be of insufficient quality, contact the Field Center as soon as possible and follow procedures outlines in section B.3.

Note: The Start Hour is set to 12:00 pm except for the few cases when a 12:00 pm start time would create a ripple effect, invalidating days that would otherwise be valid because the main rest interval extends across 12:00:00 pm (noon). In these cases, assess if setting the start-hour in three-hour increments would remedy the situation. In most cases, the situation is remedied by setting the start hour to 3 pm, thus defining a day as the time from 3:00:00 pm- 2:59:30 pm. Any and all such exceptions are documented in the "Tracking Changes Log" under the "Start Hour Exceptions" tab with the Subject ID, Contact Occasion, new Start Hour, and specific reason with excluded day(s) that caused the exception.

Figure 5. Verifying/ Setting the Actigraphy Start Hour

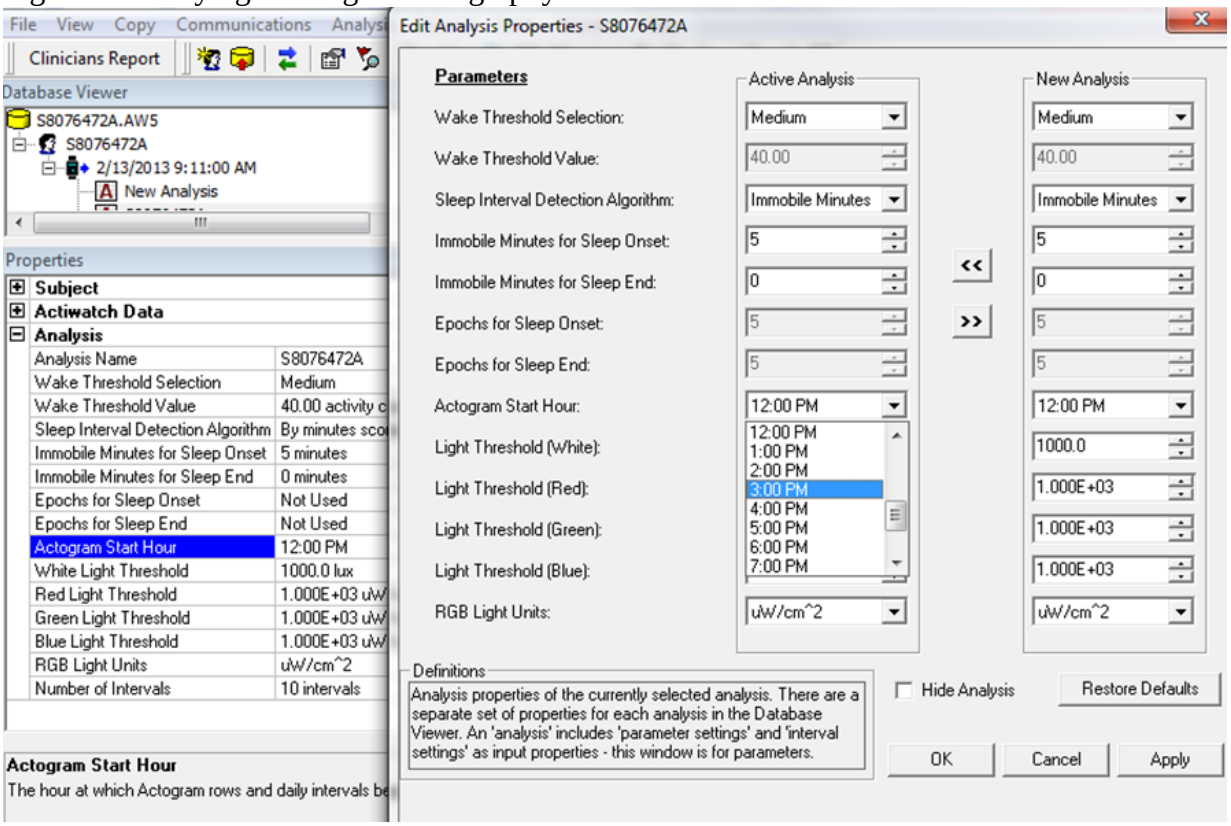


Figure 6. Actigraphy Start Hour Exceptions: Problem

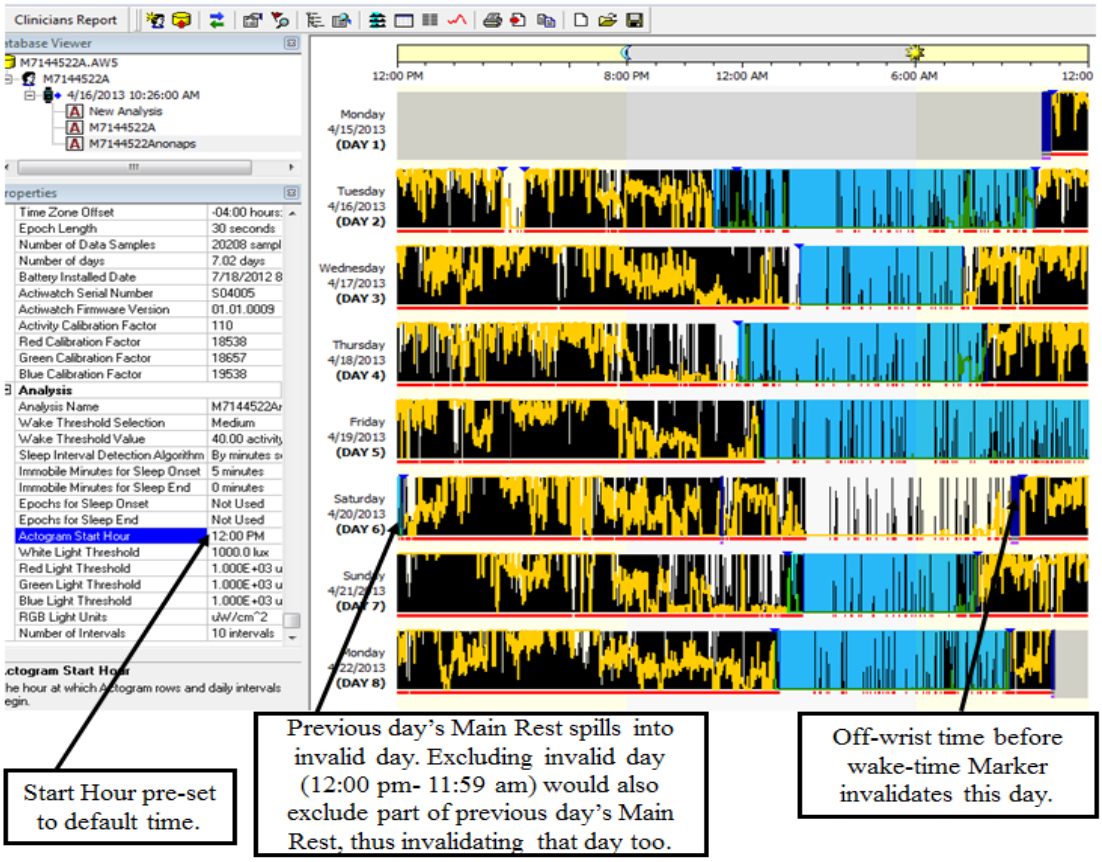
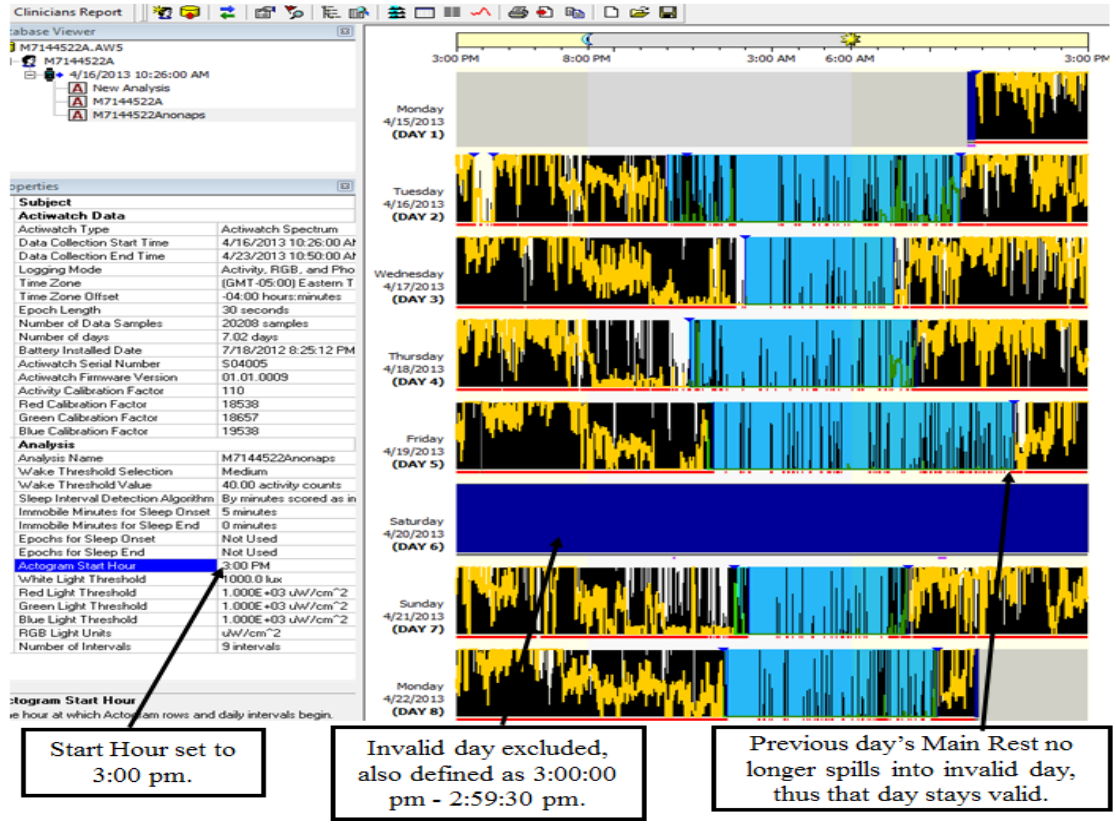


Figure 7. Actigraphy Start Hour Exceptions: Solution



1. **Adjust Settings in Actiware:**
    a. Open the desired database by opening **Respironics Actiware 5** and selecting **File > Database > Open** and search for the .AW5 file labeled with the appropriate subject ID and contact occasion. In the Database Viewer (on the left) select the subject file (has a picture of a head next to it) with the matching subject ID. Double clicking on this file will result in the appearance of a watch icon as well as the actual date and time the recording began. The rows beneath the watch icon display the data that can be viewed and edited. Select **New Analysis.** An actogram should be displayed in the Actigraphy Viewer. Each row in the Actigraphy window displays activity from 12:00:00 pm to 11:59:30 am of the next day.

Figure 8. **Database Viewer**

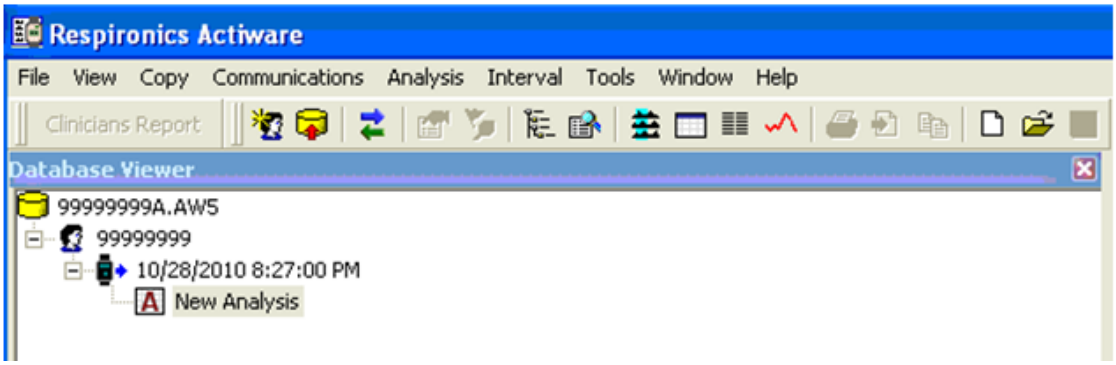
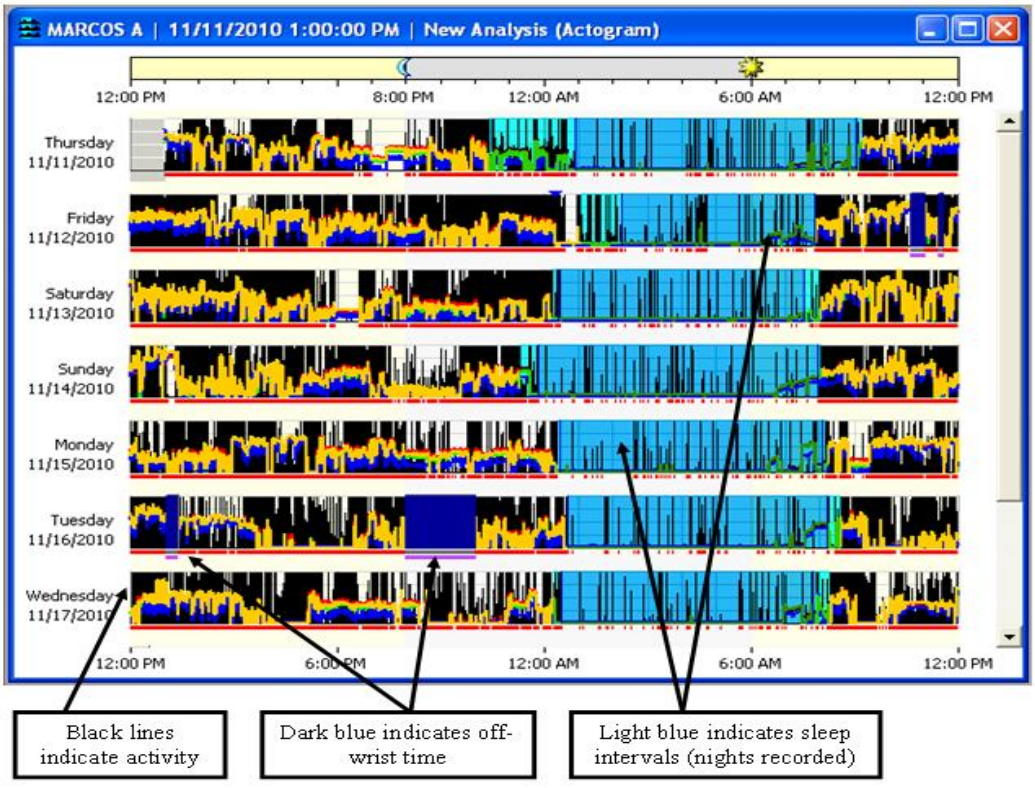
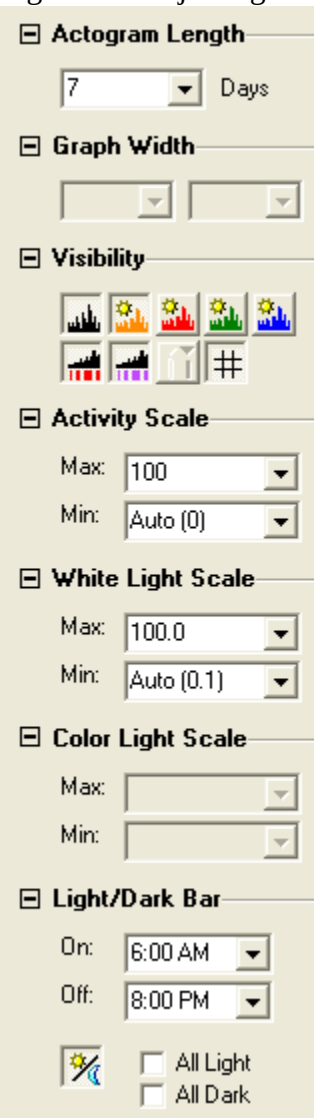


Figure 9. **Actigraphy Viewer:**



b. For ease of viewing, set the **Activity Scale Maximum to 100** and set the **Actogram Length** to the number of days with on-wrist data (on the right side of screen).
c. Under **Visibility**, deselect the colored light signals (red, green, blue) in order to get a clearer view of the Activity. Select and deselect the white light signal (orange). The white light signal provides useful information on the quantity of light. Set the **White Light Scale Maximum to 100**.

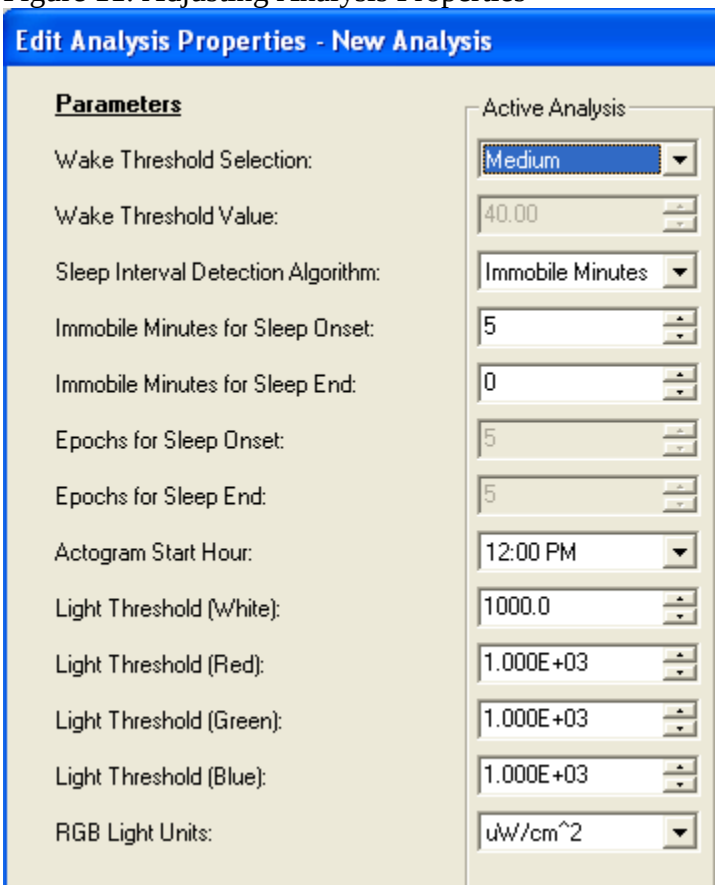
Figure 10. Adjusting Visibility Settings



d. Make changes to **Properties** by selecting **Analysis>Edit Analysis Properties** from the Respironics Actiware main menu. This will open the **Edit Analysis Properties** window. Under the **Active Analysis** column, make the following adjustments:
    i. Set the Wake Threshold Selection to **Medium**.
    ii. Set the Sleep Interval Detection Algorithm to **Immobile Minutes**.
    iii. Set Immobile Minutes for Sleep Onset to **5 minutes** and for Sleep End to **0 minutes**.

iv. Ensure the actogram Start Hour is set to the default of **12:00 PM** (or that it meets the exception rule to start at a different time as noted above).
v. Click on the button labeled **Apply** and then select **OK** (see below).

Figure 11. Adjusting Analysis Properties



2. **Brief Quality Check:**
   a. Look over the actogram and confirm:
      i. **There are a minimum of 5 days (12:00pm to 11:59am) recorded.**
      ii. **Out of the 5 days, there are at least 5 days with less than 4 hours of off-wrist, no data or data failure.**
      iii. **No off-wrist, no data or data failure during the beginning, middle or end of the sleep interval for the 5 days.**
   b. If it is not apparent simply from viewing the actogram whether there are 4 hours of off-wrist time within a day, select **View>Statistics Table**. In the statistics table window, select the **Daily** tab. Under the **Off-Wrist** column, the total number of off-wrist minutes will be displayed. If there are **240 minutes** or more of off-wrist time for a given day, then the day would be considered to have more than 4 hours of off-wrist time. *Note that only the off-wrist is displayed using this technique; time with no-data and time with data failure cannot be accounted for using this technique.*

Figure 12. Selecting Statistics Table

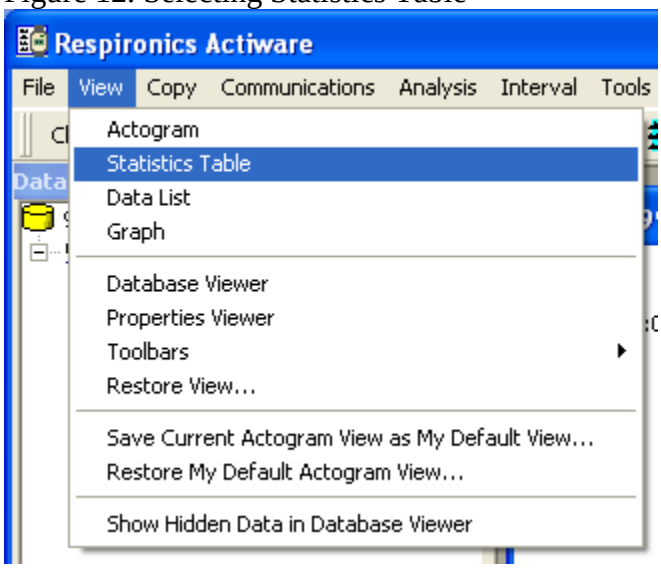


Figure 13. Statistics Table View

Rest | Active | Sleep | Custom | **Daily** | Summary | Clinicians Report

	Start Date	Start Day	Start Time	End Date	End Day	End Time	Duration	Off-Wrist
Day 1	11/1/2010	Mon	12:43:00 PM	11/2/2010	Tue	12:00:00 PM	1397.00	0.00
Day 2	11/2/2010	Tue	12:00:00 PM	11/3/2010	Wed	12:00:00 PM	1440.00	0.00
Day 3	11/3/2010	Wed	12:00:00 PM	11/4/2010	Thu	12:00:00 PM	1440.00	0.00
Day 4	11/4/2010	Thu	12:00:00 PM	11/5/2010	Fri	12:00:00 PM	1440.00	0.00
Day 5	11/5/2010	Fri	12:00:00 PM	11/6/2010	Sat	12:00:00 PM	1440.00	328.00
Day 6	11/6/2010	Sat	12:00:00 PM	11/7/2010	Sun	12:00:00 PM	1440.00	0.00
Day 7	11/7/2010	Sun	12:00:00 PM	11/8/2010	Mon	12:00:00 PM	1440.00	177.50
Day 8	NaN	NaN	NaN	NaN	NaN	NaN	NaN	NaN
Day 9	NaN	NaN	NaN	NaN	NaN	NaN	NaN	NaN
Day 10	NaN	NaN	NaN	NaN	NaN	NaN	NaN	NaN
n	*	*	*	*	*	*	7	7
Minimum(n)	*	*	*	*	*	*	1397.00	0.00
Maximum(n)	*	*	*	*	*	*	1440.00	328.00
Average(n)	*	*	*	*	*	*	1433.86	72.21
Std Dev(n-1)	*	*	*	*	*	*	16.25	130.76

More than 4 hours (240 min) off-wrist

3. **Contacting Sites:** If the study is determined to be of <u>sufficient</u> quality (5 or more days meet the criteria in B.2.a), GO TO SECTION C. If the study is determined to be of <u>insufficient</u> quality (fewer than 5 days meet the criteria in B.2.a), the field site from which the Actigraphy file was sent should be *immediately* told to contact the subject to try to obtain another round of Actigraphy if this is the first round of Actigraphy for the participant (contact occasion A or 1). *Do not* contact sites if this is the participant's second round of Actigraphy.
    a. The form entitled **Study Failure Form** should only be completed for first time studies (contact occasion A or 1) that were determined to be of insufficient quality. This form should not be completed for repeat studies (contact occasion B or 2) regardless of the quality of the study. The first half of the form is to be

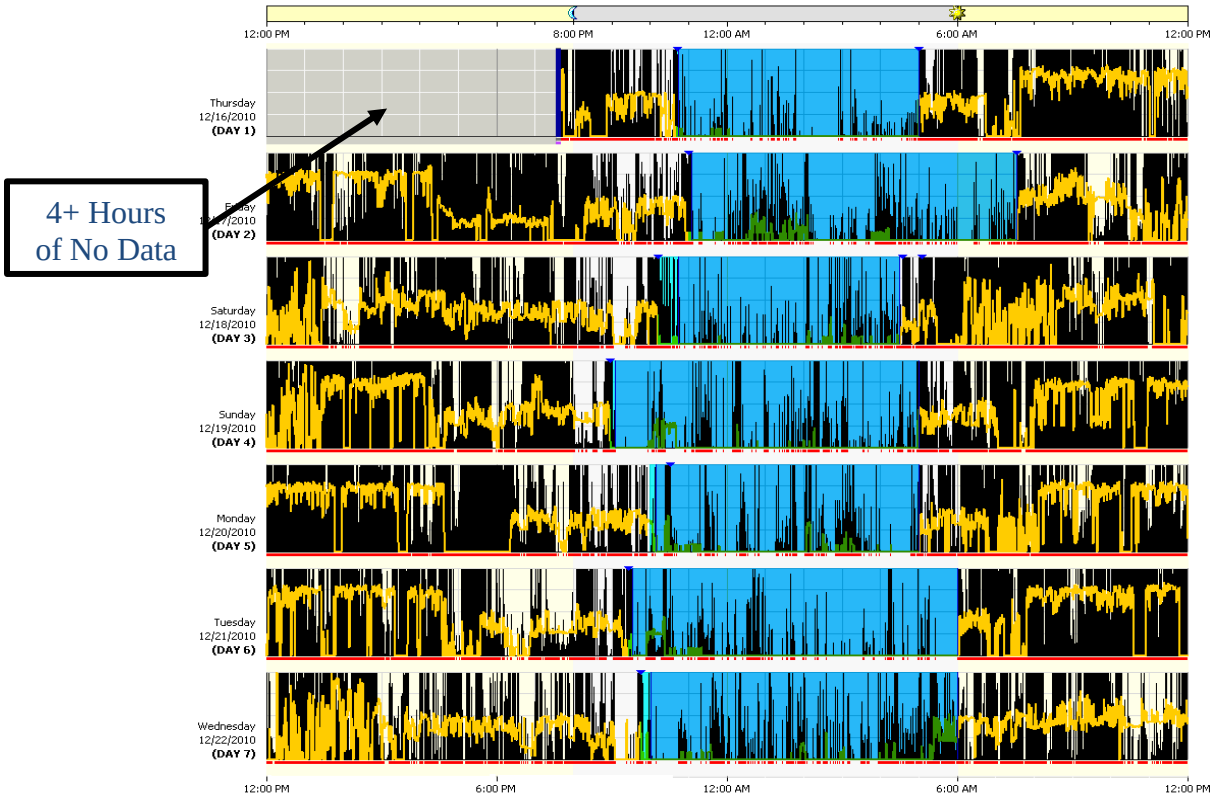
completed by the Reading Center staff and the second portion is to be completed by the Field Site staff.

i. In the Sueño database \\Rfa01\bwh-sleepepi\projects\src\sueno, select **Data>Study Fail Form** and open the file **Study Fail Form**.
ii. Enter today's date in the **Date Failed** section.
iii. Enter the participant's ID in the **ID Number** section.
iv. Enter the scorer's initials.
v. Note that only **Contact Occasion** 1 (first contact) or -1 (confusion) can be entered. Contact occasion 2 cannot be selected because this form should NOT be completed for those studies.
vi. Enter the **Failure Reason**. If the study failed because fewer than 5 days were recorded or fewer than 5 days were of sufficient quality, enter **Fewer than 5 days of valid data**. Alternatively, if the study failed because data could not be properly retrieved, enter **Data corruption/ technical failure**. For all other reasons, enter **Other**. If this option is selected, make sure to detail the failure reason in the notes section below. The **Notes** section should also be used for providing feedback to the field site about ways to eliminate this failure in future studies.
vii. After the first half of the form has been completed, the next line in the form will state **To be completed by Field Site Staff**. At this point save a copy of the form under **Data>Failed Studies>Pending**. Label the form with the participant ID and the contact occasion. *Additionally*, print a copy of this form and place it in the binder labeled **Sueño Pending**.

b. **Sueño Email Submission:** Send the Study Failure Form to field sites *immediately* from the BWH Sueño Sleep Study email account (bwhsueno@partners.org). In order to access this account, open Internet Explorer and enter the address: https://phsexchweb.partners.org/exchange/bwhsueno@partners.org. In the BWH Sueño Sleep Study email account, send an email to the Field Center staff with the participant's partially completed **Study Failure Form** as an attachment. Field Center staff is expected to return the fully completed form to the Reading Center. Once the completed form is returned, save the completed version OVER the original saved file in **Data>Failed Studies>Pending** and MOVE the completed form from the **Pending** folder to the **Complete** folder. *Additionally*, MOVE the incomplete Study Failure form from the Sueño Pending binder to the Sueño field site binder (ex: both forms would be placed in the Sueño Site 1 Albert Einstein binder in the case of a file received from the Bronx). PRINT a copy of the completed Study Failure form and add this form to the Sueño field site binder.

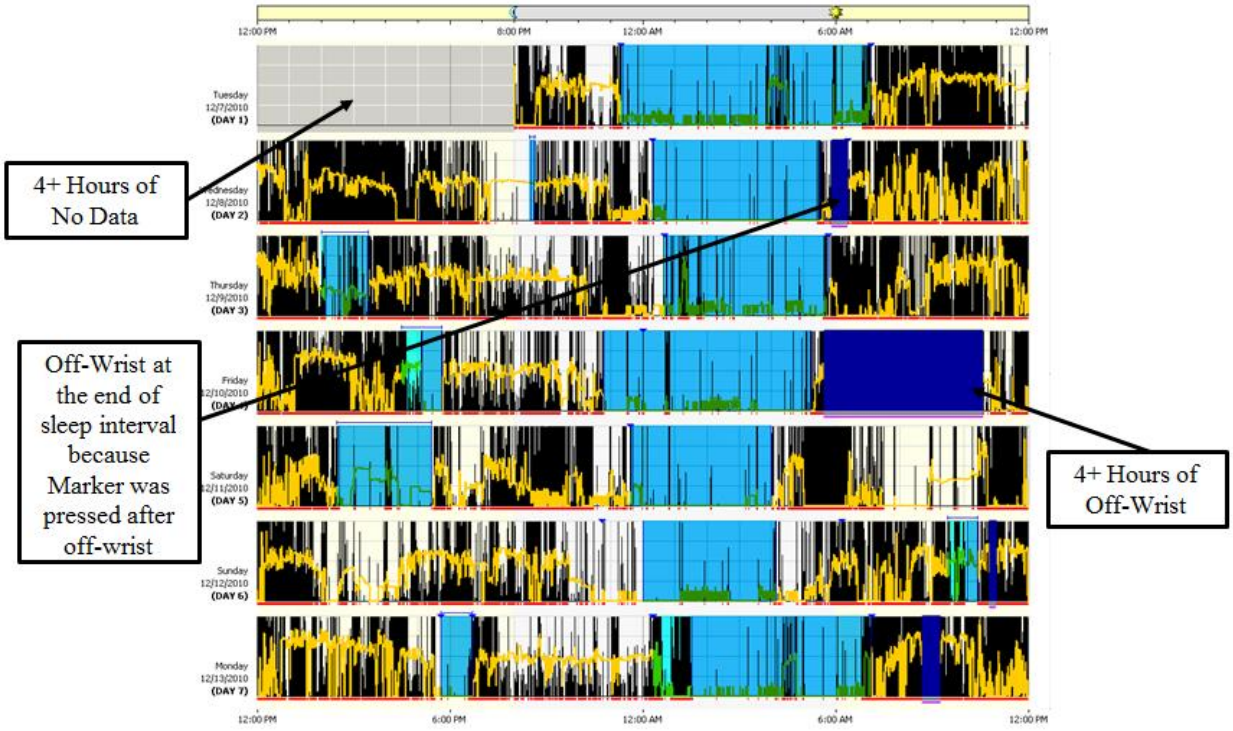
Example of a Quality Actogram: A minimum of 5 days were recorded. Out of the 7 days recorded, one of the corresponding days had more than 4 hours of no data time. There were no off-wrist, no data or data failure episodes during the beginning, middle or end of the sleep intervals that would have prevented confident estimations of sleep interval timing and duration. Therefore, 6 days had quality data.

Figure 14. Example of a Quality Actogram



Example of an Insufficient Quality Actogram: A minimum of 5 days were recorded. Out of the 7 days recorded, the first day had more than 4 hours of no data. The second day had off-wrist time at the end of the sleep interval. Since one of the parameters, the Marker, was pressed after the off-wrist episode, the end of the sleep interval as well as the duration could not be determined with confidence. The fourth day had more than 4 hours of off-wrist time. Therefore, out of the 7 days recorded, only 4 of the days had quality data. Since fewer than 5 days had quality data, a repeat trial is desirable. *Please see next page for an example of an insufficient quality actogram (Figure 15).*

Figure 15. Example of an Insufficient Quality Actogram



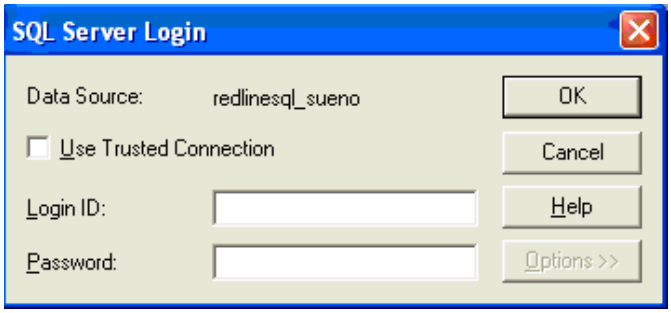
C. DAILY SLEEP LOG DATA ENTRY

Information from the Daily Sleep Log (Diary) should be entered into the Access file: **sueno sleep diary.mdb**. Entering this data will provide an electronic way to keep track of participant logs as well as provide a copy of the data from the original log. It is important to realize that the Sleep Log is a subjective recording by the participant of their sleep habits and is prone to human error. Keep the participant's Actiware file open when entering log data in order to determine when a participant's entry does not make sense based on the actigraphy recording. In this case, make sure to note that the data entered by the participant does not make sense. This will help to minimize the amount of human error present in the log data. For more information about what to do when a log entry does not make sense, see entry C.1.k.

1. Entering Daily Sleep Log Data:

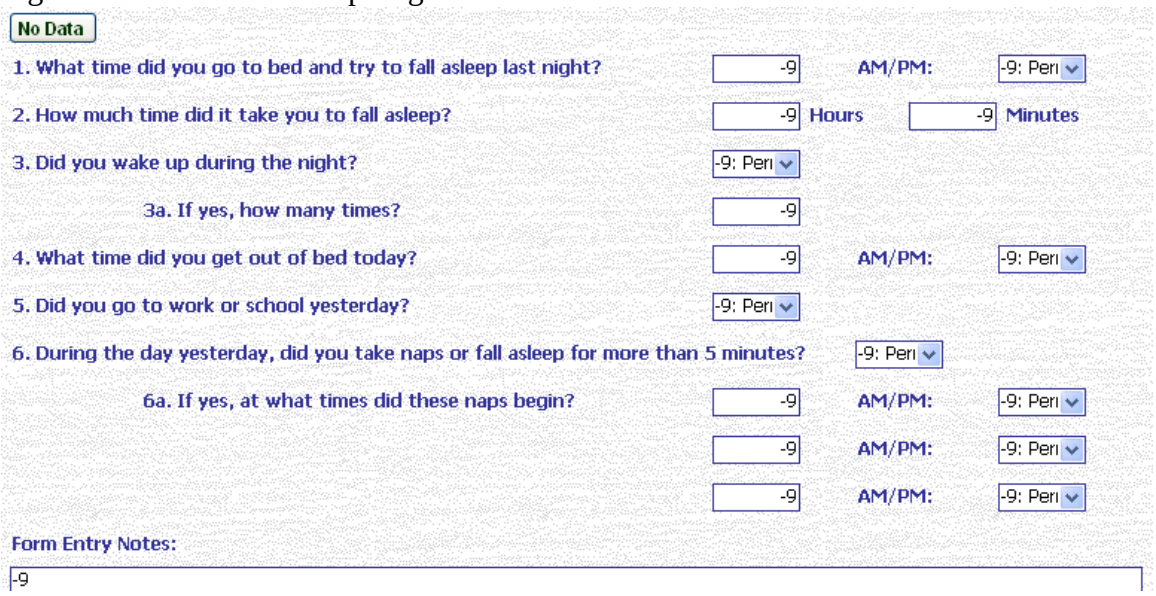
a. Select **sueno sleep diary.mdb > open.** Enter the assigned SQL **Login ID** and **Password** and click **OK**.

Figure 16. Login to Sleep Log Data



b. Select the button labeled **New** in the upper right hand corner in order to start a new form.
c. Confirm that the dates of the Daily Sleep Log entries are consistent with the dates displayed on the actogram. *Note: the Daily Sleep Log should be offset from the actogram by 1 day because the log is completed the morning after.*
d. ***Do not*** enter data from Day 0 of the Daily Sleep Log. Enter data starting with **Day 1** of the log.
e. The **Contact Occasion** should be entered as **1** if this is the first time the subject has participated, **2** if this is the subject's second time participating and **-1** if it is unclear as to the contact occasion.
f. If the subject did NOT complete a Daily Sleep Log as indicated by receipt of a blank Daily Sleep Log, select the button **No Data**. Selection of this button will result in the answer to every question on the form automatically being filled in as **permanently missing** or **-9** (see below). In instances where the dates on the diary cannot be obtained, enter the dates on the actogram and make a note in the entry that this is what you did.

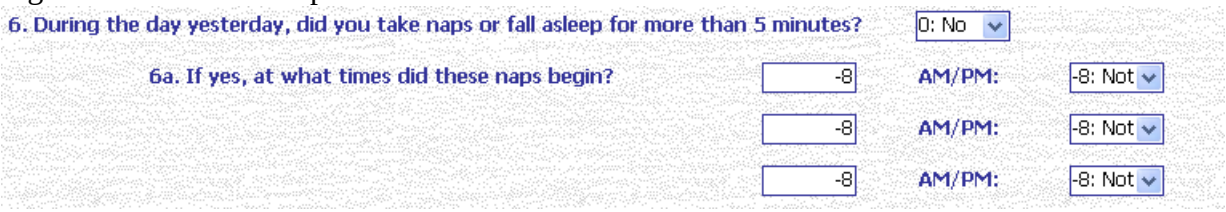
Figure 17. Blank Data Sleep Log



g. If specific items on the Daily Sleep Log were left blank by the subject, select **-9** from the drop down menu or type **-9**.
h. If it was unclear as to what the subject had intended to record, select **confusion** or **-1**.

i. If the subject did not perform a particular action, select **Not Applicable** or **-8** indicating that the question being asked is not relevant for the subject.
j. Certain inputs will result in certain fields automatically becoming filled. *For example, if a participant entered "no" in response to question 6, then all fields for question 6a will automatically be filled in with -8.*

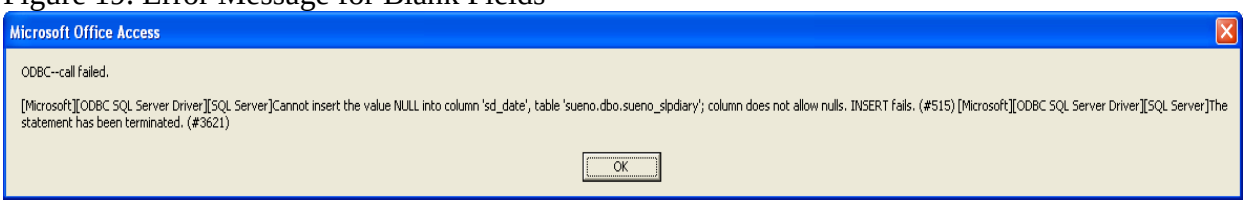
Figure 18. Automatic Inputs



k. Enter comments in the **Form Entry Notes** section as needed. ***Important note:*** *unlike the Actigraphy data, the Daily Sleep Log is a subjective recording of the participant's perception of when they went to bed and woke up. This log is prone to human error and when an entry does not make sense, use your best judgment as to what the participant intended to record. Make a note of the nonsense information in the log in this section. For example, if the participant recorded that they went to bed at 12 pm and woke up at 7 am, it is likely and can be confirmed in the actogram that the participant actually went to bed at 12 am. 12 am would be entered into the log as the answer to question 1 and this correction would be noted in the form entry notes.*

2. **Daylight Savings:** If a watch is worn over the transition to or from daylight savings, the Daily Sleep Log entries will differ from the Actigraphy data by 1 hour. It is important to make a note of this discrepancy. Please note that watches worn before or after the daylight savings transition will not exhibit this 1 hour discrepancy.
   a. For each day following a change to or from daylight savings there will be a discrepancy of 1 hour between the Daily Log and the actogram data. This discrepancy should be noted in the **Form Entry Notes** section for EVERY day following the daylight savings transition.
   b. The original time entered in the Daily Sleep Log should be entered into Access. However, the 1 hour discrepancy should be accounted for when placing sleep intervals (see section D).
3. **Saving Daily Sleep Log Data:** After the form for a specific day has been completed, select the button labeled **Submit** in the upper right hand corner and the completed form will automatically be saved in the Subject Database. *Note: It is important that all fields are filled in. If fields are left blank, an error message will appear when "Submit" is selected.*

Figure 19. Error Message for Blank Fields



a. Forms should be completed and saved for all 7 days of the Daily Sleep Log regardless of whether the subject completed all pages.
b. In the main window, confirm that all 7 daily log entries are present.
c. Exit the Sleep Diary Program in Access.

D. SETTING ACTIGRAPHY SLEEP INTERVALS

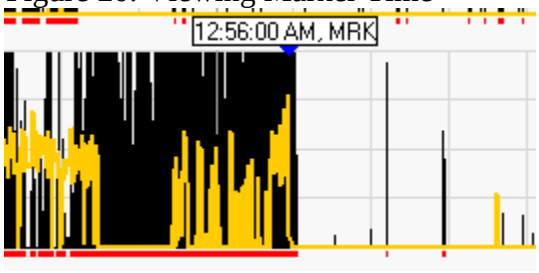
Rest intervals should be manually set in the participant Actigraphy file with the goal of capturing when the participant intended to sleep. Sleep intervals correspond to the time the Actiware software estimates that the participant was actually sleeping as opposed to lying in bed awake. These intervals are automatically generated within rest intervals. Therefore, the focus of this chapter is the accurate placement of rest intervals (periods when the participant intended to sleep). Placement will be dictated by 4 parameters: the Marker, the Daily Sleep Log, the Light Quantity and the Activity. The Marker, the Light Quantity and the Activity are recorded in the Actiware program. The Daily Sleep Log file should be referenced alongside the participant Actigraphy file. Keep in mind that the Daily Sleep Log is a subjective estimate of when the participant remembered they intended to sleep and is more prone to human error compared with the Actigraphy parameters.

Important note about Rest Intervals: Each **Rest Interval** is defined by a start and end time – the times the subject began and ended trying to sleep. These start and end times are called the bed time and wake time respectively. *Note* that these times differ from sleep onset and sleep offset, which are the times the subject first actually fell asleep and last woke up within the Rest Interval.

There are **4 Parameters** that can be used to determine when a person is sleeping: the Marker, the Daily Sleep Log, the Light Quantity and the Activity.

The presence of a **Marker**, displayed as an upside down dark blue triangle above the Actigraph, shows when the participant intended to sleep or wake up. The Marker is pressed in real time and therefore tends to be a more accurate estimate of bed/wake time in comparison to the Daily Sleep Log. The time when the Marker was pressed by the subject can be viewed on the actogram placing the mouse on top of the Marker. A time will appear followed by MRK.

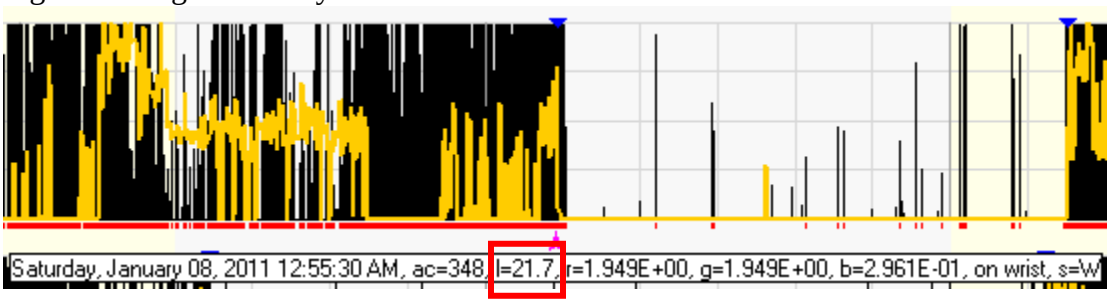
Figure 20. Viewing Marker Time



The **Daily Sleep Log** is completed by the subject for a given day the morning after. The log shows the subject's recalled bed/wake time. These bed time and wake times can be viewed in the Daily Sleep Log under questions 1 and 4. Account for the amount of time the participant recorded it took them to fall asleep (question 2).

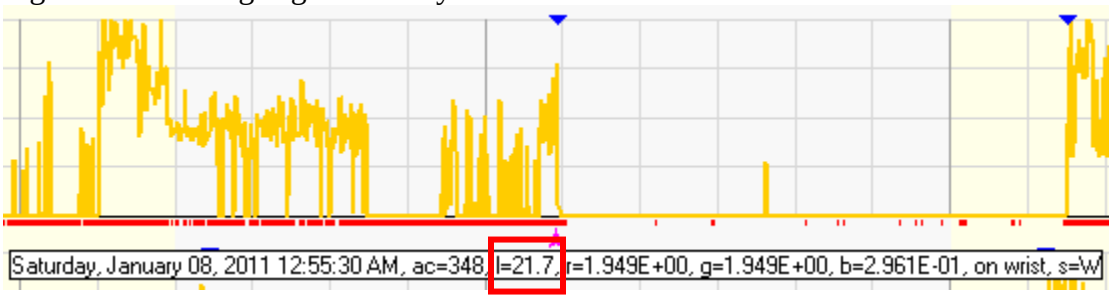
A change in the white **Light Quantity**, displayed as a yellow-orange trace in the actoram, serves to indicate bed time and wake time in addition to the Marker and the Log. A sustained decrease in the quantity of light may indicate that the lights were turned off thereby serving to indicate bed time. A sustained increase in the quantity of light may indicate the lights were turned on thereby serving to indicate wake time. Light quantity can be viewed multiple ways. In the main actigraphy window, light is shown as a yellow trace. The exact value in lux for every 30 second period can be viewed by clicking on the actogram. A caption will appear beneath the area on the actogram clicked listing the Light Quantity, l. In the figure below, this value is displayed inside a red box.

Figure 21. Light Intensity



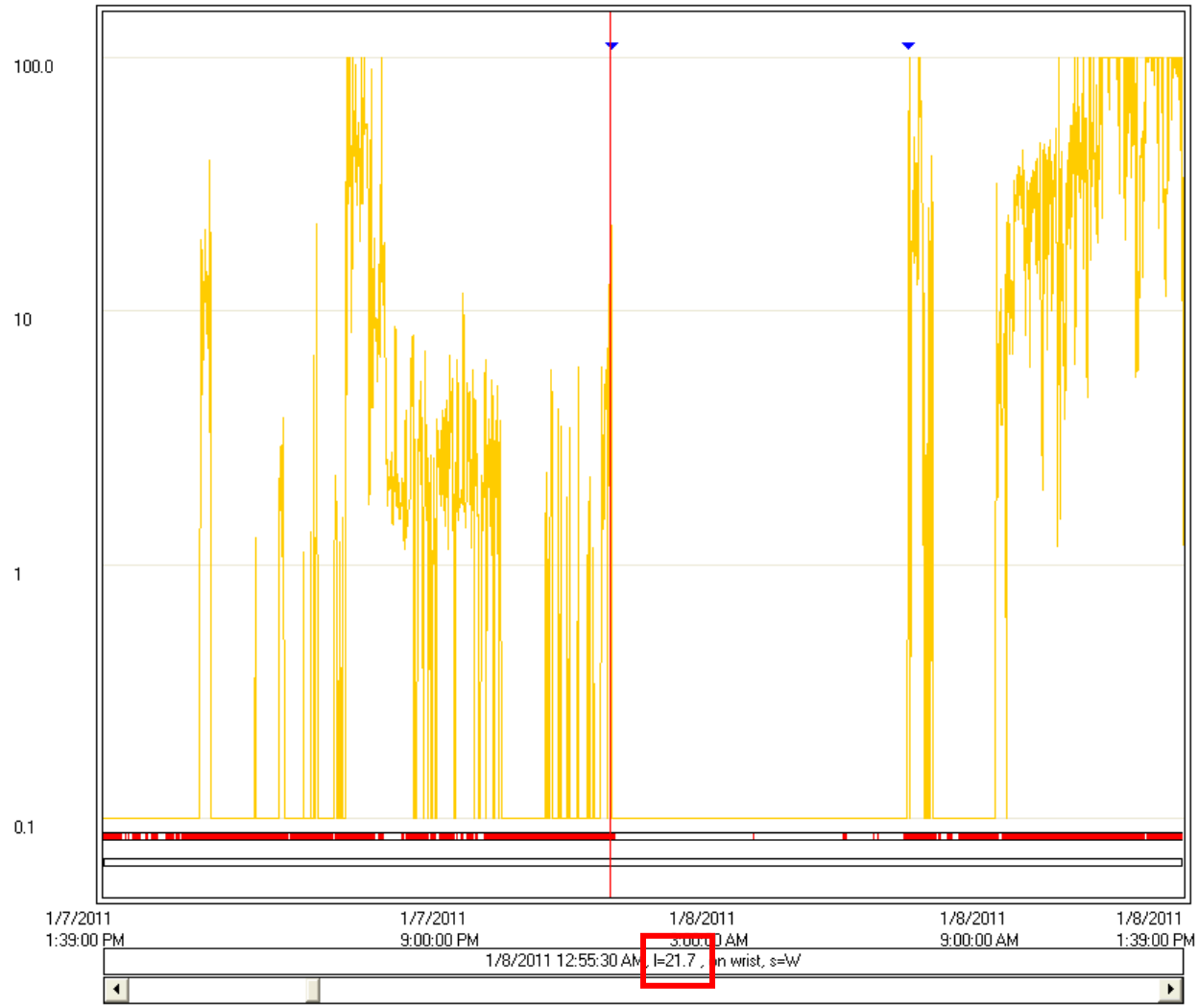
By deselecting the Activity, shown as a black trace under the Visibility section to the right of the actogram, only the light quantity will be displayed on the actogram.

Figure 22. Isolating Light Intensity



In order to get a different view of the light data, double click on the actogram on the region associated with the interval of interest. A new window entitled “Graph” will pop up. Note that in the Graph view the time scale is compressed. Of note, this view typically provides a greater visual contrast between the time in a 24 hour period when the light levels are high and the time when they are low. Therefore, it tends to be easier to see the transition in light levels between sleep and wake in this view (Figure 23).

Figure 23. Graph View of Light Intensity



In order to determine the time when the lights went off, indicating intent to sleep, find the time with the greatest sustained drop in light intensity. For bed time, the light quantity parameter would be recorded as the time the light quantity drops to less than 1 lux and remains at this level a sustained period of time, usually over 2 hours. If light does not drop to below 1 lux for bedtime, choose the time at which light intensity drops to the minimum level recorded that day. For wake time, the light parameter would be recorded as the time when the light quantity increases to more than 1 lux and remains over 1 lux for a sustained period of time. If there is a gradual increase in light intensity associated with wake time, choose the time point with the greatest increase/contrast.

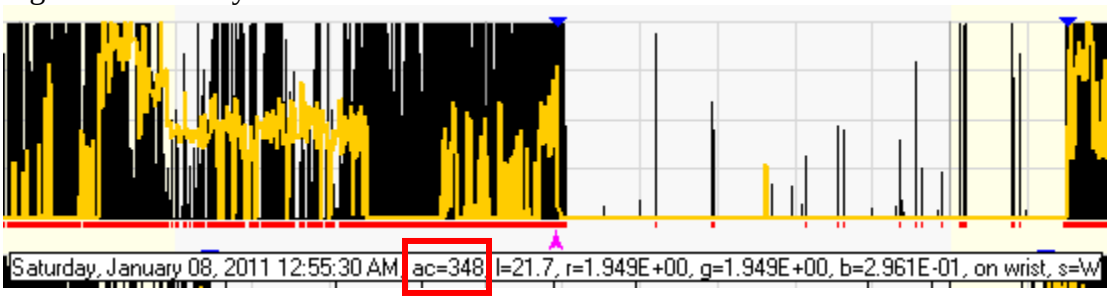
Another visual contrast that may aid in interval placement is when light goes from a constant value from epoch to epoch to a varying level, which can be an indication that the participant is moving their wrist. In some cases, contrast rather than absolute light levels will provide an indication of when the participant woke up.

A change in **Activity**, displayed as a black trace in the actogram, serves to indicate sleep onset and sleep offset, NOT bed time and wake time. Thus, a drop-off in activity may indicate sleep

onset. Similarly, an increase in activity may indicate sleep offset. ***Note:*** because sleep onset and NOT bedtime is determined by a drop in activity, it becomes impossible to determine Sleep Latency (the time from bed time to sleep onset) if the start of the sleep interval is placed at the time activity drops off.

On the main actigraphy window, activity is shown as a black trace. The activity count value for every 30 second period can be viewed by clicking on the actogram. A caption will appear beneath the area on the region of the actogram clicked listing the light activity count, ac. In the figure below, this value is displayed inside a red box.

Figure 24. Activity Count

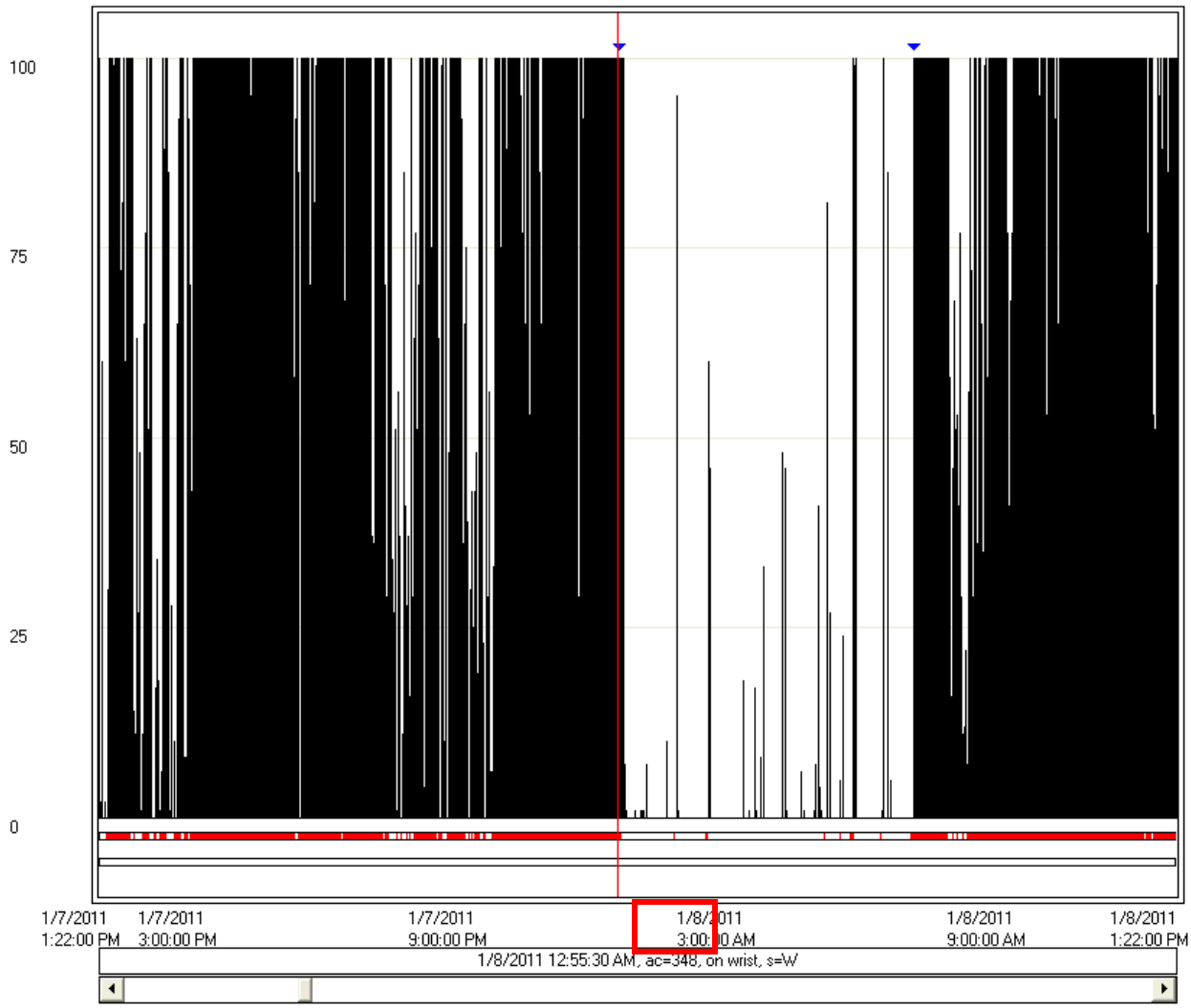


By deselecting White Light, shown as an orange trace under the Visibility section to the right of the actogram, only the activity will be displayed on the actogram.

Figure 25. Isolating Activity Count

In order to get a different view of activity, double click on the actogram on the region associated with the sleep interval of interest. Of note, this view typically provides a greater visual contrast between the times when there is a lot of activity and when there is low activity. Therefore, it tends to be easier to see the transition in activity levels between sleep and wake in this view.

Figure 26. Graph View of Activity Count

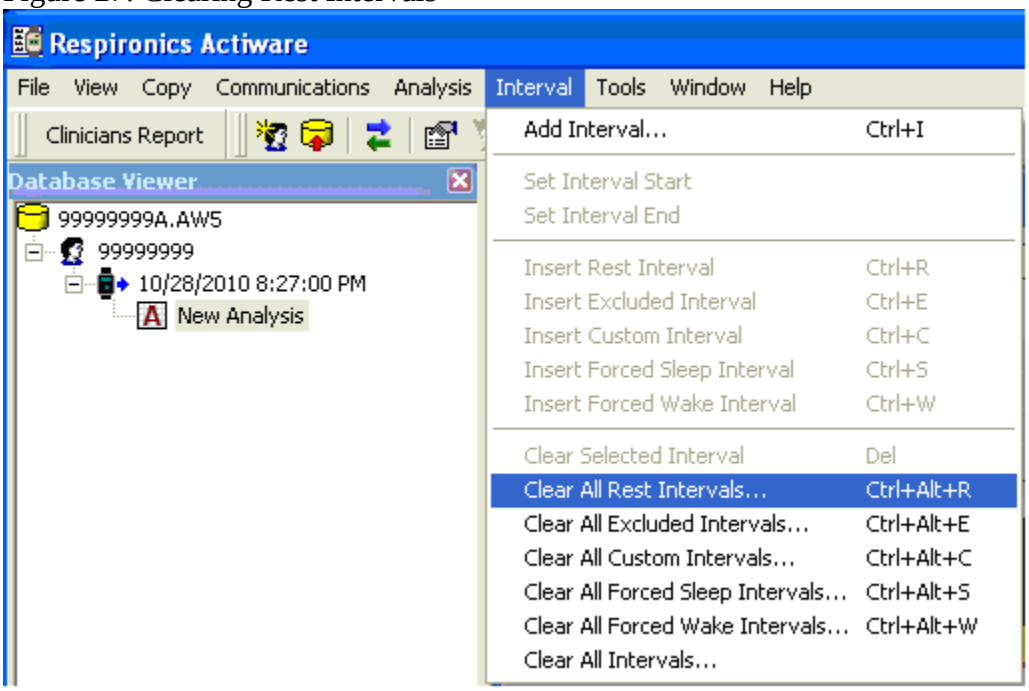


In order to determine the time the activity level drops likely indicating sleep onset, determine where on the actogram there is a transition from mostly black lines (activity) to mostly white lines (no activity). At this transition, find the time when the activity count drops to zero (ac=0) for a sustained period of time (multiple 30 second intervals where ac=0). The activity time that should be recorded is the time of the first ac=0 in the sequence of zero activity counts. In order to determine the time the activity level increases, likely indicating the subject woke up, determine where there is a transition from mostly white lines (no activity) to mostly black lines (activity). At this transition, find the time when the activity count increases from zero for a sustained period of time (multiple 30 second intervals where the majority of activity counts are substantially greater than zero). The activity time that should be recorded is the time of the first nonzero activity count in a series of mostly nonzero activity counts.

In conclusion, a pressed marker, a recorded sleep time and/or a drop in the amount of light serve as indicators that the participant tried to fall asleep. Likewise, a pressed marker, a recorded wake time and/or an increase in the amount of light serve as indicators that the participant got out of bed. In contrast, a drop in activity serves to indicate that a participant fell asleep (onset) whereas an increase in activity serves to indicate that the participant woke up (offset).

1. **Setting Sleep Intervals:** Rest intervals should only be set for **the main sleep period**, which is defined as the subject's longest period of continuous time in bed with the intent to sleep. Setting time in bed/out of bed will be based on 4 parameters: the Marker, the Daily Sleep Log, the Quantity of Light and the Activity.
    a. In the Actigraphy window select **Interval > Clear All Rest Intervals**.

Figure 27. Clearing Rest Intervals



    b. Examine each of the regions on the actogram associated with getting into bed and getting out of bed.
    c. Determine which parameters are **present** for the period of bed time and wake time for each main sleep period.
    d. Determine which parameters appear to be reliable indicators of intent to sleep and wake up. A **reliable** parameter is one that unambiguously indicates intent to sleep/wake up and seems reasonable considering the other parameters. If a parameter is unreliable, do not account for this parameter when setting an interval. *Note: Light Quantity is often unreliable as a wake time parameter because light often gradually increases as the sun rises. Activity is rarely considered unreliable.*
    e. Bed time and wake time should be determined by the set of present and reliable parameters. If no parameters are present, set a 30-second rest interval starting 12:00:00 am. If some parameters are present, but none are reliable, set a 30-second rest interval at the least unreliable parameter.
    f. Using **only present and reliable parameters**, examine the following situations to determine how to place intervals based on your set of parameters.

Important: Interval placement should be based on determining how many parameters are consistent with one another. Parameters that fall within 15 minutes of one another are considered to be consistent. For example, if the light quantity substantially changes within 15 minutes of the

marker, these parameters would be considered to be consistent with one another. Parameters are considered to fall within 15 minutes of one another if each of the parameters falls within 15 minutes of any other parameter(s). Therefore, even if a parameter does not fall within 15 minutes of every single other parameter, if it falls within 15 minutes of another parameter that is within 15 minutes of every other parameter, all of these parameters are considered to fall within 15 minutes of one another. *For example, if the Marker was pressed at 11:20 pm, 11:30 pm was recorded in the Daily Sleep Log and the Light Quantity decreased at 11:45 pm, all of these parameters are considered to fall within 15 minutes of one another even though there is a 25 minute difference between the Marker and the Light Quantity parameters.*

i. **Situation 1: All of the parameters fall within 15 minutes of one another.** If so, place sleep interval at the time corresponding to the highest priority parameter. Follow this order of priority:
    1. Marker
    2. Daily Sleep Log
    3. Light Quantity
    4. Activity

ii. **Situation 2: A single subset has parameters within 15 minutes of one another.** If so, determine sleep interval time using the subset of parameters that fall within 15 minutes of another present and reliable parameter. Follow this order of priority:
    1. Marker
    2. Daily Sleep Log
    3. Light Quantity
    4. Activity

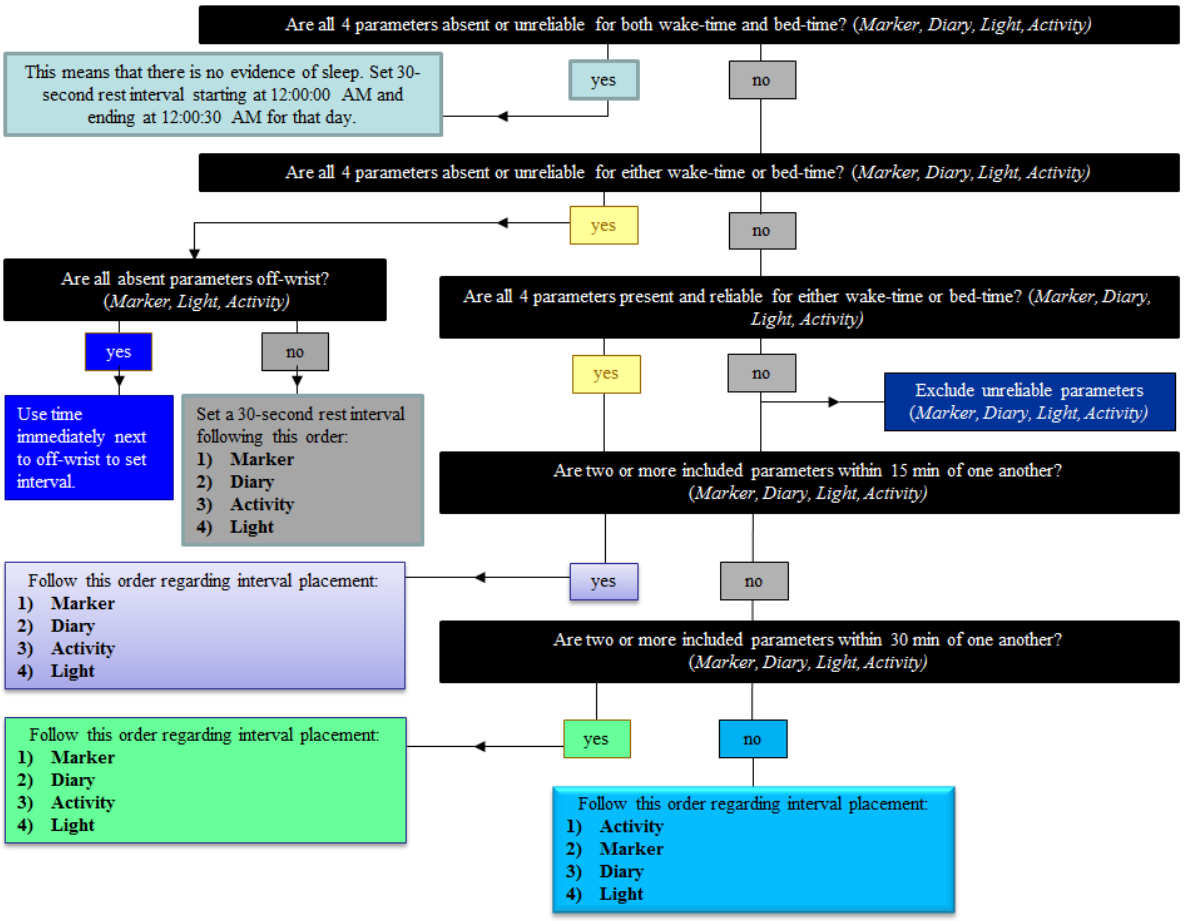
iii. **Situation 3: Multiple subsets have parameters within 15 minutes of one another.** If there is no majority of present and reliable parameters that fall within 15 minutes of one another, but rather there are multiple sets of parameters, follow the instructions below:
    1. If the Marker and the Daily Sleep Log fall within 15 minutes of each other, set the interval at the Marker time.
    2. If the Marker and the Daily Sleep Log are present and reliable, but are not within 15 minutes of one another, determine whether a change in light falls within 15 minutes of the Marker. If so, set interval at the Marker time. Alternatively, if light is within 15 minutes of the Daily Sleep Log entry time, set interval at the Log time.

iv. **Situation 4: None of the parameters fall within 15 minutes of one another.** Determine whether any of the parameters fall within 30 minutes of one another.
    1. **All or some of the parameters fall within 30 minutes of one another.** If so, determine interval placement using the same reasoning that was used when parameters fell within 15 minutes of one another. Refer to situations 1 through 3 above substituting 30 minutes for 15 minutes.
    2. **None of the parameters fall within 30 minutes of one another.** If all of the parameters are more than 30 minutes apart, set interval

based on Activity (the time when Activity visibly decreased or increased).

3. **None of the parameters fall within 30 minutes of one another and there is no activity drop associated with the interval.** If all of the parameters are more than 30 minutes apart, but the interval cannot be set based on Activity, follow this order of priority:
    a. Marker
    b. Daily Sleep Log
    c. Light Quantity

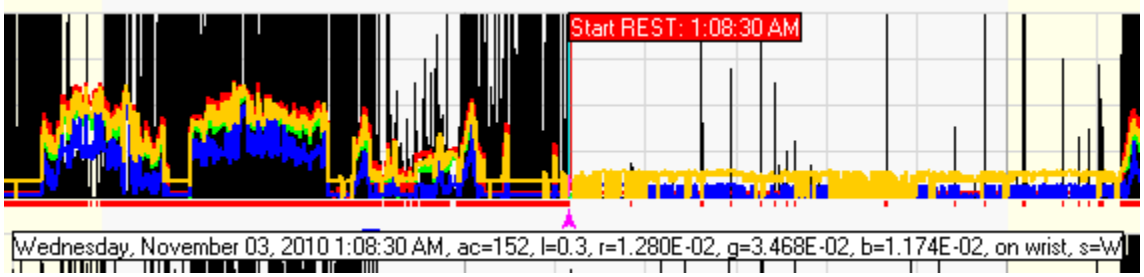
Figure 28. Setting Rest Intervals Flowchart



g. After the placement of the main sleep period has been determined, set the time in bed by clicking on the actogram in the desired location. Clicking on the actogram will result in the appearance of a pink arrow beneath the activity plot. In order to make adjustments to the placement of the arrow, tap the right and left arrow keys. This will result in the pink arrow moving to the right or left in 30 second intervals.

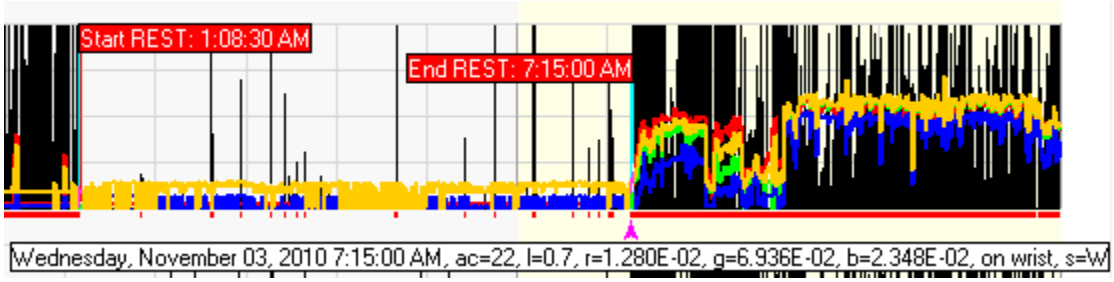
h. When the arrow has been placed at the desired start of rest time, type **r**. This action will result in the appearance of a red flag stating **Start REST**.

Figure 29. Starting a Rest Interval



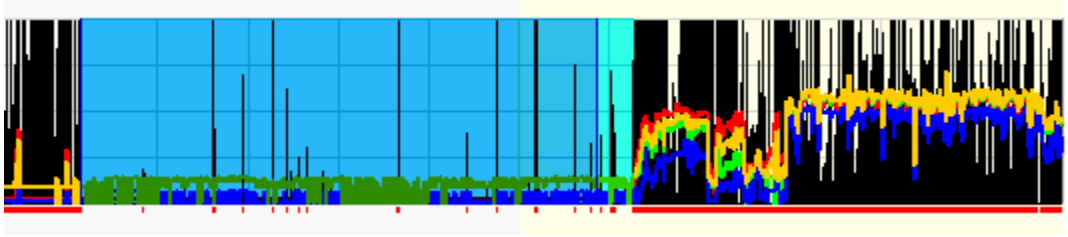
i. Next, when the arrow has been placed at the desired end of rest time type **Shift + r**. This action will result in the appearance of a red flag stating **End REST**.

Figure 30. Ending a Rest Interval



j. In order to set the rest interval, type **Ctrl + r**. A light blue color should appear indicating the presence of a **Rest Interval**. The appearance of a medium blue color indicates the presence of a **Sleep Interval** (see Interval Legend in the lower right hand corner of the Actigraphy window). Note that in some cases the set rest interval will appear as mostly or all light blue in color. Sometimes the set rest interval will appear as mostly or all medium blue. In either case, this interval is still considered to be a rest interval regardless of the relative proportion of light versus medium blue color.

Figure 31. Setting a Rest Interval



k. **Brief Quality Check:** determine whether there was any off-wrist, no data or data failure that prevented the ability to set intervals confidently. Following this check, if there are now fewer than **5 valid days**, and the file is for *contact occasion 1 or - 1*, repeat steps in section B.3.a-b.

2. **Setting Nap Intervals:** Naps are considered periods of sleep outside the main sleep period. Normally, there is one main sleep period per day and the remaining sleep periods

are considered naps. Napping can occur during the day or at night. Nap intervals should ONLY be set if there is a Marker and/or Daily Sleep Log entry. Nap intervals should NOT be set for periods of low activity outside the main sleep period that are not associated with a Marker and/or Log entry.

a. Examine each of the regions on the actogram associated with a Marker and/or Daily Sleep Log entry.
b. Determine which parameters are present and reliable. In many cases, light quantity will not be a reliable indicator of napping. Use **only present and reliable parameters** to set nap intervals.

Important: Participants record naps for a given day the following morning. When a participant records a nap, they are often estimating when their naps took place many hours later. Therefore, estimates of nap times as recorded on the Log tend to be less accurate compared with estimates of bed time and wake time. Therefore, a period of low activity within **4 hours** of the time recorded in the daily sleep log is considered to be associated with the log entry time. *Note: do not set a nap interval if the Daily Log entry time coincides with a main sleep period and there is no drop in activity within 4 hours of the entry that is outside of the main sleep period. Do not set a nap interval if the participant indicated in the Log that they took a nap but no nap time was recorded and no other supportive evidence for this nap was present making it impossible to place a nap interval. Another important note is that when participants take naps in the morning, they often record these naps on the wrong day. They record them for the previous day because they are filling out their diary the morning of their nap. Use your best judgment in deciding which day to classify these naps under.*

i. **Situation 1: A Marker and/or Diary are present and fall within 15 minutes of each other or of a significant change in Activity or light.** Set the nap interval at the time corresponding to the highest priority parameter. Follow this order of priority:
    1. Marker
    2. Activity
    3. Light Quantity
    4. Daily Sleep Log

    If the marker was pressed, and any of the remaining three parameters are within 15 minutes of the Marker time, set the nap interval start time at the Marker time. If only one Marker is present for the nap interval, set the nap start or end time (whichever one is not associated with a Marker) using the remaining three parameters in the following order: Activity, Light, and Diary.
ii. **Situation 2: A Marker and/or Diary are present and associated with a significant change in Activity or Light, but only Light and Activity fall within 15 minutes of each other.** If the decrease in light and activity for bed time are within 15 minutes of each other, start the nap interval at the time corresponding to the significant change in Activity. Likewise for an increase in light and activity at wake time.
    Reminder: parameters are considered to be associated with each other if they fall within 4 hours of one another.
v. **Situation 3: A Marker and/or Diary are present and associated with a significant change in Activity or light, but no parameters fall**

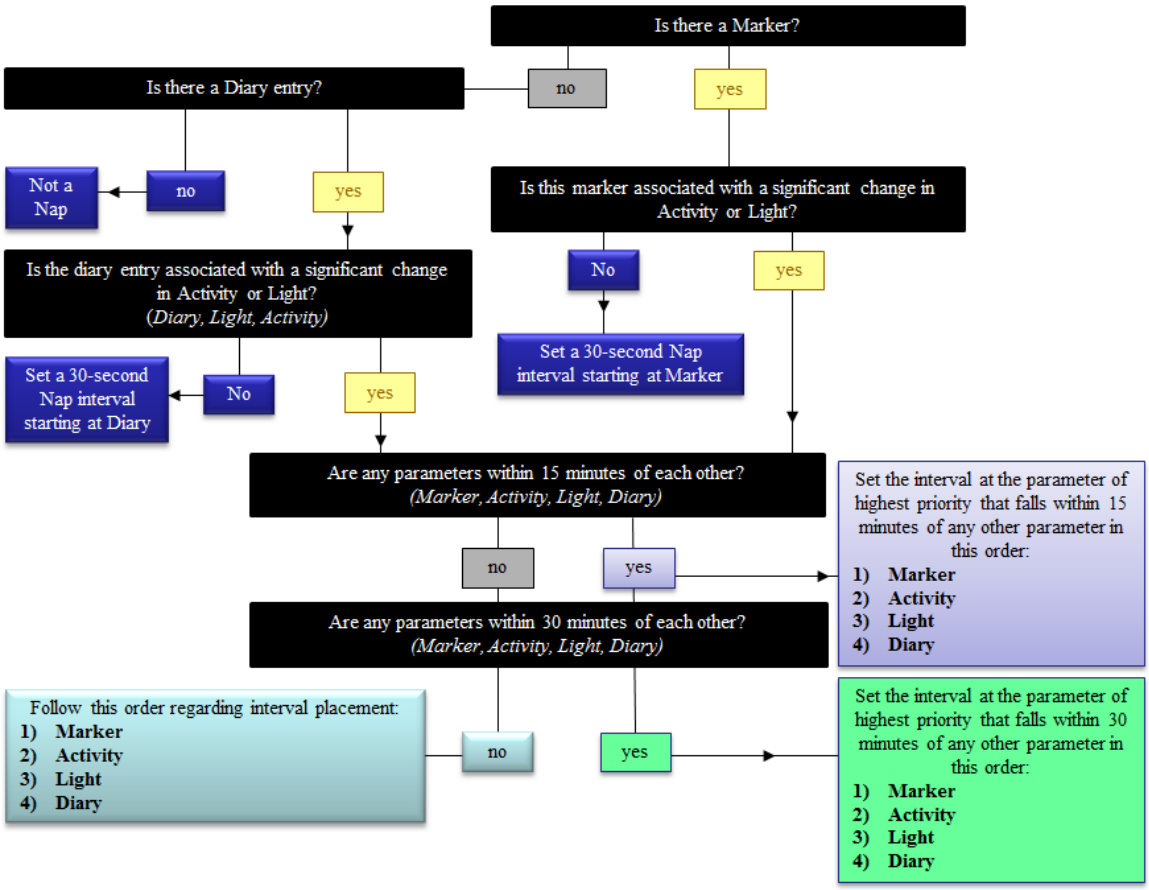
within 15 minutes of each other. Determine whether any of the parameters fall within 30 minutes of one another.

1. **All or some of the parameters fall within 30 minutes of one another.** If so, determine interval placement using the same reasoning that was used when parameters fell within 15 minutes of one another. Refer to situations 1 and 2, substituting 30 minutes for 15 minutes.
2. **None of the parameters fall within 30 minutes of one another.** If all of the parameters are more than 30 minutes apart, set interval based on Activity (the time when Activity visibly decreased or increased).
3. **None of the parameters fall within 30 minutes of one another and there is no activity drop associated with the interval.** If all of the parameters are more than 30 minutes apart, but the interval cannot be set based on Activity, follow this order of priority:
    a. Marker
    b. Light Quantity
    c. Daily Sleep Log

ii. **Situation 4: Neither a Marker nor a Daily Sleep Log entry, if present, is associated with an unambiguous decrease in the quantity of light or a drop in Activity.** In this case, set the nap start time at the Marker time if the Marker is present. Set the nap end time 30 seconds after the nap start time. If the Marker is absent, set the nap start time at the time recorded in the Daily Sleep Log. Set the nap end time 30 seconds after the nap start time.

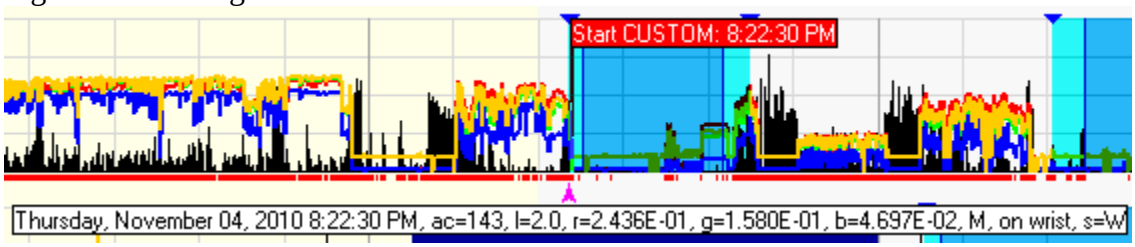
For further instruction regarding rules for setting the onset of nap intervals, refer to the flow diagram in Figure 32 (next page).

Figure 32. Setting Nap Intervals Flowchart



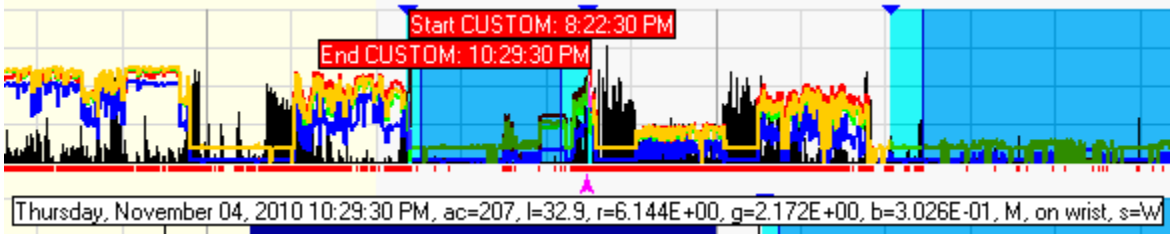
c. Set the start of the nap interval and the end of the nap interval using the same keys that were used to set the in/out of bed times (D.1.i-k).
d. In addition to setting rest intervals in the actogram in order to indicate sleep intervals, **custom intervals** should be placed over nap intervals in addition to rest intervals. Every nap should be marked by a rest interval **AND** a custom interval. The custom interval should occur over the identical interval (same start and end time) as the rest interval. Marking naps as custom intervals allows the software to distinguish sleep time in the main sleep period from sleep time in naps.
e. After the rest interval has been placed over a nap, move the pink arrow to the same time as the start of the rest interval. When the arrow has been placed at this time, type **c**. This action will result in the appearance of a red flag stating **Start CUSTOM**.

Figure 33. Starting a Custom Interval



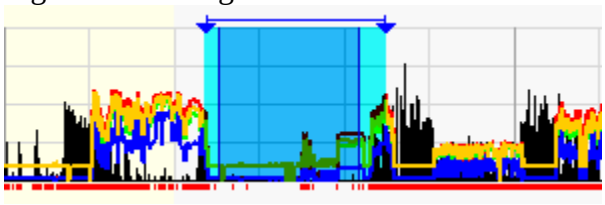
f. Follow the same steps in order to place the pink arrow at the end of the rest interval. When the pink arrow has been placed at this time, type **Shift + c**. This action will result in the appearance of a red flag stating **End CUSTOM**.

Figure 34. Ending a Custom Interval



g. In order to set the custom interval, type **Ctrl + c**. A horizontal blue bar will appear **above** the rest interval previously set. The presence of both the rest interval and the custom interval indicates the presence of a nap (a rest interval outside the main sleep period).

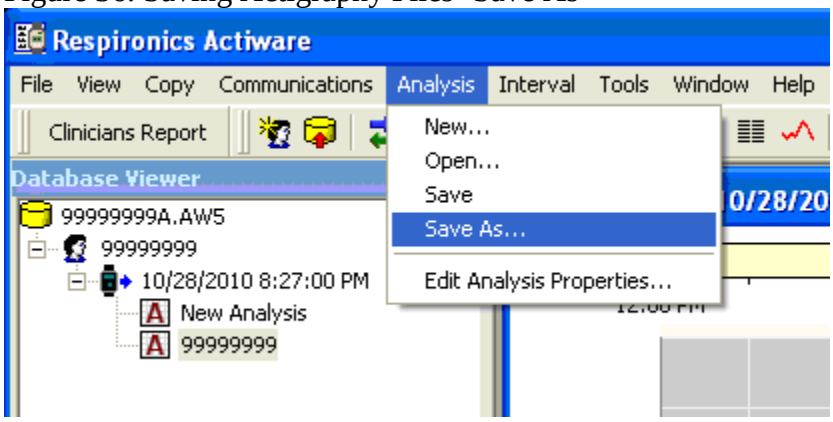
Figure 35. Setting a Custom Interval



h. **Brief Quality Check:** determine whether there was any off-wrist, no data or data failure that prevented confident placement of the nap intervals. Following this check, if there are now fewer than **5 valid days**, and the file is for *contact occasion 1 or -1*, repeat steps in section B.3.a-b.

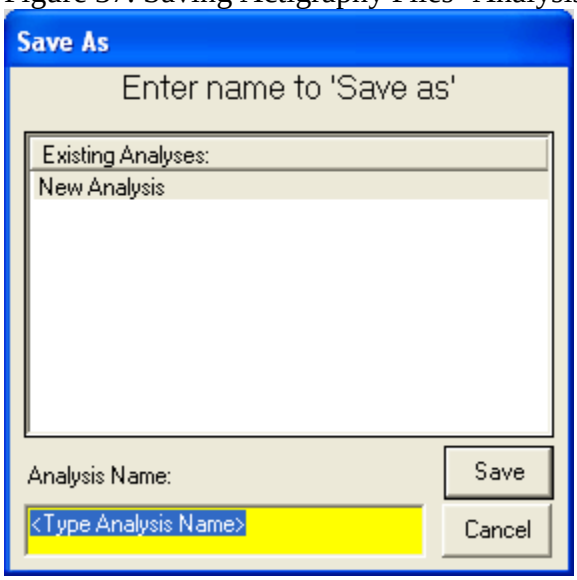
3. **Saving Actigraphy Files:**
   a. Select **Analysis > Save As.**

Figure 36. Saving Actigraphy Files- Save As



b. Enter the **subject ID** under **Analysis Name** and click **Save**. *For example: C6123456.*

Figure 37. Saving Actigraphy Files- Analysis Name



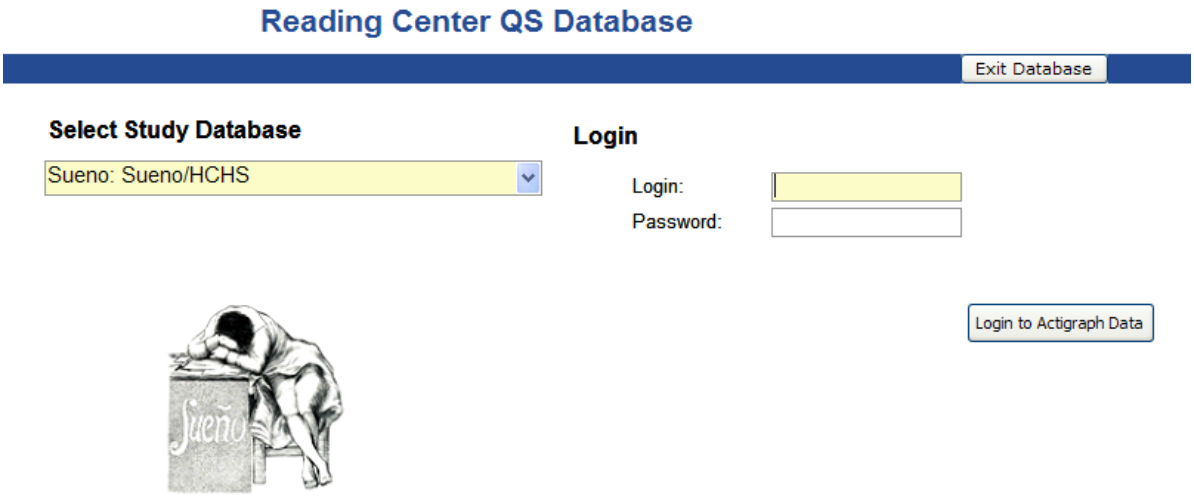
4. **Printing Actogram:** Print this report by selecting **File>Print Report**. The printed report should be placed in the Sueño binder labeled with the field site the participant's file was sent from. *For example, if the Actigraphy file was from the Bronx, place the report in the binder labeled: Sueño Site 1 Albert Einstein.*

E. DOCUMENTING QUALITY

The quality of the received sleep data will be documented using the **Actigraphy Quality Form**. The general purpose of this form is to indicate the level of confidence that the intervals placed are an accurate reflection of the participant's actual sleep habits for the time the Actiwatch was worn.

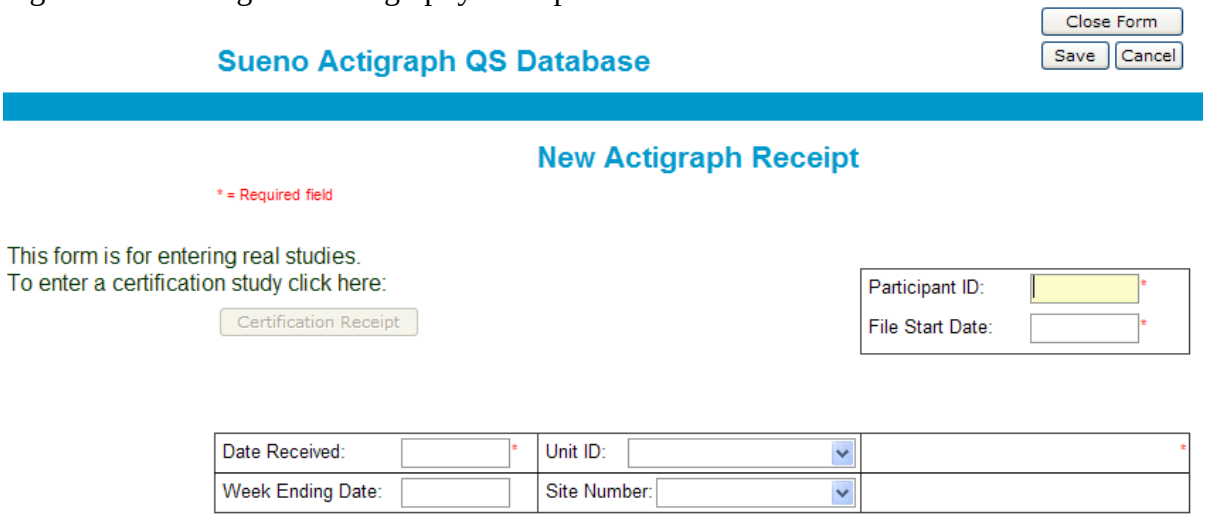
1. **Start the Actigraphy Receipt form:**
    a. Select **RC_bwh.mdb**. A window in Microsoft Access will open.
    b. Under **Select Study Database**, select **Sueno: Sueno/HCHS** from the dropdown menu.
    c. Under **Login**, enter **SQL username/password**. Then press the **Login to Actigraph Data** button.

Figure 38. Login to Reading Center QS Database



d. Select **New Receipt** from the upper left hand corner.
e. In the **New Actigraph Receipt**, enter the **Participant ID** (first letter of the field site + 7 digits).

Figure 39. Entering New Actigraphy Receipt



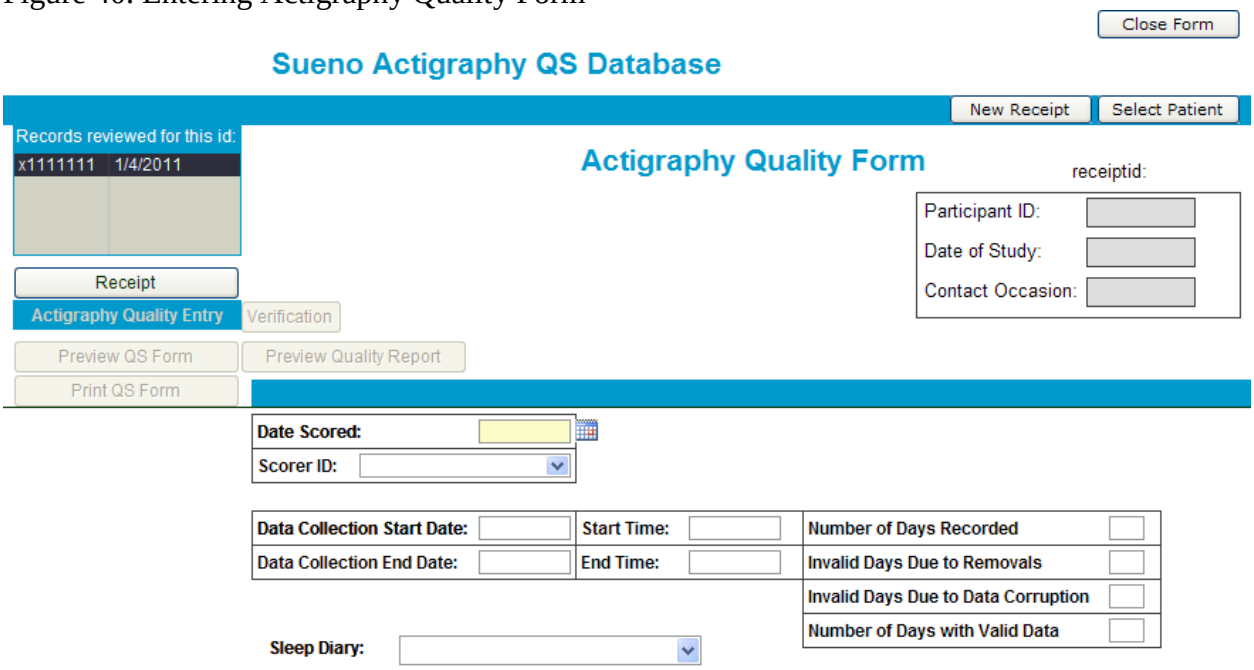
f. Enter the **File Start Date**, which is the date of the first on-wrist episode. Reference the participant's actogram for this information.
g. Enter the **Date Received**, which is the date the file was received at the Reading Center. Reference received Diplomat emails.
h. Enter the **Week Ending Date**. This value corresponds to the Friday after the study was *received* unless the study was received on a Friday. In this case, enter the date the study was received on.
i. Select the **Unit ID** from the dropdown menu. The unit ID corresponds to the last 4 digits of the Actiwatch serial number. The serial number can be located in the participant's printed **Actiware Print Report** in the upper right hand corner under **Actiwatch SN**. The serial numbers begin with the letter "S" followed by 5 digits. Confirm that the last 4 digits are consistent with the origin site of the watch. Enter

-9 or missing only if the serial number of the watch cannot be retrieved. Enter -1 or confusion if there is conflicting data as to what the serial number is.

j. Enter the **Site Number** (Site 1: Bronx, Site 2: Chicago, Site 3: Miami, Site 4: San Diego, Site 99: Boston). Confirm that the site number is consistent with the unit ID. Enter -9 or missing only if the site from which the data was sent is unknown. Enter -1 or confusion if there is conflicting data as to the identity of the site from which the data was sent. In some instances, watches originally from the Boston site will be sent to a different site as temporary loaner watches. In these instances, the Unit ID should correspond to the original site (Boston) and the site number should correspond to the site the Actigraphy and Daily Sleep Log data was sent from.

2. **Save New Actigraph Receipt:** click on the **Save** button in the upper right hand corner of the New Actigraph Receipt form. Close this form and return to the main window where the participant's record should be displayed under **Select Record**. Confirm that the record is present.
3. **Complete Quality Form:** It is important to complete *every* field on this form. Make sure to select an answer for every dropdown item. The purpose of the quality form is to provide a record of the degree of confidence that the sleep intervals manually set in the participant actogram correspond to the times the participant actually intended to sleep and wake up.
    a. Under **Select Record**, select the participant's record. In the **Actigraphy Receipt Form**, *do not* complete the rest of the receipt. Instead, select the **Open QS Form Entry** button located in the leftmost column. This action will result in opening the **Actigraphy Quality Form** window.

Figure 40. Entering Actigraphy Quality Form



b. Enter the **Data Collection Start** and **Data Collection End Dates** based on the Actigraphy file. *Note: the data collection start date is the date of the first **on-wrist***

episode *and the end date is the date of the last on-wrist episode. In order to find the date and time of the first on-wrist episode, click on the actogram near the start of the first on-wrist time. A pink arrow with a white caption listing the date and time will appear beneath the actogram. Adjust the arrow placement by using the right and left arrow keys. The time when the first activity count (ac) occurs is the first on-wrist episode. Record the date displayed in the white caption as the Data Collection Start Date. In order to find the date and time of the last on-wrist episode, click on the actogram near the last on-wrist time. Position the pink arrow to the last activity count (ac) and record the date displayed in the white caption as the Data Collection End Date.*

c. Enter the **Data Collection Start** and **Data Collection End Times** based on the Actigraphy file. It is important to enter times in **MILITARY TIME**. Therefore, 8:00 am would be entered as 0800 and 8:00 pm would be entered as 2000. If these times end in ":30" or 30 seconds, do not record the extra 30 seconds on this form. Do not round up. *Follow the steps in E.3.b to find the exact times of the first and last on-wrist episodes.*

d. Enter the **Number of days recorded,** which corresponds to the number of days (12:00:00 pm to 11:59:30 am) with on-wrist data including day 1 onward. For details regarding how day 1 is determined, see E.8.

e. **Invalid Days Due to Removals** are days when the Actiwatch was off-wrist for more than 4 hours and/or during the main sleep period making it impossible to confidently estimate the sleep interval time and duration or both. Additionally, if there were more than 4 hours of NO DATA for a given day, this would be considered an invalid day due to removal.

f. **Invalid Days Due to Data Corruption** are days when there was a Data Failure for more than 4 hours and/or during the main sleep period making it impossible to confidently estimate the sleep interval time or duration or both.

g. The **Number of Days with Valid Data** is the number of days recorded minus the number of invalid days.

h. The **Daily Sleep Log** is considered reliable if it aided in the confidence of the placement of the sleep intervals in the actogram. Enter "-9 Permanently missing" if the sleep log is blank or otherwise missing. Enter "-1 Confusion" if the log is unclear.

4. In/Out of Bed Grades: Grades are assigned to both the Time in Bed and Time Out of Bed separately. The grade assigned to the Time in Bed for a given sleep interval should not influence the grade assigned to the Out of Bed Time and vice versa. The Time in Bed/ Out of Bed should be filled in as a grade ranging from 0 to 3. This grade is a measure of the level of confidence that the time the sleep interval was set matches the actual time that the participant intended to sleep. A grade of 1 or unreliable indicates that the time set was a guess/approximation. In contrast, a grade of 3 or mostly reliable indicates that the interval set is likely the actual time the participant intended to sleep.

a. A grade of **3** or **Mostly Reliable** is assigned when it is likely that the time the sleep interval was set corresponds to the actual time the participant intended to sleep. Most of the present and reliable parameters indicate that sleep occurred at the time the interval was set with only minor inconsistencies. Conversely, it seems unlikely there is an alternative sleep time.

b. A grade of **2** or **Somewhat Reliable** is assigned when it is probable that the time the interval was set corresponds to the actual time the participant intended to

sleep, but there is also a reasonable alternative time at which the sleep interval could have been placed.

c. A grade of **1** or **Unreliable** is assigned when the time the interval was set is at best a guess or approximation of the actual time the participant intended to sleep. In most cases, there are major inconsistencies between parameters preventing a robust prediction of the time sleep actually occurred.

d. A grade of **0** or **No Evidence of Sleep** is assigned when there is no indication that the participant intended to sleep on a given day. This grade is typically assigned when there is a brief on-wrist episode on the last day the participant wore the watch. *For example, if the participant permanently took their watch off at 2:00 pm, there would be two hours (12:00:00 pm to 2:00:00 pm) of on-wrist data for the last day the watch was worn. If there was no evidence that sleep occurred over the two hours the watch was worn, the Time in Bed and Time Out of Bed grades for this day would receive a grade of 0.*

e. A grade of **-1** or **Confusion** is assigned when some or all of the parameters are missing due to invalid, excluded, and/or off-wrist data. This grade is typically assigned when there is an off-wrist episode during the in-bed or out-bed transition or between any of the four parameters at either transition. *For example, if the participant marked a bed-time of 11:00 pm on the Sleep Log, took the watch off between 11:15 pm-11:17pm, and then pressed the marker and went to bed at 11:20, the transition will be at 11:20 pm, but the In-bed score will receive a grade of -1.*

5. **In/Out of Bed Parameters:** In addition to entering a grade for each In/Out of Bed episode, the parameter (Marker, Diary, Light Quantity, Activity) that was used to place the In or Out of Bed interval should also be indicated. Only the parameter that had the exact same time as the time entered for the interval placement should be entered as "1" or "Checked" in the Quality Assessment Form. Therefore, a single parameter should be checked for each of the In/Out of Bed episodes per day. All other parameters listed should be filled in as "0" or "Not Checked." If a grade of "0" was assigned, enter "-8" for all parameters.

6. **Napping Grades:** The grade assigned in response to the question "did napping occur?" for a given day should be based on how confident the scorer is that naps actually took place. The grades assigned range from 0 to 3. Reference both the subject's Actigraphy file as well as Daily Sleep Log when assigning a grade. The napping grade assigned should be based on ALL of the naps taken for a given day. **Important:** the grade assigned should be based on the grade given to the LEAST reliable nap. Remember that any periods of low activity that are not associated with a Marker and/or Daily Sleep Log should not be counted as naps.

    a. A grade of **3** or **Mostly Reliable** is assigned when all of the naps for a given day reported by the participant in the form of Diary and/or Marker entries are likely to have occurred based on associated distinct drops in activity.

    b. A grade of **2** or **Somewhat Reliable** is assigned when there is some evidence that the least reliable nap reported by the participant occurred. All Marker and Log entries should be associated with some supportive evidence that the least reliable nap occurred such as a drop in the quantity of light or a brief drop in activity.

    c. A grade of **1** or **Unreliable** is assigned when the least reliable nap reported by the participant did not have an associated drop in light and/or activity or it seems very

unlikely this nap actually occurred. A napping grade of 1 should be assigned to days where default 30 second nap intervals are present.

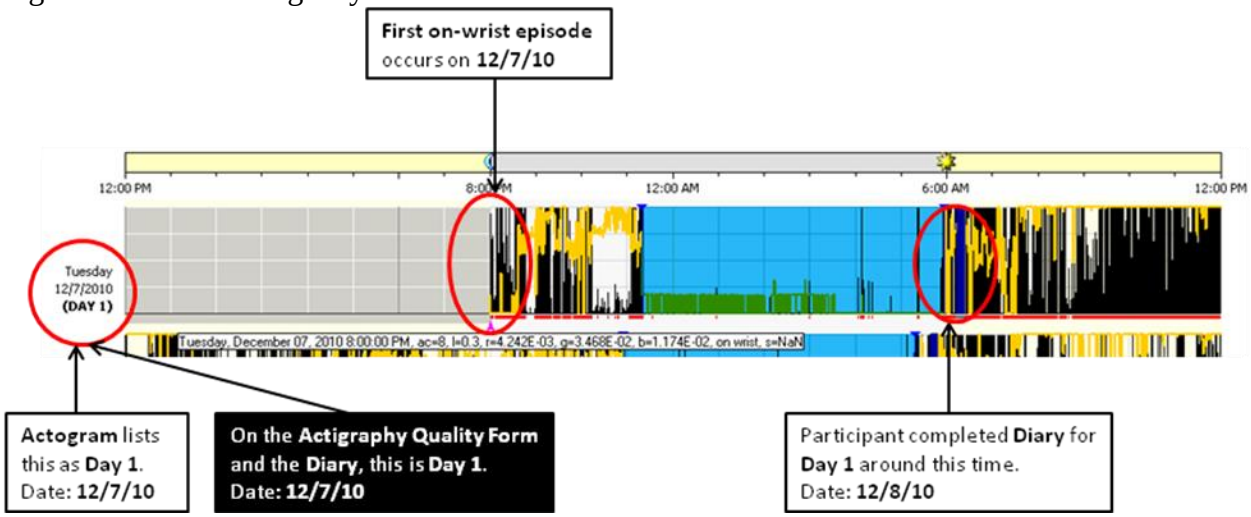
d. A grade of **0** or **No Evidence of Sleep** is assigned when there is no Daily Log entry or Marker indicating the presence of naps for a given day.
e. A grade of **-1** or **Flag/Confusion** should be assigned when there is no way to determine where a default 30 second nap interval should be placed. This can occur if the nap recorded by the participant overlapped with a main sleep period or if the participant recorded the nap as having taken place when the device was off-wrist. Alternatively, if the only evidence the participant took a nap for a given day is in the form of "yes" in response to the Daily Sleep Log question "during the day yesterday, did you take a nap or fall asleep for more than 5 minutes?" but the actual nap time was not entered and there was no other conclusive evidence, then it would be appropriate to assign this grade. If any of the naps for a given day received the grade of -1, the grade assigned for the entire day should be -1.

7. **Napping Parameters:** Nap intervals can only be set if there was a Marker and/or a Daily Sleep Log entry indicating the presence of a nap. Check the parameter(s) that served as evidence that napping occurred (Marker, Daily Log or both). If a grade of "0" was assigned, enter "-8" for all parameters. If there are multiple naps on a given day, check the parameter(s) that were used to set all nap intervals. *For example, if the Marker was used as evidence of the first nap interval and the Diary was used as evidence of the second nap interval, both the Marker and the Diary should be checked off in the Quality Assessment form for that day.*
8. **Entering Grades and Parameters Properly:**
    a. The day entered as **Day 1** in the Actigraphy Quality form should satisfy the following conditions:
        i. Day 1 recorded in the Actigraphy Quality form should always match day 1 in the Daily Sleep Log. *Note: the <u>date</u> of day 1 in the log will be off by one day compared with the date on the actogram because participants complete the log the morning after.*
        ii. The ***<u>date</u>*** of day 1 in the Actigraphy Quality form should always match the **Data Collection Start Date**. The data collection start date is defined as the date of the **first on-wrist episode**. For instructions as to how to find this date, see E.3.b. *<u>Do not</u>* simply record the date listed to the left of the actogram for the day on-wrist begins as the data collection start date. Instead, click on the actogram and move the pink arrow to the start of first on wrist.
        iii. Day 1 in the Actigraphy Quality form may or may not match the ***<u>day</u>*** listed as day 1 directly to the left of the actogram.

For additional information on how to designate **Day 1 in the Actigraphy Quality form**, refer to the following examples:

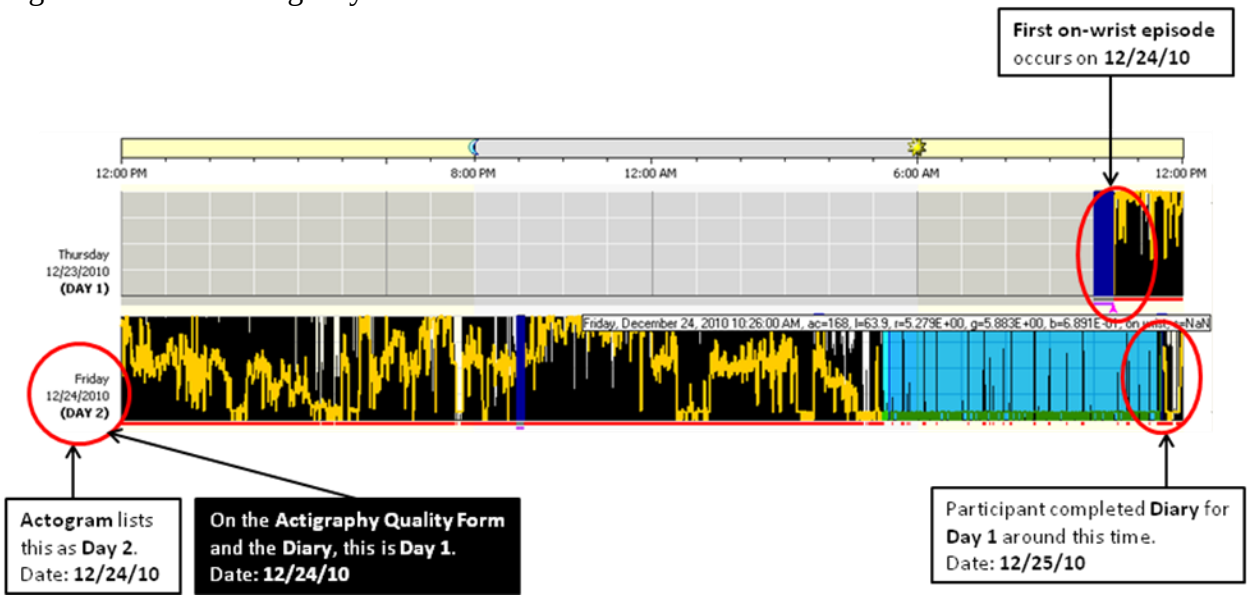
Determining day 1 when first on-wrist episode is <u>at or after</u> the preset start time (in most cases 12:00:00 pm)**:** the day the **actogram** lists as day 1 should match day 1 in the **Daily Sleep Log**. This is also the same day that should be entered into the **Actigraphy Quality Form** as day 1. The date of the first **on-wrist episode (data collection start date)** is the same date as that of day 1 in the Actigraphy Quality Form.

Figure 41. Determining Day 1 with Data at or after Pre-set Start Time



Determining day 1 when first on-wrist episode is <u>before</u> the preset start time: The day the actogram lists as day 1 is <u>NOT</u> the same as day 1 in the **Daily Sleep Log**. The day that should be entered into the **Actigraphy Quality Form** as day 1 should match day 1 in the Daily Sleep Log. The date of the **first on-wrist episode (data collection start date)** is the same date as that of day 1 in the Actigraphy Quality Form. *Note: on the actogram, the first on-wrist episode will appear to be listed on a separate day and date compared with day 1 in the Actigraphy Quality form. By actually clicking on the region of the actogram associated with the first on-wrist episode and moving the pink arrow to the first on-wrist episode, the white caption that appears under the arrow will list the same date for the first on-wrist episode (data collection start date) as the date for day 1 in the Actigraphy Quality Form.*

Figure 42. Determining Day 1 with Data before Pre-set Start Time



b. **Entering all Grades and Parameters:** Grades should be entered in the leftmost field in the Time in Bed, Time Out of Bed and Napping columns. Parameters should be checked in the rightmost field in all three columns. If a parameter was not checked, select "0" or "unchecked" in the dropdown menu for this parameter

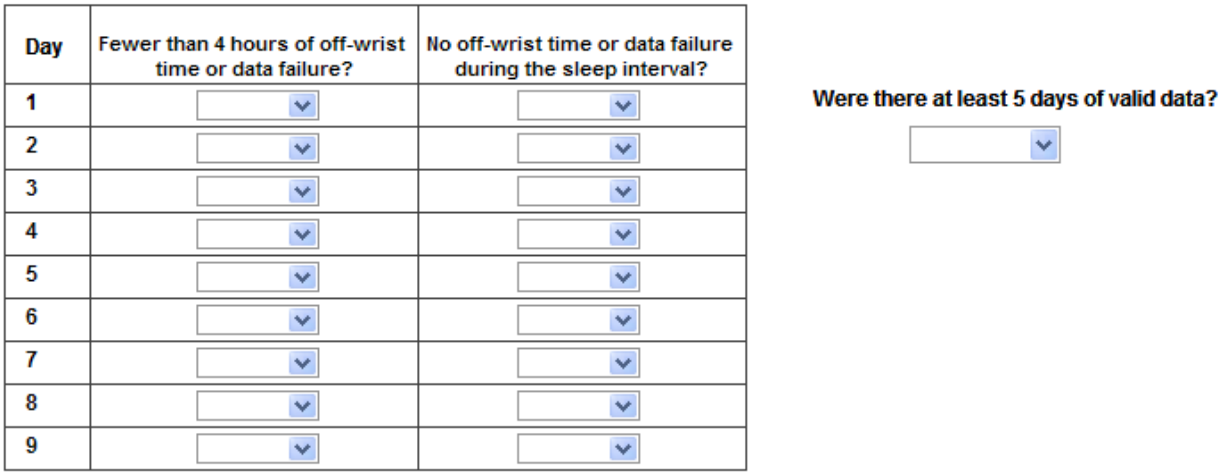
rather than leaving the field blank. If a grade of zero was assigned, all of the parameters corresponding to this grade should be filled in as "-8" or "Not Applicable." Make sure that every field of this form is complete. If there are fewer than 9 days of on-wrist data, enter a grade of "-8" for all fields for the remaining rows. Figure 43 (below) shows a blank version of the Actigraphy Quality Form.

Figure 43. Entering Grades and Parameters Used in Quality Form

Day	Time in Bed		Time Out of Bed		Did Napping Occur?	
1		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
2		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
3		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
4		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
5		Marker		Marker		Marker
		Diary		Diary		Diary
		Light		Light		
		Activity		Activity		
6		Marker		Marker		Marker

9. **Determining How Many Days of Valid Data:** Enter data for this section in the table below on the Actigraphy Quality Form:

Figure 44. Determining the Number of Valid Days



a. **Fewer than 4 hours of off-wrist time or data failure:** This value should be the sum total of all of the off-wrist, no data and data failure time for a given day. Off-wrist intervals are indicated by dark blue bands (excluded intervals). Note that a day starts at 12:00:00pm and ends at 11:59:30am. Check "yes" if there were fewer than 4 hours or 240 minutes of off-wrist time, no data and data failure cumulatively. Check "no" if there were 4 or more hours of off-wrist time, no data and data failure combined for a given day. For further instruction, see B.2.b.

b. **No off-wrist time or data failure during the sleep interval:** If there was no off-wrist time or data failure during the beginning, middle or end of sleep (including all naps), check "yes." If dark blue bands (excluded intervals) or grayed regions of no data or data failure are present at the beginning, middle or end of sleep (including all naps), check "no."

c. **At least 5 days of valid data:** Initially determine how many main rest intervals are present. If there are fewer than five, check "no." Then determine how many days had no checked for the question "Fewer than 4 hours of off-wrist time or data failure?" and/or the question "No off-wrist time or data failure during the sleep interval?" Days that had "no" as inputs for either or both question(s) are considered to be invalid. Determine how many valid days remain. If there are fewer than 5, check "no" for this question. If there are still 5 or more valid days, check "yes." If "no" was selected, make sure that a **Study Failure Form** has been sent to the original field site. Additionally, make sure that the answer to this question is consistent with the **Number of Days with Valid Data** previously entered.

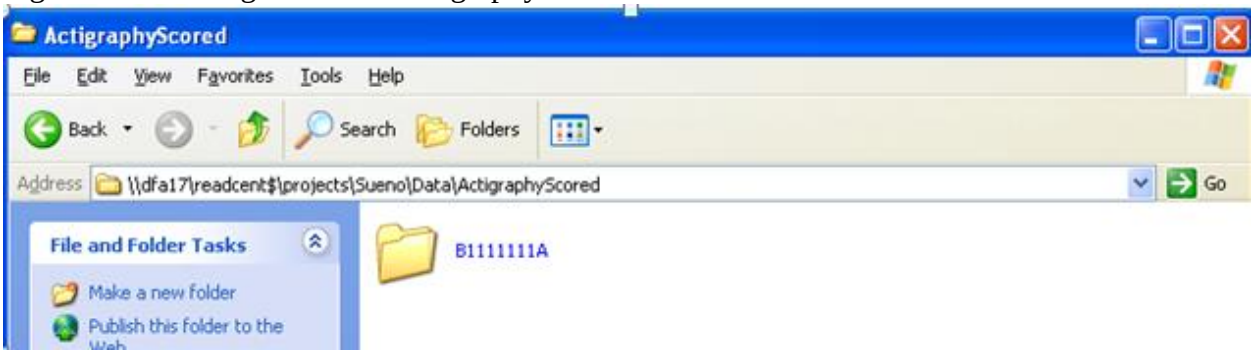
10. **Study Comments:** Enter comments as needed. Enter "-8" or "Not Applicable" if no comments are necessary.

Figure 45. Study Comments Field

11. **Saving Quality Form:** After all fields have been completed in the Actigraphy Quality Form, click on the **Save** button in the upper right hand corner.
12. **Moving Files in the Sueño Database:** Move the folder labeled with the subject ID and contact occasion that contains the Actiware file, the Daily Sleep Log and the Quality Assessment form from the **ActigraphyRaw** folder to the **ActigraphyScored** folder. Make sure the folder labeled with the subject ID and contact occasion is no longer in the ActigraphyRaw folder. See below:

ActigraphyScored Folder: This folder should contain a folder labeled with the subject ID and contact occasion (ex: B1111111A).

Figure 46. Labeling of Scored Actigraphy Folder



Subject ID + Contact Occasion Folder: This folder should contain the subject's Actigraphy file, Daily Sleep Log and the completed Quality Assessment form. This folder should be saved in the **ActigraphyScored** folder.

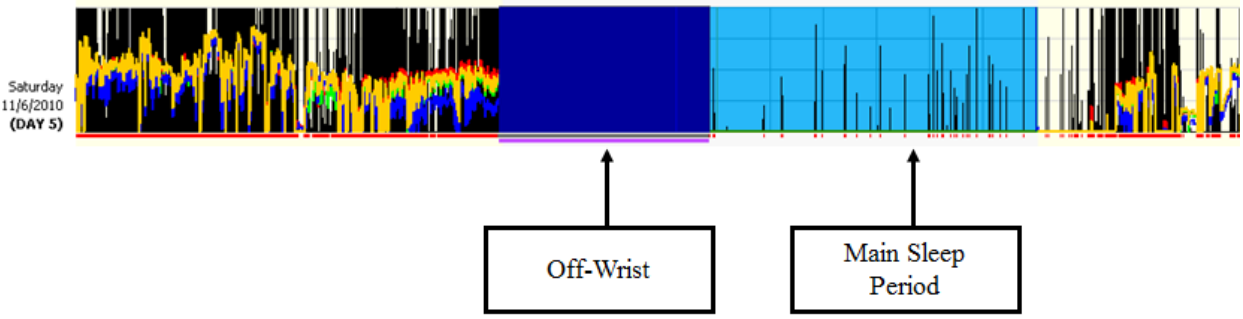
Figure 47. Verifying Contents of Scored Actigraphy Folder

F. CREATING "NO NAPS" ACTIGRAM

The modified "no naps" actogram is created so that there is an actogram only containing valid main sleep intervals. The original file containing naps provides a record of all of the data present in the file including naps, whereas the "no naps" file provides a record of only the valid main sleep periods. Both of these files will be useful in terms of statistical analysis.

1. **Open Participant Actogram:** In the actogram window, open the saved Actiware file for the subject by going to the Database Viewer and selecting the actogram labeled with the **subject ID** instead of New Analysis.
2. **Remove Naps:** Click on each nap interval and press the **Delete** key. Successful removal will be indicated by the disappearance of the **rest** and **custom** intervals. Alternatively, right click on the rest interval and select **Clear Interval**. Then right click on the custom interval and select **Clear Interval** as well.
3. **Set Default Intervals:** Every day must have a rest interval. For days lacking rest intervals, set a rest interval from 1:00:00 pm to 1:00:30 pm for these days. If there was off-wrist at this time, select an alternative location to place the default interval. *Note: days begin at 12:00:00 pm and end at 11:59:30 am.*
4. **Set Excluded Intervals:** For main sleep periods (not naps) where the duration of the rest interval is unclear, exclude the entire day (12:00:00 pm to 11:59:30 am). *Example: when the subject had the Actiwatch off-wrist during the time they went to bed (see below).*

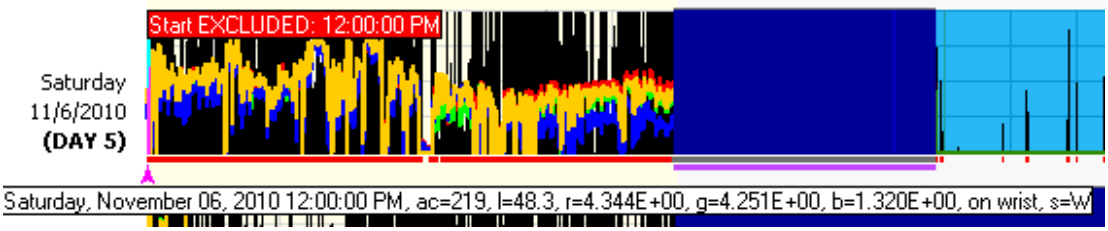
Figure 48. Excluding Invalid Day Due to Unclear Sleep Duration



Important: The exclusion criteria are <u>not</u> the same as the criteria for determining whether an actogram is of sufficient quality (B.2.a). Days should only be excluded when there is off-wrist time or data failure during the beginning, middle or end of main sleep periods, making it impossible to determine the duration of sleep periods. If there is off-wrist time or data failure in a nap, the entire day should <u>not</u> be excluded on this basis alone.

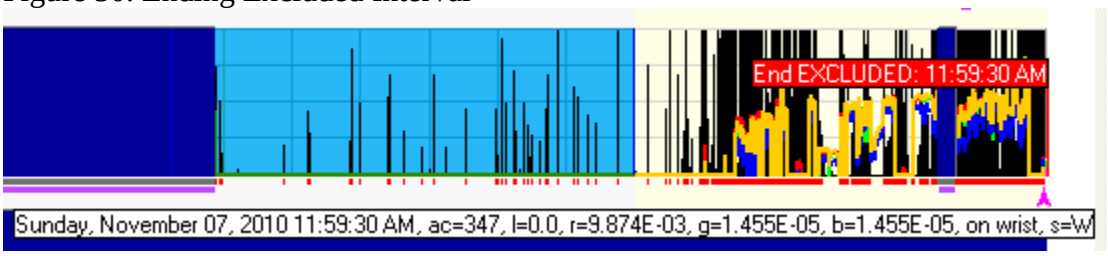
a. Position the pink arrow at the Start Hour, normally 12:00:00pm, of the day containing the unclear rest interval and type **e**. This action will result in the appearance of a red flag stating **Start EXCLUDED**.

Figure 49. Starting Excluded Interval



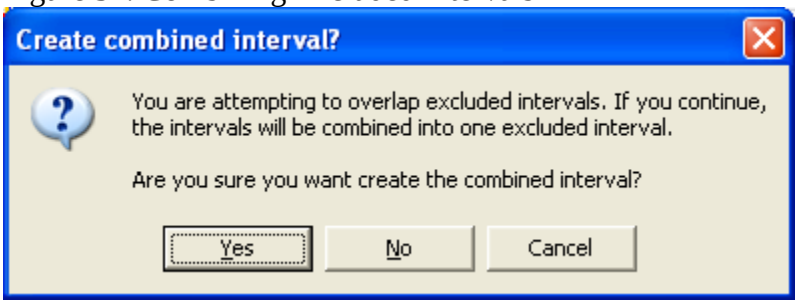
b. Position the arrow the end of the actigraphy day, (in most cases 11:59:30 am), and type **Shift + e**. This action will result in the appearance of a red flag stating **End EXCLUDED**.

Figure 50. Ending Excluded Interval



c. Set the Exclusion interval by typing **Ctrl + e**. A dark blue band should appear indicating the presence of an Excluded interval (see Interval Legend). Make sure to delete all **rest** and **custom** intervals for the excluded day. *Note: if there is an excluded interval already present, a message will appear asking to combine intervals. Select yes*

Figure 51. Combining Excluded Intervals



The entire day from Start Hour to End Time, should be marked as excluded (dark blue). **Important:** If a sleep period is considered invalid and extends past 11:59:30 am, create a 24-hour excluded interval that includes the invalid sleep period portion after 11:59:30 am.

Figure 52. Setting Excluded Interval

5. **Saving "No Naps" Actogram:** The modified actogram should be saved as **subject ID + nonaps** in the Actigraphy file. Select **Analysis>Save As**. ***Do not*** save over the original file with naps included labeled with just the **subject ID**.

Important note: even if no modifications were necessary, save a second copy of the actogram following the "no naps" naming system.

6. **Confirming Sleep Intervals:** Check that the intervals were set correctly by selecting **View > Statistics Table > OK**. Under the **Rest** tab, look up and down intervals and confirm that the number of rest intervals is consistent with the number of main sleep periods.

Figure 53. Selecting Statistics Table View

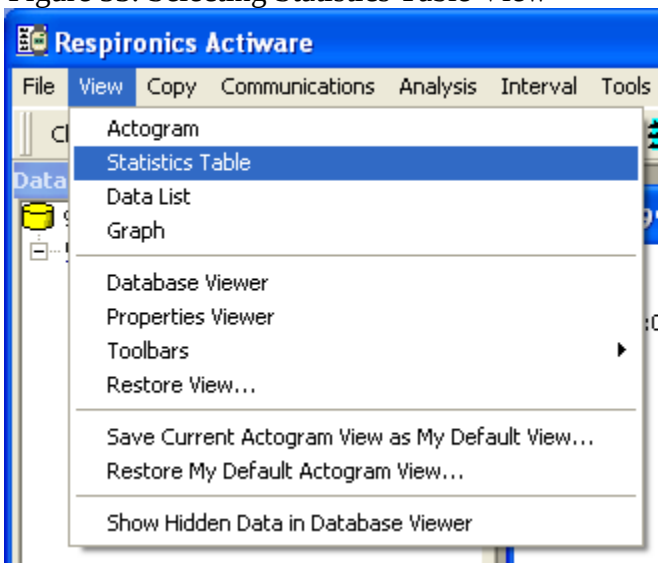


Figure 54. **Statistics Table**

Rest | Active | Sleep | Custom | Daily | Summary | Clinicians Report

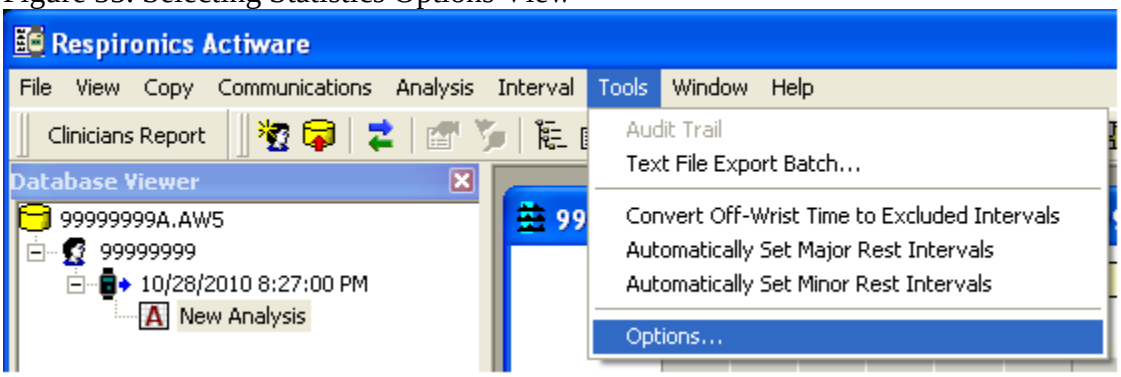
	Start Date	Start Day	Start Time	End Date	End Day	End Time	Duration	Off-Wrist	%Off-Wrist	Total AC
Interval 1	10/28/2010	Thu	11:00:00 PM	10/29/2010	Fri	6:00:00 AM	420.00	0.00	0.00	3514
Interval 2	10/29/2010	Fri	10:40:00 PM	10/30/2010	Sat	5:45:00 AM	425.00	0.00	0.00	5217
Interval 3	10/31/2010	Sun	12:55:00 AM	10/31/2010	Sun	7:10:00 AM	375.00	0.00	0.00	2591
Interval 4	10/31/2010	Sun	9:40:00 PM	11/1/2010	Mon	6:10:00 AM	510.00	0.00	0.00	5856
Interval 5	11/1/2010	Mon	11:20:00 PM	11/2/2010	Tue	5:00:00 AM	340.00	0.00	0.00	6955
n	*	*	*	*	*	*	5	5	5	5
Minimum(n)	*	*	*	*	*	*	340.00	0.00	0.00	2591
Maximum(n)	*	*	*	*	*	*	510.00	0.00	0.00	6955
Average(n)	*	*	*	*	*	*	414.00	0.00	0.00	4826.60
Std Dev(n-1)	*	*	*	*	*	*	63.97	0.00	0.00	1765.15

G. EXPORTING ACTIGRAPHY FILES

Both the original file containing naps marked with custom intervals labeled with the **subject ID** and the "no naps" file labeled with the **subject ID + nonaps** should be exported as .csv files. The original file containing naps marked with custom intervals will be saved in the **Naps** folder and the "no naps" file will be saved in the **No Naps** folder.

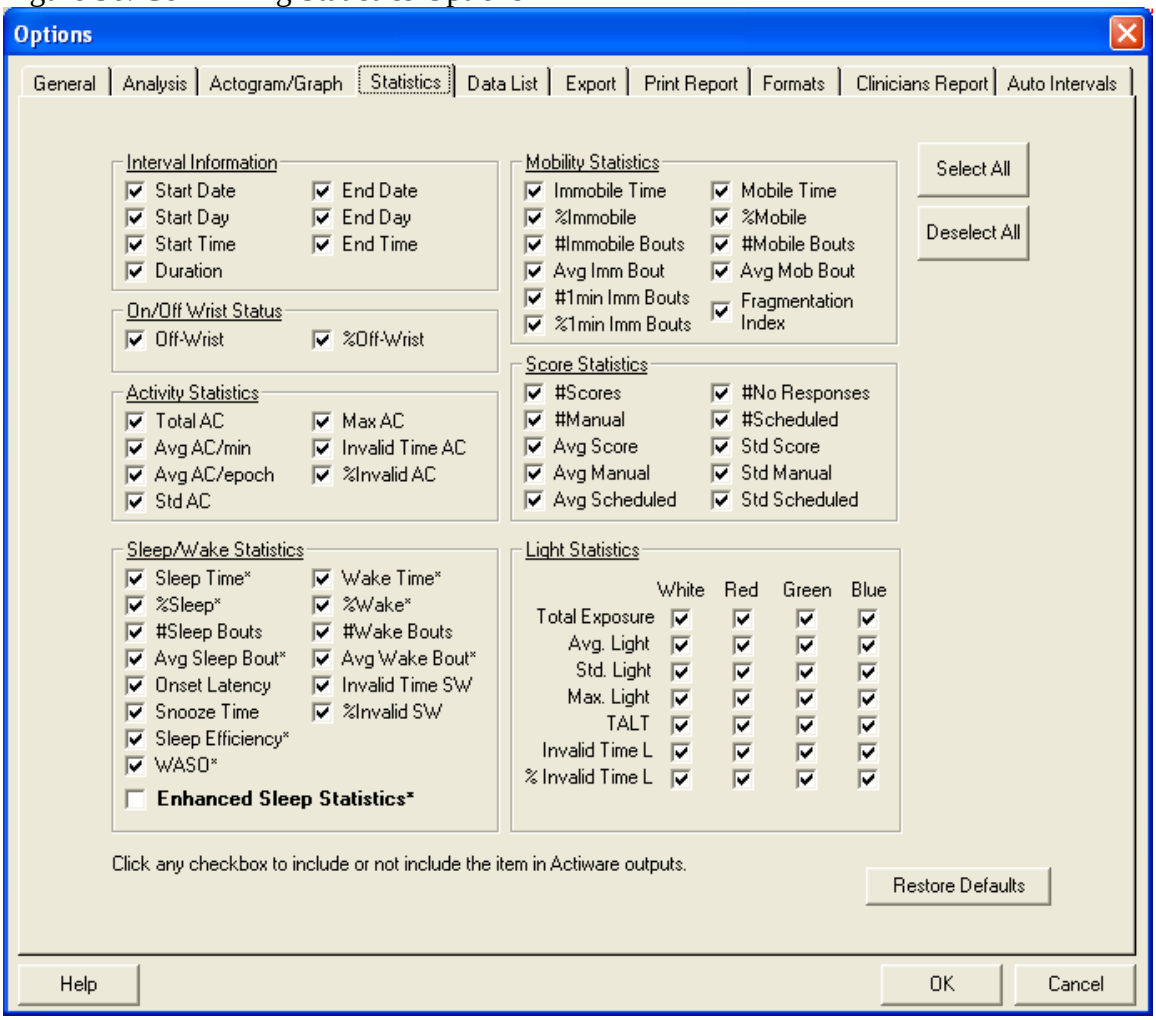
1. **Confirming Statistics:**
   a. For the newly saved actogram file labeled with the **subject ID + nonaps**, select **Tools > Options**.

Figure 55. Selecting Statistics Options View



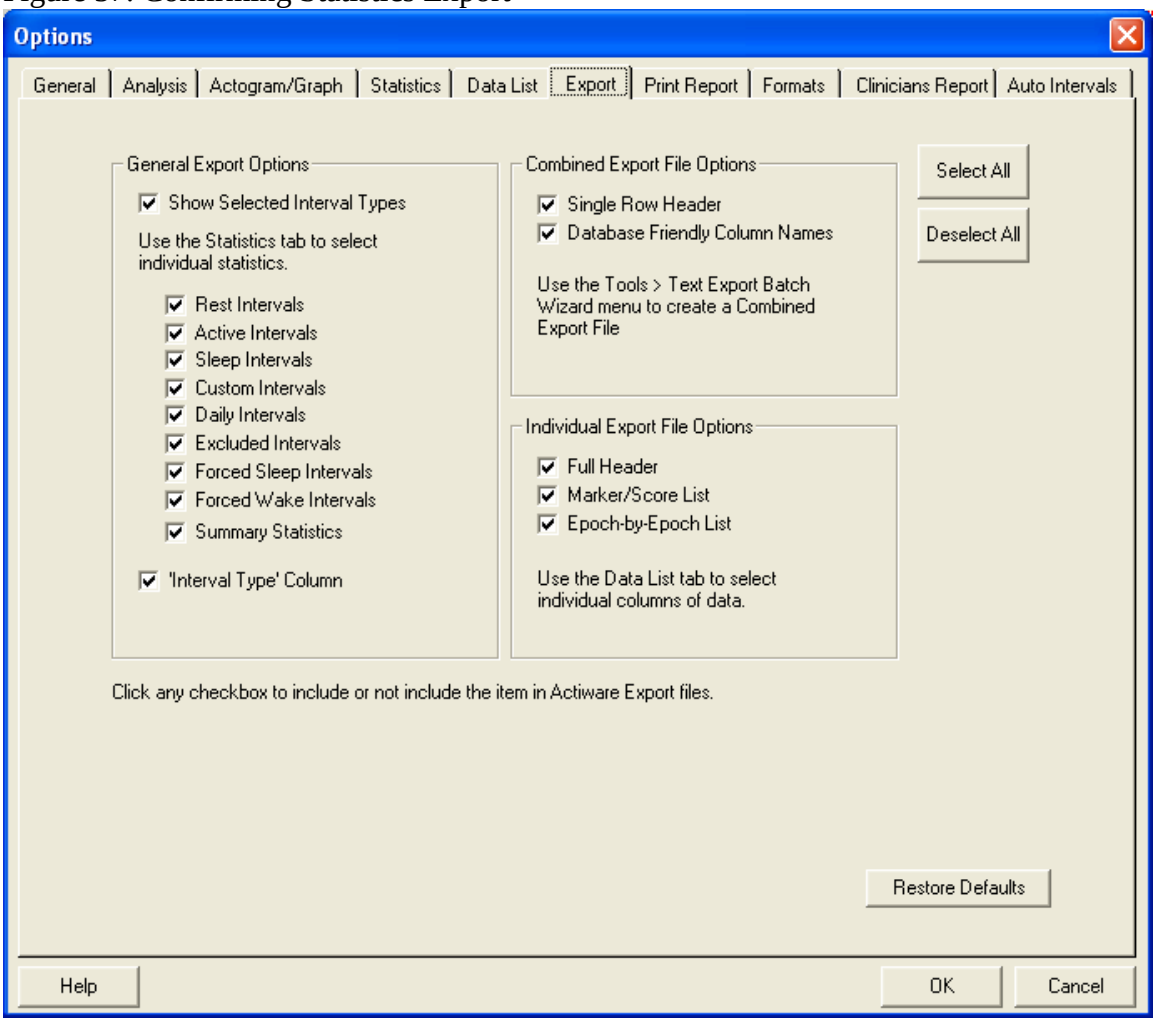
b. In the **Statistics** tab, confirm that all items are selected, except **Enhanced Sleep Statistics**.

Figure 56. Confirming Statistics Options



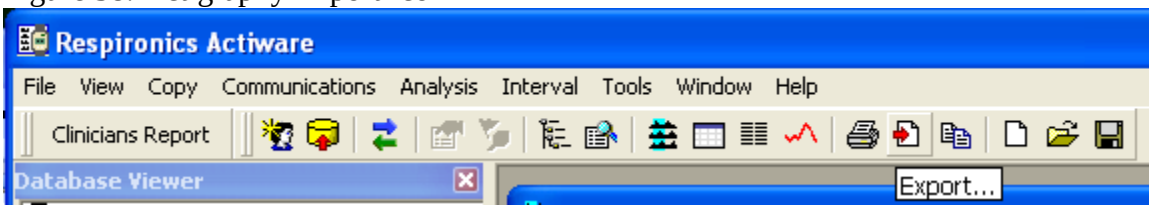
c. In the **Export** tab, confirm that all items are selected. Close the Options window.

Figure 57. Confirming Statistics Export



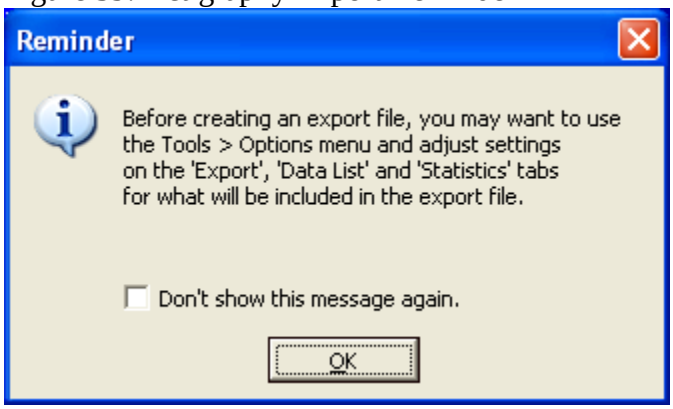
2. **Exporting Actogram Files:**
   a. In the main Actiware window, select the **Export** icon (a red horizontal arrow on top of a white page).

Figure 58. Actigraphy Export Icon



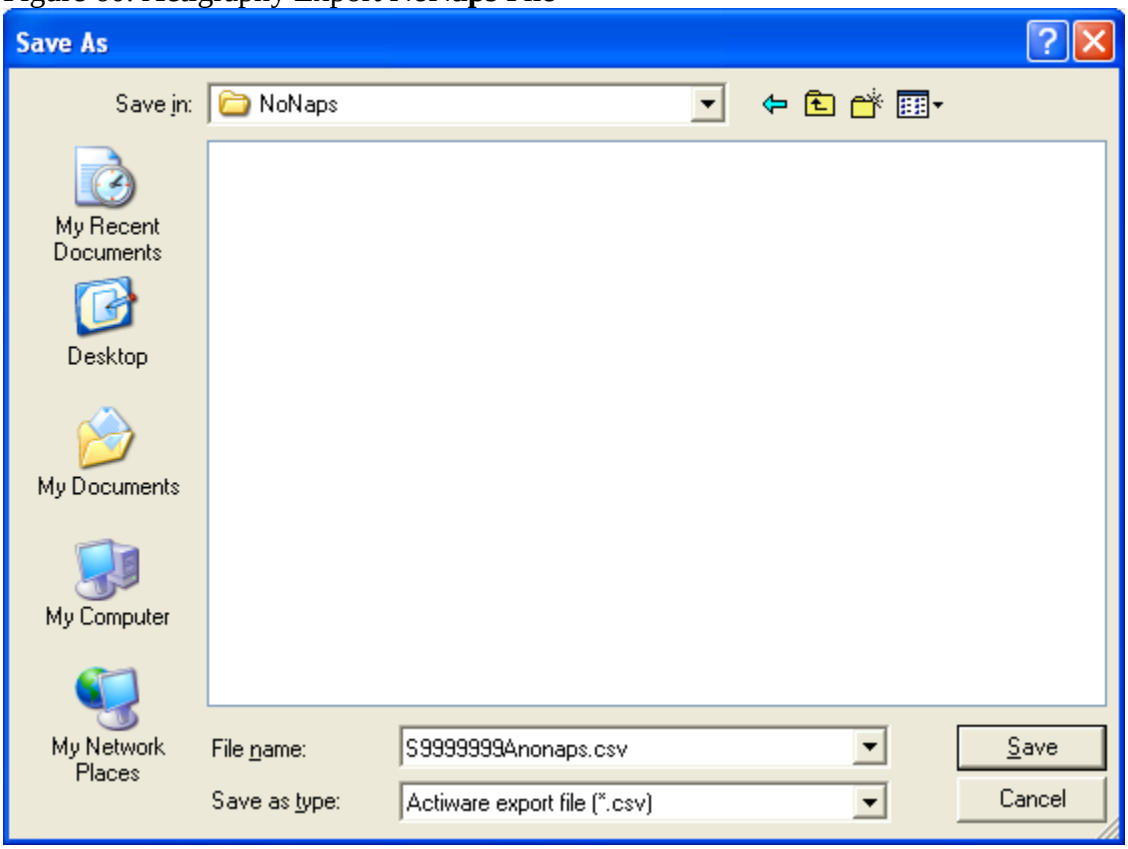
b. A reminder message will appear. Select **OK**.

Figure 59. Actigraphy Export Reminder



c. **Save** the actogram file in the **NoNaps** folder under the folder **Actigraphy_sasReports**. Label the **.csv** file with the **subject ID + contact occasion + nonaps**.

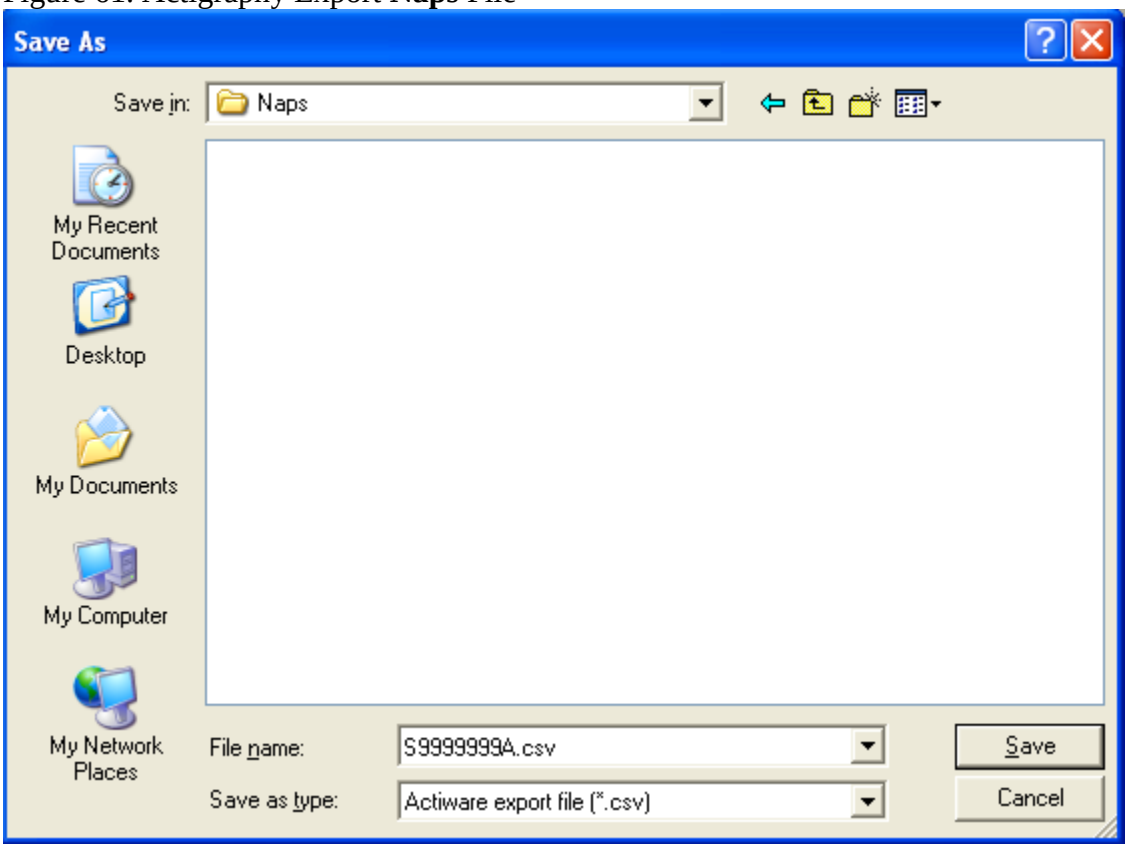
Figure 60. Actigraphy Export **NoNaps** File



d. **IMPORTANT:** Repeat steps G.1.a- 2.b for the original actogram file with naps included labeled with only the subject ID.

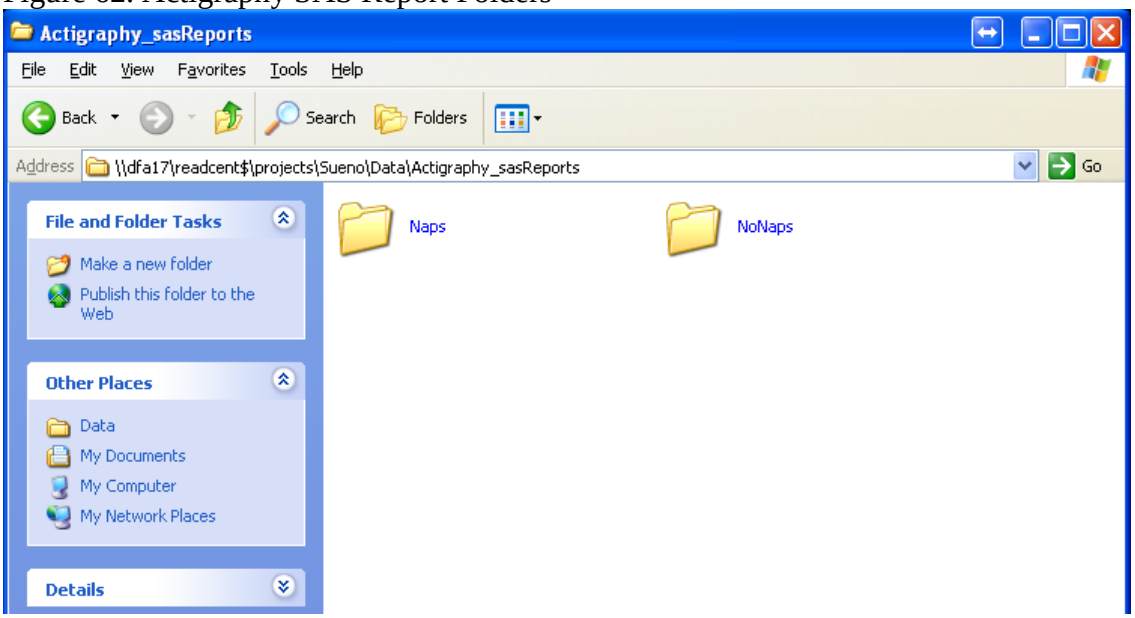
e. **SAVE** the original actogram file in the **Naps** folder under the folder **Actigraphy_sasReports**. Label the **.csv** file with the **subject ID + contact occasion**.

Figure 61. Actigraphy Export **Naps** File



Both the original and the new version of the actogram should be exported as a .csv file. These files should be saved in the **Actigraphy_sasReports** folder. The original version of the actogram should be saved in the **Naps** folder and the new version of the actogram should be saved in the **NoNaps** folder.

Figure 62. Actigraphy SAS Report Folders

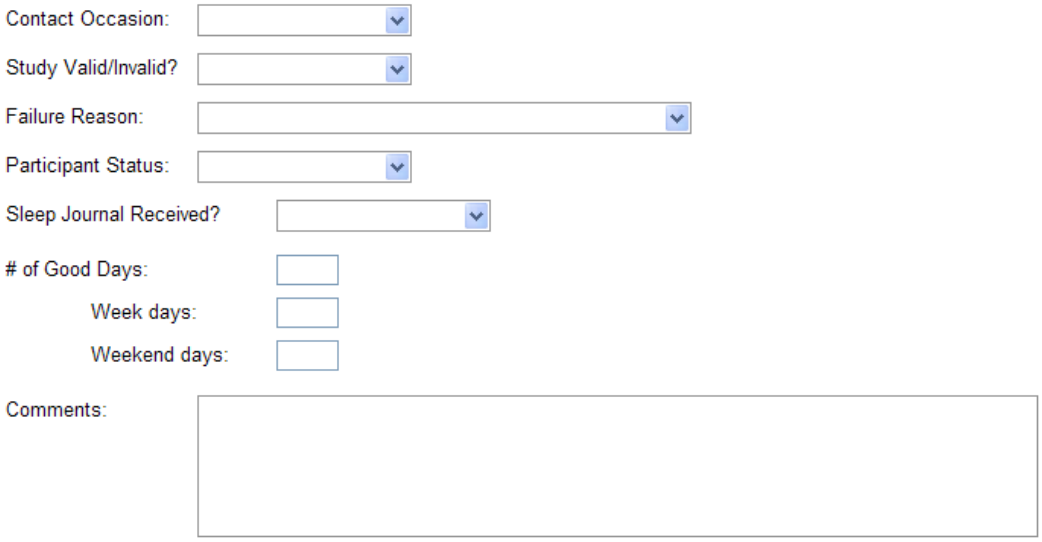


H. READING CENTER DATABASE ENTRY

Actigraphy data will be entered into this database so that there is a catalog of the received files. The first part of the receipt should have been completed prior to entering data into the Actigraphy Quality Form (see E.1-2). It is important to have completed the Actigraphy Quality Form *prior* to completing this receipt.

1. **Complete Actigraph Receipt Form:**
    a. Inside the Reading Center Database: **RC_bwh.mdb**, select the participant's file listed under **Select Record**.
    b. In the Actigraphy Receipt Form that had already been partially completed, enter the **Contact Occasion**. If it is unclear as to the contact occasion, enter "-1."

Figure 63. Entering the Actigraphy Receipt Form



    c. Enter whether the study is **invalid** or **valid**. An invalid study would be one where there were **fewer than 5 days of valid data**. Refer to the completed **Actigraphy Quality Form** for this information.
    d. **Failure Reason:** If **Valid** was entered, the Failure Reason field will auto fill as "-8" or "Not Applicable." If **Invalid** was entered, select the Failure Reason from the dropdown menu:
        i. **Contact Occasion 1 or -1:** Reference the **Study Failure Form** in order to obtain this information. If a Study Failure form is absent for the participant, refer to the **Actigraphy Quality Form**. Select the failure reason from the dropdown menu.
        ii. **Contact Occasion 2:** A Study Failure Form should NOT be present for this occasion. Reference the **Actigraphy Quality Form** in order to obtain this information.
        iii. Select **-8** or **Not Applicable** only if the failure reason cannot be determined.
    e. **Participant Status:** The purpose of this field is to determine whether a repeat trial will take place. If **Valid** was entered, the Participant Status field will auto fill

as "-8" or "Not Applicable." If **Invalid** was entered, select the Participant Status from the dropdown menu:

i. **Contact Occasion 1 or -1:** Reference the completed **Study Failure Form** in order to obtain this information. If the field site has not yet returned a completed version of the Study Failure Form with the Participant Status data entered, select "8" or "Pending" from the dropdown menu. When the completed Study Failure Form is returned to the Reading Center, change the Participant Status field referencing this form. If the site has clearly communicated that they are unwilling or unable to return a completed version of the Study Failure Form, enter "9" or "Missing".

ii. **Contact Occasion 2:** A Study Failure Form should NOT be present for this occasion. ***Always*** select **-8** or **Not Applicable** for the Participant Status when it is the second contact occasion and the study was invalid.

f. In the **Sleep Journal Received** field, enter whether the Daily Sleep Log was received. Select from the following dropdown options:
   i. Enter "-1" or "confusion/flag" if it is unclear whether there is a journal present for the participant that has the same contact occasion as the Actigraphy data.
   ii. Enter "-9" or "missing" if a sleep journal was never received from the field site.
   iii. Enter "0" or "no" if a blank sleep journal was received from the field site.
   iv. Enter "1" or "yes" if a sleep journal was received that had some amount of data entered by the participant.

g. For the **# of Good Days** field, enter the number of days that were considered to be valid based on the **Actigraphy Quality Form**. Under **Week days**, enter the number of days between and including Sunday and Thursday that were considered valid. Under **Weekend days**, enter the number of days that are Fridays or Saturdays that were considered valid. Refer to the **Actigraphy Quality Form** and the **Actigraphy** file for these values.

h. Enter **Comments** as needed.

2. **Save Completed Actigraphy Form:** click on the **Save** button in the upper right hand corner of the Actigraphy Receipt form. Click on the **Close** button in the upper right hand corner of the form, which results in automatically returning to the main window where the participant's record should be displayed under **Select Record**. Confirm that the record is present.