Wrist-worn Actigraphy

Investigators' Instructions

1. Connecting to a computer

The computer provided to support this trial has, on the Desktop, a shortcut to an application called OMGUI. If you want to set up a trial or download data from a sensor, you will do it through this application. **Double-click the OMGUI shortcut to open it**. Now, **connect the AX3 device to the computer** (Fig. 1), using the USB cable provided.

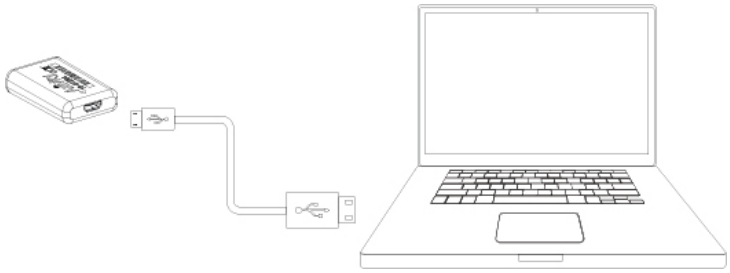

Fig. 1 Connecting AX3 device to a computer

Wait for the device to be recognized. It will appear in the **Device Browser Panel** (Fig. 2).

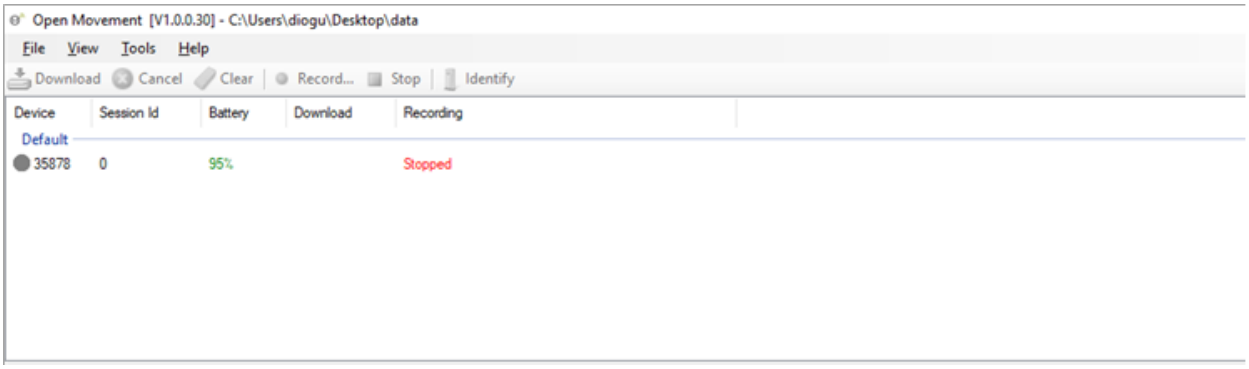

Fig. 2 OMGUI Device Browser Panel with one connected device (95% of battery, and stopped recording)

2. Learning to work with OMGUI

OMGUI (Open Movement Graphical User Interface) is the native application to operate with the AX3 activity sensor. Through it, you will be able to check the status of the devices (battery, data, and recording status), set up data collection, and download the data files from the sensor. Figure 3 shows an overview of OMGUI main screen.

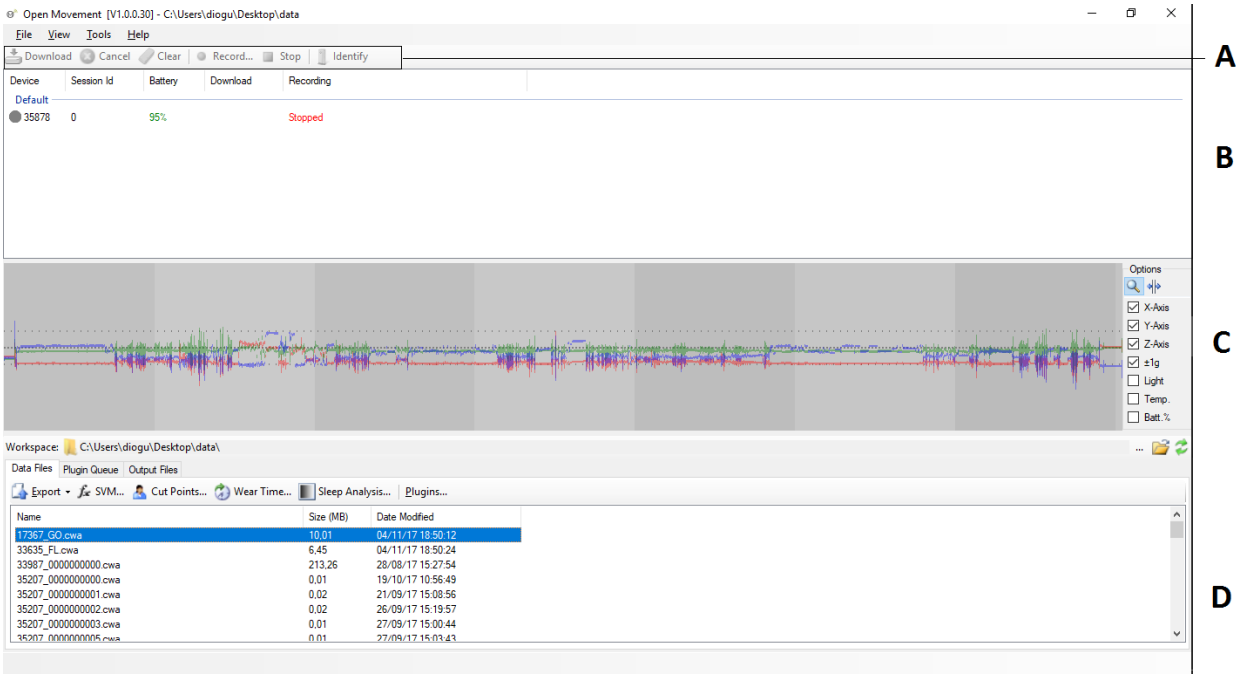

Fig. 3 OMGUI screenshot. **A)** Top Menu, **B)** Device Browser Panel, **C)** Data Preview Panel, **D)** Data Workspace

OMGUI presents a top menu and three main areas:

- In the Device Browser Panel (B), you will be able to see a list of the AX3 devices connected to the computer and their statuses. You can select a device by clicking on its row. If the device has data, you will see it plotted in area C.
- Once a device is selected, the top menu (A) will become interactive. Options will appear to Download data from a device, Clear the data from the device, Schedule a recording, Stop a recording, among others.

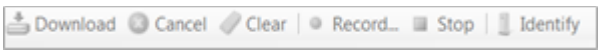

Fig. 4 Top Menu options (in this case, disabled. They become interactive when a device is selected).

- The Data Preview Panel allows you to see an overview of the data on a device.
- In the Data Workspace (D), you will be able to set up where you want your files to be saved, and to see the list of downloaded files.

3. Setting up Data Collection

Before you hand a device to a subject, you will need to set up data collection. In parallel, while the device is connected, it will be charging. To have the device ready, you should do the following:

- Open OMGUI and connect the AX3 sensor to the computer with the USB cable;
- Select the device in the Device Browser Panel;
- If the battery is low, keep it connected until it charges completely (a value above 85% is considered acceptable to issue for usage);
- If the device shows to have data, press “Clear” in the Top Menu (ensure that you have downloaded any previously collected data before pressing “Clear”; see section 5);
- Press the Record button, in the Top Menu;

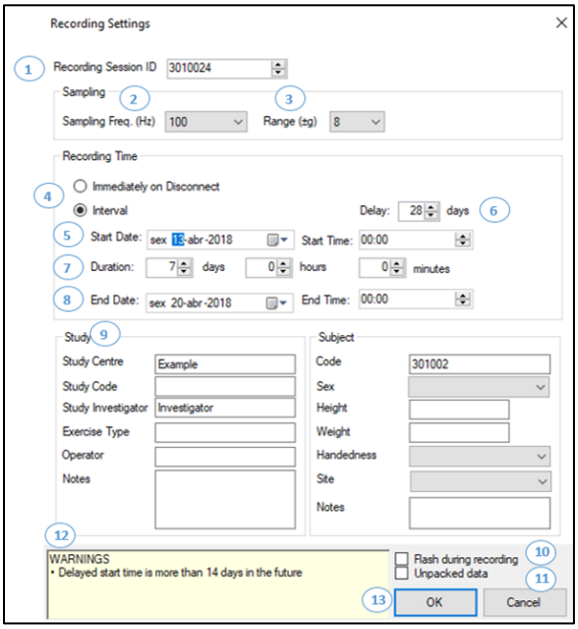

Fig. 5 Recording Settings dialogue.

- In the Record Settings dialogue, set up data collection as follows:
  1) Recording Session ID: input a unique ID. It will be the **Subject Number followed by the Visit Code** (of the visit, when the device is handed to the subject).

     Visit Codes: 1 (= VS1)
     2 (= VR)
     3 (= V1C)
     4 (= V2C)

     Example: Subject no. 301002, visit V2C, Recording Session ID 3010024.

2) Sampling Frequency: the value should be of **100**.
3) Sampling Range: the value should be of **8**.
4) Recording Time Schedule: select **Interval**.
5) Start Date: it should be **set to three days before the next onsite visit**. As an example, if the visit is on the 14th (any time), the start date will be on the 11th. **Start Time** should be set to **00:00**.
6) Delay: do not change this value.
7) Duration: the value should be of **7 days**.
8) End Date: do not change this value.
9) Study and Subject: identify the **Study Centre** and **Investigator** with their **initials**. As for **Subject**, input the **subject 6-digit code**.
10) Do not tick “Flash when Recording”;
11) Do not tick “Unpacked data”;
12) Warnings: these can be about battery or space. If a warning appears you should let the battery charge and/or clear the data, if you haven’t done so. Also, check the values in the boxes to make sure everything is as presented in this document. In the Figure, the warning is showing because we scheduled a 28 days recording, which is likely to cause exhaustion of the battery;
13) Click OK.

- You can now disconnect the device from the computer. The recording will start in the scheduled date and time. You can connect the device to the computer before handing it to the subject to guarantee it goes fully charged.
- Insert the sensor in the bracelet with the letters (“Axivity”) and a small arrow visible to you. The arrow on the bracelet should align with the arrow on the sensor (Fig. 6).

Fig. 6 Placing the sensor into the bracelet.

- Document the serial number of the sensor in the medical records of the subject and in e-CRF.

4. Instructing the Trial Subjects

Subjects should be instructed to wear the bracelet, as they would use a regular watch, for a period of three complete days before the **on-site visits VR, V1B, V2B, and V3B**. They will receive a call one or two days before they have to put the bracelet on to remind them accordingly and to check on the battery status, i.e. to exclude that the device is flashing a brief red light (if the device is flashing a brief red light, the subject needs to come to the site for replacement or recharging). They should wear it **continuously** on their **non-dominant arm and leave it on until the appointment** (also in case the visit is postponed). The design is neutral and unisex, and is constructed from a skin safe, soft touch silicone material. The sensor is waterproof. If subjects need to take the bracelet off for some reason, they should put it back on as soon as possible. Along with the bracelet, subjects shall receive a paper file with succinct instructions on how to wear it (i.e. the *Activity Bracelet Patient Instructions*). Please go through them with the subjects and clarify doubts they may have.

5. Collecting and storing the data

When the trial subjects bring the bracelet to the visits **VR, V1B, V2B and V3B,** you will need to download the data to the PC. To do so, follow these instructions:

- Open OMGUI and connect the sensor (after removing it from the bracelet) to an USB port on the computer;
- When the device is recognized, check the status of the recording. If it still shows as being recording, press “Stop”, in the Top Menu;
- In the Data Workspace Panel, select the folder where you want to save the data to (Figure 7).

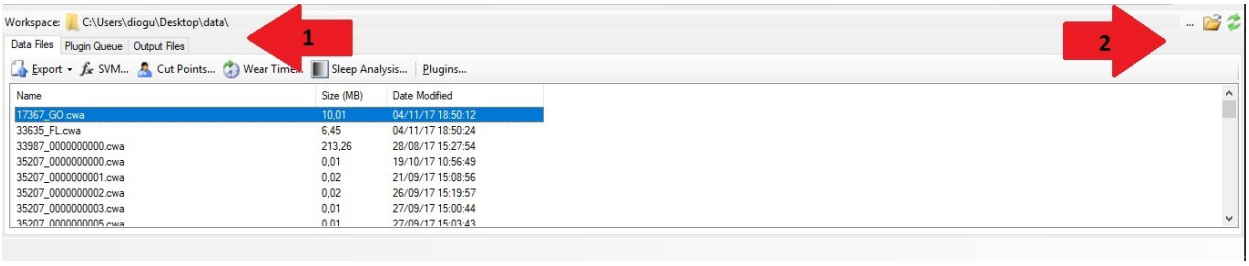

Fig. 7 Data Workspace Panel. Arrow 1 points to the current workspace. Arrow 2 points to the icons where a new workspace folder can be selected.

- This folder should be inside C:\AX3\. Inside that folder, there should be a sub-folder for each subject, i.e. the folder is named with the 6-digit subject number. Inside each subject's folder, there should be a folder for each visit (VR, V1B, V2B, and V3B). Select the folder for the current Subject and Visit (e.g. C:\AX3\301002\V2C).
- Press the Download button. This will take a while: you will see the progress of the download in the respective field, in the Device Browser Panel; make sure it gets to 100% (Complete). When that happens, a new file will appear in the Data workspace; select that file and check if the signal is visible in the Data Preview panel.
- If the graph shows no activity, try to understand if it wasn't worn by the subject, and re-explain the procedure.
- Clear the contents of the device (in the Top Menu).
- Disconnect the sensor from the USB port.

6. Extra Support

There is a website available with detailed instructions, screenshots and videos, for your perusal:

actigraphy.info

(password: thn102)