

Horizon 2020

Societal Challenge: Improving the air quality and reducing the carbon footprint of European cities



ICARUS

Project: 690105 – ICARUS

Full project title:

Integrated Climate forcing and Air pollution Reduction in Urban Systems

MS9 - Sensor-based exposure monitoring protocol

WP4 Population exposure and health impact assessment

Lead beneficiary: AUTH



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	WP4: Population exposure and health impact assessment	Security:	PU
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1 Introduction

The overall aim of this milestone is to present the latest advances in external sensor technologies and geo-referenced systems used to define the external exposure at individual level. To this end, a literature review has been made following the Extensive Literature Search (ELS) principles and guidance (see deliverable D1.3 – WP1).

The main review questions related to the use of sensor technologies in defining external exposure at individual level include but are not limited to the following questions:

- To what extent new sensor technologies are being used to assess exposure of individuals?
- What kind of information new sensor technologies provide (complexity, level of detail, integration with other tools and approaches used for exposure assessment etc.)?
- Are the sensors fit for purpose? Are personal sensors able to indicate forms, duration, regularities/irregularities (spatial, time) and other circumstances and specifics, which contribute to the determination of types and levels of external exposures?
- What is sensitivity/accuracy (trustworthiness) of personal sensors that are in use?
- What are their advantages and disadvantages?


Based on the outcome of the analyses of studies included in this ELS, conclusions are drawn and suggestions made on the selection of suitable candidate sensor technologies to be used by volunteers within the ICARUS project (*Task 4.1 Collection of multi-sensor data for personal exposure monitoring*).

This document describes the protocol for the WP4 sensors campaign. The entire protocol will be trialed using a known associate before it is applied to the general public. After this trial, 100 participants will be recruited in each of 9 study centers-participating cities. A sampling campaign will be conducted in each city by the local ICARUS partner institute. A data collection platform is developed by AUTH. Data collected will be analysed and published and lessons learned will be reported.

2 Sensors review

Personal sensors – wearable technology

The determination of a person's exposure to air pollutants requires the knowledge of the various microenvironments where one moves and the carried-out activities he/she undertakes. Technological advances in the recent years have produced sophisticated monitoring devices which can be placed in indoor environments or even carried or worn by a person during their regular daily routine allowing for personal exposure to be monitored explicitly. Smartphone apps, wireless devices and the downsizing of monitoring technologies and costs makes it possible for various environmental stressors and exposure factors to be measured more easily and frequently, thus providing a more reliable “time–geography of exposure” shifting the current paradigm from a population to an individual level. A variety of sensors and applications that can help assess exposure to air pollution have been developed. We will summarize two major types in this section and discuss their involvement in exposure studies: a) Physical Activity (PA) sensors and b) Air Quality (AQ) sensors.

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2.1 Physical Activity (PA) sensors

Location

Global Positioning System (GPS) devices can be used to track people's location, allowing the matching of pollution data with a person's location. This can be used in tandem with a personal monitor, or, through modelling, can reconstruct a person's exposure (Gerharz, Krüger et al. 2009, de Nazelle, Seto et al. 2013). The information they provide can reduce personal exposure measurement error by providing a more reliable "time-geography of exposure". Either a GPS unit or a GPS-enabled mobile phone can be used, and smartphone apps for the latter are available, where users can enter in location information, providing an aid to data-processing. There are numerous exposure studies where GPS has been used to track subject locations (Adams, Riggs et al. 2009, Wu, Jiang et al. 2011, Dueker, Taher et al. 2014) whereas time-activity diaries have also been used in order to obtain additional information on the undertaken activities in every location (Klepeis 1999, Schweizer, Edwards et al. 2007).

Activity

Physical activity is both a risk factor for disease and relates to environmental exposures. Measuring physical activity and respiration is important for estimating exposure variables. For example, information on individual physical activity as tracked by personal sensors allows the estimation of the breathing rates during different activities which in turn is translated to inhaled dose. There are numerous types of physical activity sensors available complemented by accelerometers and gyroscopes, both designed for research purposes and for public consumption (Yang and Hsu 2010, Bassett 2012). Sensors may be worn on a single area of the body (e.g. wrist or waist), or on several areas of the body. The waist is often a default location as it is close to the centre of mass of the body, although for long-term constant use the wrist may be more convenient for the user. The accelerometer output needs to be transformed into a meaningful unit for interpretation, such as steps or metabolic equivalents (METs). Already, commercially available fitness monitors allow individuals to measure their own physical activity, energy expenditure, and sleep (Mammen, Gardiner et al. 2012). Numerous sensors of such kind, have been used in recent studies (Yang and Hsu 2010, Bassett 2012), so as to obtain comprehensive activity patterns of different population groups.



Table 1. Physical activity sensors

Name	Type	Wearable	Cost	Steps	Active minutes	Calories / Energy	Sleep	Respiration	Heart Rate	Oximetry	GPS	Temp	Light
FitBit Flex	Physical Activity	Wrist	\$80.00	x	x	x	x						
FitBit Charge 2	Physical Activity	Wrist	\$90.00	x	x	x	x		x				
FitBit Surge	Physical Activity	Wrist	\$200.00	x	x	x	x		x		x		
Garmin Vivosmart HR+	Physical Activity	Wrist	\$140.00	x	x	x	x		x		x		
Garmin vívoactive	Physical Activity	Wrist	\$220.00	x	x	x	x		x		x		
Samsung Gear Fit 2	Physical Activity / Smartwatch	Wrist	\$130.00	x	x	x	x		x		x		
Huawei Fit	Physical Activity / Smartwatch	Wrist	\$130.00	x	x	x	x		x				
Jawbone UP3	Physical Activity	Wrist	\$40.00	x	x	x	x		x				
Withings Pulse	Physical Activity	Wrist / Belt / Pocket	\$100.00	x		x	x		x	x			
Misfit Ray	Physical Activity	Wrist	\$80.00	x		x	x						x
Misfit Shine 2	Physical Activity	Wrist	\$80.00	x		x	x						x
TomTom Fitness Tracker	Physical Activity	Wrist	\$80.00	x	x	x	x		x				
TomTom Runner 3	Physical Activity	Wrist	\$170.00	x	x	x	x		x		x		
Apple Watch	Physical Activity / Smartwatch	Wrist	\$450.00	x	x	x	x		x				
Moov Now	Physical Activity	Wrist	\$50.00	x	x		x						
Actiwatch 2 - Philips Respironics	Physical Activity	Wrist		x	x	x	x						x
Actigraph wGT3X-BT Monitor	Physical Activity	Wrist		x	x	x	x		x		x		x
Zephyr Pebble Watch + BioModule	Physical Activity	Wrist	\$650.00	x		x		x	x				
Mimobaby Tracker	Physical Activity	Full Body	\$200.00	x			x	x			x	x	



2.2 Air Quality (AQ) sensors

Air pollution sensors can be separated into two main categories, those that measure the concentration of gas phase species and those that measure either particulate matter mass concentrations or various properties of particles (e.g., through scattering or absorption methods). Lower-cost air pollution sensors are available for several gases and particles.


The increasing popularity of small sensors, open-source programs, hardware such as the Arduino microcontroller board, and cloud computing has allowed the collection and integration of many types of personal level data. The relatively lower cost and easy access to some of these technologies have encouraged the development of citizen science projects, crowdsourcing campaigns, and student projects to bring environmental monitoring to the public (e.g. EveryAware and CitiSense projects, Public Lab, Air Quality Egg). The benefits of the “easy-to-use”, the acquisition of high-time resolution data and the connection to the internet for remotely access of the data collected have been already recognized. These technologies could facilitate wider-scale and longer-term monitoring of multiple exposures at the same time for studies associating air pollution with human health effects.

Direct reading monitors help us to identify whether peak exposures are more important than average exposure values, identify specific exposure pathways that dominate in critical time windows over an individual’s lifetime, and finally build individual exposure profiles.




Table 2. Air quality sensors


ID	Sensor model	Cost Estimation	CO	CO2	NO	NO2	O3	VOCs	SO2	PM	Other	Type	Portability/Size
1	Shinyei	upon request								x		PM sensor - Light Scattering	stationary / microsensor
2	Shinyei PMS-SYS-1	upon request								x		PM sensor - Light Scattering	stationary / microsensor
3	Airbeam - Aircasting	\$250								x		PM sensor - Light Scattering	portable / relatively small
4	Air Quality Egg (PM)	\$280								x		PM sensor - Light Scattering	stationary / relatively small
5	Air Quality Egg (nitrogen dioxide)	\$280	x			x						Gas phase sensor	stationary / relatively small
6	Air Quality Egg (O3 and SO2)	\$280					x		x			Gas phase sensor	stationary / relatively small
7	Air Quality Egg (VOCs)	\$280						x				Gas phase sensor	stationary / relatively small
8	CairPol CairClip PM - prototype	Research project								x		PM sensor - Light Scattering	portable?
9	Airviz Speck v2	\$150								x		PM sensor - Light Scattering	stationary / relatively small
10	RTI MicroPEM	Upon request								x		PM sensor - Laser Particle Counters	portable / wearable
11	Dylos DC1100/DC1100 Pro	\$260								x		PM sensor - Laser Particle Counters	stationary / medium size
12	Dylos DC1100	\$200								x		PM sensor - Laser Particle Counters	stationary / medium size
13	Dylos DC1700	\$425.00								x		PM sensor - Laser Particle Counters	stationary / medium size
14	AQMesh	Upon request	x	x	x	x	x		x	x		PM and Gas phase sensor	stationary / medium size
15	MetOne - Aerocet 831	\$3,000								x		PM sensor - Laser Particle Counters	handheld monitor / medium size
16	CairClip	Upon request				x	x					Gas phase sensor	portable / microsensor

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ID	Sensor model	Cost Estimation	CO	CO2	NO	NO2	O3	VOCs	SO2	PM	Other	Type	Portability/Size
17	Cairclip NO2/O3, USB version (ozone)	Upon request				x	x					Gas phase sensor	portable / microsensor
18	Aeroqual Series 500 (ozone)	Upon request					x					Gas phase sensor	handheld monitor / medium size
19	Aeroqual Series 500 (NO2)	Upon request				x						Gas phase sensor	handheld monitor / medium size
20	AirCasting (nitrogen dioxide)	Upon request				x						Gas phase sensor	portable / microsensor
21	CitiSense (nitrogen dioxide) The CitiSense monitor also includes sensors for carbon monoxide and ozone	Research project	x			x	x					Gas phase sensor	portable / microsensor
22	U-Pod DIY	?				x	x					Gas phase sensor	stationary / small
23	Unitec SENS-IT	?	x			x	x				benzene	Gas phase sensor	portable?
24	Air Guard K (Corean promising sensor)	?								x		PM sensor - Light Scattering	Stationary / small
25	Smartcitizen.me	~\$220 - not yet ready								x		PM sensor - Light Scattering	Stationary / small
26	EveryAware SensorBox (Kit with Alphasense and M pod sensors etc)	Upon request	x			x	x	x				Gas phase sensor	portable / microsensor
27	M-pods	Research project	x	x		x		x				Gas phase sensor	portable / microsensor
28	Intel-Berkeley Common Sense	Research project	x			x	x					Gas phase sensor	handheld monitor / medium size
29	TSI AirAssure PM2.5 Indoor Air Quality Monitor	Upon request ~\$1000								x		PM sensor - Light Scattering	stationary / medium size
30	Aretas	Upon request	x	x		x	x	x		x		PM and Gas phase sensor	stationary / medium
31	AirThinx by Netronix	Upon request ~\$1000		x		x				x	Formaldehyde	PM and Gas phase sensor	stationary / relatively small
32	DIY Alphasense OPC-N2 Optical Particle Counter using a Raspberry Pi	estimation ~\$350								x		PM sensor - Light Scattering	portable / microsensor

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ID	Sensor model	Cost Estimation	CO	CO2	NO	NO2	O3	VOCs	SO2	PM	Other	Type	Portability/Size
33	TZOA PM Research Sensor	upon request ~\$600								x		PM sensor - Laser Particle Counters	portable / microsensor
34	TZOA Consumer sensor	upon request								x		PM sensor - Laser Particle Counters	portable / microsensor
35	SDS011 by Inovafit for PM	€ 25								x		PM sensor - Laser Particle Counters	portable / microsensor
36	SPEC Sensors, LLC 968-001	\$ 50	x									Gas phase sensor	small microsensor
37	Amphenol Advanced Sensors T6613-F	\$ 114		x								Gas phase sensor	small microsensor
38	Parallax Inc. 605-00007	\$ 5.99	x									Gas phase sensor	small microsensor
39	SparkFun Electronics SEN-09405	\$ 4.95									LPG	Gas phase sensor	small microsensor
40	GlobalSat LS-111E CO2 LoRaWAN	€ 220	x									Integrated with calibrated CO2 sensor	stationary / relatively small / electrically powered - custom work to make it portable
41	GlobalSat LS-112E CO LoRaWAN	€ 190		x								Integrated with calibrated CO sensor	stationary / relatively small / electrically powered - custom work to make it portable
42	GlobalSat LS-113E PM2.5 LoRaWAN	€ 240								x		PM sensor - Light Scattering	stationary / relatively small / electrically powered - custom work to make it portable
43	Magnasci LoRaWAN	Upon request	x	x		x	x		x	x		PM sensor - Light Scattering and a set of electrochemical sensors	stationary / relatively small / electrically powered - custom work to make it portable
44	MyExposome	\$ 1000 including the analysis										EDCs, PAHs/O PAHs, PCBs, Passive sampler	portable - wristband

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ID	Sensor model	Cost Estimation	CO	CO2	NO	NO2	O3	VOCs	SO2	PM	Other	Type	Portability/Size
											pesticides, BFRs		



3 Study Objectives

- Collect data on external environmental exposure and exposure determinants by **combining** location and activity data, and data on air pollution in different microenvironments
- Demonstrate feasibility of using **new sensor and mobile technologies** in collecting exposure data.
- **Analyse and compare exposure data** in several different European cities.
- Use data to parameterize and/or validate simulation models – ABM modelling

4 Study Design

4.1 Overall study design

This study will require participation of individuals living in the respective participating city. The study aims to characterize urban population exposure to air pollutants by measuring personal exposure through a combination of measured data related to (a) personal sensors and (b) the outdoor and indoor place(s) air pollution levels that they spend the most time in.

Each participating city (or study center) will recruit 100 individuals. Volunteers from all ages and all sociodemographic groups will be recruited, with a focus on including people living in hot spot areas (e.g. near roads and in other locations with high pollution concentrations and vulnerable groups of population (e.g. asthmatics, children and elderly).

The study will include both at home and personal monitoring for 7 days, including a weekend. The process will be executed in the same way in both summer and winter in order to capture seasonal variation. The types of information to be collected include exposure monitoring devices, smart phone apps and questionnaires. During the monitoring period volunteers, can contact fieldworkers, if needed.


Some of the data collected will be viewable by the subject during the monitoring period, as they will be measured using do-it-yourself devices. Some of the data will need to be sent to a laboratory for analysis.

Subjects will be given a subject information leaflet, explaining the study's aims and objectives. The test procedures will be explained to each subject and each will be given an opportunity to ask questions prior to them providing consent for themselves, their household, and child to participate on the study by means of a signed Subject Consent Form.

4.2 Inclusion criteria

These are the criteria for a household to participate in our study.

- Subjects must give voluntary informed consent for themselves, the household, and child(ren)
- Subjects and other household members must be willing and able to have sampling equipment in home and accept fieldworkers to survey their home, and place data collection devices in the home.
- Subjects must be willing to carry around personal monitors and perform any functions required to maintain or record data from them
- Subjects must be willing to use the ICARUS electronic portal for data gathering and answer any questionnaires requested of them

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- Subjects must be willing to share anonymised data with external parties and with the ICARUS portal.
- Subjects must be willing to accept use of all anonymised data, including publication, and the confidential use and storage of all data by study.
- Subjects should own a Smartphone with Bluetooth that runs either iOS 7 or Android 4.0 and up.
- Subjects must have a desktop or laptop with internet access and wireless connection at home and allow use of this connection for study devices

4.3 Exclusion criteria

If potential subjects meet any of the following criteria they will be excluded from the study.

- Restrictions on ability to have study devices at home or other locations (such as work)
- Live outside the study area
- If the study researcher or field worker deems that the subject is not functionally capable of giving informed consent.


4.4 Sample size

For each study center (participating city) 100 hundred individuals will be recruited.

5 Campaign equipment and questionnaires

5.1 Investigational treatment

In this study, volunteers will be asked to allow fieldworkers to place indoor air quality sensors in the home, and use do-it-yourself monitoring devices during a period of 7 days (for each campaign). The exposure assessment monitoring devices and questionnaires are described in more detail below. Each volunteer and household will be given a non-identifying username, email address, and password for the study. These will be used to set up accounts on the devices listed below. For any apps where information can be shared with other users in the community, privacy settings will be set to the most restricted viewing.

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5.2 Personal data collection devices

5.2.1 Physical Activity Sensors

Fitbit

The Fitbit Flex is a personal activity monitor. It can measure the number of steps a person takes and, using the person's height, weight, and age, estimates energy expenditure. It can also be used to estimate sleep efficiency. Fitbit Flex is worn on the wrist and uses Bluetooth to sync with a smartphone or computer. Steps, energy expenditure, and sleep efficiency can be seen on the Fitbit web platform or by downloading the Fitbit smartphone app. Fitbit will be synced to the ICARUS portal. The Fitbit should be worn at all times by the participants, unless there is a reason it needs to be removed (e.g. charging, need to go through security, swimming). It can also be worn while sleeping. **Fitbit Surge** could also be used so that we capture location, based on the built-in GPS sensor.




Moves

The Moves app can be downloaded to a person's smartphone. This app tracks a person's location, activity (as steps), and can estimate the mode of transportation being used. Volunteers will be asked to label locations, not already/automatically labeled by the app, such as "home," "work," etc. The app can be run in a battery saving mode if smartphone's battery drain is a concern. Moves will be synced to the ICARUS portal. Volunteers will be asked to carry their phone with them at all times, except when it is not feasible (e.g. while sleeping, in the shower).



5.2.2 Air Quality Sensor(s)

For measuring personal exposure, custom made sensors will be used based on the SDS 011 Sensor (from inovafit) for measuring PM which is a good compromise between portability and accuracy. For gaseous pollutants, custom modified gaseous sensors for CO, NO₂ and O₃ will be combined based on Alphasense 4-electrode sensors, integrated at an Arduino setting, able to transmit data wirelessly. In addition, custom made silicon wrist band (similar to the MyExposome) will be provided for the assessment of semi-volatile organic compounds.

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5.3 In-home data collection devices

Netatmo

The Netatmo is a home environment sensing device with two modules. One module will be placed in a child's bedroom and the other in the room where the child spends a lot of time. Each Netatmo module measures temperature, humidity, and carbon dioxide, with one module also measuring noise (in dB), which will be placed in the child's bedroom. The Netatmo needs to be connected to the household's Wi-Fi network. The data collected by the Netatmo modules are synced to the online account, which will be set up for each household, using an anonymous username and email address that the study assigns. Volunteers can see their household measurements data by downloading the Netatmo app on their smartphone. Netatmo data will be also synced to the ICARUS portal.



Air Quality Egg

The Air Quality Egg (AQE) is an Open source hardware Internet of Things platform and a device for crowdsourced citizen monitoring of airborne pollutants. The device is consisted of two identical-looking plastic enclosures vaguely resembling white eggs. One unit, the base unit, is connected to the user's ethernet LAN connection. The second unit, based on the module used, monitors NO₂, CO, VOC or PM levels and reports these readings every few minutes back to the base unit via a custom wireless protocol. The Egg detects particles from 0.5 microns to 10 microns.




5.4 Questionnaires

The subjects will also be asked a set of questions by the fieldworkers, including information about the housing characteristics and household, demographics and socio-economics. Questions that are administered by the fieldworkers will be recorded preferably by tablet, for later upload into a database, or by paper, if the tablet option is not working. The subjects will also be asked to answer a questionnaire about their experience with the study at the end.

6 Data collection portal

ICARUS Portal

The ICARUS portal is an online 'personal data portal' on which data from multiple devices can be uploaded or synchronized. Participants have the opportunity to see all the data in one portal while it allows researchers to collect the encoded data for data analysis. Data from wireless devices and apps will be uploaded to the ICARUS portal automatically. Subjects are free to check their data as often as they wish

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7 Methods

7.1 Study parameters/endpoints

The study's primary endpoints will be the exposure related data collected. These may also be used in further studies to estimate personal exposure. Data collected include:

- Time-activity-location patterns
- Indoor air and environmental quality parameters
- Socio-economic information

Study variables that will be used as potential predictors include the questionnaire data on building characteristics and occupant behavior.

Additionally, the study will evaluate the potential of do-it-yourself devices for measuring exposure parameters by subjects. Given the 7 day monitoring period, we will evaluate the percent completeness of the real-time measurements per day and over the entire 7 days.

Usability of the devices will be assessed with a questionnaire on user-experience with do-it-yourself devices at the end of the study. This questionnaire will encompass questions on how often the devices are used, the context in which the device is used, the satisfaction of the user with the device, the effects of the device on user behaviour, the ease of use and the problems encountered. We will encourage participants to report any problems or issues encountered on the ICARUS portal during the study period.


7.2 Study procedures

7.2.1 Subject contact

If a person has expressed interest in this study during the recruitment process, a research staff member will contact the person by phone and/or e-mail and provide an explanation of the study. If the person agrees to participate, the staff member will set up an appointment for the first visit and reserve a date and time for the second visit. Names of subjects will not be stored with their phone numbers on mobile or other phones. A copy of the participant information sheet and consent form (Appendix 9) will be sent to the participant in advance of the first visit, so that they will have time to read it and think about it in advance.

7.2.2 First visit

Volunteers will be provided with another copy of the information sheet and the research staff will explain each part of the sheet to volunteers, who will then be given an opportunity to review the sheet and ask questions. Volunteers will have to consent for themselves and their child to be in the study. Once they have signed the consent checklist, the fieldworkers will administer questionnaires to the adult subject, set up measurement equipment in the home, and set up and provide instructions to the adult subject about using the personal measurement devices and apps. The fieldworkers will set up all devices and will ask the subject for permission to link to their home wireless internet connection. They will also help the subject set up the apps on the subject's smartphone. The fieldworkers will go through all the procedures for use of the do-it-yourself devices, apps, and websites with the adult. The subject will receive a folder with instructions, their anonymized study username, email, and password, and who to contact in case of questions or an emergency. All subject data will be aggregated in an encoded

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manner in the ICARUS portal. Volunteers together with the fieldworkers will also confirm the date and time of the next visit. This visit is expected to take approximately 2 hours.

7.2.3 During the study

Volunteers will be provided with a phone number to call in case of questions or problems with the equipment. The fieldworkers will call the adult subject mid-way through the sampling period to see if the subject has any questions, to remind them to use their devices, and to confirm the date/time of the second visit. The subject will also receive notifications on their phone periodically (not more often than once a day) to remind them to use their devices. Any data that is linked to the ICARUS portal will be monitored by the fieldworkers and research staff, and if there are any questions regarding this information, the subject will either be contacted during the study or will be asked during the second visit, depending on the nature of the issue. We estimate that each day the participant would take 15 minutes on activities, such as syncing their Fitbit. It will vary by participant and day but we do not anticipate more than 15-30 minutes/day.

7.2.4 Second / Final visit

During the second visit, which will be scheduled for 7 days later, the fieldworkers will log and remove all in-home measurement devices and take back the personal monitoring devices. The fieldworkers will ask if the subject had any problems and go over any issues that may have arisen during the study, including questions about the data from the ICARUS portal that the research staff may have. Additionally, the fieldworkers will administer a questionnaire to the subject about their experience with the study and use of the devices. This visit will take about 1.5 hours.


8 Ethical considerations

8.1 Regulation statement

The study will be conducted in compliance with the protocol and all amendments to the protocol. The protocol and any changes to the protocol effecting the design, rationale or objectives of the study, or the burden of or health risks for the volunteers will only be implemented after written approval of the ethics committee of the School of Life Sciences of Heriot-Watt University.

The study will be conducted according to:

- The current revision of the World Medical Association
 - Declaration of Helsinki.
 - 64th WMA General Assembly, Fortaleza, Brazil, October 2013.
 - Note of clarification on paragraph 29 added by the WMA General Assembly, Washington, 2002.
 - Note of clarification on paragraph 30 added by the WMA General Assembly, Tokyo 2004;
 - The current national regulations.
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8.2 Recruitment of subjects

Each participating city will develop its own recruitment plan based on previous experience. Some common approaches include:

- Information desks will be organised, where ICARUS research teams can further inform people at social events during days like the World Health Day (7th of April) or European Immunization Week (last week of April).
- NGOs, nurseries and groups that sponsor activities for parents, children and/or elderly will be approached, by posting informational posters and providing information. Advertisements through online sites, social networks, local magazines and via word-of-mouth will also help.

Campaign's printed or online leaflets will always link (QR code in printed version / direct link in online version) to an online form so that potentially interested volunteers could fill in their details. In all cases, the recruitment materials will include a telephone number and email for people to contact with.

Researchers will contact the potential subject via telephone and/or email. If a person has expressed interest in this study during the recruitment process, a research staff member will contact the person by phone and/or e-mail and provide an explanation of the study. If the person agrees to participate, the staff member will set up an appointment for the first visit and reserve a date and time for the second visit.

Subjects will be given a subject information leaflet, explaining the study's aims and objectives. The test procedures will be explained to each subject and each will be given an opportunity to ask questions prior to them providing consent for themselves, their household, and child to participate on the study by means of a signed Subject Consent Form.

Names of subjects will not be stored with their phone numbers on mobile or other phones. A copy of the participant information sheet and consent form will be sent to the participant in advance of the first visit, so that they will have time to read it and think about it in advance.


8.3 Information and consent

Subjects will be given a subject information leaflet, explaining the study's aims and objectives. The test procedures will be explained to each subject and each will be given an opportunity to ask questions prior to them providing consent for themselves, their household, and child to participate on the study by means of a signed Subject Consent Form. Subjects will also be asked to consent to terms and conditions of the devices used for data collection. For devices and apps which require a log in and password, the study staff will provide subjects with an anonymised email address and username.

Subjects will be informed that they are allowed to withdraw at any time and without explanation.

8.4 Risks to participants

The devices used pose low risk of harm. The fieldworkers will need to take precautions that any devices placed in the home or worn by the adult caretaker will pose minimal threat of harm to the household members and children. This includes instructing the adult subject to be watchful of the devices, especially in the presence of children, so that they are not accidentally misused. The fieldworker will place measurement devices, with consultation from the adult subject, in areas where a child cannot easily access the devices.

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All equipment will be checked upon return from the field and prior to use in the field. If any problems are noted in the field, the fieldworkers are instructed to not use the device and use either a backup or to bring another functional device later, if possible.

The subjects will be instructed to report any incidents involving study equipment or procedures as soon as possible to study staff. If a study device is accidentally broken by the subject, they will not be required to make any payment or replace the device. Any other incidents that may adversely affect the subject during the study or the subject's ability to comply with study procedures should also be reported.

9 Administrative aspects, Monitoring and Publications

9.1 Data Management and Security

Data collected under this project will be subject to compliance with the Data Protection Act 1998.


All researchers will be trained in the ethics of human subject research and in the appropriate information governance. Subject names and contact information will be kept in a separate file, linked with the person's ID code for the study. This will be kept encrypted on a password protected computer. Only personnel authorized by the study will have access to this and any other files containing private information. Any paper documents with subject information will be kept in a locked cabinet, and only study personnel will have access to the keys.

A data management system will be used to securely store and share data via the internet, ensuring that only authorized ICARUS personnel have access. The stored data will be encrypted. Any data to ultimately be made public will be adequately de-identified. No potentially identifying data will be revealed in any public data or data publication.

Data collected using do-it-yourself devices will be uploaded to an online portal using an anonymous account. After a subject is included in the study, he/she will be provided with an envelope including a login for an email account (which is linked to the subject number) and a password. Prior to the start of the study, for each subject number an account is created for Fitbit (activity monitor), Moves (Smartphone app), Netatmo, and the ICARUS portal. The email account will be linked to these accounts. Data from these applications will be synchronized to the ICARUS portal via an Application Protocol Interface (API). The portal is hosted on a server, constantly monitored and maintained by UPCOM. For authorisation we use the Spring Security framework, which is responsible for the control of passwords (encrypted and decrypted) and the relevant different users (e.g. subject, fieldworker, administrator etc.) Furthermore, the subject data and personal information will be stored in two different and separate databases. All links implemented into the portal work with the OAuth authentication, which is a part of Spring Security. Spring Security is a long-established framework with a large support. All providers (Netatmo, Fitbit, Moves) will be linked to the ICARUS portal work with this platform.

Only anonymized data can be downloaded from the ICARUS portal for subsequent tabulation and statistical analysis. Subjects and households will be assigned a unique identification code that does not include any identifying information. Information such as address and phone number will be kept in a separate, encrypted database and will not be linked to subject data in analyses.

The documentation of this study consists of the study protocol, correspondence, report, raw data, source documents or authenticated copies of these.

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For privacy reasons, documents containing data of individual subjects will be identified only by their pre-entry or entry number.

9.2 Device and sample management

Electronic and do-it-yourself devices will be re-used throughout the study. In all cases, data will be downloaded and removed from the device before re-use in another household and for another subject. Do-it-yourself devices will be reset for use with a new user and password, and the past user's information will not be available to the next user. Each device will be assigned a unique ID, which will be linked with any identifiers, such as a serial number, for the device, and will not be changed during the study. This will allow researchers to track any issues that may come up with certain devices. The device ID used for each household/subject will be recorded and entered into a database.

Passive air and dust samplers that are set out by the fieldworkers on the first visit and the vacuum dust contents will be logged with a unique sample ID, which will be linked to the household ID. These will be associated with a chain of custody form, that will be filled out by each person handling the samples, and which will be kept with the samples. These forms will only use household and sample ID numbers for identification. The location and status of samples throughout their life cycle (i.e. from laboratory to home, back to laboratory, to any further analysis) will be logged in a database. Any associated measurements or treatments of the sample will also be logged in this database. If the sample is sent outside of the IOM for analysis, courier tracking will be used, and appropriate transit conditions will be used (e.g. use of a cooling box or other method for storage, next day delivery, etc.). Recipients will be required to sign and send the original of the chain of custody form back to the IOM, keeping a copy. All transactions will be logged in the sample database.


9.3 Monitoring and quality assurance

Audits of the data collection and processing procedures will be taken throughout the project. For example:

- An audit of the data collection process employed by the fieldworkers will be carried out at regular project meetings, between study centers.
- Most of the data collected will not be manually entered. Research staff will be responsible for checking that data is uploaded to the ICARUS portal during the collection period for each household and to the database during and after the collection period.
- Any manually entered data will be checked for completeness of entry and compared to the paper questionnaire and data logs by someone who did not enter the data.
- All devices will be tested before use in the field. Tests will include co-location, reliability for the sampling time, and comparison with a reference instrument, if available.
- Approximately 10% of passive air samples will be co-located duplicates and 10% will be blank.

9.4 Annual and end-of-study progress reports

If required, the sponsor/investigator will submit a summary of the progress of the trial to the ethics committee once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

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9.5 Public disclosure and publication policy

Public disclosure may include:

- Summarized study results issued on the study or institutional website;
- Oral or poster presentation at conferences, symposia or other public meetings;
- Full publication in peer-reviewed scientific journals.

In any case only encoded data will be used and no reference to any information leading to the identification of the participant subjects will be disclosed.

9.6 Report back to study subjects

The study subjects will be able to view their data on the do-it-yourself devices. As this is a demonstration project, some of the collected samples (e.g. dust) may be stored and analysed at a later date. Within 6 months of data collection the study participants will receive an overview of their results that are available at that time.

10 Literature

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