

Standard Operation Procedures

Feasibility Study on Surveillance Work Package 1.3 Subtask 1.3.2.2



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1. GENERAL INFORMATION

1.1 Background and Aims

To address major societal challenges and enhance cooperation in research across Europe, the European Commission has initiated and facilitated ‘joint programming’ (JPI). The Determinants of Diet and Physical Activity (DEDIPAC) Knowledge Hub (KH) is the first action of the European JPI ‘A Healthy Diet for a Healthy Life’. The objective of DEDIPAC is to improve understanding of the determinants of dietary, physical activity and sedentary behaviours.

The overall aim of Task 1.3.3 is to provide the pan-European research community with a roadmap towards a harmonised surveillance system for dietary behaviour, physical activity and sedentary behaviour and their determinants. As a first step towards this roadmap, an “Inventory of existing surveillance systems and infrastructures in Europe” (Subtask 1.3.3.1) has been conducted. A preliminary evaluation of this inventory has shown that sedentary behaviour in children and adolescents is least covered in European surveillance systems, Therefore, the advancement and testing of instruments to assess sedentary behaviour suitable for surveillance purposes is indicated and will be the focus of the feasibility study for surveillance (Subtask 1.3.2.2).

Physical activity (PA) and sedentary behaviours (SB) have traditionally been assessed by self-reporting in large-scale cohort studies and surveillance systems. However, objective assessment methods, such as accelerometry have emerged as potential methods to assess PA and SB in large scale studies. While much research has been conducted on the feasibility, validity and reliability of objective methods to assess PA, less is known about these measurement techniques when used to assess SB in special populations, such as school children. Therefore, the best available method of assessing SB and related determinants in large-scale surveillance systems needs to be identified.

The aim of this study is to quantify feasibility and acceptability of a newly developed subjective instrument as well as objective instruments in surveillance systems targeting European children and adolescents.

1.2 Study Description

The selection of method(s) or instruments that can be used in surveillance systems for the collection of public health data to measure SB is critical and depends on the objectives and target group of the surveillance system. Various aspects such as the type of data required,

available resources or the target population need to be taken into account in order to collect data on SB that are most accurate, sufficiently powerful and are feasible to identify health impacts in large numbers of individuals.

Instruments used in on-going national or pan-EU surveillance programs in participating DEDIPAC countries listed in the “Inventory of existing surveillance systems and infrastructures in Europe” were identified and reviewed. During the search process, particular focus was given to grey literature and direct contact with responsible principal investigators. The review has shown that in most surveillance systems SB is assessed with questions about media consumption. Therefore, similar questions will also be included in the feasibility study.

To date, objective assessment of SB is not widely implemented in surveillance systems. Therefore, implementation of objective instruments (e.g. ActivPAL) to assess sedentary behaviour is also part of this feasibility study.

Within WP2.3 a Systematic Literature Review (SL) on key determinants of SB in children and adolescents has been conducted. This SLR was taken as a basis for the selection of determinants, which will be assessed in this study, and the respective instruments.

Selection criteria for the instruments included their suitability for pan-European implementation and their potential for methodological harmonization across European regions. Selected instruments were combined to provide an integrated measurement method (English language). Translation to national languages will be organized for those countries where feasibility tests are to be conducted: Germany and Ireland. Based on the results of the feasibility studies, the set of integrated methods and related material (SOPs, training manual) will be amended and finalized.

In addition to the (objective and subjective) assessment of sedentary behaviour and its determinants, questionnaires assessing feasibility aspects of instruments and methods (“Feedback Questionnaires”) will be completed by the study participants, teachers and Survey Centers.

The feasibility study therefore comprises 4 modules:

- Module 1: Accelerometer (objective assessment) (for children)
- Module 2: Questionnaire Sedentary Behaviour and Determinants (subjective assessment) (for children/parents)
- Module 3: Questionnaire about School Characteristics (for teachers)
- Module 4: Feedback Questionnaires for (children/parents, teachers and Survey Centers)

The process regarding the selection of instruments is displayed in Figure 1.

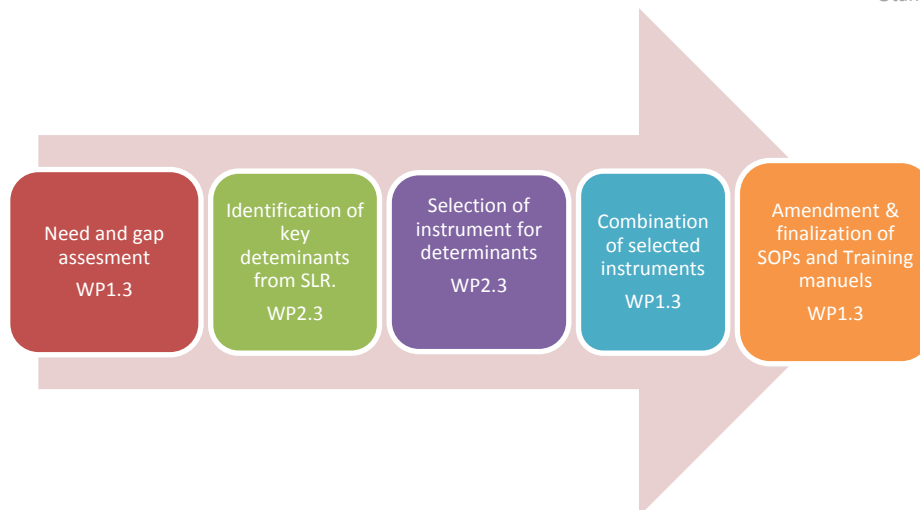


Figure 1: Feasibility Study on Surveillance

The recruitment of participants and collection of data will be coordinated on a setting basis (schools in participating countries) (see 1.4). During the investigation period, children will wear the accelerometer for 7 days (at least 6 days , preferably including one weekend day (with the aim of a minimum of eight valid hours per day)), and fill in questionnaires for subjective collection of sedentary behaviour and determinants at the end of the wearing time. However, for the assessment of socioeconomic status (SES) parents will be asked to provide this information when providing informed consent. For children up to the age of 10, parents will complete proxy-questionnaires (including information on SES) on behalf of their children.

Furthermore, teachers will fill in a questionnaire about school-characteristics related to sedentary behaviour in school and its determinants.

Immediately after filling in the Questionnaire Sedentary Behaviour and Determinants, children and parents of children up to the age of 10 will fill in the Feedback Questionnaire while Survey Centers also answer the Feedback Questionnaire in order to enable the evaluation of logistics and implementation of the instruments and methods. Teachers will fill in a Feedback Questionnaire as well.

Based on the results of the empirical study, specific recommendations and a roadmap for the collection of sedentary behaviour and related determinants in Surveillance studies in children and adolescents will be derived (Subtask 1.3.3.3).

1.3 Description of study regions

The following criteria should be considered when choosing the study region:

- Children and adolescents will be recruited exclusively from primary, secondary schools, high schools, junior high schools or other high schools.
- Where possible, schools from districts with different social status or schools with mixed SES structure should be included.

1.4 Inclusion criteria for study participants

Sample design

Sample size calculations were made based on results from the I.Family pre-test. The proportion of parents willing to complete the questionnaire again was 23%. The required sample size for the survey can be calculated as follows:

$$n = \frac{z_{1-\alpha/2}^2 \times p(1-p)}{d^2},$$

Where n denotes the required sample size, $z_{1-\alpha/2}$ the $100*(1-\alpha/2)$ percentile from the standard normal distribution (i.e. assuming a significance level of α , e.g. $z_{1-\alpha/2} = 1.96$ for a level of $\alpha=0.05$), p is the assumed prevalence of readiness to complete the questionnaire again which should be estimated with a margin of error (certainty) of d .

Example

It is assumed that roughly 23% of the parents in the pre-test were willing to complete the questionnaire. Using the above formula a sample size of $n=96$ is necessary to estimate the true (but unknown) prevalence within the margins of ± 8 percentage points (at a significance level of 5%) (Lemeshow 1990).

To allow also an investigation of the validity of the questionnaire, we aim for a sample size of 240 children in total.

Every Survey Center should therefore include 80 children (20 girls and 20 boys) from each of the following grades:

- 2nd (approximately 7-8 years)
- 9th grade (approximately 14-15 years)

The procedure for selecting children should be as follows:

1. Firstly, one or more schools that cover the required grades will be selected on a convenience basis. At least two different schools would be desirable in order to achieve higher heterogeneity. Facilities that accommodate only physically and / or mentally disabled children are not suitable and are therefore not eligible.
2. Several classes per grade will be approached to achieve the minimum sample size. The selection of the class(es) occurs in agreement with the headmaster of the respective school.
3. Parents will be informed about the study e.g. via parent-teacher conferences. All children of the respective class and their parents, respectively, as well as the teachers will be asked whether they would like to participate in the study. Parents and children above 10 years of age will have to sign an informed consent. Children may be excluded if the parents have insufficient knowledge of the German language and the employment of interpreters and/ or translators is not possible. In these cases, a graded procedure could be possible (for example, only the use of the accelerometer). The procedure must be documented for possible special arrangements in future evaluations.

The sample needs to be balanced with regard to gender. The minimum sample size in each strata is displayed in Table 1:

Table 1: Minimum required sample size stratified by grade, gender and Survey Center

Country	Partner #	Girls/ 2 nd grade	Boys/ 2 nd grade	Girls/ 9 th grade	Boys/ 9 th grade	TOTAL
GER	130	20	20	20	20	80
	169	20	20	20	20	80
IRL	214	20	20	20	20	80
						240

1.5 Quality assurance procedures

Training

Prior to the start of the DEDIPAC study, a training course for the fieldworkers covering survey procedures and all methods will take place. The aim of this training is to ensure that the survey is of high quality and to make sure that survey team members have matching knowledge with respect to data collection. The training can serve as a platform to exchange experiences and to answer questions that were not addressed previously.

Pre-Test

After translation to national languages, instruments will be tested in a convenience sample in each survey centre. Reports about the pre-tests will be sent to the coordination centre BIPS and instruments adapted if necessary.

1.6 Ethics and Privacy issues

Prior to the start of the surveys, the approval of the local ethics committees and the Data Protection Officer must be obtained. All data shall be provided with an identification number and separately stored from data which allow for personal identification.

Any documentation and data of the study participants can only be allocated with an ID number (pseudonymisation) so that confidentiality is maintained. All data and results are – assigned with the identification number only - stored so that only authorized personnel have access. All participant material are kept locked in a filing cabinet. The required list for the allocation of identification numbers are also kept in a separate locked filing cabinet.

All employees of the study pledge to keep the secret the data collected in the course of the study by signing a Privacy Statement. All staff involved in the analysis of the study data has no access to participants' personal data. The collected data will be exclusively used in the study. The commercial use of data or samples is prohibited. One year after completion of the study, all personal data is deleted.



Standard Operation Protocol

1.7 Corporate identity/Company Image

A DEDIPAC logo will be used for official correspondence and the distributed material



Fig 2: Corporate Identity Logo for official use

2. COMMUNICATION AND APPEARANCE

2.1 Teams approach towards schools and students

The survey team of >insert your center affiliation here< is

- Representative of the study and
- Representative of the leading research institution (>insert your center affiliation here<)

when approaching the schools and the students.

The survey team of the >insert your center affiliation here< explains:

- Who carries out the study
- The purpose of the study
- The study objectives and – contents
- Privacy Questions
- Questions on research institutions carrying out the study

The members of the survey team are those who build a trust relationship with school and students. Whether the school perceive the survey as positive, free of complications and if the person to be interviewed feels they are taken seriously and are willing to participate and complete the questionnaire, will depend on the survey team's approach.

2.2 Communication

The good communication of the survey teams with the schools and students can positively influence and facilitate survey procedures.

A basic model of interpersonal communication is sending and receiving messages. A "sender" tells the "receiver" something. The "receiver" accepts this message and interprets them.

This communication is done via the spoken content, appearance, gestures and facial expressions:

- ◆ Intonation
- ◆ Scientific terms
- ◆ Surroundings
- ◆ Pitch.
- ◆ Posture
- ◆ Face
- ◆ Voice
- ◆ Speech style
- ◆ Clothing
- ◆ Pronunciation
- ◆ Sentence structure
- ◆ Charisma
- ◆ Dialect

From the reaction of the "Receiver", the "Sender" can conclude whether and how he has been understood. This is referred to as "Feedback".

2.3 Role of the Survey Team

The team is always polite and helpful to the schools. Dealing with the students is friendly, patient, but also distant. The team is familiar with the procedures and the questionnaire and can answer any questions. The team members are active during the survey. They control the survey process and make sure to create a calm, relaxed survey atmosphere during the handing out of accelerometer and questionnaires.

The individual members of the team must remain neutral during data collection, i.e. they should not utter astonishment or disapproval to student questions and are always polite and correct, even if the student is rude or incorrect. Respondents' answers should be taken seriously, and not commented on.

The course of the survey itself can often unconsciously be influenced by the survey team. It is through the aforementioned communication element, such as:

- ◆ Intonation
- ◆ Scientific terms
- ◆ Surroundings
- ◆ Pitch.
- ◆ Posture
- ◆ Face
- ◆ Voice
- ◆ Speech style
- ◆ Clothing
- ◆ Pronunciation
- ◆ Sentence structure
- ◆ Charisma
- ◆ Dialect

They influence how students feel perceived, whether they feel better in the situation or if they lie or do not feel taken seriously. The esteem of the "Receiver" and thus the relationship to the "Receiver" are expressed through the introduced communication elements.

3. SURVEY PROCEDURES

3.1 Settings

1) >please insert the names and affiliations of your selected settings/schools here>

NAME SCHOOL 1

Street address

Postal Code

State/Province/Region

Country

Contact person: First Name, Name, Room number, tel:

Headmaster: First Name, Name, Room number, tel:

Secretary: First Name, Name, Room number, tel:

Study period from mm/2015 to mm/2015

2) >please insert the names and affiliations of your selected settings/schools here>

NAME SCHOOL 2

Street address

Postal Code

State/Province/Region

Country

Contact person: First Name, Name, Room number, tel:

Headmaster: First Name, Name, Room number, tel:

Secretary: First Name, Name, Room number, tel:

Study period from mm/2015 to mm/2015

3) >please insert the names and affiliations of your selected settings/schools here<

NAME SCHOOL 3

Street address

Postal Code

State/Province/Region

Country

Contact person: First Name, Name, Room number, tel:

Headmaster: First Name, Name, Room number, tel:

Secretary: First Name, Name, Room number, tel:

Study period from mm/2015 to mm/2015

[add more if applicable]

3.2 Module Accelerometry

The Device shall be worn by each participating child/ adolescent for 7 days. Before handing out the device, the participants will receive an introduction in the handling and functions of the accelerometer (s.b.).

3.3 Module Questionnaire Sedentary Behaviour and Determinants

Every parent of participating children age group 7 to 8 y will receive a proxy-questionnaire on Sedentary Behaviour and Determinants (“Questionnaire for Children”) which includes basic information questions (age and gender of the child, SES, etc.) as well as information on sedentary behaviour and related determinants of the child.

Elder children (14-15y) will be asked to complete the respective questionnaire themselves (“Questionnaire for Adolescents”). However, for the assessment of SES, parents of the elder children will be asked to provide this information when providing informed consent (“Questionnaire for Parents”).

Questionnaires should be briefly checked for completeness, in order to complete questions missed if possible. To increase participation, parents can be helped in completing questionnaires e.g. if a parent is illiterate. Alternatively, the proxy-questionnaire can be performed in the form of an interview (in person, by phone or in group sessions). This must be documented.

3.4 Module Questionnaire about School Characteristics

Teachers will receive a questionnaire to acquire basic information about the class (e.g. number of class periods per week) and school (e.g. duration of breaks) that are related to sedentary behaviour and its determinants (“Questionnaire for Schools”).

3.5 Module Feedback Questionnaires

The Feedback Questionnaire contains questions about the acceptability of the related instruments and method. For the younger children there will be a proxy-version (parent-report) (“Feedback-Questionnaire for Children”), elder children will answer the questions themselves (“Feedback-Questionnaire for Adolescents”). Furthermore, teachers (“Feedback-Questionnaire for Schools”) and Survey Centers (“Feedback-Questionnaire for Survey Centers”) will fill in a Feedback Questionnaire.

3.6 Data Collection Procedure

Children 7-8 y (2nd grade):

At a first visit in class, accelerometers will be distributed and handling will be explained to children. Teachers will be provided with the questionnaires and asked to give them to the children after 4 days so that they can hand them over to their parents. An accompanying letter to the parents will request to complete the questionnaires on the 7th day and give questionnaires and the accelerometer to the child in order to deliver everything on the 8th day at school (to the teacher/ survey staff). Simultaneously with the distribution of questionnaires to children for their parents, the teacher will be handed out the respective questionnaires ("Questionnaire for Schools", Feedback--Questionnaire) and asked to fill them in until the next day.

Children and 14-15y (9th grade):

Information about SES will be collected from parents with a questionnaire that is distributed together with a letter in which the parents will be informed about the exact data collection period.

At a first visit in class, accelerometers will be distributed to children (day 1). At a second visit in class, children fill in the "Questionnaire for Adolescents" as well as the "Feedback-Questionnaire for Adolescents". Furthermore, accelerometers will be collected (day 8). Teachers will fill in the "Questionnaire for Schools" and the "Feedback-Questionnaire for Schools" also on day 8.

Assuming availability of 25 accelerometers per Survey Center, a data collection period of 6 weeks is suggested:

Example:

2nd grade:

Wednesday, 3rd June: 1. Visit, distribution accelerometers, distribution of questionnaires to teacher

Monday, 8th June: Teacher distributes of questionnaires to the children to be handed over to parents

Wednesday, 10th June: 3. Visit, collection accelerometers, collection of questionnaires filled in by parents and the teacher

Thursday-Tuesday, 11th-16th June: Download accelerometer data, new initialization, collection of missing accelerometers

9th grade:

Wednesday, 1st July: 1. Visit, distribution accelerometers

Wednesday, 8th July: 2. Visit, collection accelerometers and filling in of questionnaires by children and the teacher

Thursday-Tuesday, 9th-14th: Download accelerometer data, new initialization, collection of missing accelerometers

4. THE ACCELEROMETER

4.1 The Device

Fout! Verwijzingsbron niet gevonden.

- activPAL3M Professional Physical Activity Monitor.



Figure 1: activPAL^{3M} device

4.2 Prerequisite for study participation

- Parental consent must be obtained.
- Only children that are clear of any conditions which may limit participation in physical activity can participate in this feasibility study.
- Children with physical disabilities or limited movement possibilities (e.g. broken leg) should be excluded from this feasibility study.

4.3 Accelerometry – activPAL^{3M}

- The device should be worn for a minimum of 7 days.
- The device should be worn at all times, even when sleeping, and playing sports
- The activPAL^{3M} can be worn when showering. However, the device must be removed for swimming, when having a bath or for any other water based activities when the device is immersed in water for prolonged periods.
- The only other time the device should be removed is if it is necessary to change the dressings which attach it to the individual.
- If the device is obstructive during a sporting activity (e.g. Judo, Taekwondo), it can be removed, but efforts should be made to wear the device at all times.
- The device should be worn on the anterior aspect of the midline of the right thigh, halfway between the knee and the hip as shown (Figure 2).

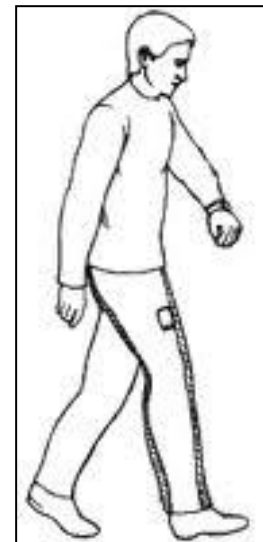


Figure 2

4.4 activPAL^{3M}: Getting Started

4.4.1 Download the activPAL software

- Download the activPAL software from the link:
<https://paltechnologies.sharefile.com/download.aspx?id=bedfefb7fec3402c>
- Click the Download button
- When alerted, click “Save as” and save the software somewhere on your PC.
- Double click on the saved file (activPAL3xsetup_PC.....).
- Click “Next” to begin installation.
- Click “I accept the terms and conditions” button, and then click “Next”
- Click “Next”, allowing for a desktop icon to be installed.
- Click “Install”.
- Click “Finish”.

4.4.2 Functional Test of the activPAL^{3M} activity monitors (ALL)

- Launch the activPAL software from your desktop (Figure 3).



Figure 3: activPAL software icon

- The following front panel of the activPAL software appears.

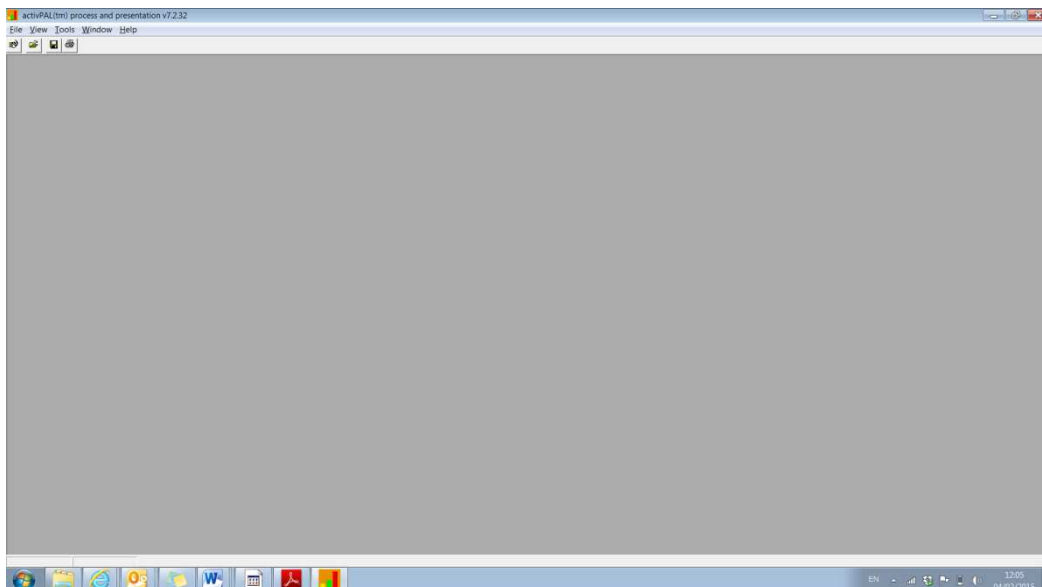


Figure 4: Front panel of activPAL software when opened.

- Connect an activPAL^{3M} device to the USB interface (Figure 5). Please note, the 10 parallel ports are for charging the devices only. The front port is for connecting the devices to the PC. Please ensure the device is fully charged prior to insertion into connection port. A description of how you know whether the device is charged, and what all other lighting arrangements mean, is provided in Figure 6.

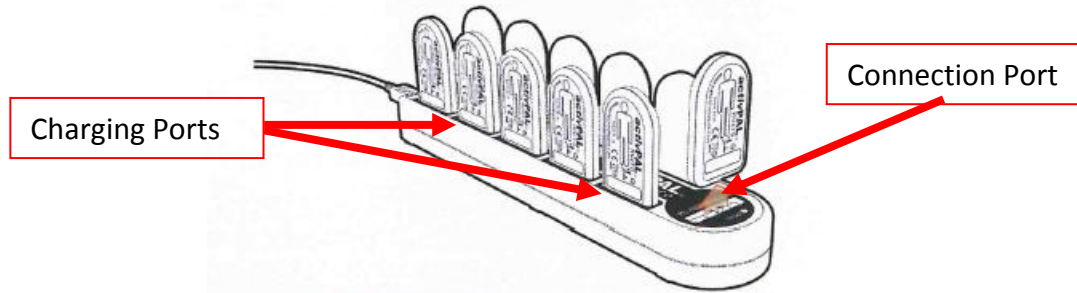


Figure 5: Diagram of USB interface for activPAL^{3M} devices.

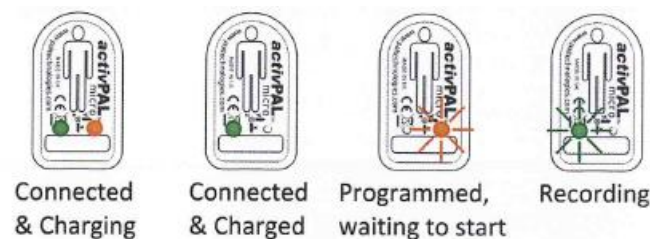


Figure 6: Description of lights on the front of the activPAL^{3M}, and what they mean.

1. Green and Orange constant = Connected and Charging
2. Green constant = Connected and Charged
3. Orange Flashing = Programmed and waiting to start
4. Green Flashing = Programmed and Recording.

N.B. PLEASE USE THE SAME USB PORT ON YOUR PC/LAPTOP FOR THE activPAL SETUP AND DOWNLOAD AT ALL TIMES.

- Complete step 2 of the activPAL^{3M} Functionality Test (Figure 7)

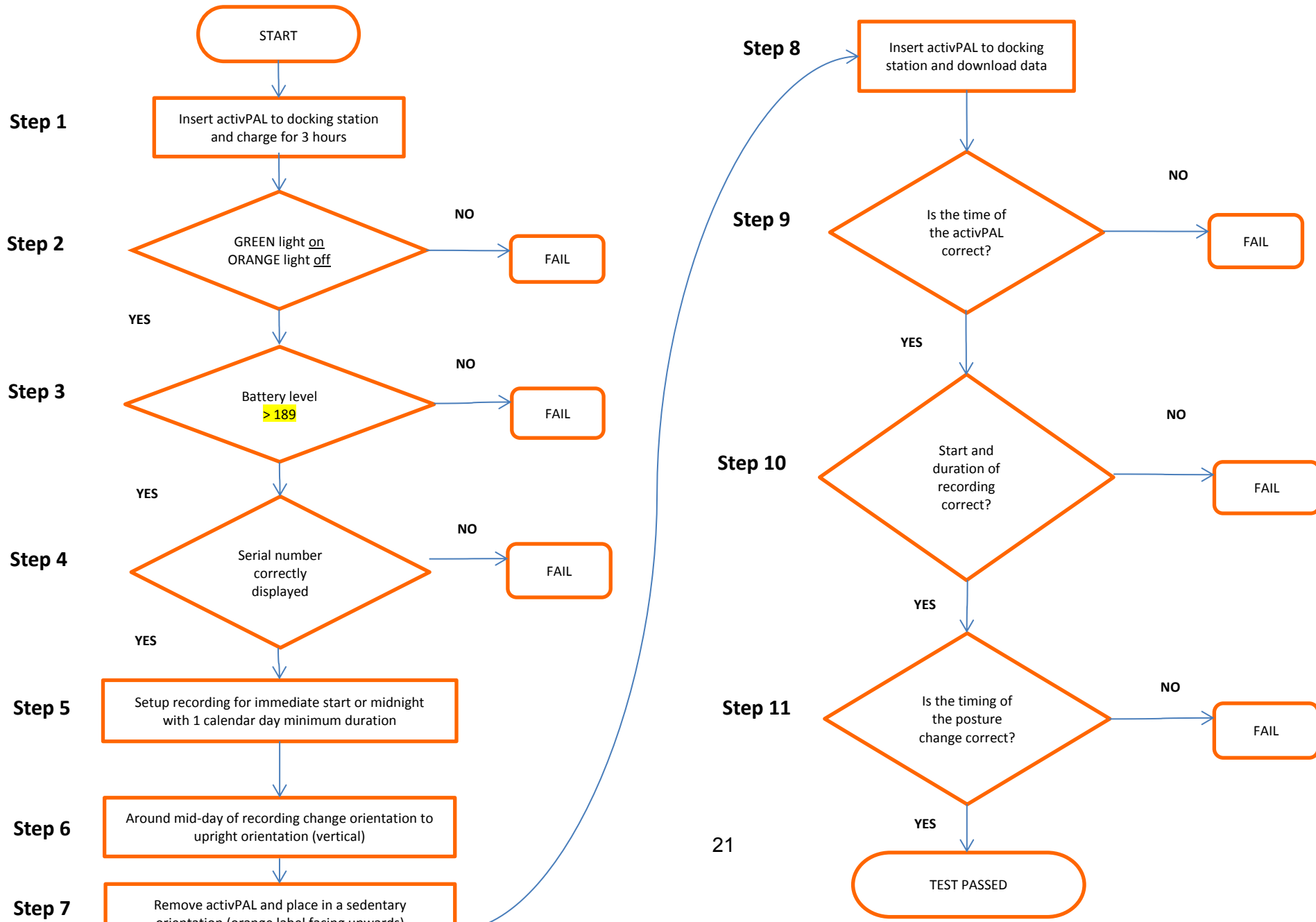
Figure 7: Functional Test for activPAL^{3M}



Standard Operation Protocol

Stage 1: Setup recording

Stage 2: Check Data



Standard Operation Protocol

- To communicate with the connected device, click on the “Connect” button (Figure 8)

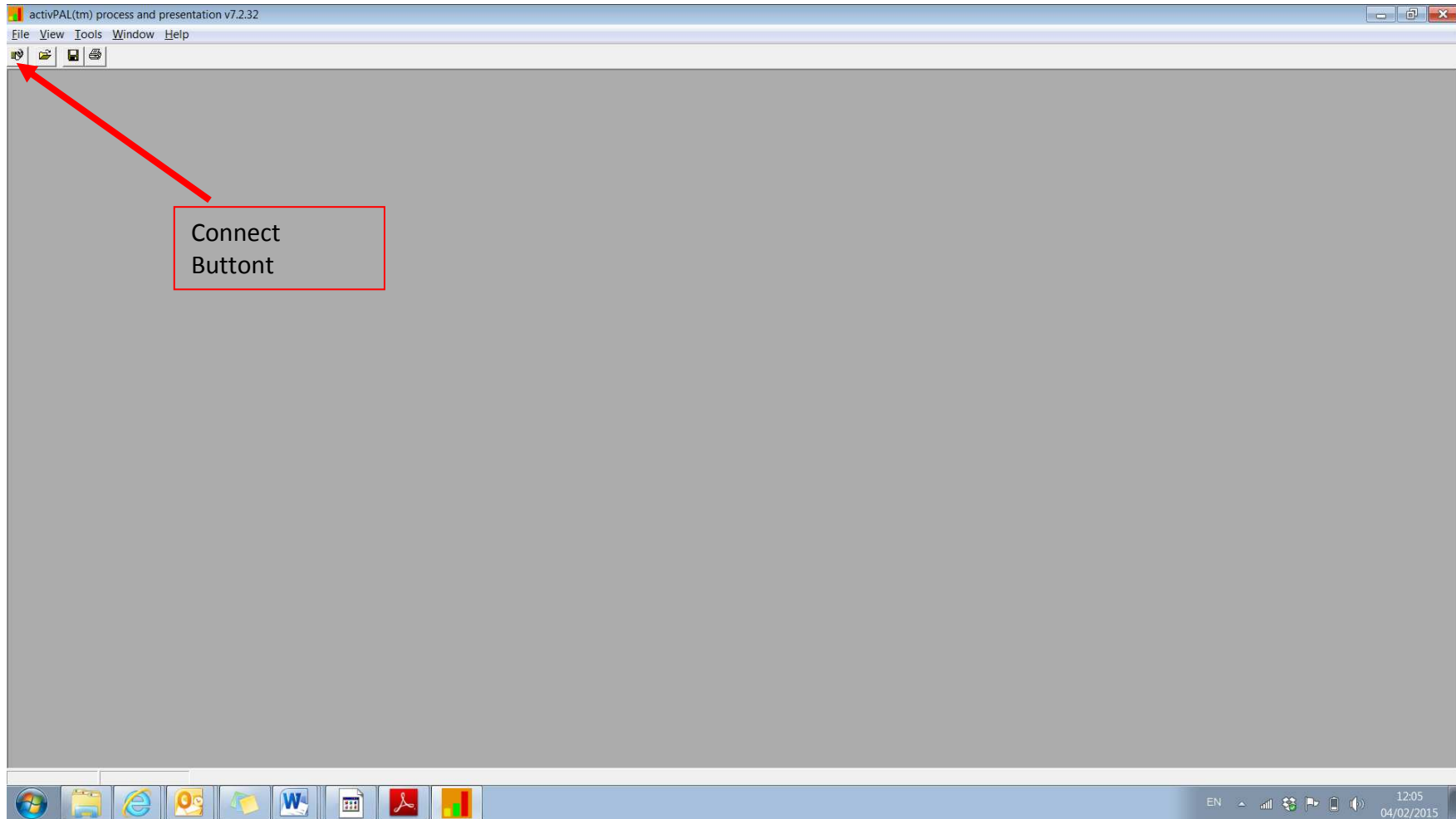


Figure 8: Connecting to the activPAL^{3M} from front panel

- The following screen should appear (Figure 9).

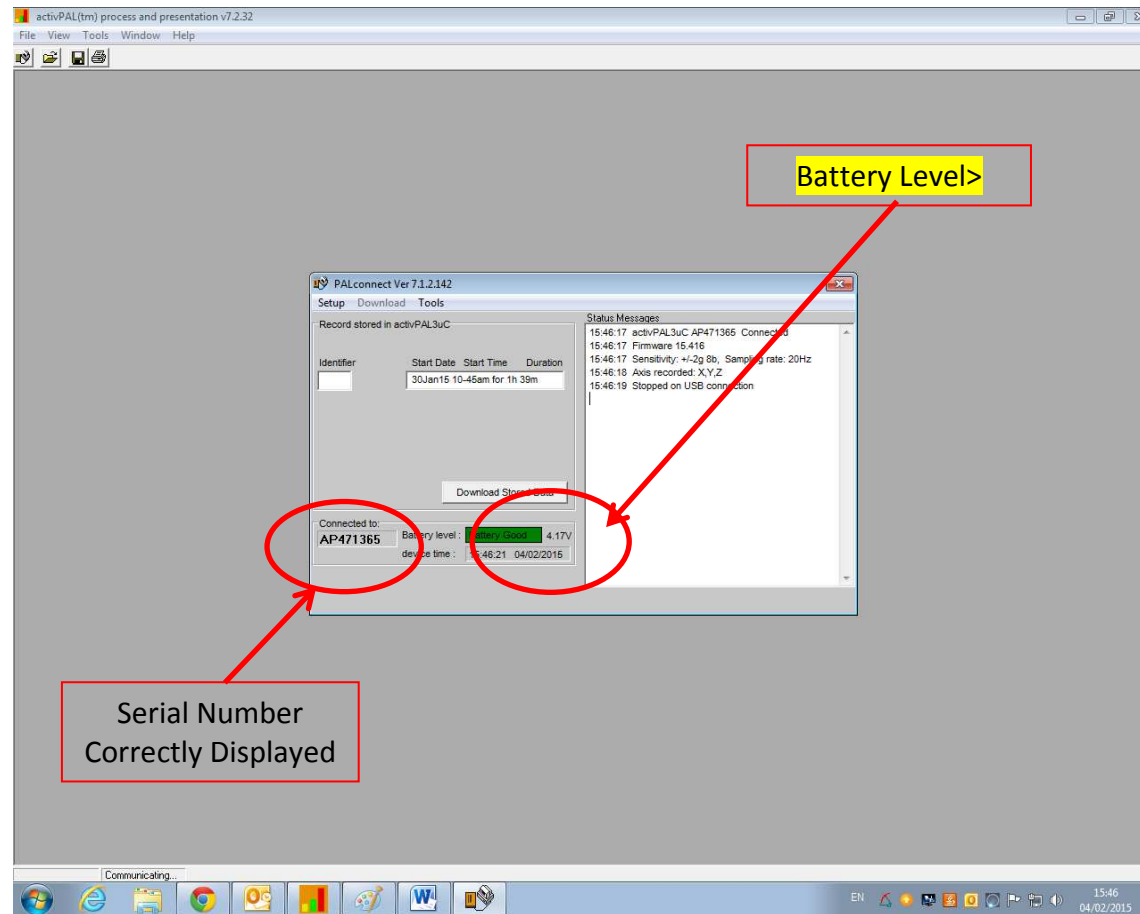


Figure 9: Connection pane of activPAL^{3M}.

- Complete steps 3 and 4 of the functional test (Figure 7).

- Step 5: Setup recording:
 - Click “Setup” on top left corner of the open window. The window face should change to as below (Figure 10).

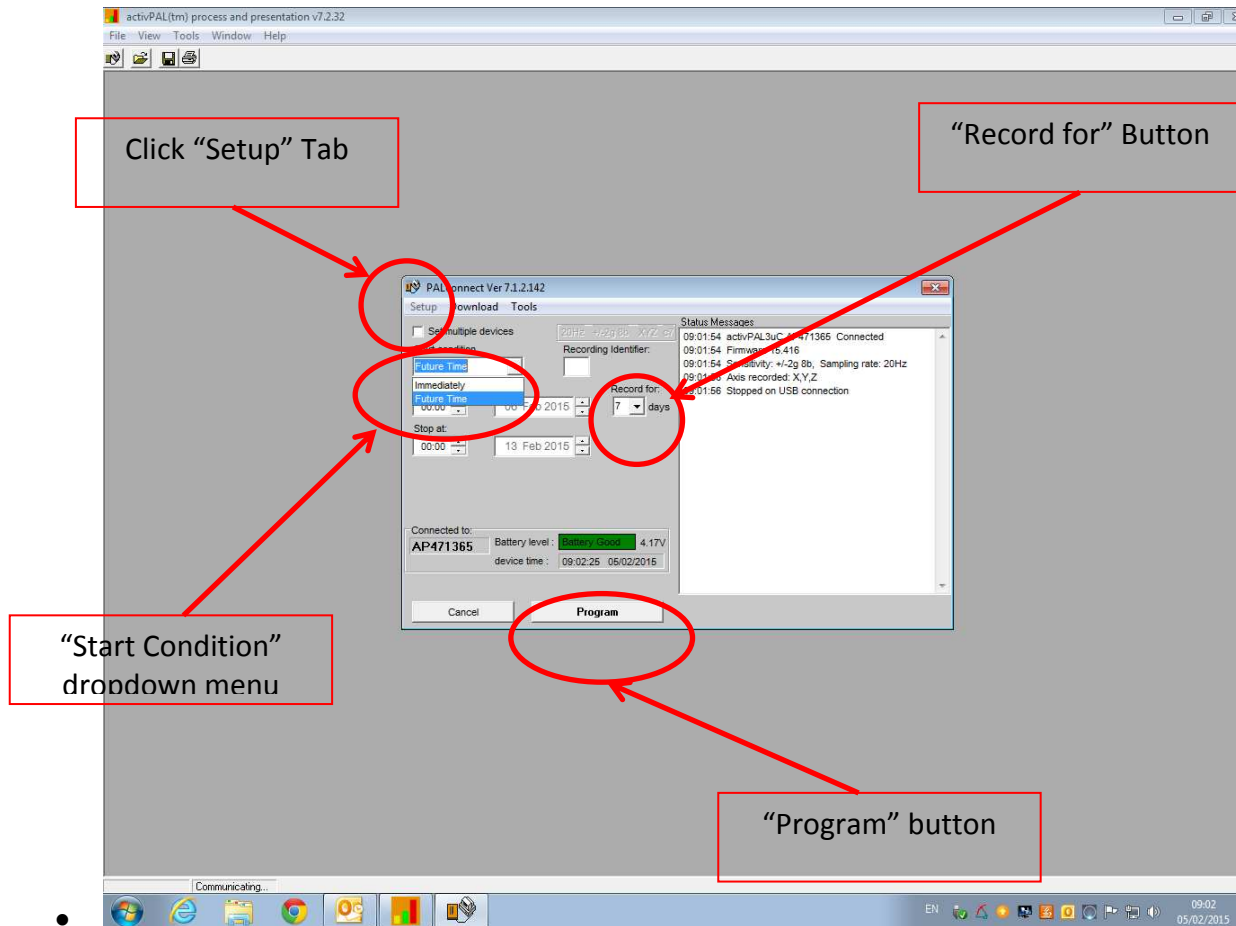


Figure 10: Setting up the activPAL^{3M} for recording.

- Under the “Start Condition” dropdown menu, select “Future Time”. Set future time to Midnight **on that night** (Figure 10).
 - Set “Record for” button to 8 days (Figure 10).
 - Click the “Program” button, and allow the activPAL^{3M} to setup for recording (Figure 10).
 - Once completed, record the time that the device was setup for recording (Figure 10).
 - Remove the device from the USB interface, and check that the green light is flashing every 5-7 seconds (Figure 6).
-
- Remove the activPAL^{3M} device, and complete step 6 and 7 of the functional test (Figure 7).
 - When data collection for functional test is completed, complete step 8 of the functional test (Figure 7).
 - Again, click the “Connect” button to communicate with the activPAL3M device (Figure 8).
 - When the screen for the connected activPAL3M opens, click the download button (Figure 11).

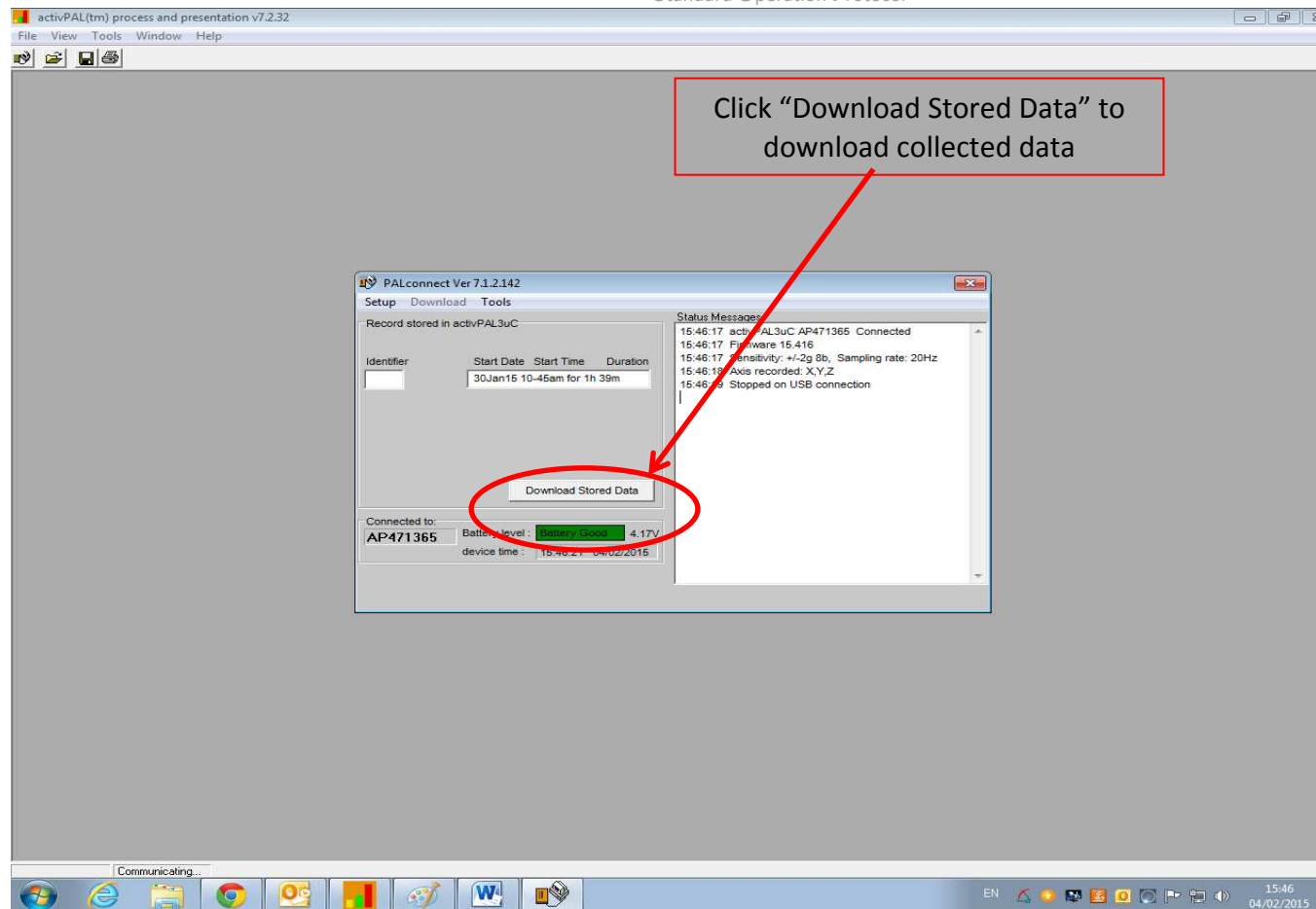


Figure 11: Downloading data from the activPAL3M.

- The activPAL3M data should now be downloaded. A screen (similar to Figure 11 and Figure 12) will appear, but it will only include yellow and green information (no red). Below is a sample of free-living activity information.

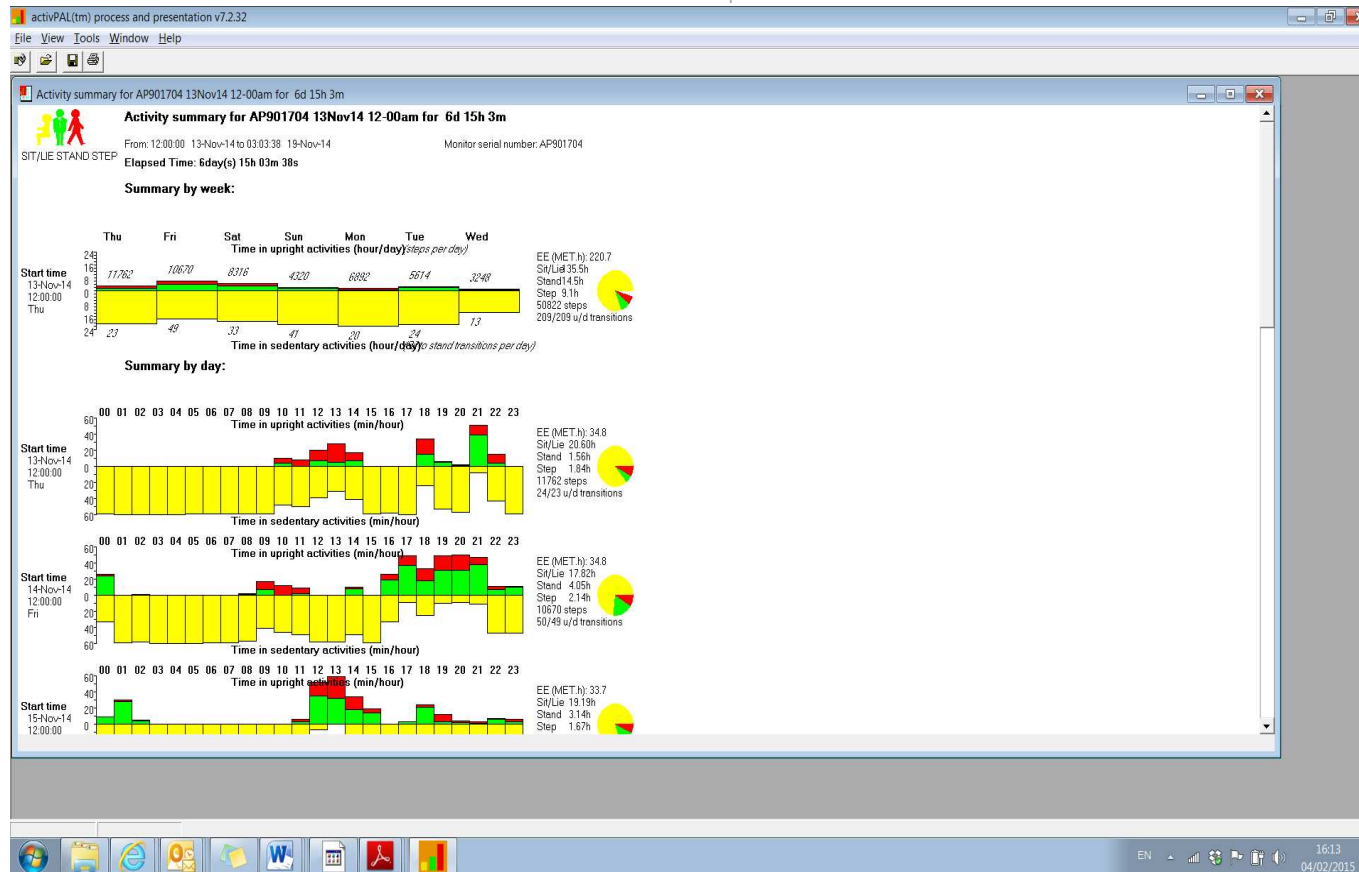


Figure 12: Example of downloaded activPAL3M data.

- Complete step 9 and step 10 by visually inspecting the data. The change in posture should be identified by a change from yellow (sitting/lying) to green (standing) on the software output.

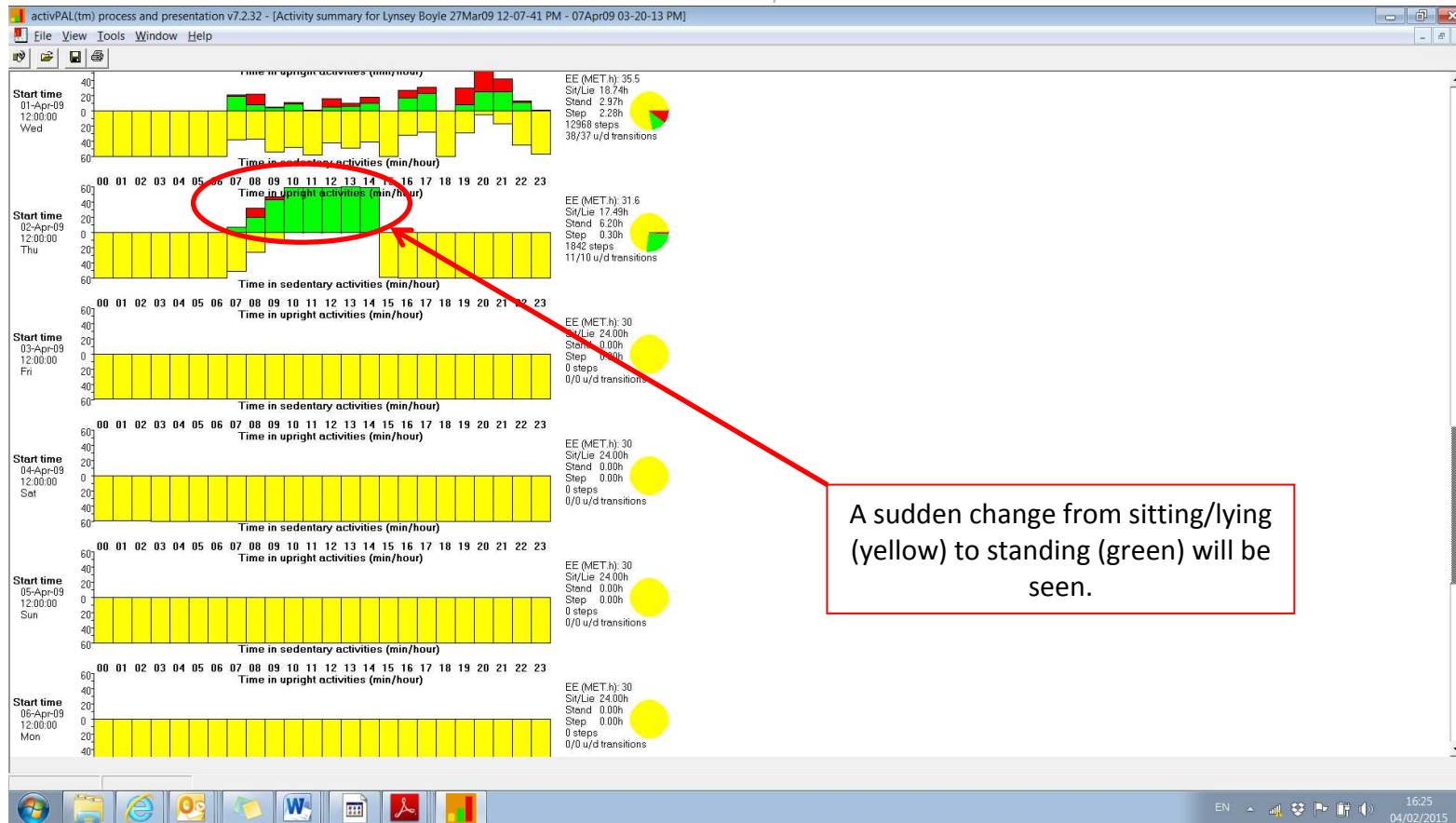


Figure 13: Example of activPAL3M data.

- If all of the tests have passed successfully, the device has successfully passed the functional test.

4.4.3 Initialization of the activPAL^{3M} activity monitors

- The initialization and download of data should only occur on the designated PC or laptop.
- When initializing the device, the following information should be recorded on a master sheet. This data should be recorded in the designated table found in the designated folder on your PC/Laptop.
 1. When initialized (date and time)
 2. Participant that will wear the device (ID number)
 3. School and Class of participant
 4. Device number (Model Number).
- Devices will be individually labelled with a white “sticker” that will have the participant ID indicated on it. Otherwise, there is a risk of swapping devices after removing the devices in the company of their classmates (e.g. swimming lessons for school).
- Once initialized, devices will be placed in a small **sealable** bag. Included in this bag should be:
 1. 3 nitrile sleeves,
 2. 3 sheets of Tegaderm dressing (approximately 10cm x 10 cm)
 3. A hard copy of the instructions for wearing the device (See appendix A)

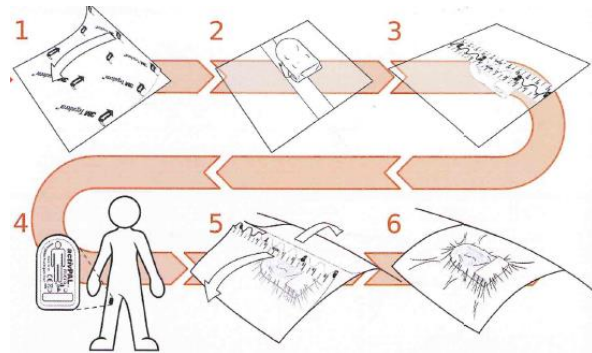
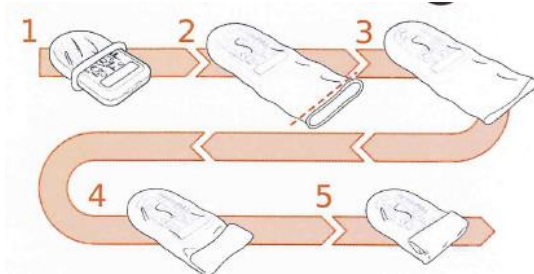
4.5 Handing out the activPAL^{3M} activity monitors to Children and Adolescents

- Handing out will take place during 1) physical education/physical activity lessons in class or 2) at the end of school with parents present. Option 2 would be preferable.
- The child/adolescent must be carefully instructed in the application of the device. It should be explicitly explained that the device is not waterproof and must be handled with care.
- A user manual (see Appendix A), which contains all the important information on proper use, should also be handed out.
- The device should be handed over only after both oral instruction and demonstration to ensure the concentration of children and adolescents. Each child **MUST** be wearing the device prior to leaving the school on day of administration.

4.6 Wearing the activPAL^{3M}

Step 1:

The activity monitor must first be waterproofed. The diagram on the right will help you. Place the sleeve (curved edge first) over the device, so that the activPAL is positioned at the very bottom of the sleeve. Then, roll the sleeve up, until it reaches the base of the device. Remember to make sure this is rolled up tight, to ensure that no water could get into it.



Step 2: To attach the activPAL to the thigh, first separate the Tegaderm dressing. Remove the backing sheet from the Tegaderm dressing. Once separated, you will be left with a clear piece of dressing. You will see/feel that there is a sticky side and a non-sticky side. Place the **non-sticky** side down on a flat surface. Place the **activPAL face down** in the middle of the sticky side of the Tegaderm

dressing. Face down mean that the side with the green light flashing should be face down on the sticky clear bandage. Position the device on the middle of the front of your thigh (halfway between your knee and your hip). **The curved part of the activPAL should be facing up.** Press the clear bandage down on your leg hard, to ensure that it is stuck in place. The picture on the left may help you put the device on.

4.7 Returning the activPAL^{3M} activity monitor

- The return will be done on the 8th day through the <add your institution here> team in class.
- Members of the <add your institution here> should also record whether the activPAL^{3M} device and the questionnaire have been returned.

4.8 Downloading of activPAL^{3M} activity monitor information

- When the accelerometer is returned, open the activPAL software (Figure 3).
- Insert the device into the activPAL USB interface (Figure 5)
- Click the “Connect” button (Figure 8).
- Record the device ID number, to ensure this is the correct participant’s device.
- Click “Download Data” button, and allow the device to save the information.

4.9 Saving the activPAL data

- Create a folder on the laptop/PC being used named “activPAL_Data_**Institution Name**”.
- Within this folder, create another folder for every participant’s data. Name each folder “**Institution Name Participant ID**”
- When downloading the data, a save option will appear on screen. Save the data for each participant to their respective folder within “activPAL_Data_**Institution Name**”
- A total of 6 files will appear for each individual:
 - Event Marker file
 - Events file
 - EventsXYZ file
 - DATX file
 - DEF file
 - PAL file

Each of these files should be renamed within the folder, inserting the participant ID number in front of the file name. See example below for ID number “1001”

Original file name: AP1132484 04Feb12 12-00am for 7d 0m

Rename: 1001_AP1132484 04Feb12 12-00am for 7d 0m

- Once each file is renamed, the data has been saved successfully.

4.10 Cleaning

- After use, please be sure to **clean the device** with an alcohol wipe. Ensure that the device is as clean as it was before it was handed out. **N.B.** Make sure that **no liquid** gets into the connection to the USB interface on the device, as this will result in malfunction of the device.

4.11 Checklist Accelerometer

The following checklist includes all the important points that must be considered before the date of issue of the accelerometer:

- ✓ Class lists
- ✓ List with given informed consent per participant
- ✓ Participant list printed (for ID-codes)
- ✓ activPAL^{3M} Functionality Test complete (once when devices arrive)
- ✓ activPAL^{3M} fully charged and correctly initialized
- ✓ Adhesive labels with child's name/ID number for activPAL^{3M}
- ✓ Plastic bag with activPAL^{3M}, 2 nitrile sleeves, 3 sheets of Tegaderm dressing (10cm x 10cm), a hard copy of the activPAL^{3M} instructions included for every participant.
- ✓ Feasibility questionnaires



Standard Operation Protocol

- ✓ Pens and writing pad for any notes
- ✓ Extra questionnaires (blank)

5. QUESTIONNAIRE

5.1 Questionnaire Sedentary Behaviour and Determinants

The following points will be interrogated in this questionnaire:

- General socio demographic variables
- Sedentary behaviour in school
- Sedentary behaviour in leisure time
- Determinants of Sedentary Behaviour:
 - parental encouragement to be active
 - parental media consumption
 - etc.

Note: difference in questionnaire for children and questionnaire for adolescents:

- Cover: Notice to adolescents or children
- Children should fill the questionnaire with their parents / guardians - young people complete the questionnaire alone or with their parents/guardians

5.2 Questionnaire about School Characteristics

- Break Times
- Traffic around the School Area
- Etc.

5.3 Feedback Questionnaires

The following points will be interrogated in this questionnaire:

- Acceptance
- Perception about wearing the accelerometer by others
- Etc.

Note: difference in questionnaire for children and questionnaire for adolescents:

- Cover: Notice to adolescents or children
- Children should fill the questionnaire with their parents / guardians - young people complete the questionnaire alone.

Survey Centers will be requested to answer questions on:

- Wearing time
- Response rates
- Infrastructure/ logistics



Standard Operation Protocol

- Expertise for handling Accelerometer data
- Financial resources

6. APPENDIX

6.1 activPAL^{3M} Professional Physical Activity Monitor Instructions

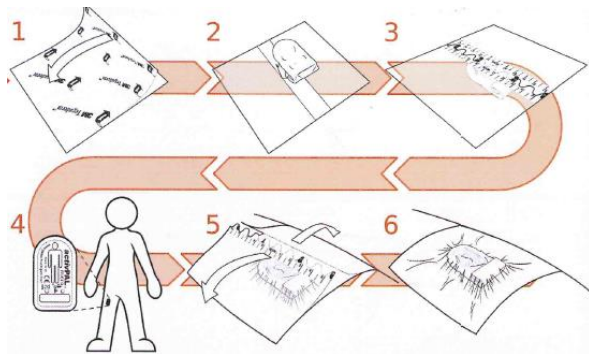
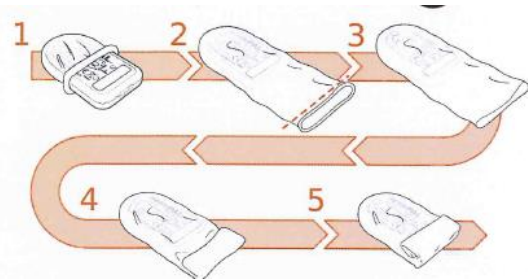
This is the **activPAL** accelerometer and it is a tiny, lightweight gadget that measures the activity that you do during your normal day. It can tell how long you spend sitting or lying, standing and walking. The accelerometer is worn on the mid part of the front of your **RIGHT** thigh and is held on by a piece of Tegaderm dressing.



Putting on the activPAL^{3M}:

Step 1:

The activity monitor must first be waterproofed. The diagram on the right will help you. Place the sleeve (curved edge first) over the device, so that the activPAL is positioned at the very bottom of the sleeve. Then, roll the sleeve up, until it reaches the base of the device. Remember to make sure this is rolled up tight, to ensure that no water could get into it.



Step 2: To attach the activPAL to the thigh, first separate the Tegaderm dressing. Remove the backing sheet from the Tegaderm dressing. Once separated, you will be left with a clear piece of dressing. You will see/feel that there is a sticky side and a non-sticky side. Place the **non-sticky** side down on a flat surface. Place the **activPAL face down** in the middle of the sticky side of the Tegaderm

dressing. Face down mean that the side with the green light flashing should be face down on the sticky clear bandage. Position the device on the middle of the front of your thigh (halfway between your knee and your hip). **The curved part of the activPAL should be facing up.** Press the clear bandage down on your leg hard, to ensure that it is stuck in place. The picture on the left may help you put the device on.

Once you leave school we would ask you to leave the activPAL on your leg all day and all night, *except* when you are swimming or doing any other water-based activities. You can wear the activPAL when having a shower, but if you are taking a bath, please remove the activPAL.

You may have to replace the clear bandage every 3 – 4 days if it begins to get loose. There are two additional bandages included in your bag, along with 2 additional sleeves for waterproofing the activPAL, which should be enough for wearing the activPAL for a full week. However, if you run out and need more bandages or sleeves, please just call ***NAME*** and **s/he** will deliver more to you.

We will visit the school next week to collect the activPAL and any remaining contents of the bag from you.

Frequently Asked Questions

Where should I apply the activPAL^{3M}?

It is most comfortable to wear the activPAL on the mid line of the right thigh, about half way down between the hip and the knee.

What if the activPAL^{3M} is not secure?

Ensure that you have the correct side of the bandage sticking to your leg. The sticky side of the bandage will not work well if your leg is wet, or if any lotions (moisturiser or fake tan for example) are on the leg. If the bandage comes loose, you may need to replace it.

When should I remove the activPAL^{3M}?

The activPAL can be worn comfortably all day and all night and should not impede normal activities. It can be kept on while taking a shower. However, it **MUST** be removed before taking a bath and swimming or before any other activities which may mean the activPAL could come into contact with water for a prolonged period.

How do I know the activPAL^{3M} is working?

The activPAL is a continuous recorder so will never stop recording. But you can be sure by checking the little light in the front panel. The light will flash green every six seconds. If it is not flashing green please ring ***NAME*** immediately!

What if I lose the activPAL^{3M}?

Don't panic. If you lose or misplace the activPAL, please ring ***NAME*** **IMMEDIATELY**. **S/he** will then try to retrace your steps with you, and will help you look for (and hopefully find) the activPAL. activPAL's are not cheap, so it is very important that you contact ***NAME*** as soon as you have misplaced the device!

What if I'm in trouble or have a question?

At any stage, day or night, if you are having a problem with the device or have a question please give us a ring or text. No matter how small or silly you think the question is, it could turn out to be very important later on.

NAME Mobile Number: **Insert mobile number here**

"Once again, thank you for all your help and co-operation!"