1

Infancia y Medio Ambiente

INMA 11-12 YEARS

FOLLOW UP PROTOCOL

FINAL VERSION 30/05/2017

1   Contenido

2

1   Introduction

The birth cohort INMA-Sabadell began in 2004. All women that attended the CAP II Sant Félix of Sabadell between July 2004 and July 2006 between the 4th and the 6th week of pregnancy, that were willing to give birth in the Hospital of Sabadell, were invited to participate to the study. Inclusion criteria were 16 years old or older, single pregnancy, not having followed an assisted reproduction programme, free of chronic diseases at the time of conception. A total of 657 women were included, who were followed every trimester of the pregnancy until the moment of birth. Children have thereafter been evaluated at the age of 6 and 18 months, and 2.5, 4, 7 and 9 years (Figure 1). 550 children are expected to participate in the 11 years old follow up.
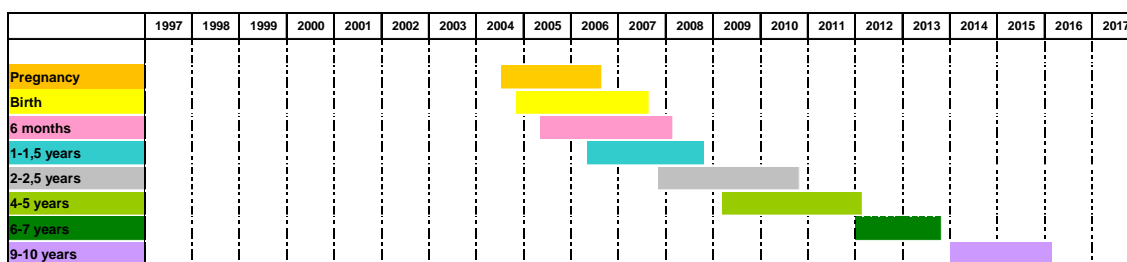

Figure 1 *Summary of the follow up visits of the INMA-Sabadell cohort.*

This birth cohort is now planning a new follow-up visit in 2016-2017, when children will be 11 years of age. This new visit will be conducted as part of 3 different projects with the following main objectives:

1. To investigate whether fetal and infant life-style, social and environmental exposures influence cardiovascular risk profiles in pre-adolescents;

2. To evaluate the complex longitudinal association between radiofrequency electromagnetic fields (RF-EMF) exposure and sleep problems in children.

3. To investigate whether environmental exposures influence refractive errors in pre-adolescents.

1.1   Objectives

The specific objectives of this new follow-up are the following:

1) To measure cardiovascular (CV) functional phenotypes at 11-12 years of age, and to describe the association with marker of obesity and cardiometabolic (CM) risk at the same age, to determine the CV risk profiles in pre-adolescents;

2) To evaluate early predictors of CV risk profiles, including maternal risk factors and fetal and early childhood growth trajectories;

3) To examine the effect of the environmental chemical exposures during prenatal and early life (indoor and outdoor pollutants, persistent organic pollutants, non persistent pollutants) on the CV risk in pre-adolescents;

4) To examine the joint effect of environmental, social and lifestyle factor on the CV risk profiles of pre-adolescents, using a multifactorial analysis approach;

5) To examine the effects of the environmental exposure on mechanistic biomarkers, including biomarkers of metabolic dysfunction, inflammation and oxidative stress.

6) To assess cognitive development in schoolchildren;

4

7) To characterize total RF-EMF brain and whole-body exposure levels and use of wireless communication devices during different exposure windows in children;

8) To characterize sleep patterns and quality using objective, accurate, and detailed measurements in children;

9) To assess the longitudinal associations between RF-EMF exposure, use of the wireless communication devices, and sleep problems in children;

10) To assess the mediating role of sleep in the longitudinal association between RF-EMF exposure and cognitive function and behavior problems in children;

11) To investigate whether environmental exposures influence refractive errors in pre-adolescents.

12) To study the association between exposure to psychosocial stressors and preclinical cardiovascular phenotypes, and its interaction with other environmental exposures that can share some mechanistic pathways (e.g. $PM_{2.5}$);

2   Methods

2.1   Overview

All the children from the INMA – Sabadell Cohort that still live in the area, can be reached and accept to participate will be included in the follow up. No exclusion criteria will apply.

This new follow-up visit requires:

- Completion of a paper based questionnaire by both parents and child, to be filled in at home before the study visit and collected the day of the visit (45 minutes for the mother, 20 minutes for the father, 5 minutes for the child);

- Address history interview over the phone for one of the parents (2 minutes);

- Clinical examination of the child (45 minutes);

- Eye examination of the child (10 minutes);

- Neurodevelopment testing by the child (30 minutes);

- Completion of a paper based questionnaire by the child (10 minutes);

- Collection of hair sample of the child during the first visit;

- Photocopy of both hands;

- Collection of physical activity and sleep pattern data using the wrist-worn raw data accelerometer GENEActiv, that resemble a wrist watch (NEW PROTOCOL FROM DEC 2016);

- Collection of physical activity data using a smartphone prepared with the ExpoApp application (OLD PROTOCOL UNTIL DEC 2016)

- Collection of exposure to light using the light sensor HOBO

- Collection of phone use data (only for those children that own an Android phone)

Times provided above are to be considered for general conditions. Children will be evaluated at their schools. The follow up visits will be supervised by a fully trained nurse.

Participation in this study will not represent any cost for families.

2.2 Fieldwork organization

Fieldwork will be organized into two separated visits and supervised by a fully trained nurse (see Figure 2 for an overview).

Before the visits take place:

Parents will be contacted by phone to inform them about the new visit and to explain the protocol.

One week before the first visit (d-7)

If they agree to participate, one week before the visit takes place nurses will go to the school and provide children with the following:

- Informed consent to be returned signed by the parents to the nurse on the day of the visit (Annex 1)

- An information pack detailing what to expect from the visit and specific instructions (Annex 2);

- Mother and father questionnaires and child questionnaire 1, to be returned filled in to the nurse on the day of the visit (see Chapter 2.3, Annex 3, Annex 4 and Annex 6a).

The day before the first visit (d-1)

Approximately one day before the first visit families will be contacted by phone to go over instructions, and to ask if they have signed consent forms and complete the questionnaire. Also, a brief interview will be carried out (see Chapter 2.3 and Annex 5).

The day of the first visit (d0)

Parents will fill in the "Parents information recording sheet" included in the "Parents information pack" (see Annex 2)

The informed consent and the questionnaires self-completed by parents and the child will be collected and checked by the nurses at the school.

Each child will undergo a 1h30' visit, after being provided the opportunity for toilet visit, organized in two 45' sessions. This organization will allow two children to be visited in parallel (see Table 1), ideally in two separated spaces. When not possible, a folding screen will be used to preserve children privacy and decrease distractions during the neurodevelopment testing.

Table 1 Example of the schedule for two children

	Child 1	**Child 2**
9:00-9:45	Session 1	Session 2
9:45-10:30	Session 2	Session 1

Details about each session are as follow:

- ***Session 1 (in the following order):***

  - Clinical examination (see Chapter 2.4). The examination will include in the following order: anthropometric measurements, bioimpedance measurement, pulse wave velocity measurement, blood pressure measurement, retinal photography, spirometry

- ***Session* 2 (in the following order):**

- o   Neurodevelopment tests by the child (see Chapter 2.7)

- o   Visual acuity and contrast sensibility (see Chapter 2.5)

- o   Child questionnaire 2 (see Chapter 2.3 and Annex 6b)

- o   Hair sample collection (see Chapter 2.6.1)

This organization of the visit will ensure spirometry to take place after retinal photography and blood pressure measurement, therefore not interfering with these measurements. Timing of the fieldwork is flexible, but time of the visit should be recorded in the clinical examination datasheet (Annex 7) for statistical analyses and future follow-ups.

At the end of the visit, nurses provide the child with the GENEActiv accelerometer be carried on his/her wrist for one week, to measure his/her physical activity and sleep pattern (see Chapter 2.9), as well as the light sensor HOBO to measure his/her light exposure (see Chapter 2.10). They will instruct to place the HOBO sensor in a specific position in a flat surface close to the bed in their bedroom. They also provide the child with a daily diary to be filled in every day after they wake up, and explain carefully how to fill it in. Also, the XMobiSense app will be installed on the child's personal mobile phone (only for those children that own an Android phone) (see Chapter 2.15.1). A photocopy of both hands will be taken on the day of the first visit (see Chapter 2.13).

Six days after the first visit (d6)

The nurses will call the families to remind to return the smartphone at school the day after.

Seven days after the first visit (d7)

At the end of the one week monitoring period, nurses will go to the school to collect the GENEActiv accelerometers, the HOBO devices, and the daily diaries completed. Data will be downloaded after each monitoring.

The day before the second visit

Approximately one day before the second visit parents will be contacted by phone to go over instructions.

The day of the second visit

The second visit will include:

- •   Colour discrimination (6') (see Chapter 2.5)

- •   Eye examination of the child (10') (see Chapter 2.5)

What		Who	Where	1 week before						Day before	Day of the first visit	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	...	Day 28	...	Day of second visit
Handing out of	Informed consent	Nurse	School	▓																		
	Information pack	Nurse	School	▓																		
Fill in questionnaires		Parents/Child	Home	▓	▓	▓	▓	▓	▓	▓												
Sign consent		Parents	Home	▓	▓	▓	▓	▓	▓	▓												
Phone call	Go over intructions	Nurse	Home							▓												
	Answer phone interview	Nurse/Parents	Home							▓												
Fill in "Parents information recording sheet"		Parents	Home								▓											
Bring questionnaires and signed consent		Child	School								▓											
Child visit	Clinical examination	Nurse/Child	School								▓											
	Neurodevelopment tests	Nurse/Child	School								▓											
	Eye exam 1 (FRACT)	Nurse/Child	School								▓											
	Questionnaire	Nurse/Child	School								▓											
	Hair sample	Nurse/Child	School								▓											
	Hand copy										▓											
	Installation XMobiSense	Nurse	School								▓											
	Eye exam 2 (Auto-refractometery, ocular biometry and CCT)	Technitian	School																			▓
GENEActive to child		Nurse	School								▓											
Physical activity and sleep pattern recording		Child	School/home								▓	▓	▓	▓	▓	▓	▓	▓				
GENEActive from child		Nurse	School															▓				
XMobiSens app installation		Nurse	School								▓											
XMobiSens recording		Child	Schoo/home								▓	▓	▓	▓	▓	▓	▓	▓	▓	▓		

Figure 2 Overview of the 11 yo INMA Sabadell visit (Legend: CCT, Cambridge Colour Test; FRACT, Freiburg Visualt Acuity and Contrast Test)

2.3 Questionnaires and interview

2.3.1 Mother questionnaire

The mother will be asked to complete a paper based questionnaire at home that will be collected the day of the first visit by the nurse. If it is not possible for the mother to fill in the questionnaire, then a shorter version of the questionnaire can be filled in by the father or the legal guardian of the child.

The **Mother questionnaire** (see Annex 3) will take approximately 45 minutes and will contain the following subject areas (related to the child if not specified):

- General information

- Information about the child

  o Use of new technologies

  o Sedentary behaviors;

  o Sleeping patterns;

  o Puberty development (Puberty Development Scale; Tanner's stages);

  o Body image perception;

  o Neurobehavioral clinical phenotypes (Conner's questionnaire and Strengths and Difficulties Questionnaire [SDQ]) (see Chapter 2.7, for further information);

  o Asthma and allergies;

  o Diet (dietary behaviors, KIDMED and selected questions from the Food Frequency Questionnaire to address fish, nuts and sweet beverage consumption);

  o Treated problems;

  o Child's medical history of refractive errors;

- Information about the mother

  o Socio-demographic information;

  o Psychosocial factors (see Chapter 2.8 for further information):

    ▪ Parental life satisfaction (Satisfaction With Life Scale [SWLS])

    ▪ Mental health (General Health Questionnaire 12 [GHQ-12]);

    ▪ Perceived stress (Perceived Stress Scale [PSS-4]);

    ▪ Life events (The List of Threatening Experiences [LTE]);

    ▪ Mother health behaviors;

  o Personal and family history of cardiovascular disease, diseases related to metabolic syndrome, refractive errors;

The Spanish validated version of the above mentioned questionnaires will be used.

2.3.2 Father questionnaire

The father will be asked to complete a paper based questionnaire at home that will be collected the day of the first visit by the nurse. If it is not possible for the father to fill in the

questionnaire, then a shorter version of the questionnaire can be filled in by the mother or the legal guardian of the child.

The **Father questionnaire** (see Annex 4) will take approximately 20 minutes and will contain the following subject areas:

- Information about the child

    o Neurobehavioral clinical phenotype (Strengths and Difficulties Questionnaire [SDQ]) (see Chapter 2.7 for further information);

    o Body image perception;

- Information about the father

    o Socio-demographic information;

    o Psychosocial factors (see Chapter 2.8 for further information):

        ▪ Parental life satisfaction (Satisfaction With Life Scale [SWLS]);

        ▪ Mental health (General Health Questionnaire 12 [GHQ-12]);

        ▪ Perceived stress (Perceived Stress Scale [PSS-4]);

        ▪ Life events (The List of Threatening Experiences [LTE]);

        ▪ Father health behaviors;

    o Personal and family history (excluding the child participating to the study) of cardiovascular disease, diseases related to metabolic syndrome, refractive errors (father);

The Spanish validated version of the above mentioned questionnaires will be used.

2.3.3 Child questionnaire

The **Child** will be asked to fill in **two Questionnaires**.

Child's questionnaire 1 (approx 5 minutes; Annex 6a) will investigate the use of new technology and will be filled in by the child at home, with child's parents help if needed.

Child's questionnaire 2 will be filled in at the end of Session 2 of the visit (approx 10 minutes; Annex 6b). The questionnaires will be filled in by the child. The nurse will help the child with reading. The following subject areas will be covered in Child's questionnaire 2:

-

- Health problems in the last days (Asthma attacks, common cold, etc);

- Psychosocial factors (see Chapter 2.8 for further information):

    o Health-related Quality of Life (Kidscreen 27);

    o Experiences of being bullied/bullying (adapted from the Olweus Bully/Victim Questionnaire [OBVQ]);

- Body Image Perception

- Cigarette smoke and alcohol consumption

The Spanish validated version of the above mentioned questionnaires will be used.

2.3.4 Short interview over the phone for the families

The **interview** will be carried out over the phone by the nurses during the first contact (see Annex 5), and will take approximately 2 minutes. It can be answered by the mother, the father or the legal guardian. The following information will be collected:

- Family address history (since the last follow up);

- Community (for those who changed address since the last follow up);

- Child mood in the last week.

2.4 Clinical examination

Clinical examination will be carried out at the school during the Session 1 of the first visit, in a dedicated room, and will be supervised by a fully trained nurse (see Chapter 2.1 for an overview).

The clinical examination will include, in the following order:

Preparing for the visit

- Remove outer clothes (jumper, coat, trousers/skirt if heavy) and shoes (2')

Standing position

- Anthropometric measurements (5') (Annex 8)

Supine position

- Resting in supine position (5')

- Bioimpedance (1') (Annex 9)

- Pulse wave velocity (5') (

- Annex 10)

Sitting position

- Resting in sit position (5')

- Blood pressure (5') (Annex 11)

- Retinal photography (5') (Annex 12)

- Spirometry (10') (Annex 13)

Getting dressed

During resting and some measurements (e.g bioimpedance, pulse wave velocity) the nurse can read a book to distract the child. Also, between blood pressure measurements the child can draw to relax.

Clinical examination will be conducted by trained nurses and results will be recorded in the clinical examination datasheet when needed (Annex 7).

2.5 Eye examination

Eye examination will include the following ophthalmological tests:

- First visit
    o Visual acuity and contrast using the Freiburg Visual Acuity and Contrast Test

(FRACT) (2') (Annex 14) (this will be done on a laptop after the neurodevelopment tests)

- Second visit (carried out by a fully trained technician supervised by the nurse).

  o Colour discrimination using the Cambridge Colour Test (CCT) (6') (Annex 14)

  o Auto-refractometry (5') (Annex 15)

  o Optical biometry (5') (Annex 16)

2.6 Biological samples

2.6.1 Hair samples collection

Proximal locks of hair will be collected after the neurodevelopment test and will be put in a zip-lock bag for posterior measurement of cortisol (Annex 17).

2.7 Neurodevelopment

We will assess a variety of neurobehavioral outcomes sensitive to environmental exposures, including several functional domains, investigated in the child using neurodevelopment testing, and clinical phenotypes, investigated using behavioral questionnaires filled in by both parents. These outcomes will be assessed by **internationally standardized tests and questionnaires**. The cognitive functions assessed will be non-linguistic and culturally blind.

2.7.1 Neurodevelopment testing

Neurodevelopment testing will take place in the Session 2 of the first visit, in a dedicated room (see Chapter 2.1 for an overview and Annex 18).

The tests will be administered to children through laptops and a fully trained technician will give a standardized brief explanation to the child before each test. The instructions of the software will be then followed to start the tests. Data will be automatically stored on laptops upon test completion and a backup to an external hard disk will be done daily. The general conditions in which the administration of the tests takes place will be recorded by the nurses in the clinical examination datasheet (Annex 7).

The space used during the testing should be quiet and the tests will be done with minimal interference, moreover headphones will be used.

We will assess three main functional domains in the child by computer tests (approximately 30'):

1. Working memory

  - N-BACK test (computer test) (5 minutes)

2. Attention and Cold Executive Function (EF): Cold cognition is the use of logical and rational thinking in cognitive processing

  - Flanker (computer) (10 minutes)

3. Hot Executive Function: Hot cognition employs emotional influence on decision making

  - Cups Task (Roulette Version) (computer) (8 minutes)

4. Visual reasoning: As a proxy of perceptive-performance IQ:

  - Primary Mental Abilities (Reasoning) (PMA-R) (computer) (6 minutes)

2.7.2 Clinical phenotypes

We will also assess two clinical phenotypes behavioral by questionnaires. Questionnaires will be completed at home by both parents (Chapter 2.3, Annex 3 and Annex 4), without any interference from the nurses (except if the parents require clarification).

1. Child ADHD symptoms:

- Conner's Questionnaire (5') (Conners, C. K. (1997). Conners'Rating Scales–Revised: Technical manual. North Tonawanda, NY: Multi-Health Systems)

2. Child behavioral and emotional problems:

- Strengths and Difficulties Questionnaire (SDQ, 7') (Goodman R. Journal of Child Psychology and Psychiatry, 1997;38:581-586; Spanish version obtained from the website http://www.sdqinfo.com/py/sdqinfo/b0.py)

2.8 Psychosocial factors

Our hypothesis is that early life exposure to psychosocial stressors can lead to increased inflammatory markers and in turn to subclinical changes in cardiovascular function phenotypes that can play a role in clinically evident CVD development later in life, both independently and interacting with other exposures that can share some mechanistic pathways (e.g. $PM_{2.5}$) (see Figure 3).
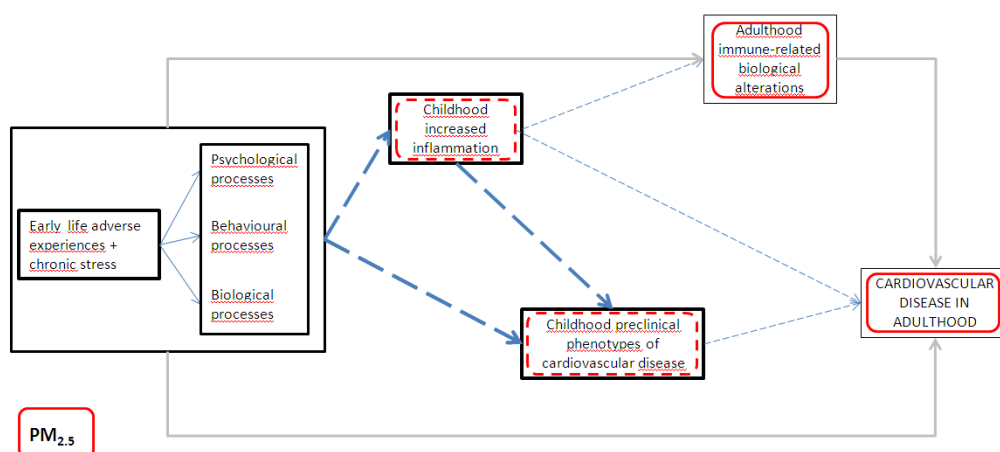
Figure 3 *Early exposure to stressors and CVD. Conceptual model with pathways shared by psychosocial stress and pollutants (in this case $PM_{2.5}$.) Thicker arrows are the hypothesis we want to test. (Modified from Slopen et al. 2012).*

We will measure exposure to several psychosocial factors using validated questionnaires for both parents and the child (see Table 2 for a summary), and we will then build a cumulative stress score. Questionnaire are described in Chapter 2.3. We will also collect a **sample of child's hair to measure hair cortisol levels**, an innovative non-invasive and relatively cheap method to assess the physiological response to chronic stress (weeks to months), therefore suitable for epidemiological research (see Chapter 2.6.1).

Table 2 *Summary of psychosocial factors investigated and questionnaires used*

Psychosocial factor	Measure/ questionnaire	Person filling in the questionnaire			References
		Mother (Annex 3)	Father (Annex 4)	Child (Annex 6)	
Socio-economic environment	Idem previous visits	X	X	-	-
Emotional environment	GHQ-12	X	X	-	Goldberg DP et al. Psychol Med. 1997; 27:191-7. – Spanish Version Validation Navarro P et al. Gen Hosp Psychiatry. 2007;29:1-7.
	SWLS	X	X	-	Diener, E. et al Journal of Personality Assessment. 1985;49:71-75; Spanish Version Validation Vázquez C et al. Span J Psychol. 2013;16:E82.
	PSS-4	X	X	-	Cohen et al. Journal of Health and Social Behavior. 1983;24:385-396. – Spanish Validated Version obtained from the author website
Parental health behaviors *(Smoking, alcohol, physical activity, BMI)*	Idem previous visits	X	X	-	-
Stressful events	LTE	X	X	-	Brugha TS and Cragg D. Acta Psychiatr Scand. 1990;82(1):77-81.Validated Spainsh version Motrico, E. et al. Journal of affective disorders. 2013;150(3):931-940
	Address change	X	-	-	-
Child behavior	SDQ	X	X	-	See Chapter 2.7.2
Health-related quality of life	Kidscreen-27	-	-	X	Ravens-Sieberer, U. et al. Revisión de Expertos de Farmacoeconomía y Resultados de Investigación, 2005;5(3);353-364. Spainsh version obtained from the project website.
Bullying	16 questions adapted from OBVQ	-	-	X	Olweus, D. (1996). The Revised Olweus Bullying Questionnaire. Mimeo. Bergen, Norway: Research Center for Health Promotion (HEMIL), University of Bergen, N-5020 Bergen, Norway. Spanish Version obtained from the author.
Screen-time & sedentary behavior	Adapted from the HELENA Screen-based Sedentary Behaviors Questionnarie	X	-	-	Rey-López JP et al. Eur J Public Health. 2012;22(3):373-7 (originally in Spanish)

Legend: GHQ-12, General Health Questionnaire; LTE, List of Threatening Experiences; OBVQ, Olweus Bully/Victim Questionnaire; PSS-4, Perceived Stress Scale; SDQ, Strengths and Difficulties Questionnaire; SWLS, Satisfaction With Life Scale.

2.9   Physical activity with ExpoApp (until December 2016)

A smartphone-based system called ExpoApp will be used to assess physical activity of the child (Annex 19). We will use the Samsung Galaxy Young smartphone. Children will carry the smartphone in a pouch with an elastic belt in front of their belly throughout the week. The smartphone has to be switched on and should be working wherever they go. They will only take it off when sleeping at night, showering, swimming or when they perform any activity that can have a risk for the child or the smartphone. The battery has to be charged at night.

Child will be asked to fill in the following sheet recording any problem experienced with the provided smartphone (Annex 19.1).

2.10 Physical activity and sleep patterns with GENEActiv (from December 2016)

The wrist-worn accelerometer GENEActiv will be used to assess physical activity of the child (Annex 22).

2.11 Child will be asked to fill in a daily diary recording information related to sleep, daily habits, problems with the device, and problems with the HOBO sensor (

2.12 Light exposure at the bedroom

The light sensor HOBO Pendant will be used to measure light exposure at the bedroom of the child (**Mi**

diario del sueño y actividad física

Te presentamos tu **diario del sueño y actividad física** de los próximos días. Las preguntas del diario y el reloj nos ayudarán a saber cómo duermes y a medir tu actividad física.

Hoy te ponemos el reloj y a partir de mañana cada día tendrás que contestar unas preguntas, ya verás que son las mismas cada día, en función de cómo hayas dormido y qué hayas hecho el día anterior.

El reloj se puede mojar pero si te lo quitas es **MUY IMPORTANTE** que anotes el motivo, la hora que te lo quitas y la hora que te lo vuelves a poner en la tabla de incidencias que encontrarás al final de cada día.

Te puedes duchar con el reloj, pero **NO** puedes ir con él a la piscina.

Preguntas a responder **ANTES DE IR A DORMIR**

¿Has estado mirando la televisión, una película o series, te has quedado dormido en algún momento mirando la televisión?

☐ Si   ☐ No

¿Cuánto tiempo has pasado hoy en el aire libre con luz del sol? …. horas y ….. minutos

¿Has tomado hoy Coca-cola (u otra marca), café, té, alguna bebida energética, o chocolate?

☐ Si, Coca-Cola y por última vez a las …. : ….. (hora : minutos)

☐ Si, café y por última vez a las …. : ….. (hora : minutos)

☐ Si, té y por última vez a las …. : ….. (hora : minutos)

☐ Si, bebida energética y por última vez a las …. : ….. (hora : minutos)

☐ Si, chocolate y por última vez a las …. : ….. (hora : minutos)

☐ No

Hoy, a partir de las 19h de la noche…	¿Cuántas veces?	¿Cuánto tiempo en total?	¿Cuándo fue la última vez, antes de dormirte? (hora : min)
¿Has enviado mensajes (whatsapp, SMS, snapchat, etc.)?	…… veces	……. horas y …..min	…. : ….
¿Has hablado con alguien por el teléfono móvil?	…… veces	……. horas y …..min	…. : ….
¿Has hablado con alguien por el teléfono fijo de casa?	……. veces	……. horas y …..min	…. : ….

Hoy, a partir de las 19h de la noche…

¿Has jugado a juegos con la videoconsola,	……. horas y …..min	…. : ….

ordenador, móvil o tableta?

¿Has mirado videos con el móvil, la tableta o el ordenador?	……. horas y …...min	…. : ….
¿Has mirado Facebook, Instagram, Twitter, noticias, etc.?	……. horas y …...min	…. : ….
¿Has mirado la televisión?	……. horas y …...min	…. : ….
¿Has hecho los deberes o estudiaste?	……. horas y …...min	…. : ….
¿Has leído?	……. horas y …...min	…. : ….

¿Qué programas, película o series has mirado hoy durante todo el día en la televisión?

……

……

………………………………………………………………………………………………………

¿Hoy has hecho las actividades que haces habitualmente?

☐ Si   ☐ No, especifica porqué:………………………………………………………

Incidencias con el reloj o el sensor de luz HOBO:			
Reloj u sensor luz HOBO?	Motivo	Hora inicio (horas y minutos)	Hora final (horas y minutos)
Ejemplo: Reloj	*Fui a la piscina y me lo quité*	*16:00*	*17:00*
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..

Fecha: ____/____/2017

Preguntas a responder **CUANDO TE LEVANTAS**

¿Qué hora es ahora?   …. : ….. (hora y minutos)

¿A qué hora te fuiste a la cama ayer?   …. : ….. (hora y minutos)

Teniendo en cuenta que quizás estuviste despierto un tiempo en la cama (por ejemplo, leyendo), ¿a qué hora apagaste las luces y estabas listo/a para dormir? ...:... (hora y minutos)

¿Cuánto tiempo pasó hasta que te dormiste?   ….. horas y …..minutos

¿Cuántas veces te has despertado esta noche?   ………. veces

¿Cómo has dormido esta noche? ☐ Muy bien ☐ Bien ☐ Regular   ☐ Mal   ☐ Muy mal

¿Cómo de descansado te has sentido al despertarte?

☐ Totalmente descansado/a ☐ Bastante descansado/a   ☐ Algo descansado/a

☐ Poco descansado/a   ☐ Nada descansado/a

¿A qué hora te has despertado?   …. : ….. (hora y minutos)

¿Cómo te has despertado esta mañana?

☐ Con el despertador ☐ Alguien me ha despertado ☐ Un ruido me ha despertado   ☐ Me he despertado solo/a ☐ De otra manera, especificar:………………………………………

¿A qué hora te has levantado de la cama?   …. : ….. (hora y minutos)

¿Dormiste solo/a en tu habitación?

☐ Si   ☐ No, especifica con quien dormiste en la habitación:………………………………….

¿Tuviste el ordenador, el portátil, la tableta o el teléfono móvil encendido en la habitación mientras dormías?

☐ Si   ☐ No

> **Si lo tuviste, ¿te despertaste alguna vez por haber recibido mensajes en el ordenador, portátil, tableta o teléfono móvil?**
>
> ☐ Si   ☐ No
>
> > **¿Si te despertaste por haber recibido un mensaje, qué hiciste?**
> >
> > ☐ Nada   ☐ Leí el mensaje y volví a dormir ☐ Leí el mensaje y lo contesté

Preguntas a responder **ANTES DE IR A DORMIR**

¿**Has estado mirando la televisión, una película o series, te has quedado dormido en algún momento mirando la televisión?**

☐ Si   ☐ No

¿**Cuánto tiempo has pasado hoy en el aire libre con luz del sol?** …. horas y ….. minutos

¿**Has tomado hoy Coca-cola (u otra marca), café, té, alguna bebida energética, o chocolate?**

☐ Si, Coca-Cola y por última vez a las …. : ….. (hora : minutos)

☐ Si, café y por última vez a las …. : ….. (hora : minutos)

☐ Si, té y por última vez a las …. : ….. (hora : minutos)

☐ Si, bebida energética y por última vez a las …. : ….. (hora : minutos)

☐ Si, chocolate y por última vez a las …. : ….. (hora : minutos)

☐ No

Hoy, a partir de las 19h de la noche…	¿Cuántas veces?	¿Cuánto tiempo en total?	¿Cuándo fue la última vez, antes de dormirte? (hora : min)
¿Has enviado mensajes (whatsapp, SMS, snapchat, etc.)?	……veces	….horas y …...min	…. : ….
¿Has hablado con alguien por el teléfono móvil?	……veces	….horas y …...min	…. : ….
¿Has hablado con alguien por el teléfono fijo de casa?	…….veces	….horas y …...min	…. : ….

Hoy, a partir de las 19h de la noche…

¿Has jugado a juegos con la videoconsola, ordenador, móvil o tableta?		……. horas y …...min	…. : ….
¿Has mirado videos con el móvil, la tableta o el ordenador?		……. horas y …...min	…. : ….
¿Has mirado Facebook, Instagram, Twitter, noticias, etc.?		……. horas y …...min	…. : ….
¿Has mirado la televisión?		……. horas y …...min	…. : ….
¿Has hecho los deberes o estudiaste?		……. horas y …...min	…. : ….

¿Has leído?	……. horas y …...min	…. : ….

¿Qué programas, película o series has mirado hoy durante todo el día en la televisión?
……
………………………………………………………………………………………

¿Hoy has hecho las actividades que haces habitualmente?

☐ Si   ☐ No, especifica porqué:……………………………………………………………

Incidencias con el reloj o el sensor de luz HOBO:			
Reloj u sensor luz HOBO?	Motivo	Hora inicio (horas y minutos)	Hora final (horas y minutos)
Ejemplo: Reloj	*Fui a la piscina y me lo quité*	*16:00*	*17:00*
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..

Annex 23). Children need to place the sensor in a specific position in a flat surface close to the bed in their bedroom.

2.13 Copy of both hands

Endocrine-disrupting chemicals are exogenous substances that alter endocrine system activities. The endocrine system regulates many essential body functions such as growth, behavior, and reproduction through the controlled release of hormones. EDCs include many synthetic and natural chemicals such as polychlorinated biphenyls, pesticides, phthalates, metals, and phenols. Early life exposure to these endocrine-disrupting chemicals may affect growth and development and can have important consequences on late-life cardiovascular diseases. A key event in early male life is the perinatal androgen surge, a period that is critical for hormonal imprinting and sex differentiation of the brain and the prostate, and possibly also other tissues, including cardiovascular ones (Liu PY et al. Endocr Rev. 2003; 24: 313–340; Kudwa AE et al. Neuroscience. 2006; 138: 921–928). Second to fourth digit ratio (2D:4D) is widely used as a correlate of prenatal exposure to androgens (McIntyre MH. Reprod Biol Endocrinol 4.10 2006), and it could be measured directly or indirectly, on a photocopy or scanned copy of the hand (e.g. Allaway HC, et al. American Journal of Human Biology 21.3 (2009): 365-370).

On the day of the first visit a photocopy of both hands of the child will be taken (Annex 20).

2.14 Exposure to pollutants

The exposure levels to the pollutants have been measured in previous visits.

2.15 Personal Exposure Monitoring (PEM)

2.15.1 XMobiSense

Children who own an Android smartphone will be asked to install the XMobiSense App (Annex 21), an Android based application developed in the frame of the MobiExpo study to collect information about phone use. The application collect data regarding each (date; time; duration; laterality; outgoing/incoming; network type; hands free usage), data transfer (daily amount of SMS sent/received; daily amount of data sent/received; daily WiFi usage sent/received), type of hired service (only voice, voice and data, etc). No personal data are collected. Data are automatically transmitted to the FTP servers at CREAL, only when connected to a WiFi network to prevent from data costs.

3   Statistical power

In order to improve the statistical power of the study, the majority of the outcomes will be analyzed as continuous instead of categorical. Given the study sample size (N= 550), we therefore obtain an 80% statistical power to detect a 0.3 increase in the z-score (mean 1, SD 1.5).

4 Ethical issues

Ethical issues and health risks arising within this study concern:

a. Involvement of subjects not able to give consent (children). Child consent will be granted though representation (i.e. parents or legal guardian) according to the Spanish Law on Biomedical Research;

b. The collection of information about diet and other habits;

c. Psychosocial factors collection through questionnaires and checklists;

d. The collection of a hair sample. Hair samples are considered non-invasive and do not present any particular risk.

e. The storage and transfer of data, to central data warehouse.

f. To carry a smartphone with applications to record physical activity for one week in two periods. Although no health risks has been revealed linked to smartphones, we recommend that children carry them in the small pouch provided.

4.1 Informed consent

Informed consent will be sought before the start of the follow-up visit. Once obtained, the consent form will be kept in the study subject's personal file and a copy of the signed informed consent form will be provided to every subject/subject's legally authorized representative.

The hair sample can be destroyed at the subject/subject's legally authorized representative's request if he/she do not wish his/her sample to be used in further research after the study; the samples would then be destroyed in the appropriate manner after a specified time.

The study subject/subject's legally authorized representative may always change his/her opinion in the course of the study for any reason at any time without penalty or loss of benefits to which they are otherwise entitled. Details on the possibility of study participants to request removal of their coded data from the study will be included in the informed consent information form.

4.2 Storage of the data

In order to safeguard the privacy of study subjects:

- Reported study results will pertain to analyses of aggregate data. No individual's name will be associated with any published or unpublished report of this study;

- Where personal information is used, including questionnaires and biological material it will be safety stored in secure facilities, and names will be replaced by unique study numbers, and stored separately. Primary databases and analysis files will be stored on computers with personal identifiers removed;

- Geocodes will be generated from address information and will only be linked to unique study numbers and no other information including health data. The geocodes will be used for the sole purpose of obtaining individual exposure estimates. Only these exposure estimates, and not the geocodes themselves, will be linked to any other information.

- Subjects will be identified by a unique study number. This unique identifier will link all basic data required for the study. The master key file linking the study numbers with personal

identifiers will be stored in a password protected computer file. Access to these file will be limited to authorized project personnel;

- All other files containing personally identifiable information will be stored in password protected computer files. Access to these files will be limited to authorized project personnel;

- Hard copy records or computer generated records containing personally identifiable information will be stored in locked cabinets in an office with limited access;

- All project personnel will be trained in the importance of confidentiality of individual records;

- During the project life-span information will be accessed and handled by members of the research teams only, unless specific permission has been given by the INMA executive committee.

5   Annex 1

Informed consent

See separate document, 'Annex 1 Consentimiento_catalan_11años 20160321'.

6 Annex 2

PAQUET D'INFORMACIÓ PER A LES FAMÍLIES

A dia _____ (data) el vostre fill serà visitat a l'escola. La visita que es durà a terme a l'escola inclourà: mesura de la pressió sanguínia, del pols arterial, fotografia de la retina i espirometria. Aquestes mesures es poden veure influenciades per diversos aliments i/o medicacions.

Per aquest motiu, preguem es segueixin les següents instruccions:

- Assegurar que els vostres fills no consumeixen cap producte que contingui cafeïna (per exemple, cafè, te, Coca-cola, Redbull) o qualsevol altre aliment estimulant (ex. Xocolata, ginseng) durant el matí de la visita. Recordar al nen el no consum d'aquests aliments abans de què la visita tingui lloc.

- Es recomana peces de vestir còmodes pel dia de la visita.

Assegureu-vos que el vostre fill porta a la motxil·la el seguent **EL DIA DE LA VISITA**:

☐ els qüestionaris (mare i pare)

☐ el consentiment signat

☐ el seu **PROPI** mobil smartphone (sistema Android, no Apple ni Windows), en el cas que en tingui, juntament amb el seu cable de connexió a USB.

Moltes gràcies per la seva col·laboració!

7   Annex 3

Mother questionnaire

See separate document, 'Annex 3 cuestmadresinmasab11a 20160318'

8   Annex 4

Father questionnaire

See separate document, 'Annex 4 cuestpadresinmasab11a 20160318'

9   Annex 5

Phone interview

See separate document, 'Annex 5 entrvteleffamiliasinmasab11a 20160318'

10 Annex 6

Child questionnaire

See separate document, 'Annex 6 cuestniñosinmasab 11a 20160318'

11 Annex 7

INMA SABADELL 11 YEARS VISIT
CLINICAL EXAMINATION DATASHEET

General information

Date: _____   INMA ID: _____
      (day) (month) (year)

SESSION 1
Fieldworker: _____

Time of Day (24 hrs) _____
          (Hours) (Minutes)

Session conditions

Temperature (^{o}C) _____

Relative humidity (%)_____

Observations
_____
_____

Questions

Before starting the visit please ask the child the following question and make a circle on the answer:

1. Did you take any medication in the 24 hours prior to the visit?
   - Yes → specify the medication you took and when did you take the last dosis
     _____
   - No

2. Did you suffer an asthma attack …

	Yes	No	Don't know/Do not want to answer
… in the last 3 days?			
… in the last week?			

3. Did you suffer a common cold or flu in the last week?
   a. Yes
   b. No
   c. Don't know/Don't want to answer

4. Did you suffer from any other health problem in the last week?

a. Yes, please specify _____
b. No
c. Don't know/Don't want to answer

5. Do you have a common cold today?
   a. Yes
   b. No
   c. Don't know/Don't want to answer

6. Did you consume chocolate, the, coca-cola, redbull, gingseng or any other beverage containing caffeine in the last two hours?
   - Yes, please specify _____
   - No

7. Did you exercise in the last two hours?
   - Yes, please specify _____
   - No

8. Only for girls (if it apply). When did your last period start? _____

Anthropometric measurements

	First measurement	Second measurement
Child's Height (cm)	☐☐☐ , ☐	
Child's Weight (kg)	☐☐☐ , ☐	
Child's Waist Circumference (cm)	☐☐☐ , ☐	☐☐☐ , ☐
Child's Head Circumference (cm)	☐☐☐ , ☐	☐☐☐ , ☐

Anthropometric Measurements Observations

_____

_____

Bioimpedence:

Resistance:_____ Reactance_____

Bioimpedence Observations

_____

_____

Blood pressure results (record 3 measurements):

Measurement	1st measurement	2nd measurement	3rd measurement
Systolic blood pressure			
Diastolic blood pressure			
Mean blood pressure			
Pulse			

Blood pressure observations (including cuff size)

_____

_____

Spirometry

Spirometry Measurement	Result (mL)
FVC :	
FEV1:	
FEV1/FVC:	
FEV6 :	
FEV1/FEV6:	
FEF 25-75%:	
MEF 50:	
PEF:	

Spirometry observations

_____

_____

Pulse Wave Velocity

Path length [ ][ ] , [ ]   cm   x 80%   [ ][ ] , [ ]
=

Pulse Wave Velocity observations

_____

_____

SESSION 2

Fieldworker: _____

Time of Day (24 hrs) _____

(Hours) (Minutes)

Neurodevelopment testing conditions

Weather:

1. Sunny

2. Sunny/cloudy

3. Cloudy/Rainy

Noise:

1. No noise

2. Some noise

3. Noisy

Quality of the testing

1. Normal

2. Some problems (difficulties to concentrate, etc)

3. Not usable

Neurodevelopment testing observations

_____

_____

FRACT testing conditions

Light conditions in the room

_____ Lux

FRACT

Visual acuity

Dec. VA _____

logMAR _____

Contrat sensitivity test

Does the child usually wear glasses?
☐ Yes → Did he/she use it during the contrast test? ☐ Yes   / ☐ No
☐ No

Threshold contrast _____ %

Weber _____ logCS

FRACT observations

_____
_____

Hair collection

Site of collection

1. Posterior vertex area

2. Other → specify _____

Hair collection observations_____

_____

Copy of the hands

1. Yes

2. No

Copy of the hands observations_____

_____

Questionnaire

Please, select

☐ Child read the questionnaire alone, without help or interference from the nurse

☐ Child read the questionnaire alone, with some clarification from the nurse

☐ Nurse helped the child to read the questionnaire

☐ Nurse read the whole questionnaire to the child

Observations _____

XMobiSense (only for children with personal mobile phone)

IMEI code of mobile phone _____

12 Annex 8

ANTHROPOMETRIC MEASUREMENTS

The evaluation and interpretation of anthropometric data require standardized measurement procedures, trained personnel, use of appropriate, regularly calibrated instruments and collection of reliable data. Fieldworkers collecting anthropometric data should be trained and refresher sessions should be held periodically.

The process of taking body measurements does not impose any physical harm or risk to the child. However, there are certain precautions to be observed by the examiners due to specific positioning for the varied measurement components.

Prepare the child by explaining the procedure in a simple way.

Instruments

1. Digital weight scale: Seca 770, d=100g. In order to check the accuracy of the weight scale, objects with known weight are applied.

2. Stadiometer: Seca 214, d=1mm

3. Metric tape: Seca 201, d=1mm

Always read the manual of the instrument for details on operation, cleaning etc. All instruments used should be maintained in good order.

Common errors

The most common errors in anthropometrics are body positioning, reading measurements and recording. Errors made in measuring technique are minimized by the recorder's role in assisting the examiner. Reading errors frequently occur as a result of parallax, the phenomenon where an examiner sees a different value on a measuring device depending on the angle from which it is viewed.

General

Body measurements are taken on the right side of the body. However, some measurements may be taken on the left side of the body because of several reasons that does not allow the measurement on the right side. When this occurs, note the fact and the reason in the comments section on the body measurement results hardcopy form.

All measurements should be taken to the nearest tenth of a centimeter or 1.0 millimeter. Weight is measured according to the accuracy of the weight scale (i.e. 0.1 kgr).

Height and weight are once measured. Circumference measurements will be recorded in duplicates.

Ideally the same examiner should perform measurements in the whole cohort, always record the name of the examiner in the 'Clinical examination datasheet' (Annex 7) for posterior analysis. The date and the time that the measurements are performed in the 'Clinical examination datasheet' (Annex 7).

1. Weight

Children must be weighed without shoes and with light clothing. If not, do the measurement and record the fact. The examiner should make sure that the scale is positioned horizontally on the floor. When the scale is turned on, the digital LED readout should show 000.00 before weighing a child. Have the child stand on the center of the weight scale platform and make sure that he/she is not holding or touching the examiner or the wall for example. Record the weight in the 'Clinical examination datasheet' (Annex 7).

2. Height

Children must be measured without shoes. If not, do the measurement and record the fact. Have the child stand upright and centrically on the floor board of the stadiometer with his or her back to the vertical backboard of the stadiometer. The weight of the child is evenly distributed on both feet. The legs should be straight. The heels of the feet are placed together with both heels touching the base of the vertical board. Place the feet pointed slightly outward at a 60 degree angle. The heels, buttocks, scapulae, and head are positioned in contact with the vertical backboard (Figure 1a). If this is not possible, children are positioned so that only the heels and buttocks are in contact with the vertical board, and the body is positioned vertically above the waist. The shoulders should be relaxed and the arms hang freely by the sides of the trunk with palms facing the thighs.

The examiner goes down to a face-to-face level with the child and position the child's head so that is maintained in the Frankfort Horizontal Plane (Figure 1b).The examiner lowers the horizontal bar snugly to the crown of the head with sufficient pressure to compress the hair. Hair ornaments, buns, braids, etc. must be removed to obtain an accurate measurement. Check once again the position of the child and record the height in the 'Clinical examination datasheet' (Annex 7).

a.   b.
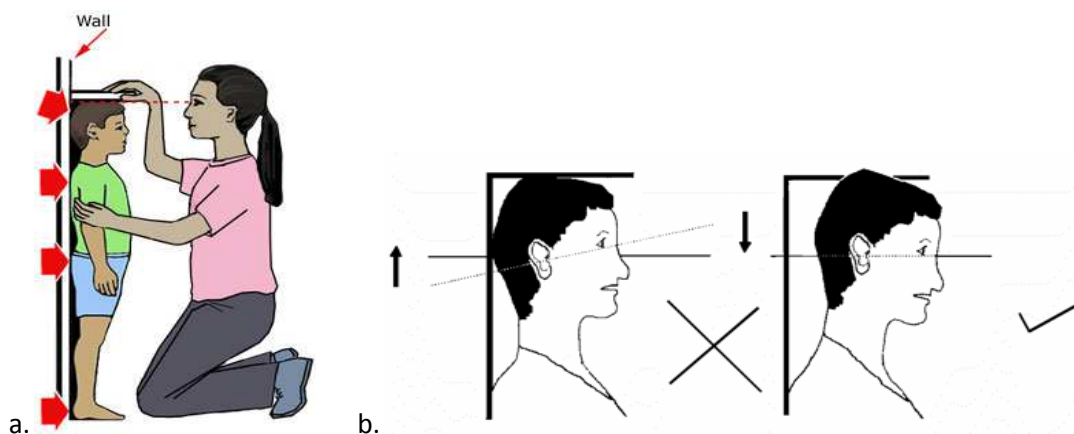
Figure 1. a. The heels, buttocks, scapulae, and head are positioned in contact with the vertical backboard, b. The Frankfurt Horizontal Plane. A horizontal line drawn from the ear canal to the lower edge of the eye socket ran parallel to the baseboard.

3. Waist Circumference

The child should be in a standing position with his/her weight evenly distributed on both feet. The examiner stands behind the child and palpates the hip area for the right iliac crest. Any clothes and underclothing of the child must be lowered slightly for the

examiner to palpate directly on the hip area for the iliac crest.The examiner marks a horizontal line at the high point of the iliac crest (Figure 2).

The examiner then stands on the child's right side and places the measuring tape around the trunk in a horizontal plane at this level marked on the right side of the trunk. The recorder should make sure that the tape is parallel to the floor and that the tape is snug, but does not compress the skin. The measurement is made at minimal respiration. Record the waist circumference in the 'Clinical examination datasheet' (Annex 7), and repeat the measurement..

a.   b.   c.   d.   e.
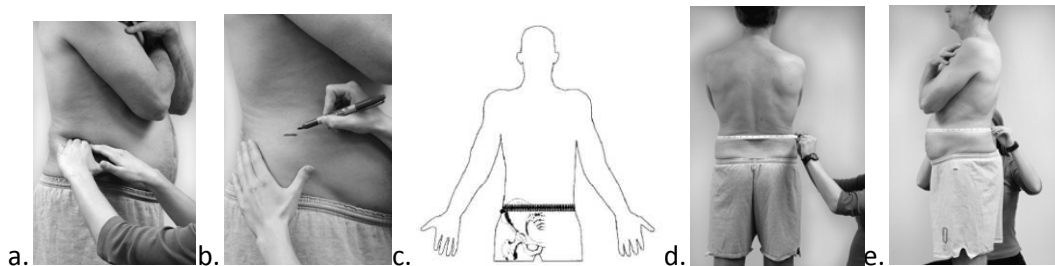
Figure 2a) Palpate the iliac crest b) Mark a horizontal line c and d). Place the tape e) Record the value at minimal respiration.

4. Head circumference

The child either sits or stands. The tape is placed across the frontal bones just above the eyebrows, around the head above the ears on each side, and over the occipital prominence at the back of the head. The examiner holds the tape snugly around the head. Hair ornaments and braids should be removed. The tape is moved up and down over the back of the head to locate the maximal circumference of the head. The tape should be perpendicular to the long axis of the face and should be pulled firmly (tight) to compress the hair and underlying soft tissues. Record the head circumference in the 'Clinical examination datasheet' (Annex 7), and repeat the measurement.
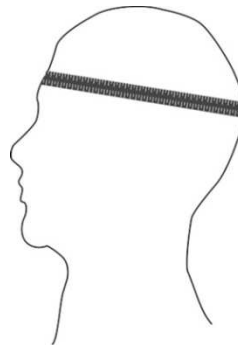
Figure 4. Tape position for the head circumference measurement.

References

1. NHANES, III., *Body Measurements (Anthropometry)*. 1988: Rockville, MD 20850.
2. *WHO Multicenter Growth Reference Study Group, Measurement and standardization protocols for anthropometry used in the construction of a new international growth reference. Food and Nutrition Bulletin, vol 25, no 1 (supplement 1), 2004*
3. Handbook of anthropometry. Physical measures of human form in health and disease. Victor R.

Preedy. 2012

13 Annex 9

BIOIMPEDENCE

V1 21 March 2016 (adapted from V2 24 January 2014 from HELIX Project)

Bioelectric impedance analyses (BIA) provides a valid and reliable measure of body composition if standard protocol procedures are followed, and population-specific equations are available and utilized. BIA will provide an objective measure of body fat composition. Appropriate and population-valid equations will be used *a posteriori* to obtain body-fat measures.

Instruments

Bodystat 1500 (default option 50 KHZ)

Associated Software: Bodystat Body Manager

Other required Equipment:

- Bodystat adhesive electrodes (ref: 0515)
- Alcohol wipes
- Somewhere to lie down
- 6 extra Duracell AA Type LR6

Weekly instrument testing:

Confirm that the machine is working properly using the test electrode (see photo bellow). **If the device is calibrated, impedance measurement should be between 496 and 503**. If impedance measurement is out of this range, replace batteries and test again. If impedance measurement is still out of this range, please contact the cohort coordinator.
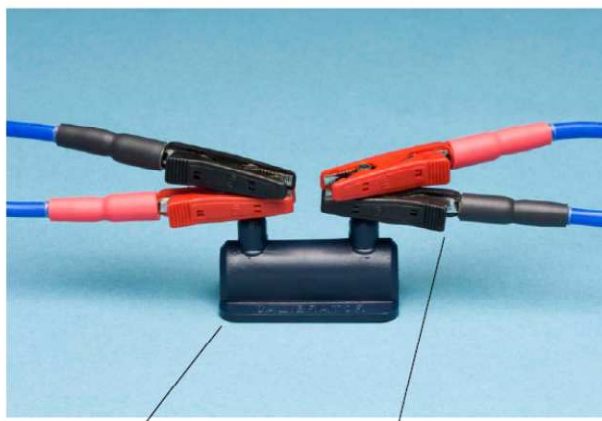
Procedure

1) Ask the child to go the toilet to empty bladder.

2) Explain that it is a way to estimate the body composition of the child.

3) Ask the child to take off shoes, socks and heavy clothing (eg. jackets). Any metal jewellery should be also removed.

4) Ask the child to lie down with feet apart and arms away from the body (as shown in the photo bellow). **Please, ensure that no parts of the body are touching**. There should be no contact with a metal surface.

5) The child should spend **5 minutes laid at rest** before the bodystat measurement is taken. You could read them a book during this time if necessary.

6) It is Important to use for every child four **new** (unused) electrodes. Ensure that the metallic part of the cable clips is in direct contact with the metallic part of the electrodes (i.e. the side of the electrode in touch with the body) and that the clips are aligned to the center of the electrodes.

7) After cleaning the skin contact areas with a little alcohol, place one pair of electrodes in the right hand and the other in the right foot as shown in the photo.

Electrode placement (**correct placement of the electrodes is essential**!):

    a. **Right HAND**:   - The **RED** lead is placed behind the knuckle of the middle finger.

        - The **BLACK** lead is paced on the wrist next to the ulna head.

    b. **Right FOOT**:   - The **RED** lead is placed behind the 2ND toe next to the big toe.

        - The **BLACK** lead is paced on the ankle at the level of the between the medial and lateral malleoli (the large protruding bones on the side of the ankle).

8) Turn on the device; Record the displayed bodystat patient code on to clinical data sheet

9) Insert data on:

- child's sex,

- age,

- height

- and weight,

- activity level (put low / medium),

- circumference (leave as default, correct value can be entered to PC later for parental report),

- hip circumference (leave as default),

10) Press enter to conduct measurement and record measurement of **impedance to data sheet** .

(The next steps can be done after the interview with the mothers)

11) Use the **Body Manager software** to download and store data from the Bodystat device to a PC (requires a Bluetooth connection).

   Body Manager Options to set in all cohorts:

   Go to *Options* >> Regression equation: 4. Children

   Metabolic formula: Schofield

   Optimal weight range: BMI

12) Having set the above options, record from the 'Informe de la composición corporal' the body fat and body fat % estimations in the 'Clinical examination datasheet' (Annex 7).

At the time of data analyses, children fat mass and fat free mass will be further calculated based on values of impedance, using race-specific equations available in literature and results will be compared to those obtained using the Bodystat children specific algorithm.

INFORME DE LA COMPOSICIÓN CORPORAL

Examiner: Dania
PACIENTE0   viernes, 24 de enero de 2014

Sexo	Mujer	Peso	45,5 kg
Edad	7	Estatura	147 cm
Actividad	Muy Baja	Impedancia 50kHz	498
		Equación de Regrezion	4

If Body Manager Options are set correctly, the regression equation shown in the report should be **"4"** (children)

	Medido	Límite Normal	Medido %	Límite Normal
Peso Corporal (Composición)	45,5 kg	44 kg a 46 kg		
Peso de la Grasa	8,5 kg	7 kg a 9 kg	18,7%	15% a 19%
Peso Muscular	37,0 kg	36 kg a 38 kg	81,3%	81% a 85%
Agua Corporal	28,7 lts	29 lts a 30 lts	63,1%	63% a 66%
Peso Masa Magra Seca	8,3 kg			

Metabolismo Basal   1523 kcal/dia (33,5 kcal/kg)
M.B. calcula la Energía necesaria en reposo.

Metabolismo Actividad 2132 kcal/día
Seleccione el nivel estimado de energia que su cuerpo necesita para su nivel de actividad.

Peso : normal
Grasa % : normal
Agua % : normal

Record from the Body Manager report, child's body fat and body fat %.
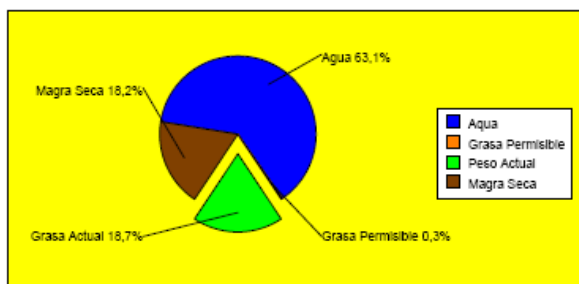
Other important notes:

- **Batteries**: The use of **Duracell AA Type LR6** is strongly recommended for all Bodystat devices (estimated duration= 40 hours). DO NOT use other battery types or rechargeable batteries as this may influence measurements.

- When removing the lead wires from the device, pull the black socket NOT the lead wires as this can damage the wires.

- When measures are completed, the lead wires should then be removed from the device, gently coiled together and kept in a safe **place. DO NOT WRAP THE LEAD WIRES AROUND THE DEVICE** – this will cause the lead wires to bend and eventually break.
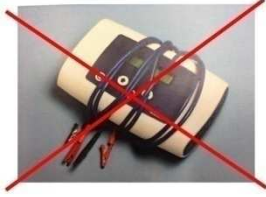
14 Annex 10

PULSE WAVE VELOCITY USING VICORDER

Arterial stiffness refers to the material properties of the arterial wall, which in turn has functional consequences for the artery affecting the manner in which pressure, blood flow, and arterial diameter change with each heartbeat. It is associated with changes in the mechanical properties of the wall (that is alteration of stress/strain characteristics due to modifications of properties of the load-bearing structural components).

Stiffness is not uniformly disseminated throughout the vascular tree but is often patchy, occurring in central and conduit vessels while sparing more peripheral arteries. Aortic stiffness is an important predictor of future cardiovascular events, particularly in adults.

Arterial stiffness can be measured invasively or non-invasively. The measurement of the velocity of the pulse wave travel in a segment of vessel (pulse wave velocity, PWV) is generally accepted as the most simple, non-invasive, robust, and reproducible method to determine arterial stiffness. In its **recommendations** for improving and standardizing vascular research on arterial stiffness **American Heart Association (AHA)** recently stated that "**it is reasonable to measure arterial stiffness clinically by determining PWV**", and the assessment of PWV in clinical practice is recommended in the 2013 European Society of Hypertension/European Society of Cardiology (ESH/ESC) guidelines for the management of arterial hypertension.

PWV can be measured in different arterial segments. The **carotid-femoral PWV** (cfPWV) is a direct measurement along the aortic and aorto-iliac pathway, and it is the **most clinically relevant**, since the aorta and its first branches are what the left ventricle (LV) 'sees' and are thus responsible for most of the pathophysiological effects of arterial stiffness. CfPWV has been used in the epidemiological studies demonstrating the predictive value of aortic stiffness for CV events, and it is therefore considered the **'gold standard'** measurement of arterial stiffness.

Arterial stiffness measurement as cfPWV in children by Vicorder has been validated in children against the non-invasive gold standard (i.e. applanation tonometry) as recommends by AHA.

Instruments

VICORDER® - Arterial Stiffness Testing System

Associated Software: VICORDER® vascular diagnostic program package

PC/Notebook System requirements:

- DualCore CPU (AMD® oder Intel®)
- min. 2 GB RAM, hard disk min. 150 GB
- TFT color display - Keyboard, touchpad
- CD/DVD-R/RW-drive
- MS Windows® 7 or 8 operating system

Other required Equipment:

- 1 neck cuff (20 mm) + red pressure line

- 1 femoral cuff (100 mm width) + blue pressure line

- Measuring tape

Instrument preparation

1. Connect the Vicorder to the laptop (both red and black USB should be connected to ensure power supply);

2. Connect the pressure lines (blue and red) to the Vicorder (be sure that the double arrow sign ⬌ is in the upper part of the plug (see Figure 4)

Figure 4 Pressure line connected to the Vicorder

General

PWV measurements will be recorded in triplicate measurements taken in a row. Mean values of the three measurements to be used for further analyses.

Since in the measurement of cardio-femoral pulse wave velocity (cfPWV) the major source of inaccuracy lies in the determination of the travel distance of the pulse wave, in this study the path length used is the 80% method (80% of the measured direct distance between the carotid and femoral recording sites), that ensures the smaller measurement error..

Procedure

1. Ask the children to use toilet to empty bladder before measurement.

2. Explain that it is a way to measure of the stiffness of the child's vessels.

3. Ask the child to take off their shoes, socks and heavy clothing (eg. Jackets, thick trousers).

4. Place a cushion under the head and shoulder, or raise the head piece of the couch in order to have **head and shoulder raised 30° above heart level** to prevent venous artefacts according to manufacturer's recommendations.

5. Double click on the "Vicorder" icon on Windows Desktop for starting the Vicorder program. The Vicorder program opens the "Main Screen". Press "New Patient", bottom left (red arrow in **¡Error! No se encuentra el origen de la referencia.**). Fill in the "Last Name" fild with "**N**" and the "ID" field with the INMA ID of the child. Click on the "save and exit" button
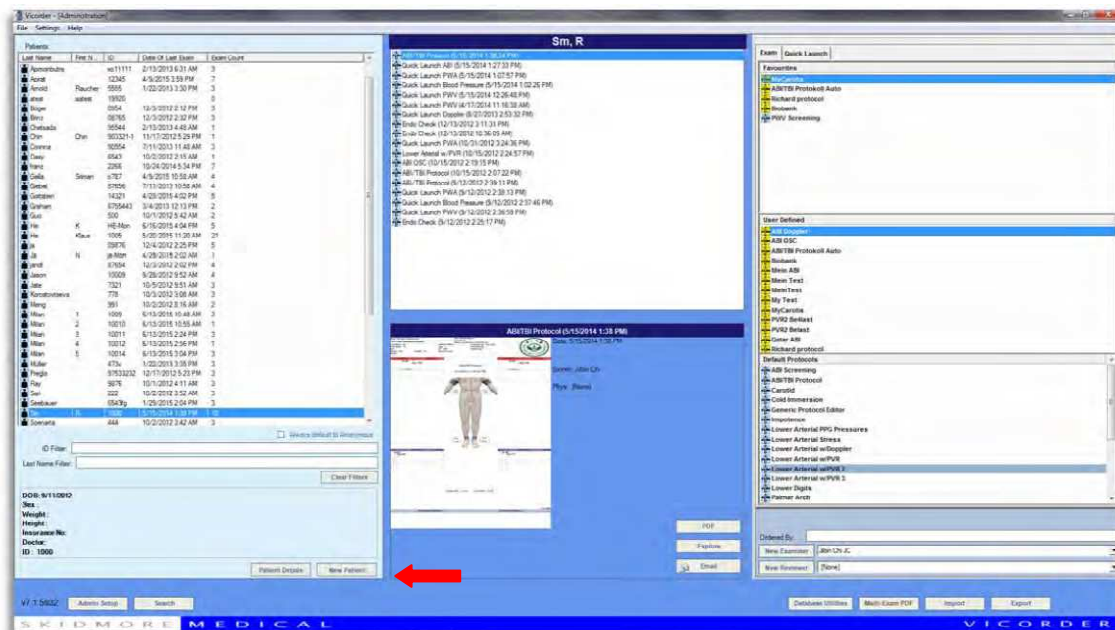
Figure 5 *Vicorder "Main Screen"*

6. Place the **thigh cuff** on the upper right thigh as high as possible toward the crotch. Thin, loose clothing, such as a shirt or blouse, thin slacks etc. do not need to be removed and will not affect the measurement. Close the cuff really tight assuring a good coupling of the cuff to the femoral artery. The bigger and softer the thigh is, the harder the cuff should be closed. Please take care to place the cuff bladder over the inner part of the thigh (above the femoral), particularly in obese patients.

7. Before you place the **cuff on the neck** palpate the pulse on the right common carotid artery in the center between base of the neck and chin. Ask the patient to lift his head and place the longer section of the neck band snugly around the neck. Now the patient can put his head back onto the head rest or cushion in order to relax the neck muscles avoiding muscle tension. Ensure that the cuff bladder is right over the carotid. The cuff should fit snugly but must not be unpleasantly tight. Observe a cuff position with the pressure line and connector pointing down (Figure 6). See 'Quality Assurance notes' at the end of the procedure for further information.

Figure 6 Neck cuff placement

8. Use the provided compass to measure the following distances (see **¡Error! No se encuentra el origen de la referencia.**):

   a. Distance from the site of the carotid artery (Car), which is the mid of the neck cuff (CarCuff) and the femoral artery, that is the mid of the femoral cuff (FemCuff). (It is suggested to mark the mid of the femoral cuff with a permanent marker to make the measurement easier".

9. Calculate the path length multiplying the obtained distance by 0.8 and record the result on the 'Clinical examination datasheet' (Annex 7).

10. **Ask the child not to move from now on (movements will change the measured distance).**

Quality assurance notes:

If the bladder lies snugly over the carotid region, it will "palpate" the pressure from the carotid artery. In that case you will be able to see the carotid pressure wave on the screen - with well visible pulsatile systolic upstrokes, slightly delayed but synchronous to the systolic peaks of the femoral pressure wave.

If the neck band is too loose, the carotid pressure wave will not be transferred adequately, resulting in unstable waves with small amplitudes as shown in Figure 7 below. With a loose neck cuff, the carotid wave will look instable, noisy or jittery, and dampened.

A similar effect will appear if the bladder is placed not properly over the carotid – but more frontally or laterally. A wave as shown in Figure 8 below may result.

Usually a slender neck allows easy palpation and stable wave form display, even if the neck cuff is not very tight. A thick, soft neck is harder to palpate and needs a firm, tight placement of the cuff for good signal transfer.

During the exam the average PWV will be given after two full sweeps. Observe the stability of the transit time (TT) and PWV reading.

Instable wave forms will result instable data. Stop the test, replace the cuff(s) and repeat the test.
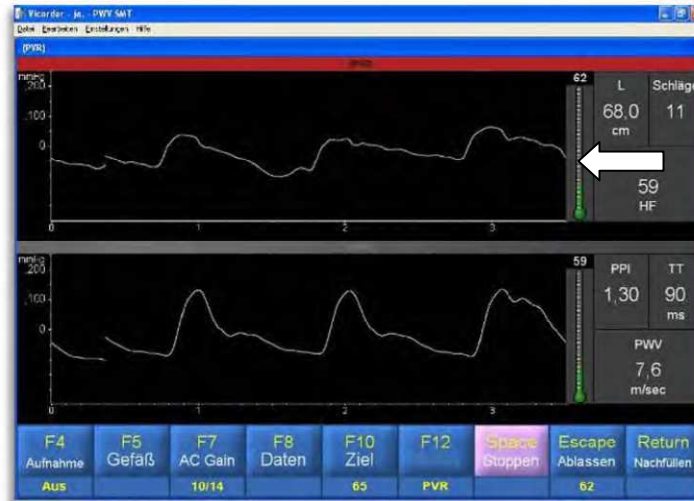
Figure 7 Pressure waves caused by a loose neck cuff
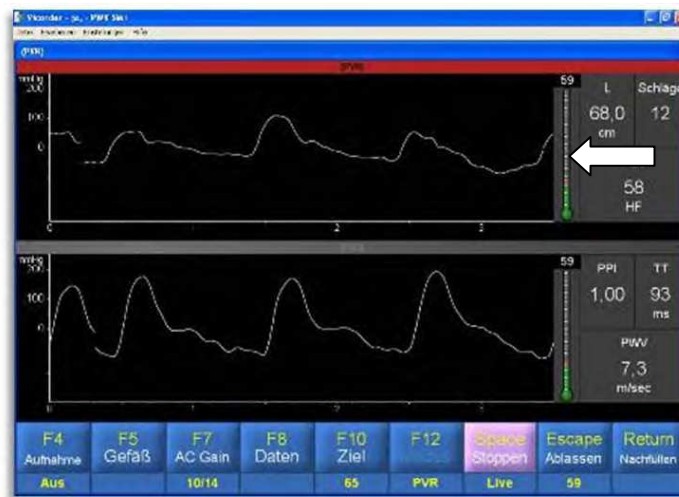
Figure 8 Neck cuff not placed over carotid artery

11. Choose "PWV" from the "Quick Launch" tab on the right side of the "Main Screen". Double click on "PWV". (Figure 9)
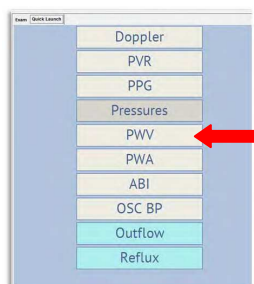
Figure 9 Choosing PWV from the Quick Launch menu

The exam screen with a pop-up window opens (Figure 10). Mark the entry field by double clicking on "Length". Enter the distance as determined above with an accuracy of one decimal.

Press the "Enter" key on the keyboard or click on "OK". The pop-up window will disappear and the exam screen fully displayed (Figure 11).
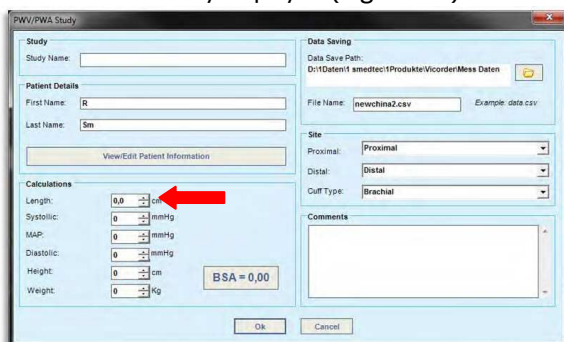
Figure 10 PWV/PWA Study window for entry of distance/length

Figure 11 PWV exam screen

12. Check "Mode" to be in "PVR" otherwise press "F12" or click on "Mode" until "PVR" is shown. "Target" should be at 65 mmHg. If needed (low or high diastolic pressure), adjust target pressure (left click +, right click -). Check connection of pressure tubes to the cuffs (red=proximal/neck, blue=distal/thigh). You may produce an artifact by tapping on the cuff and observe the pressure wave in the appropriate channel.

13. Start the test by clicking on "Space/Inflate" or pressing the space bar on the keyboard. In the upper channel you can see the signal from the carotid, in the lower from the femoral artery. The transit time (TT), the lag in the systolic rise between the two waves, is indicated in real-time. The PWV is given continuously in m/s, the ratio of length over TT. A drift in the baseline of the carotid wave as seen in Figure 12 does not affect a good measurement at all. Yet, if waves are jittering and expose a low amplitude, the algorithm for the evaluation of TT won't work properly. In this case a better positioning and a little tightening of the neck cuff should be considered, leading to a stable evaluation. Wait for stable waves, as seen in Figure 12. Record approx. 10-12 beats (red arrow in Figure 12). A clearly distinct systolic rise is the most important

factor in attaining stable quality results. **Ask the child to relax and not to speak, move or swallow during each recording.**
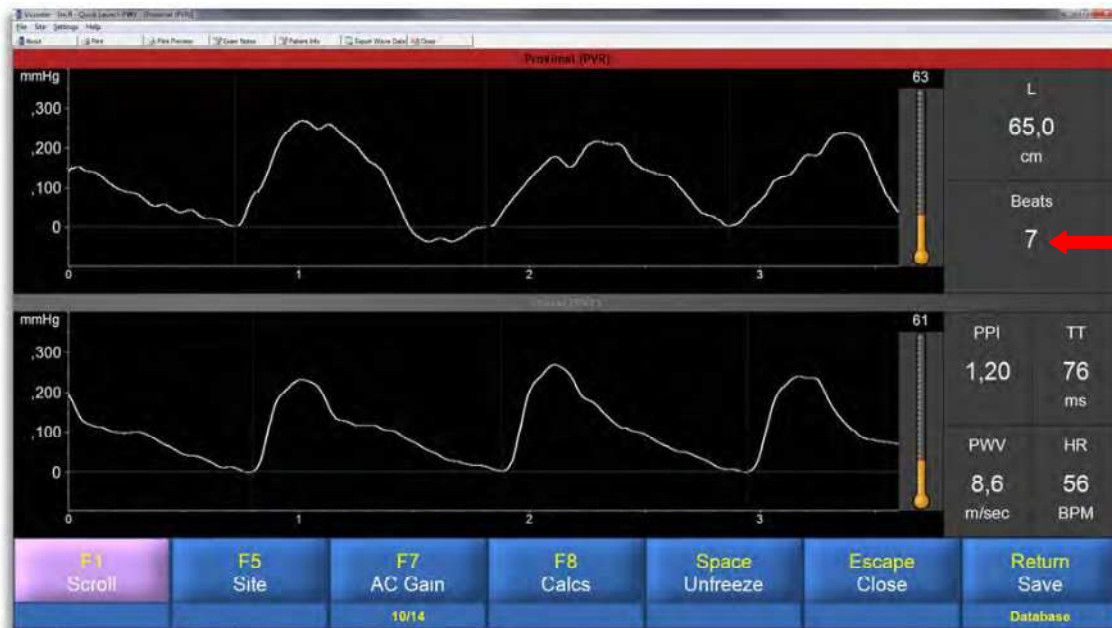
Figure 12 PWV test with carotid and femoral pressure waves

14. Press the space bar on the keyboard or click on "Space". The screen will be frozen and the pressure released from the cuff.

15. The result screen appears.

16. **Confirm and save the results by clicking on "Return/Save" or pressing the "Enter" key on the keyboard.**

17. **Repeat the measurement three times. Remember to confirm and save results from each measurement by clicking on "Return/Save" or pressing the "Enter" key on the keyboard.**

18. Neck band and thigh cuff may be removed now.

A backup to an external hard disk will be done daily.

References:

1. Townsend, R. R. et al. Recommendations for Improving and Standardizing Vascular Research on Arterial Stiffness. Hypertension 66, 698–722 (2015).

2. Mancia, G. et al. 2013 ESH/ESC guidelines for the management of arterial hypertension: the Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). Eur. Heart J. 34, 2159–219 (2013).

3. Laurent, S. et al. Expert consensus document on arterial stiffness: methodological issues and clinical applications. Eur. Heart J. 27, 2588–605 (2006).

4. Thurn, D. et al. Aortic Pulse Wave Velocity in Healthy Children and Adolescents: Reference Values for the Vicorder Device and Modifying Factors. Am. J. Hypertens. (2015).

5. Wilkinson, I. B. et al. ARTERY Society guidelines for validation of non-invasive haemodynamic measurement devices: Part 1, arterial pulse wave velocity. Artery Res. 4, 34–40 (2010).

6. Kracht, D. et al. Validating a new oscillometric device for aortic pulse wave velocity measurements in children and adolescents. Am. J. Hypertens. 24, 1294–9 (2011).

15 Annex 11

BLOOD PRESSURE

Instrument

OMROM 705IT

Other required Equipment:

- Cuffs of different width and lenght.

Set up

Cuff size choice:

Cuff bladder width: 40% of the arm circumference at a point midway between the olecranon and the acromion.

Cuff bladder length: 80% to optimal 100% of the arm circumference. If a cuff is too small, the next largest cuff should be used, even if it appears large. Blood pressure measurements are overestimated to a greater degree with a cuff that is too small than they are underestimated by a cuff that is too large. This is the safest way to choose the appropriate cuff size for each child. Avoid choosing cuff size according to child's age.

The following video may be helpful as well https://www.youtube.com/watch?v=a-77B0hNn3U

The cuff size will be recorded in the Clinical examination datasheet (Annex 7)
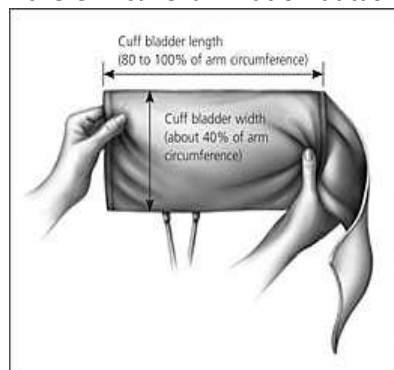
Measurement

---

1. Placement of the cuff

First assure that all residual air is squeezed out of the cuff. Position the artery index marker over the child's brachial artery and wrap the cuff around the child's arm. Cuff should be applied snugly, allowing only enough room for one finger to be slipped between the cuff and the skin surface. Note that the elbow crease should not be covered.

The following video may be helpful as well

http://www.youtube.com/watch?v=Ja2uB_FAG0Q
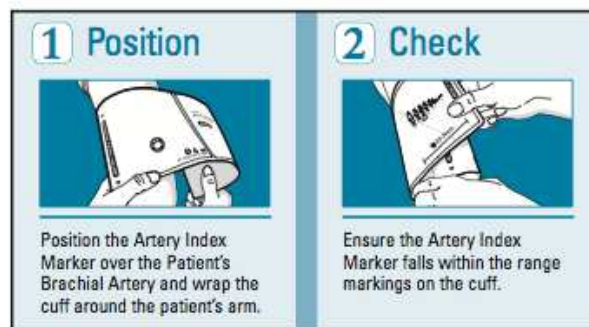
Before BP measurement

Children should not be stressed, tired, feeling pain, or unwilling to participate. Ensure that the child doesn't have the urge to urinate and that the room is not too warm or too cold. Prepare the child by explaining the procedure in a simple way. Don't forget to mention that during the measurement the cuff may feel tight but it will go away after a little while.

During BP measurement

The following measures should be collected: Systolic Blood Pressure, Diastolic Blood Pressure, Mean Blood Pressure and the Pulse indicated on the instrument for each measurement. Also record the date, time, the name of the examiner, the child's behavior (quite, talkative, moving, crying) and other comments if any.

Position of the child: Sitting position with the arm and back supported and the legs uncrossed with both feet flat on the floor. The arm should be bared and unrestricted by clothing with the palm of the hand turned upward and the elbow slightly flexed. The arm should be positioned so that the midpoint of the upper arm is at the level of the heart. The location of the heart is the junction of the fourth intercostal space and the lower left sternal border.The right arm is used. This is the preferred arm because of the possibility of decreased pressures in the left arm caused by coarctation of the aorta. If the measurements cannot be taken in the right arm, they are taken in the left arm. If there is a condition with both arms, the blood pressure is not taken.

Procedure: After 5 minutes of rest, 3 consecutive measurements are taken with one-minute time intervals between them. The estimated time is 10-15 minutes. It would be very pleasant for the child and helpful for the examiner to read a children's book meanwhile, or try anything else instead as far as the child doesn't get too bored or too excited. The child should not talk during the measurement and should not move his or her arm during the measurement because artifactual readings may be caused with an oscillometric device.

Record the following measurements three times on the clinical datasheet: Systolic Blood Pressure, Diastolic Blood Pressure and Pulse Clinical examination datasheet (Annex 7)

16 Annex 12

Digital Retinal Camera CR-2

Retinal photography provides a non-invasive, *in vivo*, method for characterizing the human microvasculature since retinal vessels are 60–300 µm in diameter. Several studies have found that narrower arteriolar diameters and wider venular diameters, as measured by retinal photography, are each associated with increased risk of myocardial infarction, stroke, and cardiovascular mortality, independent of other traditional risk factors.

Instrument

Canon CR2-plus nonmydriatic camera (including power cord and usb cable)

Laptop with the Retinal Imaging Control Software installed

Other required Equipment:

- Towel, when indicated

Set up

Install the Canon CR2-plus nonmydriatic camera according to the manufacturer's instructions and connect to the laptop.

- Ask participant to take off glasses (if needed)
- The participant takes place behind the camera with his/her chin on the chin rest and his/her forehead pressed to the overhead bar, as shown in Figure 13.
- Either sufficiently darken the room or place a towel over the participant's head.
- Register whether the participant is wearing contact lenses in the Clinical examination datasheet (Annex 7)

Figure 13 Retinal imaging set-up.

- Adjust the chin rest when necessary using the "CHIN REST" control, so that the child's eye is aligned with the "height adjustment mark" (Figure 14)
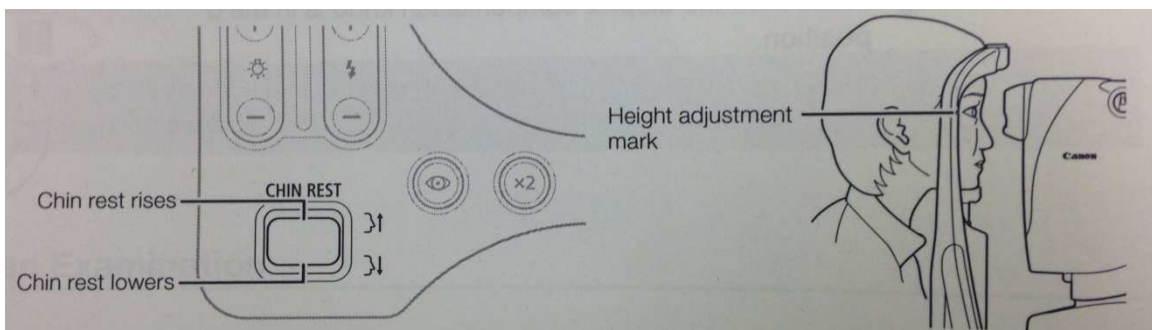
Figure 14 Chin rest adjusting

Procedure

1. Open the Retinal Imaging Control Software and fill in the required password.

2. Open a new study and enter the participant's ID.

3. Unlock the platform (Figure 15)
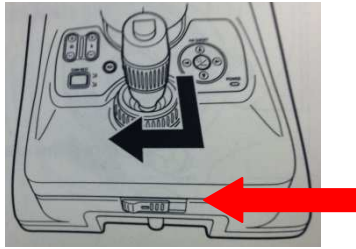
Figure 15 Unlock the platform

4. Move the camera in the horizontal (X-Y) plane to the right or left eye.
5. Ask the patient to look straight into the lens of the camera (he/she should see the reflection of his/her eye in the camera).
6. Align the eye
   a. Use the chin rest to position the cornea of the patient inside the two circles that appear on the camera display. Fine-tune by using the wheel on the joystick.
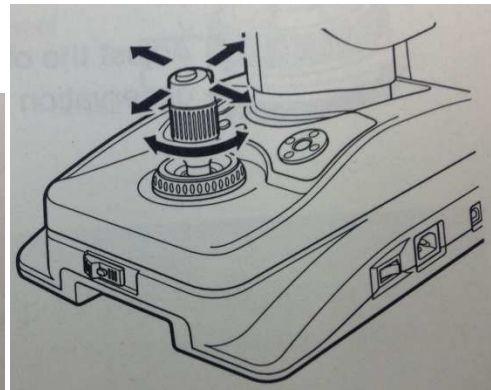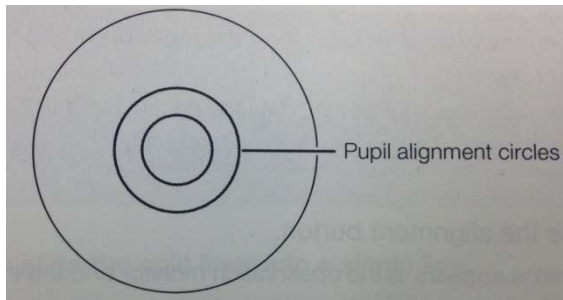
   b. Ask the child to look at the green light in the camera
   c. Move the camera forward, backward, and sideways in the X-Y plane in order to position the pupil of the patient within the circles. Make sure the pupil forms a continuous circle. By doing so, the iris of the child will be split up in two pieces (Figure 16 left).
   d. Mover the "joystick" forward and backward to unify the two pieces (Figure 16 right).
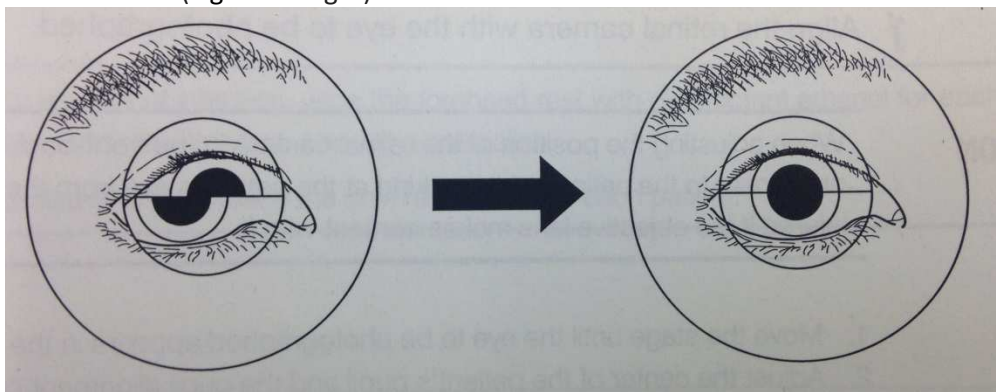
Figure 16 Iris split in two (left) and aligned (right)

7. Use the "back trigger" on the joystick to switch from the cornea to the retina (Figure 17). At this stage, the child keeps looking at the green light.
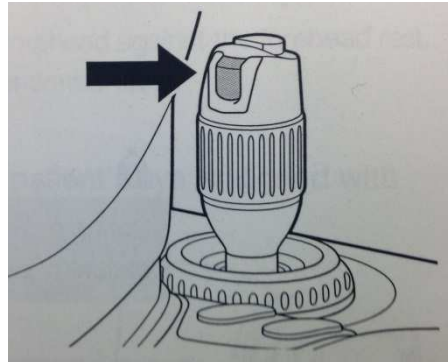
Figure 17 Back trigger

8. Adjust brightness of the picture (Figure 18)
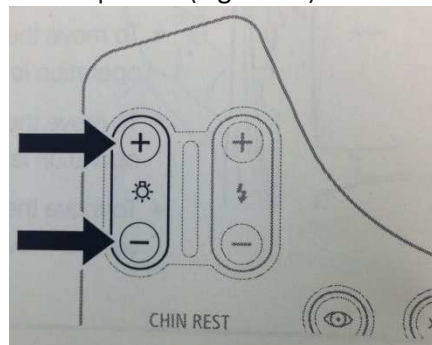
Figure 18 Brightness adjustment

9. Use the green light to place the eye in the optimal position for a photograph. If required, move the light using the "FIX TARGET" arrow buttons at the right side of the camera. Position the green light in a way that the optic disc is centered on the camera display. Then pulse the "Set button" to make it blink.
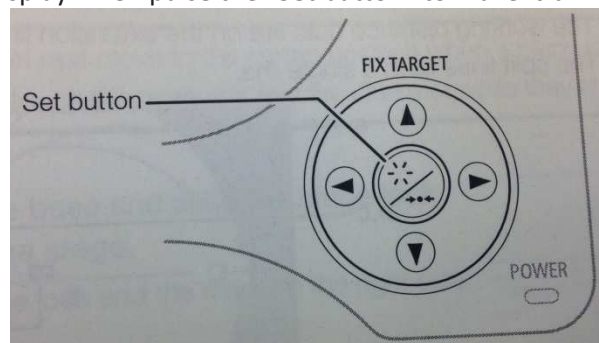
Figure 19 FIX TARGET buttons

10. Focus the camera by aligning the two lines that pop up when the "focus ring" (i.e. the wheel at the base of the joystick) is turned (Figure 20 left and right). Turn the wheel until the two lines form a continuous line.
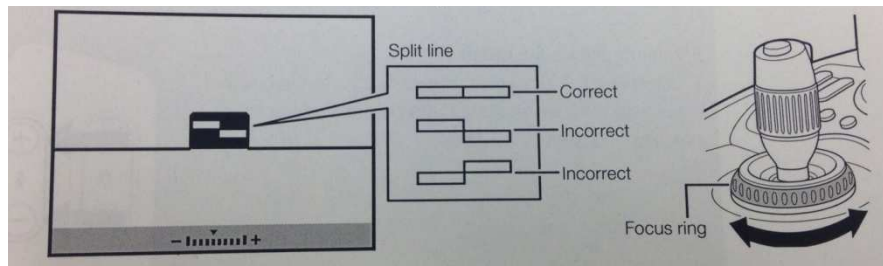
Figure 20 Focus ring

11. Before taking the picture (Figure 21)
    a. Lights are green
    b. Search for 2 white spots which appeared after switching to the retina (in step 7). To find the spots, move the unit in the X-Y plane. The spots are visible as a blurry stain. Move the unit forward or backwards until blurry stains turn into bright, white spots. The brighter and rounder the spots, the better the quality of the picture is. Position the spots until both are visible. Use the little wheel on the joystick to bring the spots to the middle of the camera display on the reference guide.
    c. The two lines from stap 10 form a continuous line
    d. The optic disc is centered on the camera display and is flanked by two bright, white spots.
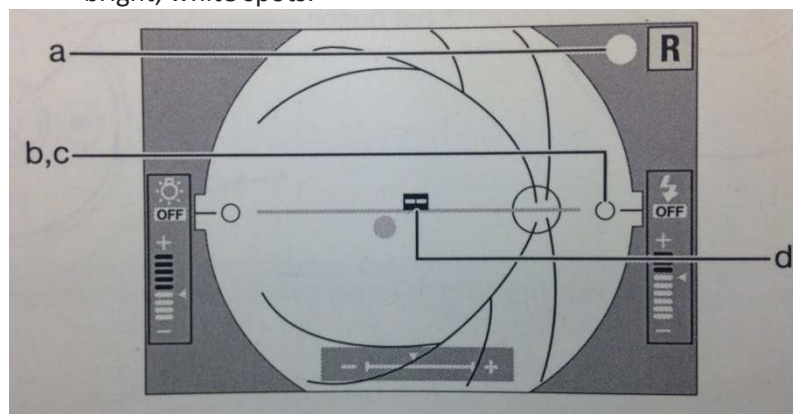
Figure 21 References to take a good picture

12. Take the retinal photograph by firing the button on top of the joystick.
13. Check for picture quality
14. Save the photograph by pressing the "Study Complete" button on the lower right corner of the computer screen. Completing the study will automatically save the pictures in a map and close the study.

Backup to an external hard disk will be done daily.

17 Annex 13

Spirometry

Aparato
Espirometro easyone

Material adicional

- Cable (screen connector)
- Boquillas

Procedura

Calibración del aparato:

- Poner una boquilla al espirómetro.
- En la parte final de la boquilla, introducir la boquilla de calibración y luego un adaptador.
- Utilizar una jeringa de 3L. Debe tener una accuracy de +-/15 mL ó +-/0.5% en la escala completa. El volumen de accuracy del espirómetro debe ser revisado a diario, con una única descarga de una 3L jeringa calibrada.
- Encender el espirómetro. (ON/OFF unos segundos)
- Con las fechas movernos por el menú hasta llegar a Control Calibrac.
- Apretar enter.
- En la pantalla saldrá LISTO, apretar ENTER.
- Tocar la superficie de la jeringa el mínimo posible.
- Con un movimiento suave pero rápido, hacemos mover el embolo de la jeringa. (Escucharemos un pitido)
- Salir del programa calibración.

Montar el aparato:

- Introduciremos al Easyone una espireta nueva, con cuidado sin tocar la boquilla de la espireta con las manos.

- Encenderemos el portátil. Abriremos el programa easyware. Conectaremos a un puerto USB el screenconector.

- Encenderemos el Easyone.

- Introduciremos los datos del paciente. (icono: hoja con una estrella roja en una esquina).

- Conectaremos el portátil con el easyone. (icono: ordenador y aparato conectados por un cable).

- Se introduce el peso y la talla del niño.

Explicación al niño de cómo realizar la prueba:

Con la ayuda de un espantasuegras se le explica al niño que debe soplar soltando el aire de una sola vez y fuerte. El niño practica algunas veces con el espantasuegras.

Espirometria

- Se comprueba que el niño esté tranquilo, sentado con la espalda recta (tocando el respaldo), y sin cruzar brazos y piernas.

- Escogemos la primera opció (ENTER), rellamada (ENTER) ya empezamos la prueba.

- Cada vez que empiece la prueba tendremos que decir enérgicamente que empiece a dejar el aire y seguir animándolo a que continúe, aunque el crea que no tiene más aire.

- El easyone nos indicará que las pruebas son correctos o incorrectas y donde falla el paciente. (poco aire, a titubeado…)

- Es posible que ninguna de las pruebas sean dadas como correctas por el aparato. Se guardan igualmente.

- No haremos más de 8 pruebas por paciente.

- Retiraremos la boquilla.

Se hará un backup cada dia.

Freiburg Visualt Acuity and Contrast Test (FRACT) and Cambridge Colour Test (CCT)

Light conditions at display and at child eye level will be measured before testing and recorded in the'Clinical examination datasheet' (Annex 7).

FRACT is a computer test to evaluate visual acuity and contrast sensitivity. This test takes about 2 minutes to be completed.

Instrument

For FRACT windows laptop with the FRACT 3.9.3 software installed

For the Cambridge Colour Test an apple laptop with the Psykinematix software installed

Other required Equipment:

- Measuring tape

- Keyboard

- Light meter (suggested instrument Digital Lux Meter, Lifenergy Portable Handheld High Precision Digital Light Meter Range 0 – 200.000Lux)

Before taking the test

Measure ambient light right in front of the child's face with the light meter and record the result in the "Clinical examination datasheet" (Annex 7).

Set up of FRACT

- The screen luminosity must be at three levels lower than the maximum level (press F2 or F1 to modifity). Like this:

- The distance between the participant eyes and the screen is de 2m
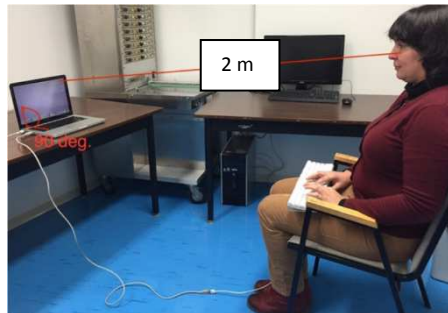
- The screen has to be at a right angle (close to 90 degrees).
- The screen should be clean
- The luminosity of the room should be constant (avoid to test near a windows where the light can changed during the day)
- An external keyboard has to be connected to the USB port of the laptop.
- Sound ON
- It is better that the participant is sitting on a stable chair (no wheels), against a wall to put his/her head on, like this he/she cannot move. If the child has glasses, it is important that he/she carries them to do the test and that you write a note on his/ her file.
- To start the software, press the icon "FRACT 3.9.3" on the desktop
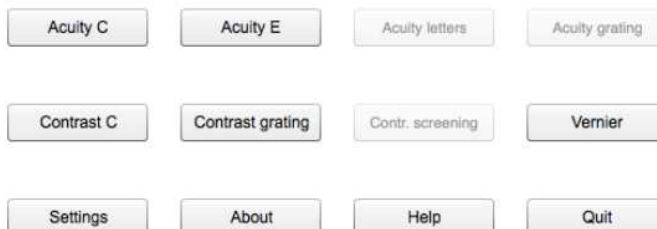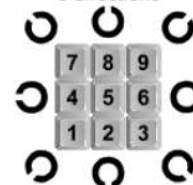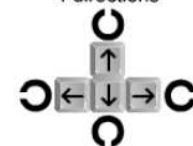
Procedure for Visual acuity C test (Landolt C)

1. To begin the visual acuity test, press on « Acuity C ».
2. Instructions for the child:
   o « You have to press the arrow on the keyboard corresponding of the opening of the C. Give him/her an example: If the C is like this, press here. ».
   o If the child finds that it is too hard to see the opening, encourage him/her: It is true that it is hard to find it but do your best and try an answer. ».
3. To re-start the test (if necessary), press « Échap » to come back to the screen of the beginning and press again on « Acuity C ».

4. At the end of the test, write the results in the "Clinical examination datasheet" (Annex 7) (Value Dec. VA and value du logMAR) because the results are not saved automatically in the computer.

Procedure for Contrat sensitivity test (Contrast C)

1. To start the test, press on « Contrast C »
2. Instructions for the child:
   a. « Again, you have to press the arrow on the keyboard corresponding of the opening of the C. Give him/her an example: If the C is like this, press here. ».
   b. If the child finds that it is too hard to see the opening, encourage him/her: It is true that it is hard to find it but do your best and try an answer. ».
3. To re-start the test (if necessary), press « Échap » to come back to the screen of the beginning and press again on « Contrast C ».
4. At the end of the test, write the results in the "Clinical examination datasheet" (Annex 7) (Value threshold contrast and value Weber), because the results are not saved automatically in the computer

Procedure for Cambridge Colour Test

1. Click on the icon « Psykinematix» on the desktop.

Figure 22 Calibration reminder

2. Click skip on the calibration reminder.

3. Click on "subjects".
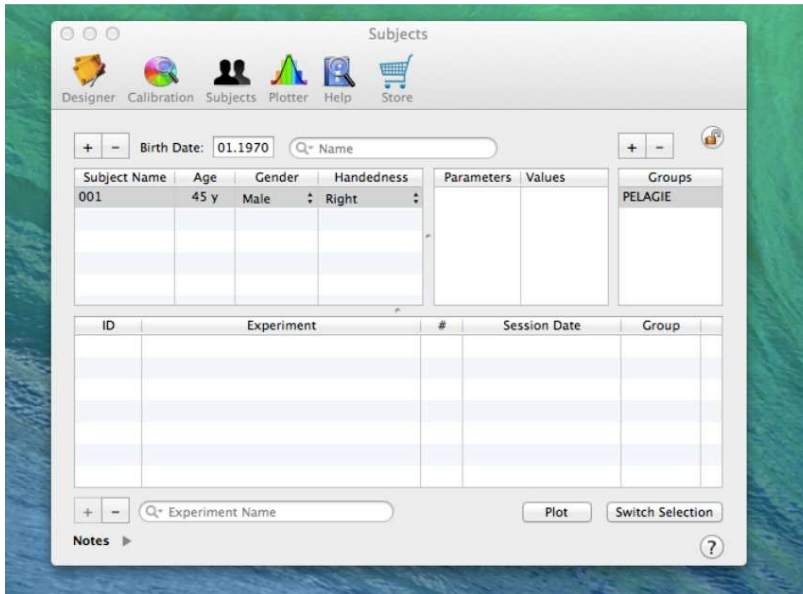
4. Press on « + » on the left, write the ID of the participant (ex. 001) and press on « Designer » icon.
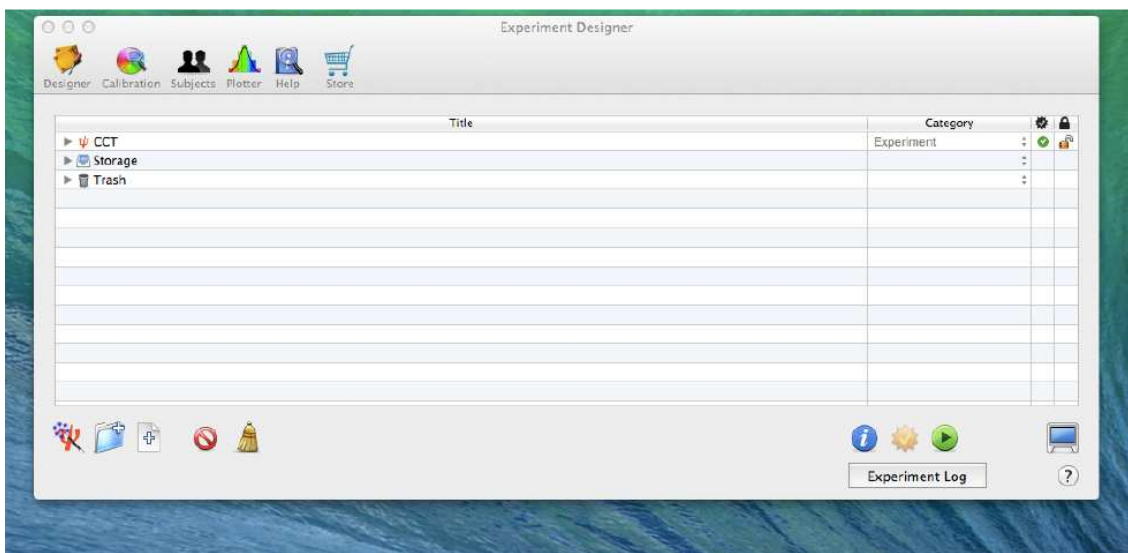
5. Select CCT by pressing one time on (background will become grey).

6. Press on to the right bottom
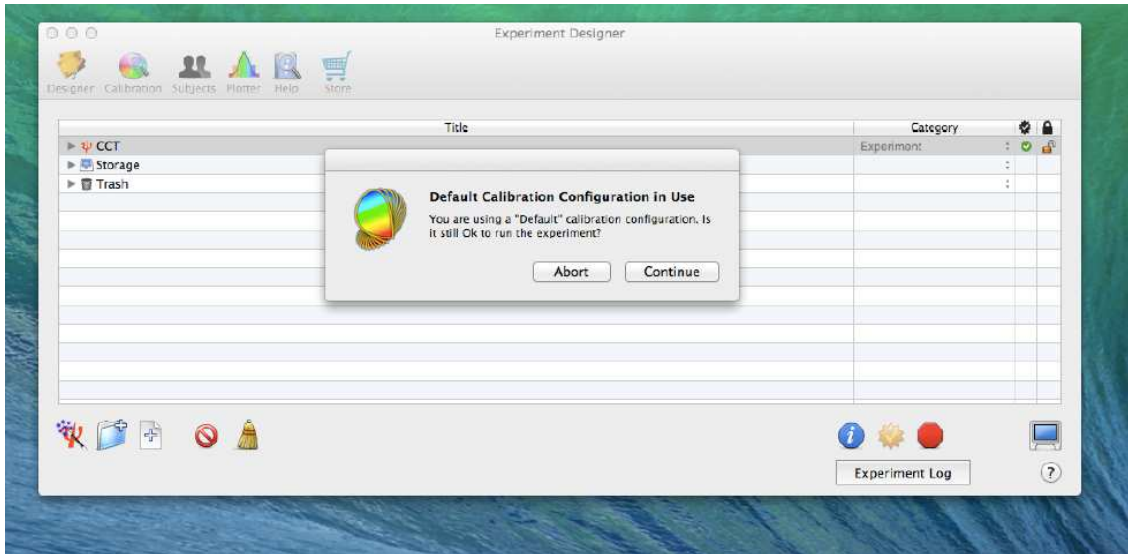
7. Click on « Continue »
8. Select the « Subject ID », the « Group » and click on « Start Session »
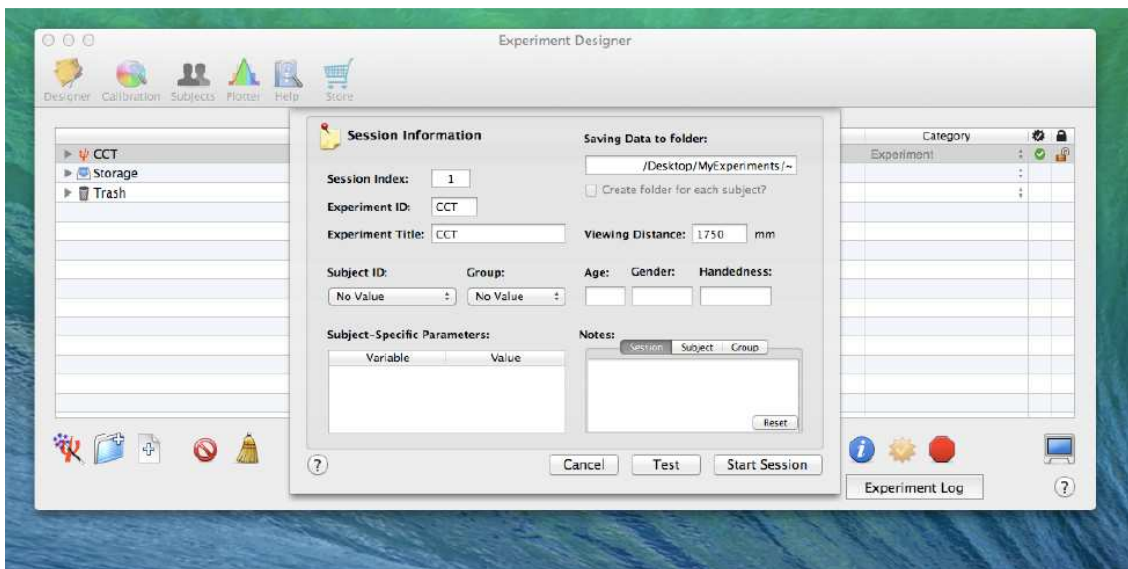
9. The screen will become black, press on « ESC » to start the task.

19 Annex 15

Auto-refractometry

- The child will be located in front of the device.
- The examiner will explain the instructions of the test condition.
- The child will be required to gaze into the light orifice of the device.
- The examiner will ensure the child feels OK before starting the test
- If he/she has not understood it, the examiner will explain it again and do the training for second time.
- Measurements will be carried out as per manufacturer instructions.
- Each test will last for a few minutes.

20 Annex 16

Optical biometry

- The child will be located in front of the device. (Figure 23)
- The examiner will explain the instructions of the test condition.
- The child will be required to gaze into the light orifice of the device.
- The examiner will ensure the child feels OK before starting the test
- If he/she has not understood it, the examiner will explain it again and do the training for second time.
- Measurements will be carried out as per manufacturer instructions.
- Each test will last for a few minutes.

Figure 23 Optical biometer

21 Annex 17

Hair sample collection

The hair strands will be cut closely to the scalp from the posterior vertex area of the head, which has been shown to have the lowest coefficient of variation (Sauvé B et al. Clin Invest Med. 2007;30:E183–E191).

Procedure

The nurse will collect approximately 50 mg of hair, ideally from the posterior vertex (crown) region at the back of the head (Figure 24). They will cut within 1mm of the scalp, and will do this as discretely as possible, avoiding any obvious patches.

Samples will be placed on labels, with the root end clearly labelled (Figure 25), and will be put in a zip-lock identified bag with the children ID for posterior cortisol measurement.

Figure 24 Posterior vertex (crown) region at the back of the head

Figure 25 Sample preparation for posterior analysis

22 Annex 18

Protocol neurodevelopment testing

1. N-back

(The instructions will be done in the same manner and for the same person always following the same notes, avoiding variability in the methodology)

Hi, my name is xxx. We will be doing some games for a while. It is very important to be in silence all the time and to listen all the explanations for the game to go well. If you don't understand something, you can ask before the game starts, but when are playing I won't be able to help you.

First of all, sit properly and check the headphones, are you comfortable?

Now, I'm going to explain THE EQUALS GAME to you.

On your screen will appear numbers one by one. What you will have to do is to press a button when the number in the screen is **the same as the previous one**. What button? You have 2 buttons with two drawn arrows on the laptop. You have to press one of these two arrows when the number in the screen is the same as the previous one. Have you understood it? Do you have any questions? You have to be very concentrated because if you press wrongly, you will lose points; if you do it correctly little faces will appear at the top of the screen.

Now you will play on your laptop. Let's start with some training. Before, put your headphones on and prepare your finger above the button. Are you ready?

(Execute training 1-back)

Do you have any question? (If the child has not understood the task, start the training again)

(Execute 1-back)

Very good! Now I'm going to explain the **2nd level**. The 2nd level is more difficult. You will have to change what you were doing; you will have to press the button when the number on the screen is the same as the second-last one number. The two numbers will be separated from other.

Have you understood the rule?

Look out! When you press the button you have to keep concentrated because the game continues, even if you have already caught a number. Let's see how do you do!

(Execute 2-back)

Well done! Now you will have to **leave two numbers in the middle** between the two identical ones. Are you ready? Remember that if you press when you don't have to you will lose points.

(Execute 3-back)

Well done! And now the most difficult level, you will leave **3 numbers in the middle** between the two identical ones. Are you ready? Remember that if you press when you don't have to you will lose points.

(Execute 4-back)

2. PMA-R

Now, you have to complete the letter series. For example, in the following letter series, which letter will continue?

1. a b a b a b a b . . .

The series follows this order: **ab ab ab.**

The **FOLLOWING** letter in this series is **a**. You will see a list of letters in the screen, you will have to use the mouse to select the letter you think that follows the series. Notice that what you have to do is to look for the groups of letters that repeat in the series, and to select the letter that follows the series. Did you understand?

Now, look at this series. Think which letter follows that series.

2. c a d a e a f a . . .

The serie follows this order: **ca da ea fa**. The correct response is **g.**

Now, look at the following letter series. Decide which is the letter that should follow the series.

3. c d c d c d . . .

The serie followed this order: **cd cd cd**. The solution was **c.**

4. a a b b c c d d . . .

The serie followed this order: **aa bb cc dd**. The solution was **e.**

5. a b x c d x e f x g h x . . .

The serie followed this order: **abx cdx efx ghx**. The solution was **i.**

Now, do this training for practice, select the following letter in each series.

---

6. a x b y a x b y a x b . . .

The order is: **axby axby axb.** The solution is **y.**

7. a b m c d m e f m g h m . . .

The order is: **abm cdm efm ghm**. The solution is **i.**

8. a b c d a b c e a b c f a b c . . .

The order is: **abcd abce abcf abc**. The solution is **g.**

Be sure that you understand this task. When I give a signal, you should solve other similar series. If you don't know how a series follows, you can skip it using the arrow bellow the list of letters. You could try again later if you have time left.

Try to go fast but without doing mistakes. You will have six minutes to do the entire task. If you don't have enough time to finish, don't worry.

3. Flanker task

The participants should place the index finger of the left hand in the left arrow and the index finger of the right hand in the right arrow.

Good job! Now you will start the third game, the arrows game. A row of 5 arrows will appear in your screen, you will have to look at the middle arrow. You will have to indicate the direction of that arrow using the buttons of the laptop (*show the buttons*). Before the arrows, you will see sometimes some clues that will indicate where the arrows will appear. It is very important to focus the eyes in the middle of the screen to go faster. Are you ready? Put the index fingers of each hand one in each button, look at the centre of the screen and let's start with some training!

(Training)

Do you have any question? The game has 4 blocks; a green screen will appear between those blocks indicating that it's time to rest a bit.

(Start the game)

4. Cups Task (Roulette version)

The participant should be seated in front of a computer in a silent room. The examiner should be present during the entire experiment.

Open the task in E-Prime, and write the appropriate participant ID. Start the task and read the instructions aloud with the participant:

"This game is called *The Wheel of Fortune*. It is a game of chance in which the goal is to make as much money as possible"

Press any key, and continue reading:

"Two wheels like those below will appear on the screen. These wheels are divided into segments. On each segment is an amount of money. The left wheel (point the left wheel) **has a segment with a larger amount of money (in this case 2$), and its other segments are empty (0$). By contrast, all segments of the right wheel** (point the right wheel) **have the same amount of 1 $. Your task is to select, using the left and right arrows on the keyboard, which wheel you want to spin. The wheel you will select will be spun for some time. When it stops spinning, a gray arrow below it will indicate on which segment it ended and thus, how much money you won."**

Pointing the left wheel and continue reading: **"The left wheels is a "risky" option because you don't know on which segment the wheel will stop spinning. The more segments, the less likely it is that it will stop on the larger amount of money."**

Pointing the right wheel and continue reading: **"The right wheel is a "safe" option because you are sure that the wheel will stop on a segment with 1$."**

Press any key and continue reading the instructions:

"Wheels can be either blue or red. On trials with blue wheels, you will gain the amount of money of the segment on which the wheel stops spinning, because there is a 'plus' sign before the number. On the trials with red wheels, you will lose the amount of money on which the wheel stops spinning, because there is a 'minus' sign before the number."

Press a key to start the demonstration trial. The demonstration should be done by the experimenter, not the participant. Say:

"Here, the left wheel has a segment with 5$, and two segments with 0$. The right wheel has three segments with 1$ each. If I spin the right wheel, I am sure to win 1$. If I spin the left wheel, I have one chance to win 5$, but two chances to win nothing. Let's suppose I want to take the risk and press the left key."

Press the left arrow key.

"Unfortunately, I have won nothing. Now, if I spin the left wheel, there is a chance that I will lose 3$, but there is also a chance that I will lose nothing. If I spin the right wheel, I am sure that I will lose 1$. Again, let's suppose I want to take the risk and press the left key."

Press the left arrow key.

"Unfortunately, I have lost 3$. Now it's your turn." (Read the instructions) **"You will have to play until the computer stops the game. You will only know the total amount of money that you have accumulated (or lost) at the end of the task. Like in a real game of chance, the computer will not change your chances of winning or losing once the game has started, so please do not try to understand what the computer is doing. Please do the task as if you were using real money, and base each of your decisions on what you would do if you were using your own money. Do you have any questions?"**

Press a key to begin the task.

(Let the participant play)

End of the task: congratulations, you would have won XX $.

23 Annex 19 (used until December 2016)

ExpoApp

Definitions

ExpoApp: Smartphone application available for Samsung Galaxy Mini
SensorLab: Software for ExpoApp to be used to extract and layout the collected data from ExpoApp
MS: Monitoring sheet (the participant sheet were you take notes during the field work)

Equipment and materials

- **Laptop** (please use the same laptop for setting and downloading all monitoring devices, with internet access and the clock synchronized (important!) with the server 'pool.ntp.org'). You can change this by going to settings of the clock of your computer.
- **Samsung Galaxy Young Smartphones**
    o SIM card with at least data-plan (if you decided to use SIM card)
    o phone charger
    o USB Cable to connect the smartphone to the PC
    o SD Card with 2GB of memory
    o battery for Samsung Galaxy Mini
    o SPIBELT for the Smartphone
- **ExpoApp**
- **SensorLab Software**

Set up

Preparation of the Smartphone
CREAL will provide the newest version of the ExpoApp already installed on the phone, so **you won't need to do this procedure** (it is only stated here in case you have to do it at some point of time). ExpoApp records geolocation and physical activity.

Some **settings of the phone** have to be changed before installing ExpoApp (see Figure 26).
- Go to '*Settings -> Location services'*
    o Tick the box '*Use wireless networks*' and '*Use GPS satellites*' (otherwise the App won't log GPS data)
- Go to '*Settings -> Application setteings -> Unknown sources'*
    o Ensure that '*Unknown sources' is activated (otherwise you won't be able to install ExpoApp)*
- Go to 'Settings -> Location and Security -> Set up SIM card lock'
    o Remove the PIN number
- Go to ' *Settings -> Wireless and Networks -> Mobile networks -> use packet data'*
    o Ensure that *'mobile data'* is activated – no need for this if the phone does not have a SIM card

It is possible to remove direct accesses from the main screen that will not be used by dragging the icon of the 'home' screen to the bin. This makes it easier for the participants.
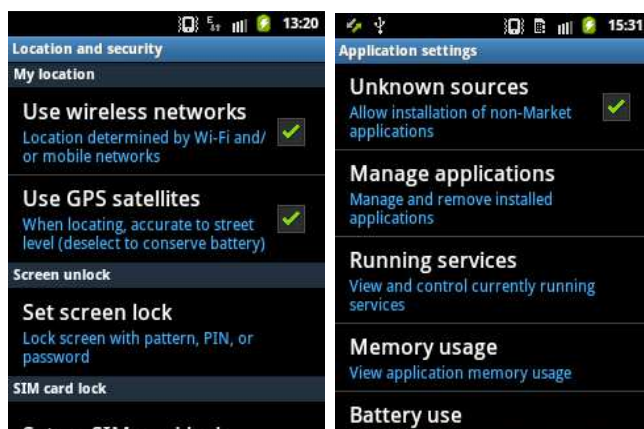
Figure 26 Preparing the phone for installation of the ExpoApp

There are two ways of setting the time:

- Go to '*Settings -> Date and time* (as shown below in Figure 27)

Automatically: then you need to check that the time of the phone is correct and the same to the time of your computer (which will be synchronized to the atomic clock). ExpoApp will record the time shown on the screen. If the time of the phone is too different from the atomic clock when then recommend setting the time manually, especially if you are not using a SIM card.

Manually: Deactivate 'automatic date and time'. Wait until the PC time shows XX:XX:59. Just the next second (when minute changes), match the minute in the smartphone. If there are some seconds of elapsed time between PC and smartphone is not a big issue. But try as much as possible to match the minutes.

IMPORTANT: On the MS please write the time you start the ExpoApp (day 0) and the time you stop it (day 8) for both atomic time and the phone time. Please make sure that the phone does not go forward/backwards from the attomic clock, otherwise set it again.

Figure 27 Setting date and time

Installing the ExpoApp Application:
- Save the file "ExpoApp2-0.2.1-nobar.apk" on your computer.
- Connect the Samsung Galaxy Mini to your computer with the USB cable.
- Open 'My Computer' on your PC.
- Access the 'Phone drive' by dragging the top bar (the device will appear under the list of drives and devices in 'My Computer'). Once connected, an external unit will appear on your PC drive.

Figure 28 Connecting the Smartphone to the PC

- Copy the "ExpoApp2-0.2.1-nobar.apk" from your computer to the phone.
- Disconnect the phone from the computer, like other external memory.
- Press on the icon ExpoApp2-0.2.1-nobar.apk. The system will ask you to install the aplication. Accept it. (if you have not activated 'unknown sources' the apk won't be able to get installed.

Procedure

---

1. MONITORING session

The following procedure will be followed in the project.

DAY 0, HANDING OUT EQUIPMENT
- Unlock the phone (no password or pattern should be required).
- Swipe down from the top of the screen and a menu will appear (Figure 29)
- Check if Wi-Fi, GPS and Mobile Data (only in case you have a SIM card) are enabled. Wifi and gps can be activated/deactivated dragging the top bar. To exit this screen, press the Home button or the back button.

Figure 29 Menu should be like shown when swiping the top bar

- Start the ExpoApp.apk by pressing the icon (Figure 30 a).
- **Check the subject ID** and change it if needed (you will be ask for the password (31415) before being able to change the ID).
- Touch the menu button (left next to centre button) and select '*Start*' by touching the screen
- The ExpoApp will start. Write down the starting time (displayed in the main menu of the App) which should be synchronized with the atomic clock.
- Unzip the compartment on the SPIBELT and place the phone inside it, with the screen facing backward (to the subject).
- Zip lock the SPIBELT and hand it over to the subject.
- Make sure that the SPIBELT is positioned on the body around the waist with the phone compartment on the front part of the subject.
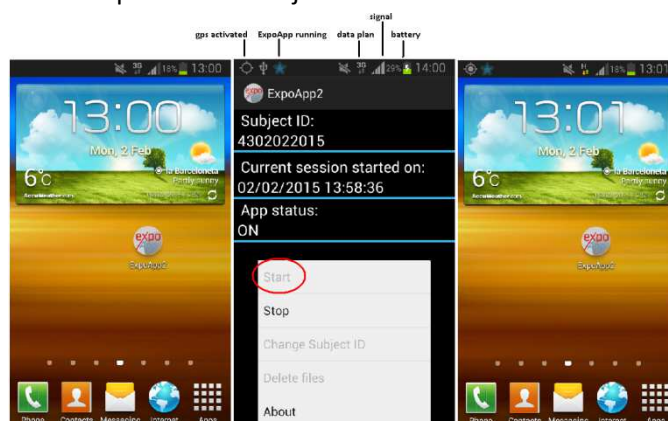
Figure 30 a) ExpoApp direct access on the Home screen, ExpoApp off. b) ExpoApp main screen display when the session has already been started (please note that the blue star and the gps symbol appear on the top-left part of the screen). I you don't have a SIM card the little arrows (saying 3G or H) will not appear, and c) Home screen when the ExpoApp is running (please note blue star and gps flashing).

DAY 8, COLLECTING EQUIPMENT

- Take the SPIBELT from the subject and open it and check if the phone is still running.
- Open the ExpoApp
- Open the menu (pressing left button) and touch 'Stop'.
- Fill out the code to stop the program. **CODE = 31415 (the number pi)**
- Write down the stopping time of the ExpoApp (displayed in the main menu of the App) which should be synchronized with the atomic clock.
- Switch off the phone and store it inside the SPIBELT compartment for transportation.

After a Monitoring session

After a Monitoring session, all data will be extracted from the Samsung Galaxy Mini phone.
- Write down the PC and Smartphone date and hour in DIFFERENCE IN TIME if needed.
- Connect the Samsung Galaxy Mini to your computer with the USB cable.
- Open 'My Computer' on your PC.
- Access the 'Phone drive'.
- Open the 'ExpoApp' folder.
- Copy the folder of the MONITORING session and paste it in the folder for this ID on the computer.
- **LEAVE THE FOLDER NAME AS IT WAS (ExpoApp.ID___)**, otherwise the software won't work.
- Erase the MONITORING session in the phone. You can leave the phone connected to charge until you see in the main screen that the battery is full.

23.1 Annex 19.1

Problem recording sheet

Child will be asked to fill in the following sheet recording any problem experienced with the provided smartphone

Día 1 – Hoja de incidencias

Num.

Id. _____

FECHA: _____ ¿A qué hora te levantaste? _____ hora _____ minutos ¿A qué hora te fuiste a la cama? _____hora _____ minutos					**Teléfono móvil Del estudio**
Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí, especifica_____

Día 2 – Hoja de incidencias

FECHA: _____ ¿A qué hora te levantaste? _____ hora _____ minutos ¿A qué hora te fuiste a la cama? _____hora _____ minutos					**Teléfono móvil Del estudio**
Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí, especifica
_____

Día 3 – Hoja de incidencias

FECHA: _____

¿A qué hora te levantaste? _____ hora _____ minutos
¿A qué hora te fuiste a la cama? _____ hora _____ minutos

Teléfono móvil Del estudio

Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí, especifica _____

Día 4 – Hoja de incidencias

FECHA: _____

¿A qué hora te levantaste? _____ hora _____ minutos
¿A qué hora te fuiste a la cama? _____ hora _____ minutos

Teléfono móvil Del estudio

Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí, especifica _____

Día 5 – Hoja de incidencias

FECHA: _____ ¿A qué hora te levantaste? _____ hora _____ minutos ¿A qué hora te fuiste a la cama? _____hora _____ minutos					**Teléfono móvil Del estudio**
Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí, especifica _____

Día 6 – Hoja de incidencias

FECHA: _____ ¿A qué hora te levantaste? _____ hora _____ minutos ¿A qué hoa te fuiste a la cama? _____hora _____ minutos					**Teléfono móvil Del estudio**
Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No   ☐ Sí,   especifica
_____

Día 7 – Hoja de incidencias

FECHA: _____

¿A qué hora te levantaste? _____ hora _____ minutos
¿A qué hoa te fuiste a la cama? _____hora _____ minutos

Teléfono móvil Del estudio

Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No   ☐ Sí,   especifica
_____

Día 8 – Hoja de incidencias

FECHA: _____

¿A qué hora te levantaste? _____ hora _____ minutos
¿A qué hora te fuiste a la cama? _____hora _____ minutos

Teléfono móvil Del estudio

Incidencia (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí,   especifica
_____

Ejemplo
Día XX – Hoja de incidencias

Por favor, escribe cualquier incidencia que hayas tenido con el Actigraph o con el móvil del estudio

FECHA: _____*5-2-15*_____ ¿A qué hora te levantaste? __*7*_____ hora _____*30*____ minutos ¿A qué hora te fuiste a la cama? ____*23*____hora _____*00*____ minutos					**Teléfono móvil Del estudio**
Incidencie (motivo)	Hora inicio	Hora fin	Actividad realizada	¿Dónde estabas tu?	¿Dónde estaba el teléfono móvil?
Olvidé cogerlo	*7:30*	*14:00*	*Clases, 1 hora* *Educ. Fis.*	*Insituto*	*En casa*
Actigraf hacia abajo	*18:00*	*19:30*	*Estudiar*	*Casa amigo*	*Casa amigo*
Me lo quité para piscina	*20:00*	*21:00*	*natación*	*piscina*	*En vestuario*
Se desenganchó el actigraf	*23:00*	*7:20*	*dormir*	*cama*	*Mesilla*

¿Has cambiado tu actividad física habitual? ☐ No ☐ Sí, especifica __ *No he anat a entreno basket* _____

25 Annex 20

Copy of both hands

Equipment and materials

Access to the school photocopier

Small paper sheets

Black towel

<u>Optional equipment</u>

Scanner connected to a laptop

Procedure

---

1) Make sure that there is nothing covering the phalangeal line of child's hands (e.g. rings) and that the hands are clean

2) Make a photocopy (or a scanned copy) of each hand separately.

3) Place a small paper sheet with the child's INMA ID and a "D" for right ("Derecha") or "I" for left (Izquierda) on the palm, so that it does not cover the phalangeal line preventing the Digit Ratio measurement

4) Place a black towel on top of the photocopier (or scanner) to improve image quality.

5) Record on the "Clinical examination datasheet" (Annex 7) whether the copy of the hands was taken or not.

26 Annex 21

XMobiSense App

Instalar la aplicación "XMobiSense" en el móvil que usen durante este tiempo. La aplicación registra por cada llamada :

- Número y duración de llamadas
- Conexiones a Wifi y 3G, volumen de descarga de datos
- Número de SMS entrantes y salientes
- Usos de manos libres: altavoz, conexión con cable para hablar.
- Lateralidad en qué lado de la cabeza se colocan el teléfono para hablar

La aplicación va guardando los datos y cada 500kb envía la información automáticamente. Los voluntarios verán como aparece brevemente el logotipo de la aplicación en la zona de notificaciones del teléfono.

Instalar la aplicación "XMobiSense" en un teléfono

La aplicación "XMobiSense" se puede instalar de dos maneras:

- Conectando el teléfono móvil al ordenador portátil del estudio
- Enviando la aplicación por email (explicar que para instalar la aplicación tendrán que abrir el mail en el teléfono)

Instalación a través del ordenador portátil

A través de un cable USB conectado al ordenador se conecta el teléfono al ordenador con el cable (estas conexiones son estándar) se abre el dialogo:

Solo se tiene que copiar la aplicación y pegar en cualquier carpeta del teléfono. Es recomendable hacerlo en "Download", porque casi todos los teléfonos ya tienen una carpeta con este nombre. Si no la tuviese se puede crear como una carpeta normal:

- Botón derecho del ratón→ nueva carpeta→ renombrar.
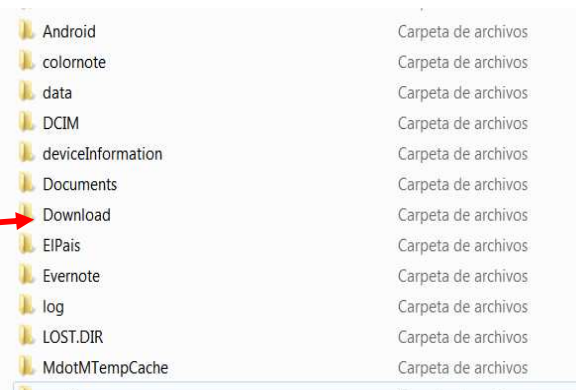
Se ha de copiar y pegar la aplicación en esta carpeta.

Ya se puede desconectar el teléfono del ordenador, se va a mis archivos del teléfono se busca la carpeta donde hayamos copiado la aplicación.

Seleccionamos la aplicación y aparece de nuevo un diálogo: seleccionar instalador de paquetes.
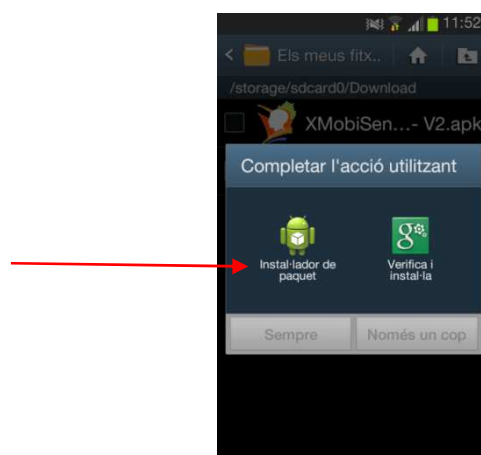
Envío de la aplicación "XMobiSense" via email

Se debe enviar un mail con la aplicación como archivo adjunto (el mail ha de ser Gmail o Hotmail). Cuando el voluntario abra el mail con el teléfono solo tiene que presionar el archivo adjunto "XMobiSense" y la aplicación se instalará sola.
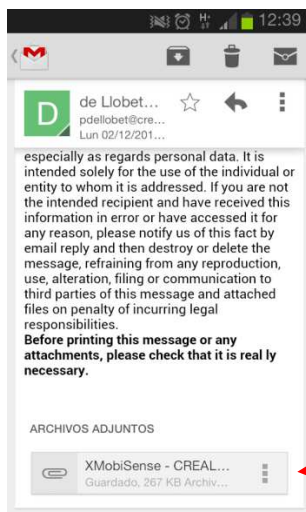
Algunos teléfonos tienen desactivada la instalación de aplicaciones que no provengan del "Google Play". En ese caso se les abrirá un diálogo como el que aparece en la foto, que les redireccionará automáticamente a "ajustes" para que seleccionen la casilla de autorización.
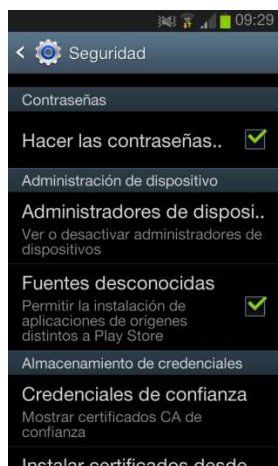
Sólo tendrán que volver al mail y dar de nuevo a instalar ("instalador de paquete").

INMA 11-12 YO FOLLOW UP Fieldwork Protocol Final Version 20170530 DEF
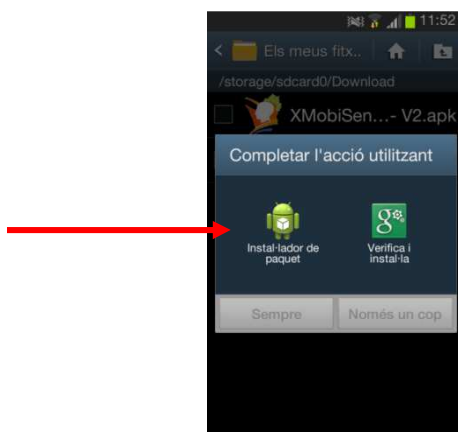
Obtener el código IMEI

Una vez instalada la aplicación es **IMPRESCINDIBLE** anotar el código IMEI del teléfono para que sepamos de qué teléfono tienemos que recuperar los datos del servidor después de acabar el estudio.

El número de IMEI se puede encontrar abriendo la aplicación "XMobiSense" en el teléfono, en la tercera línea de la información que nos ofrece la pantalla.
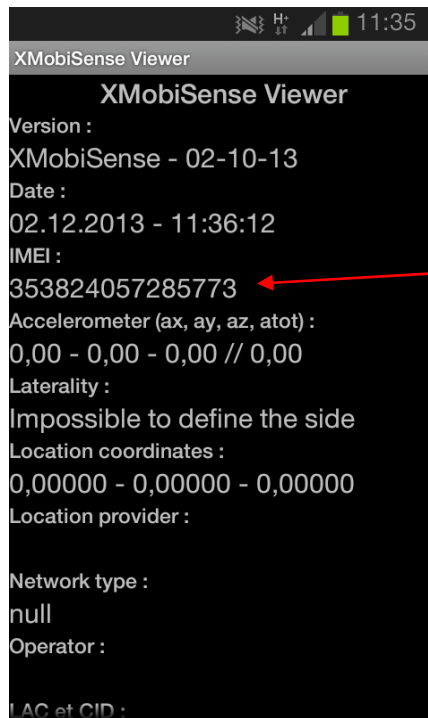
27 Annex 22 (used since January 2017)

GENEActiv

Equipment and materials

The GENEActiv pack includes the watch, the charge cradle, the USB cable to conect the cradle to the computer, and a CD which includes the software.

Since the study is performed in children, we need to change all the original plastic black straps of the watches by colorful children's wrist straps to make it more attractive for them.

Set up

The software and the drivers will be installed on the laptops of the fieldworkers. Before giving the watch to the children, the watch needs to be set up following these steps:

- Connect the charge cradle to the laptop.
- Open the GENEActiv software in the laptop .
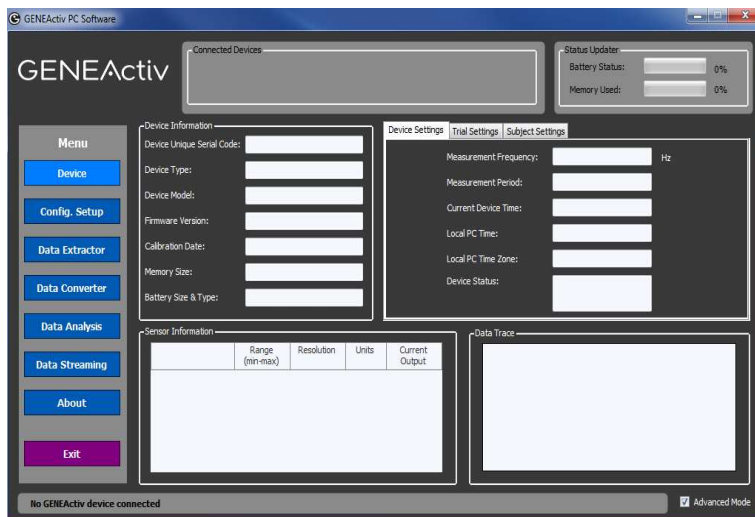
- Plug the watch into the charge cradle. Make sure that the device "clicks" into place.

- Allow GENEActiv devices to charge for 3 hours before using them with the software. A red light on the device will flash to show that it is charging. When it is fully charged, a green light will flash and the device can be removed.

- The software displays information about the device and any data previously stored on it will be shown.

- Click "Config. Setup" from the left-hand menu. This page allows you to set recording options and to enter information about the trial and test subject.
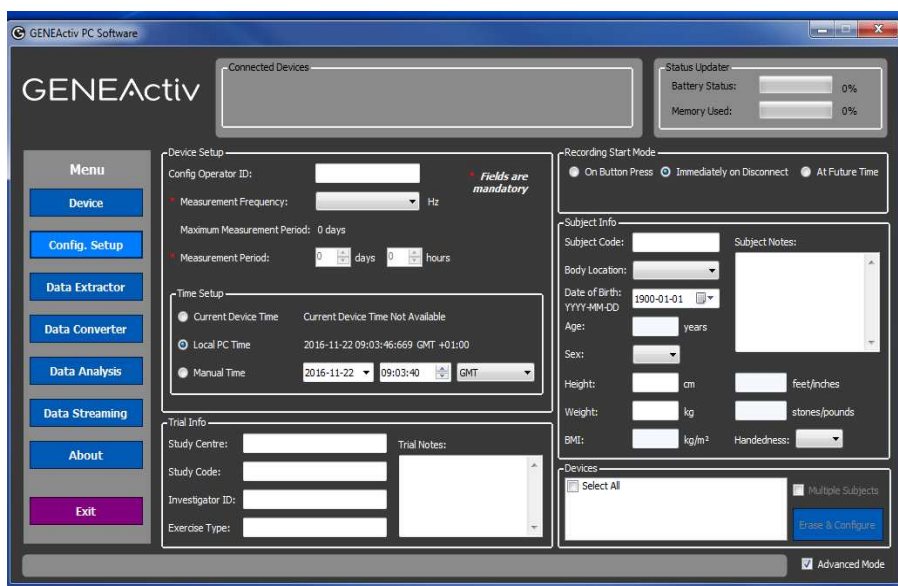
- Fill in the following:
    - o "Config Operator ID": introduce id of the child.
    - o "Measurement Frequency": the measurements frequency selected will determine the maximum time data can be recorded for, lower frequency = longer time. Select "85.7". The "Measurement Period" will be set automatically to 9 days 0 hours.
    - o Select "Local PC Time".
    - o Select when you want to recording the start, selecting "Immediately on Disconnect".
- To configure the GENEActiv and get it ready to record, select the serial number of the device in the "Devices" box in the bottom righ-hand corner of the screen (the serial number is printed on the front of the device).
- Click "Erase & Configure". Pop-up windows will advice of any problems (such as mandaroty information missing or low battery charge), and warn that configuring will erase any existing data. The configuration will take about 10 seconds and a pop-up will confirm that it has been completed successfully.
- The GENEActiv device can now be disconnected and will either start recording immediately. Recording will stop after the time selected.
- IMPORTANT!! if the device is reconnected to the charge cradle, once it has started recording, it will stop recording and require reconfiguring!!

Downloading the data

To extract data once recording is complete:

- Open the GENEActiv software and connect the charging cradle to a USB port.
- Insert a GENEActiv device into the cradle.
- Click "Data Extractor" from the left-hand menu. This page previews the first few minutes of recorded data and allows to download data to a chosen file location.
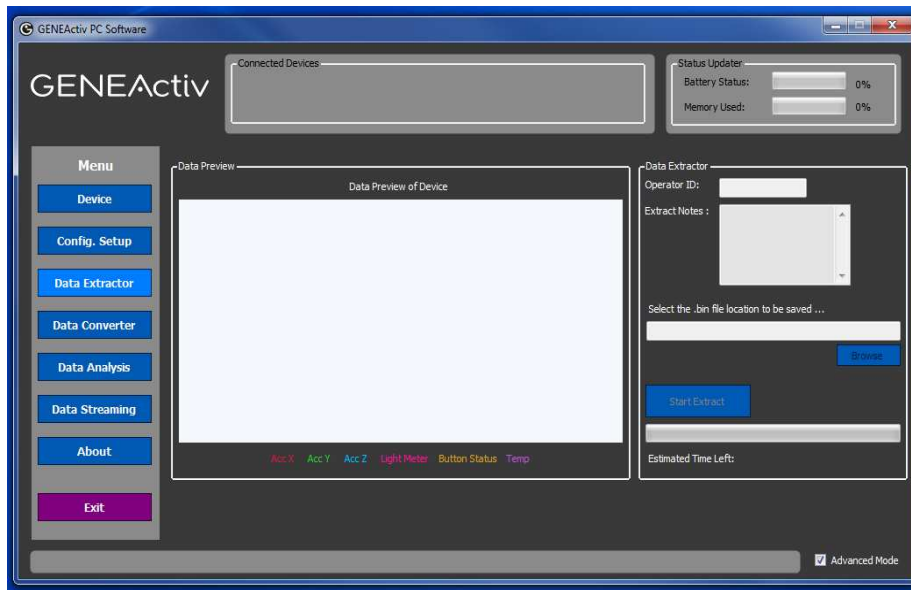
- Chose a file location and extract data with a ".bin" format. Click into "Start Extract". The data can take up to 10 minutes to download and a pop-ip will confirm completion.

- Click "Data Converter" from the left-hand menu. This page allows to convert the saved ".bin" file into a ".csv" format file.

- Select "CSV Converter". Within the "Select imput .bin file…", browse and select the previously saved ".bin" file. Then, within the "Select the output .csv file path…", browse the same folder where the ".bin" file was. Click "Start Convert"

- Click "Exit" from the left-hand menu. A pop-up message will ask to confirm that we want to exit de software. If we reply YES, the software will close.

Procedure

At the end of the clinical visit, place a watch to the child's wrist of the non-dominant hand properly configured. Steps to follow:

- Explain to the child that the watch is waterproof and that it is not necessary that he takes it our unless he is doing a risk sport that can cause damage to others or himself by wearing it (e.g. karate, etc)

- Give to the child extra wrist straps in case they need to replace the one they have

27.1 Give the daily diary to the child (

- Annex 22.1) and explain how to fill it in. Important to register in the diary when and why the child stops wearing the watch

After a week, collect the watch and the diary at the school. Charge the watch until it is fully charged, download the data, save it in the folder of the child, and configure the watch for the next child.

Problem recording sheet

Mi diario del sueño y actividad física

Id.……………….......................................

Nº Serie Reloj.………………………………

Día de inicio.…………………………………

Día Final.……………………………………

Hora de inicio.……………………….............

☀ Te presentamos tu **diario del sueño y actividad física** de los próximos días. Las preguntas del diario y el reloj nos ayudarán a saber cómo duermes y a medir tu actividad física.

☀ Hoy te ponemos el reloj y a partir de mañana cada día tendrás que contestar unas preguntas, ya verás que son las mismas cada día, en función de cómo hayas dormido y qué hayas hecho el día anterior.

☀

El reloj se puede mojar pero si te lo quitas es **MUY IMPORTANTE** que anotes el motivo, la hora que te lo quitas y la hora que te lo vuelves a poner en la tabla de incidencias que encontrarás al final de cada día.

Te puedes duchar con el reloj, pero **NO** puedes ir con él a la piscina.

Día 0

Fecha: ____/____/____

Preguntas a responder **ANTES DE IR A DORMIR**

¿Has estado mirando la televisión, una película o series, te has quedado dormido en algún momento mirando la televisión?

☐ Si   ☐ No

¿Cuánto tiempo has pasado hoy en el aire libre con luz del sol? …. horas y ….. minutos

¿Has tomado hoy Coca-cola (u otra marca), café, té, alguna bebida energética, o chocolate?

☐ Si, Coca-Cola y por última vez a las …. : ….. (hora : minutos)

☐ Si, café y por última vez a las …. : ….. (hora : minutos)

☐ Si, té y por última vez a las …. : ….. (hora : minutos)

☐ Si, bebida energética y por última vez a las …. : ….. (hora : minutos)

☐ Si, chocolate y por última vez a las …. : ….. (hora : minutos)

☐ No

Hoy, a partir de las 19h de la noche…	¿Cuántas veces?	¿Cuánto tiempo en total?	¿Cuándo fue la última vez, antes de dormirte? (hora : min)
¿Has enviado mensajes (whatsapp, SMS, snapchat, etc.)?	…… veces	……. horas y …...min	…. : ….
¿Has hablado con alguien por el teléfono móvil?	…… veces	……. horas y …...min	…. : ….
¿Has hablado con alguien por el teléfono fijo de casa?	……. veces	……. horas y …...min	…. : ….

Hoy, a partir de las 19h de la noche…

¿Has jugado a juegos con la videoconsola, ordenador, móvil o tableta?	……. horas y …...min	…. : ….

	¿Has mirado videos con el móvil, la tableta o el ordenador?	……. horas y …...min	…. : ….
	¿Has mirado Facebook, Instagram, Twitter, noticias, etc.?	……. horas y …...min	…. : ….
	¿Has mirado la televisión?	……. horas y …...min	…. : ….
	¿Has hecho los deberes o estudiaste?	……. horas y …...min	…. : ….
	¿Has leído?	……. horas y …...min	…. : ….

¿Qué programas, película o series has mirado hoy durante todo el día en la televisión?

……

……

…………………………………………………………………………………………………

¿Hoy has hecho las actividades que haces habitualmente?

☐ Si   ☐ No, especifica porqué:……………………………………………………………

Incidencias con el reloj o el sensor de luz HOBO:			
Reloj u sensor luz HOBO?	Motivo	Hora inicio (horas y minutos)	Hora final (horas y minutos)
Ejemplo: Reloj	*Fui a la piscina y me lo quité*	*16:00*	*17:00*
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..

Día 1

Fecha: ____/____/2017

Preguntas a responder **CUANDO TE LEVANTAS**

¿Qué hora es ahora?   …. : ….. (hora y minutos)

¿A qué hora te fuiste a la cama ayer?   …. : ….. (hora y minutos)

Teniendo en cuenta que quizás estuviste despierto un tiempo en la cama (por ejemplo, leyendo), ¿a qué hora apagaste las luces y estabas listo/a para dormir? ...:... (hora y minutos)

¿Cuánto tiempo pasó hasta que te dormiste?   ….. horas y …..minutos

¿Cuántas veces te has despertado esta noche?   ………. veces

¿Cómo has dormido esta noche? ☐ Muy bien ☐ Bien ☐ Regular   ☐ Mal   ☐ Muy mal

¿Cómo de descansado te has sentido al despertarte?

☐ Totalmente descansado/a ☐ Bastante descansado/a   ☐ Algo descansado/a

☐ Poco descansado/a   ☐ Nada descansado/a

¿A qué hora te has despertado?   …. : ….. (hora y minutos)

¿Cómo te has despertado esta mañana?

☐ Con el despertador ☐ Alguien me ha despertado ☐ Un ruido me ha despertado   ☐ Me he despertado solo/a ☐ De otra manera, especificar:……………………………………………

¿A qué hora te has levantado de la cama?   …. : ….. (hora y minutos)

¿Dormiste solo/a en tu habitación?

☐ Si   ☐ No, especifica con quien dormiste en la habitación:……………………………………….

¿Tuviste el ordenador, el portátil, la tableta o el teléfono móvil encendido en la habitación mientras dormías?

☐ Si   ☐ No

⤷ **Si lo tuviste, ¿te despertaste alguna vez por haber recibido mensajes en el ordenador, portátil, tableta o teléfono móvil?**

☐ Si   ☐ No

⤷ **¿Si te despertaste por haber recibido un mensaje, qué hiciste?**

☐ Nada   ☐ Leí el mensaje y volví a dormir ☐ Leí el mensaje y lo contesté

Preguntas a responder **ANTES DE IR A DORMIR**

¿Has estado mirando la televisión, una película o series, te has quedado dormido en algún momento mirando la televisión?

☐ Si   ☐ No

¿Cuánto tiempo has pasado hoy en el aire libre con luz del sol? …. horas y ….. minutos

¿Has tomado hoy Coca-cola (u otra marca), café, té, alguna bebida energética, o chocolate?

☐ Si, Coca-Cola y por última vez a las …. : ….. (hora : minutos)

☐ Si, café y por última vez a las …. : ….. (hora : minutos)

☐ Si, té y por última vez a las …. : ….. (hora : minutos)

☐ Si, bebida energética y por última vez a las …. : ….. (hora : minutos)

☐ Si, chocolate y por última vez a las …. : ….. (hora : minutos)

☐ No

Hoy, a partir de las 19h de la noche…	¿Cuántas veces?	¿Cuánto tiempo en total?	¿Cuándo fue la última vez, antes de dormirte? (hora : min)
¿Has enviado mensajes (whatsapp, SMS, snapchat, etc.)?	……veces	….horas y …...min	…. : ….
¿Has hablado con alguien por el teléfono móvil?	……veces	….horas y …...min	…. : ….
¿Has hablado con alguien por el teléfono fijo de casa?	…….veces	….horas y …...min	…. : ….

Hoy, a partir de las 19h de la noche…

¿Has jugado a juegos con la videoconsola, ordenador, móvil o tableta?	……. horas y …...min	…. : ….
¿Has mirado videos con el móvil, la tableta o el ordenador?	……. horas y …...min	…. : ….
¿Has mirado Facebook, Instagram, Twitter, noticias, etc.?	……. horas y …...min	…. : ….
¿Has mirado la televisión?	……. horas y …...min	…. : ….
¿Has hecho los deberes o estudiaste?	……. horas y …...min	…. : ….

¿Has leído?	……. horas y …...min	…. : ….

¿Qué programas, película o series has mirado hoy durante todo el día en la televisión?
……
………………………………………………………………………………………………

¿Hoy has hecho las actividades que haces habitualmente?

☐ Si   ☐ No, especifica porqué:………………………………………………………………

Incidencias con el reloj o el sensor de luz HOBO:			
Reloj u sensor luz HOBO?	Motivo	Hora inicio (horas y minutos)	Hora final (horas y minutos)
Ejemplo: Reloj	*Fui a la piscina y me lo quité*	*16:00*	*17:00*
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..
		…. : …..	…. : …..

28 Annex 23

HOBO pendant – sensor de luz

Set up

Before giving the At the end of the clinical visit, place a watch to the child's wrist of the non-dominant hand properly configured. Steps to follow:
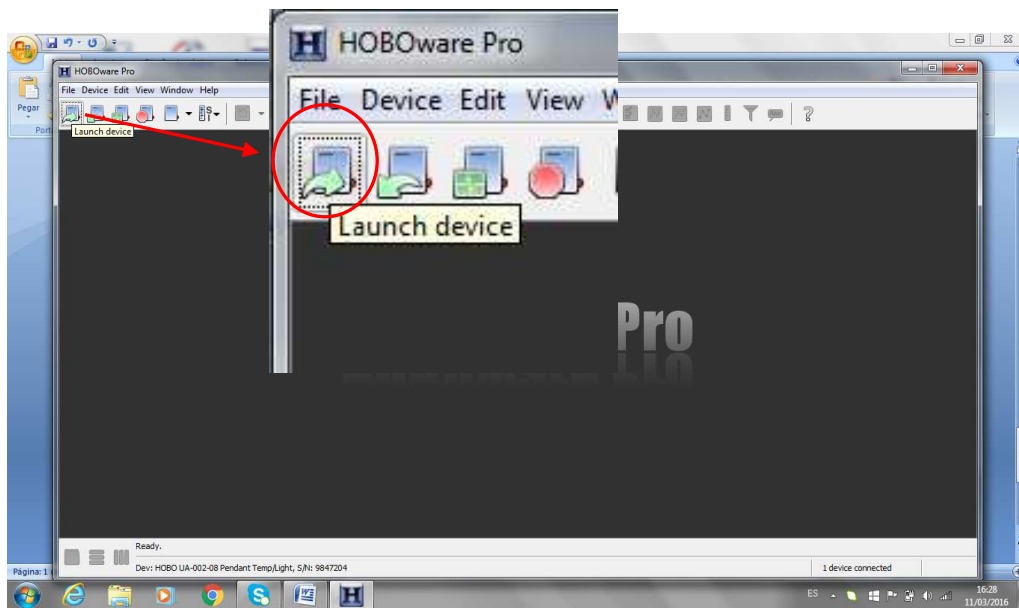
1. Encender el portátil con la sesión **"Instalar"** y poner la contraseña.
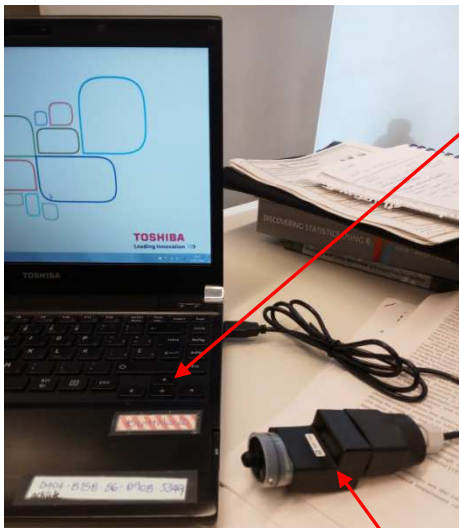
2. Conectar el dispositivo HOBO al ordenador mediante el adaptador USB.
3. Abrir el software del dispositivo: **HOBOware**

4. Seleccionar el icono **"Launch"** para poder programar le dispositivo HOBO

5. Launch Logger:
   a. Comprobar el nivel de batería **"Battery level"**
   b. **"Description"**: poner la identificación del participante
   c. **"Channels to Log"**: solamente marcar la opción 2: **"Light Intensity"**
   d. **"Logging Interval"**: lectura de luz cada **12 segundos!!**
   e. **"Launch options"**: marcar opción **"Now"**.
   f. Apretar **"Launch"** para que el aparato empiece a medir. Cuando hayan pasado 24h se apagará automáticamente.

ATENCIÓN!! En el momento de apretar **"Launch"**, se borrará toda la lectura que se haya hecho el día anterior!! Asegurar haber descargado los datos previamente (ver apartado 7).
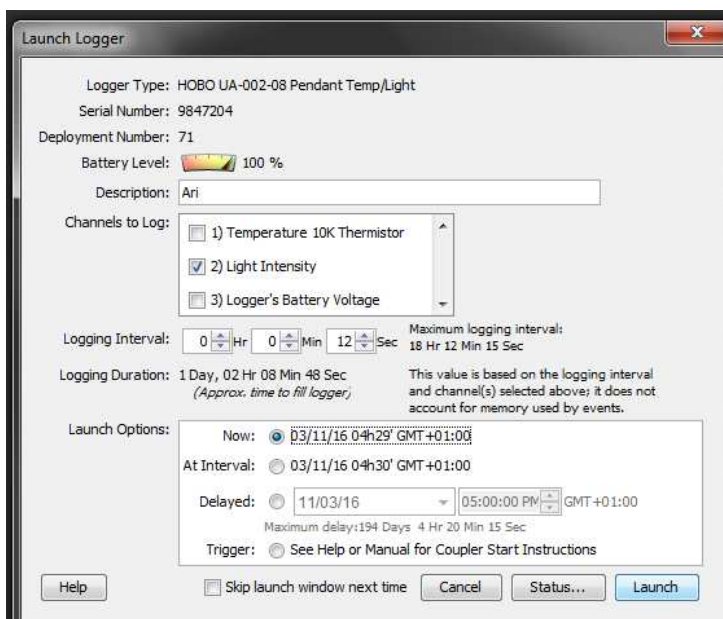
6. Asegurar que el aparato está funcionando clicando **"Device"** y después **"Status"** para que aparezca la siguiente pantalla donde se debe ver: **"Current status : Launched Logging"**.
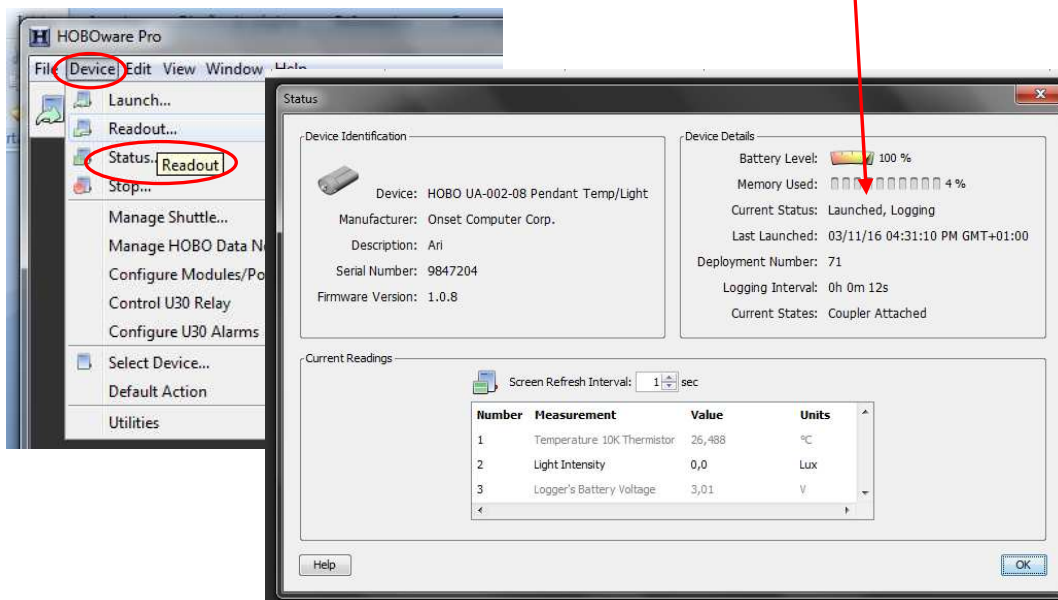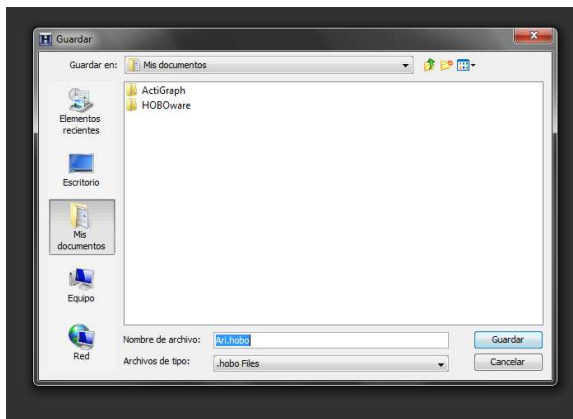

7. Cómo guardar los datos:
   a. Seguir los pasos 1, 2 y 3
   b. Clicar el icono **"Device"** y después **"Readout"**
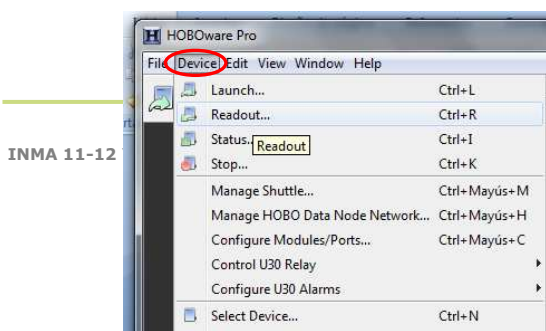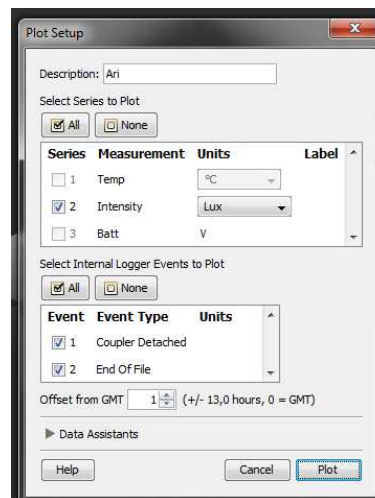
c. Seleccionar la carpeta del participante y guardar.

d. Al seleccionar **"Plot"** aparecerá un gráfico con los valores de las lecturas.

Procedure

At the end of the clinical visit, give the HOBO sensor to the child. Explain that it needs to be place in a flat surface next to the bed in their bedroom in the following position, with the "sensor" looking at the top:

The device cannot be moved or covered with anything.

After a week, collect the sensor at the school. Charge it until it is fully charged, download the data, save it in the folder of the child, and configure it for the next child.