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EDUCAT
European Regional Development Fund

KU LEUVEN

EDUCAT's

- Open, modular and adaptive framework for clinical trials
- "Obstacle Alerting System" (OAS) application

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Erasmus+ delegation
08/06/2023

Provincie Oost-Vlaanderen

EDUCAT

Empowerment of **D**isabled people through the **U**ser **C**oproduction of **A**ssistive **T**echnology (2016-2021)

6 Partners
7 Observers
3 Countries
Total Budget 3.14 M€

European Project co-funded by Interreg VA 2 Seas

Objective: develop and deliver Assistive Technologies (ATs) for the health sector that are open, modular and able to adapt their assistance (or to be adapted by the user) to the user's needs.
For that we need clinical trials, so a versatile measurement framework!

Start date: 01/09/2016, it ran for 5 years
Team: Yncréa HdF/ISEN, KU Leuven, Un. of Kent, UK hospitals, Voka Oost-Vlaanderen
Website: www.educat2seas.eu

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Outline

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- **Introduction**
  - Problem description – What we need
  - Solution: "One workflow does it all …"
  - Additional requirements for the framework
- Components of the EDUCAT framework
- OAS: the "Obstacle Alerting System"
- Direct analysis of measurement data
- Conclusions

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Problem description – What we need

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Different sensors, Powered Wheelchairs …

Input from different questionnaires, daily diaries, …

Flexible analysis is required

Development of the technology → Clinical trials → Data analysis → Results → Technology transfer and knowledge sharing

Different test set-ups, different goals, …

Different persons, multiple tests, …

We need an open, modular and adaptive framework !
We need one single database combining all the heterogenous data !

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Solution: "One workflow does it all …"

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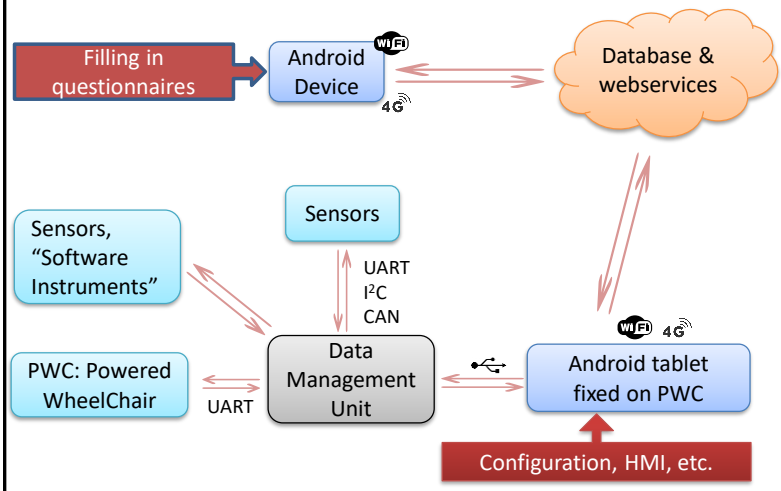

Install sensors, actuators, software modules, …

Configure the set-up, experiment, … by swiping in an app

Run measurement: storing data in the cloud, live view, daily diaries, questionnaires, OAS software instrument, etc.

Analyse the heterogenous data which is in one single database

Additional requirements for the framework

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- Pseudonymisation of the persons involved
- Authentication upon login
- Secure and robust (roaming and buffering) communication to the cloud
- Flexible graphic configuration on "off-the-shelf" Android devices
- Quick detailed first analysis and reporting & Flexible database analysis

→ A powerful, flexible system for clinical trials

→ Workflow includes pseudonymization

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Workflow for clinical trials

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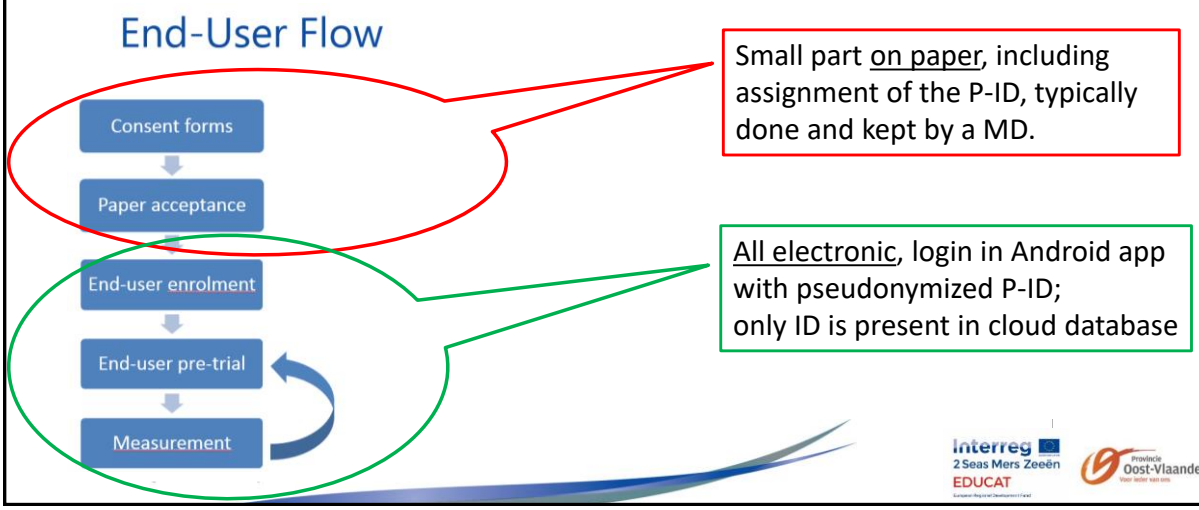
- Pseudonymisation of the persons (end-user, carer, …) involved



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Outline

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- Introduction
- **Components of the EDUCAT framework**
  - DMU: Data Management Unit
  - Android app
  - Connecting to the cloud database
- OAS: the "Obstacle Alerting System"
- Direct analysis of measurement data
- Conclusions

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DMU: the Data Management Unit

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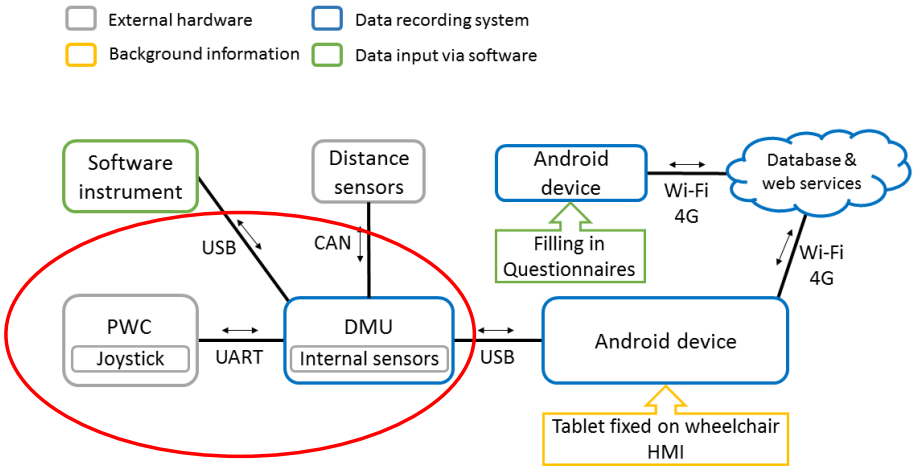

"Dispositif d'enregistrement de données hétérogènes ouvert et configurable pour tests cliniques"; Conférence Handicap 2020, 11th edition, IFRATH Université Paris 8, 4-6 November 2020. Pag. 143-148. Annemarie Kokosy, Gilles Tagne, Philippe Saey, Alexis Clemente, Ali Oukhrid, Frederic Depuydt, Mathieu Troch, De Schuyter Dimitri.

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DMU: the Data Management Unit - Hardware

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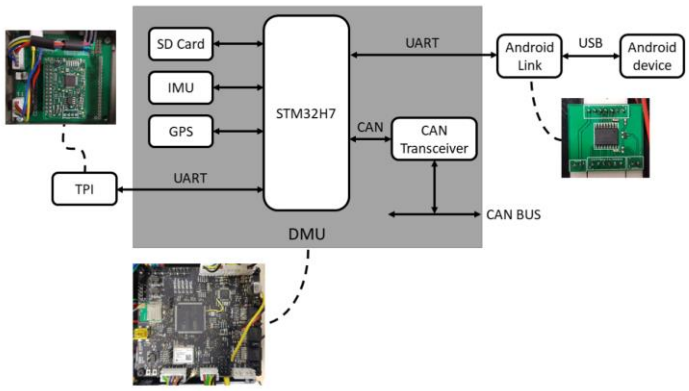
- DMU for V3, rev. 2: STM32H743ZIT6
- Real-Time OS: FreeRTOS v9.0.0
- Interfaces: UART, CAN, I²C, USB via UART, …
- GPS, IMU (1), TPI (2), RTC (3),



Application	EDUCAT Clinical Trial 2 Software Solution								
Libraries	P&G B-Net Chipset Serial API	EDUCAT DK2 Library	EDUCAT LinX Library	U-Blox Library	EDUCAT CPL Library	Hillcrest IMU Library	EDUCAT CAN Service Library	EDUCAT Configuration Library	EDUCAT Storage Library
Middleware	Real-Time Operating System FreeRTOS V9.0.0					Chan FATFS Filesystem			
Drivers	STMicroelectronics HAL Drivers STM32Cube FW_H7 V1.3								
Hardware	EDUCAT DMU V3 Rev2 Based on STM32H743ZIT6								

"Dispositif d'enregistrement de données hétérogènes ouvert et configurable pour tests cliniques"; Conférence Handicap 2020, 11th edition, IFRATH Université Paris 8, 4-6 November 2020. Pag. 143-148. Annemarie Kokosy, Gilles Tagne, Philippe Saey, Alexis Clemente, Ali Oukhrid, Frederic Depuydt, Mathieu Troch, De Schuyter Dimitri.

(1) IMU: Inertial Measurment Unit (2) TPI: connection to the PWC bus (3) RTC: Real-Time Clock.

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DMU: the Data Management Unit

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- DMU mounted on a PWC

DMU: the Data Management Unit - Software

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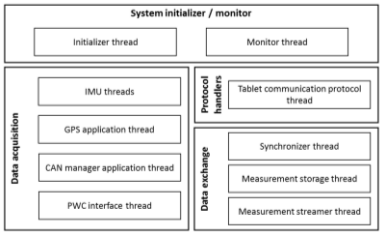
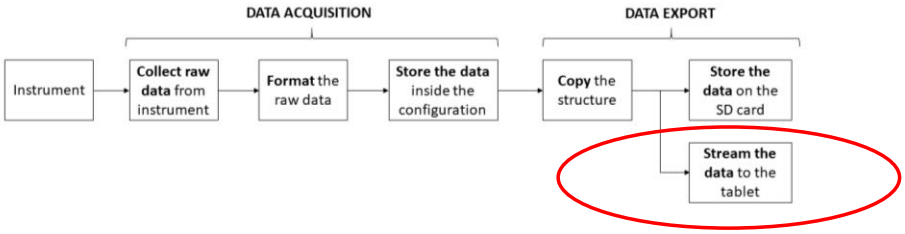
- Organized around 4 threads
- Uses the configuration set-up from the cloud database
- Android tablet/phone sends it to the DMU
- Hardware is checked for "being present and functioning"
- Ready for work!





The EDUCAT Android app

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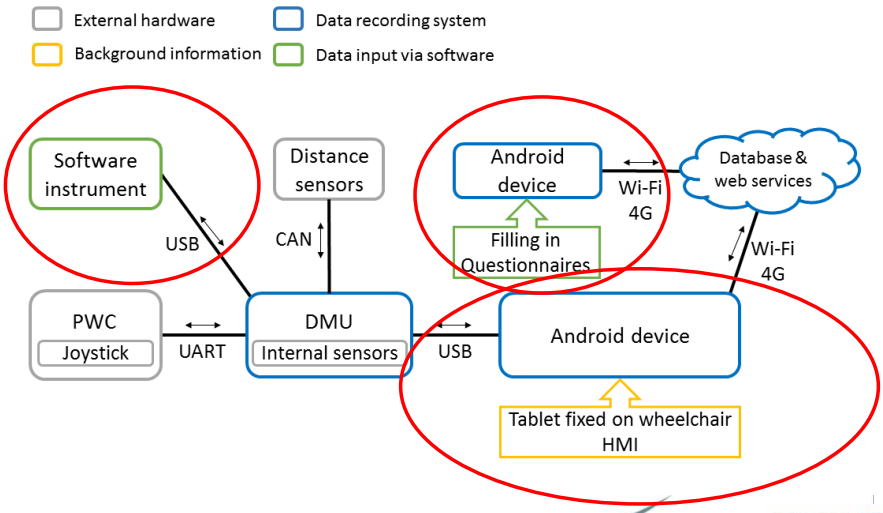

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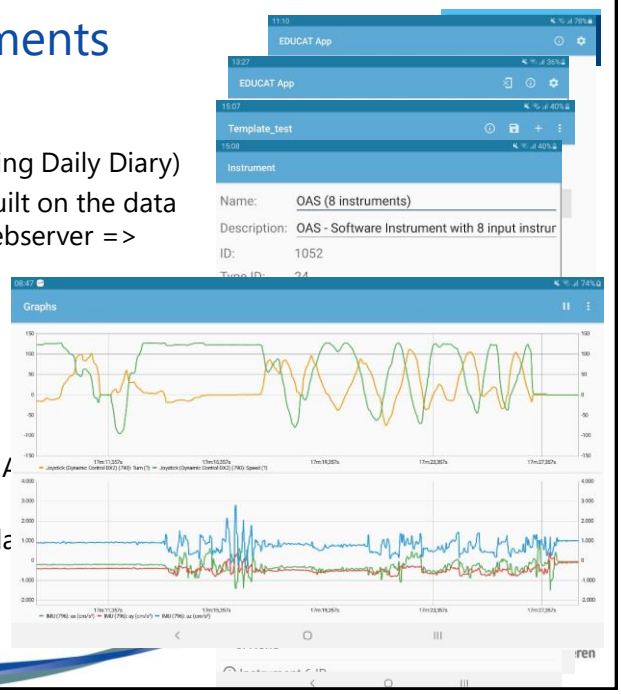
The EDUCAT app – Requirements

- Main tasks of the Android Device:
  - Filling in / Viewing questionnaires (including Daily Diary)

    The UI (User Interface) is dynamically built on the data in the JSON strings coming from the webserver => easy adding of questionnaires
  - Creating new measurement setups
  - Data stream with DMU
  - TCP data stream with cloud database
  - Live visualization
  - Run software instruments (OAS, Obstacle A System)
  - Developer information (debugging), emula datastreams for server testing



The EDUCAT app – Requirements

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- Android specifications:
  - Programming is in Android Studio (v4.1.2) – Software is on GitHub
  - Minimum requirement is Android 5.0 Lollipop

- **Demo with data streaming on tablet (graphs)**

"Open and configurable heterogeneous data recording device for clinical trials"; Kokosy, A., Saey, P., Tagne, G., Oukhrid, A., Degallaix, T., Troch, M., De Schuyter, D., Verhoeven, A. Modelling, Measurement and Control C, Vol. 81, 2020, No. 1-4, pp. 62-66.

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Connecting to the cloud database

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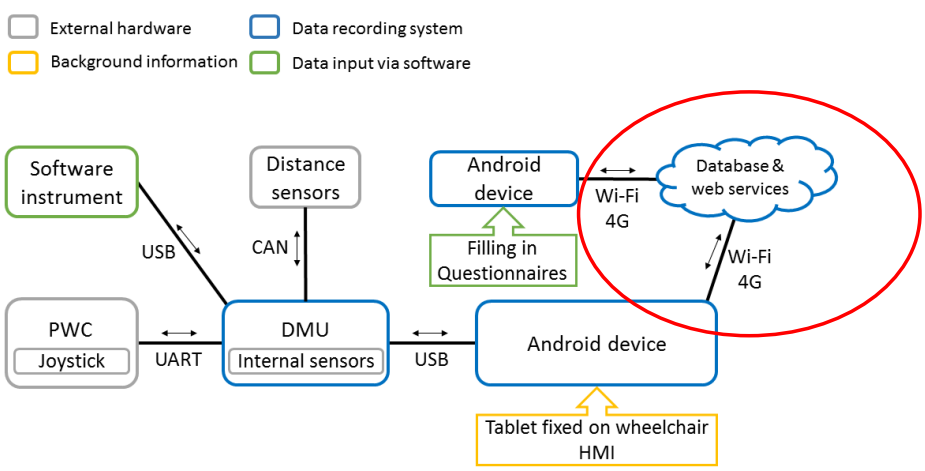

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Connecting to the cloud database – Data streams

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- Data stream every 20 ms from DMU to Android Device (AD), with ack
- Acyclic data stream for commands/responses between DMU and AD
- A cycle counter is used to identify each message, and check for missing ones

- Between Android Device (AD) and cloud database:
  - Every 20 ms for the cyclic data
  - Acyclic messages (questionnaires, set-ups, …)
- Wi-Fi or 4G

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Connecting to the cloud database – Robustness

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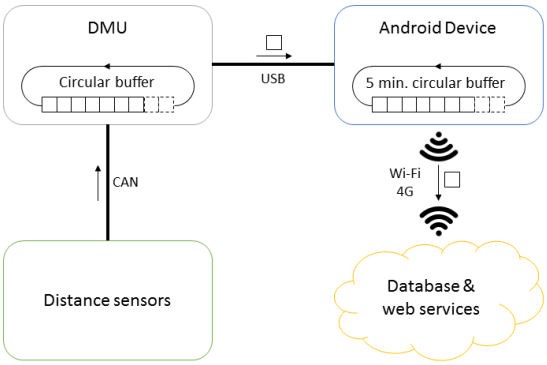
- Robustness:
  - Small local buffer for the cabled USB-communication
  - Circular buffer of 5 minutes in the Android device, for the wireless link to the database => roaming and buffering is ok
  - Every block of 1500 messages arrived in the database is acknowledged



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Connecting to the cloud database – Security

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- Authentication:
  - HTTP Digest Access Authentication (RFC 7616)
    - Method to negotiate credentials
    - Confirm the identity of the user before exchanging data
- Login with a user ID and a password
  - User ID is anonymous (list on paper connects the user ID to the persons)
- HTTPS / TLS encryption

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Connecting to the cloud database – Database

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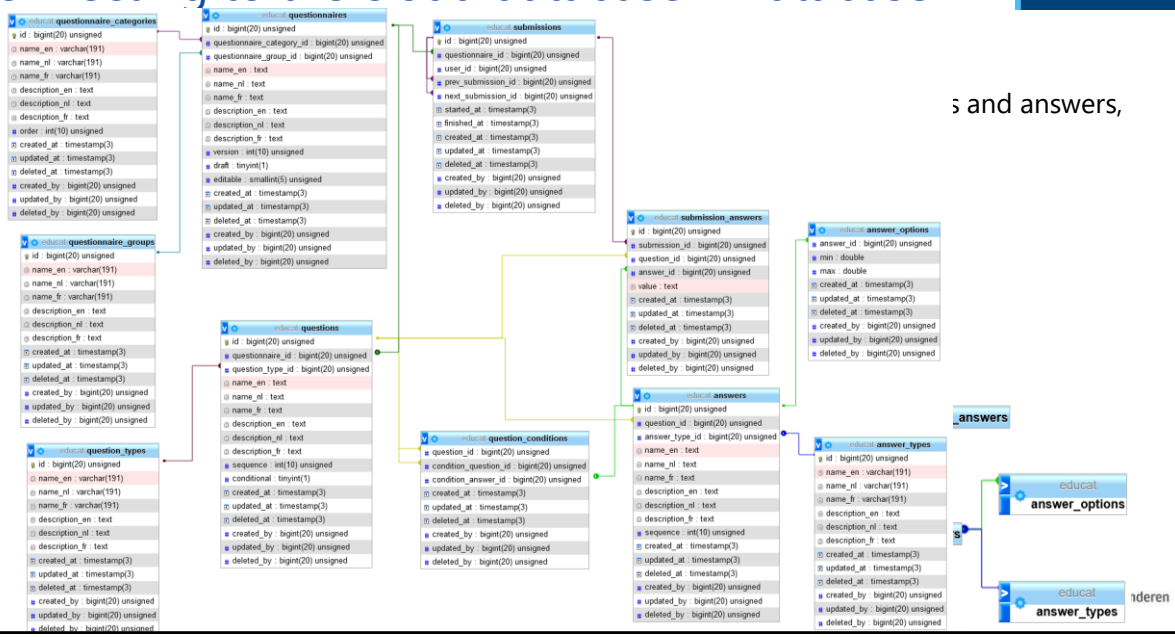

s and answers,

Connecting to the cloud database – Database

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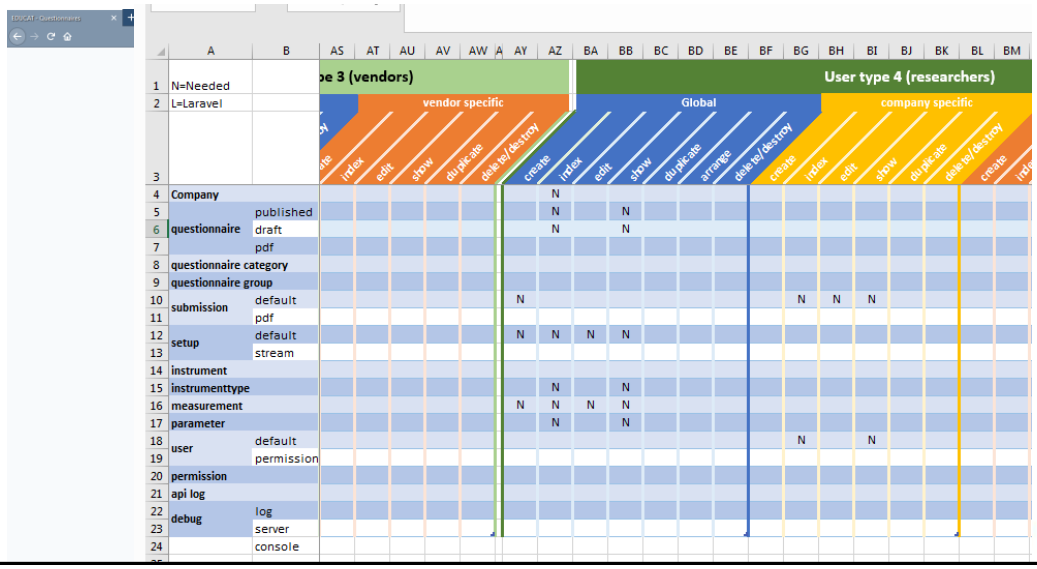
- Website:



	A	B	AS	AT	AU	AV	AW	AY	AZ	BA	BB	BC	BD	BE	BF	BG	BH	BI	BJ	BK	BL	BM
1	N=Needed		be 3 (vendors)							User type 4 (researchers)												
2	L=Laravel			vendor specific						Global							company specific					
3			ate	index	edit	show	duplicate	delete/destroy	create	index	edit	show	duplicate	arrange	delete/destroy	create	index	edit	show	duplicate	delete/destroy	create	index
4	Company									N												
5		published							N		N											
6	questionnaire	draft							N		N											
7		pdf																				
8	questionnaire category																					
9	questionnaire group																					
10	submission	default						N								N	N	N				
11		pdf																				
12	setup	default						N	N	N	N											
13		stream																				
14	instrument																					
15	instrumenttype								N		N											
16	measurement							N	N	N	N											
17	parameter								N		N											
18	user	default														N		N				
19		permission																				
20	permission																					
21	api log																					
22	debug	log																				
23		server																				
24		console																				

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Connecting to the cloud database

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- **Movie: questionnaire and view submitted**

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Outline

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- Introduction
- Components of the EDUCAT framework
- **OAS: the "Obstacle Alerting System"**
  - Adding distance sensors
  - The OAS: a "software instrument"
- Direct analysis of measurement data
- Conclusions

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OAS: Obstacle Alerting System

- Driving aid for PWC users
- Very similar to a parking system in a car
- We need:
  - Distance sensors
  - A "software instrument" for calculations and feedback
  - Feedback: buzzer, haptic (joystick), visual (on AD)
- Upon request of end-users: rear view camera

Adding distance sensors for the OAS

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- US and IR types – Connected via CAN bus to the DMU
- Flexible mounting and connecting system
- As mounted during Junia tests 2021:

The OAS: a "software instrument"

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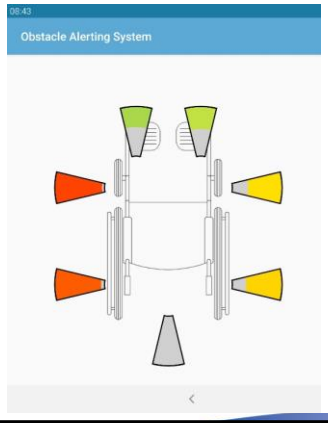
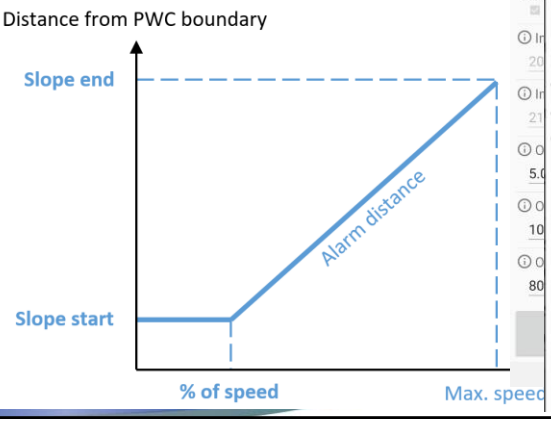
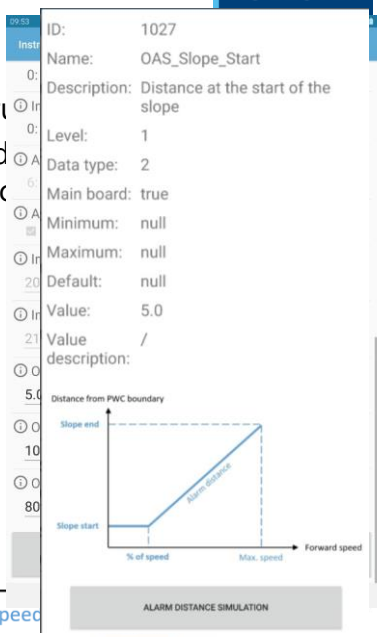
- Works on its own, no cloud connection needed
- Can of course be used in a clinical trial, as software instru
- The OAS provides a lot of data: use of the feedback (and sensors), sensor distances, OAS result, OAS characteristic







The OAS: a “software instrument“

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- **Movie configuration of a setup, incl. OAS.**
- **Movie indoor in a hall way, split view met OAS**

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Direct analysis of the measurement data

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- Setups, measurement list and basic properties, … are all available in the app.
- Database:
  - Holds all the heterogenous information (measurements, questionnaires and answers, setups, etc.)
  - Access using API (PP4 programmers)
  - Access via read-only queries by data analysts
  - **Access for quick measurement analysis via MATLAB livescript (all researchers)**
  - Access via website

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Direct analysis of the measurement data

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- Some options of the MATLAB script:
  - Select a measurement (or part of it), make some parameter choices
  - Automatically generate a full range of plots and calculated values
  - Store in html, docx, pdf and locally store in "measurement object" or individual variables in MATLAB workspace
- Calculated values:
  - Operating times joystick
  - Cumulative Joystick Path Length ("joystick distance moved")
  - NJS – Normalized Jerk Score

$$NJS = \sqrt{0.5 \times \left(\int_{t^1}^{t^2} \left(\left(d^3 \frac{x}{dt^3} \right)^2 + \left(d^3 \frac{y}{dt^3} \right)^2 \right) dt \right) \times \left(\frac{t^5}{l^2} \right)}$$

- Example of html result: Canterbury 986

"Using Kinematic Analysis to Evaluate Constraint-Induced Movement Therapy in Chronic Stroke Patients", Marco Caimmi, Et. Al. Neurorehabil Neural Repair 22, pag. 31-39 (2008).

"Parkinsonism Reduces Coordination of Fingers, Wrist, and Arm in Fine Motor Control", Hans-Leo Teulings, Et. Al. EXPERIMENTAL NEUROLOGY 146, 159–170 (1997).

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Direct analysis of the measurement data

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- Example of HTML result: Canterbury **ID 986**

Direct analysis of the measurement data

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- Use of cloud database server resources
  - CPU usage during 1 stream: 1.5 %
- Use of PC resources for the MATLAB livescript – short measurement 816
  - Processing a 2.5 minute measurement (7500 cycles): 2.4 seconds
  - Plotting all the data: one heatmap 0.3 s, all plots 15 s.
  - Generating HTML report: 7 s
- Use of PC resources for the MATLAB livescript – long measurement 906
  - Processing a 3+ day measurement (13+ mln cycles): 46 seconds
  - Plotting all the data: one heatmap 0.7 s, all plots 378 s.
  - Generating HTML report: 6.3 s

Processing = split the datablobs into separate MATLAB variables

Direct analysis of the measurement data

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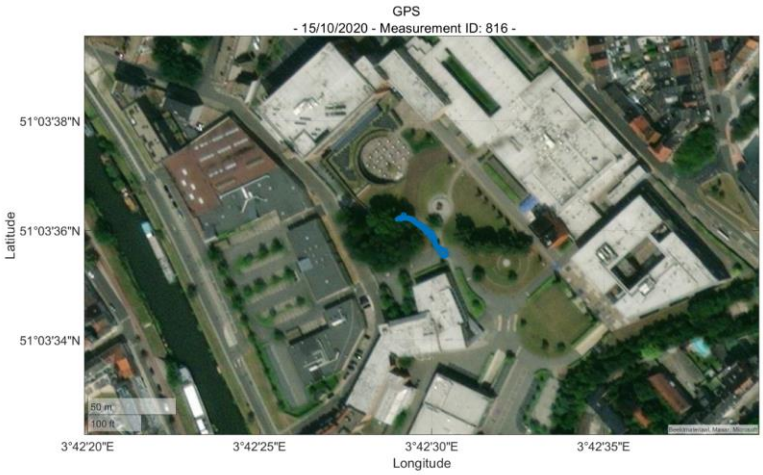
- Film outdoors on KU Leuven's Gent campus, joint Junia – KU Leuven measurements in October 2020
- Areal view, from GPS data of the measurement (ID 816)



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Conclusions

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- EDUCAT realized a powerful open, modular, adaptive framework
  - It holds DMU, Android app, cloud database, fast analysis tool for initial analysis, etc.
  - It generates and processes heterogenous data
- EDUCAT realized an Obstacle Alerting System
  - As adaptable software instrument, with extra distance sensors
  - It can be used standalone, or as one of the instruments in a clinical trial
- *Thank you for your attention !*

Acknowledgement

Alexis Clemente, Ali Oukhrid, Annemarie Kokosy, Arne Verhoeven, Bruno Stefanelli, Dimitri De Schuyter, Frederic Depuydt, Gilles Tagne, Jean-Marc Capron, Jos De Brabanter, Mathieu Troch, Michael Gilham, Philippe Saey, Robert Walker, Thomas Degallaix

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BIOSINT

- Project number: 101082863-BIOSINT-ERASMUS-EDU-2022-CBHE

BIOSINT

Co-funded by the European Union

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