POSEiDON

Pers**O**nalized **S**mart **E**nvironments to increase **I**nclusion of people with **DO**wn's sy**N**drome

Deliverable D2.4

Safety, Privacy and Ethical Considerations

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Contents

Executive Summary

D2.4 summarizes safety, privacy and ethical considerations related to the POSEIDON project and its users. On the one hand, it focusses on person-related issues, on the other hand technology-related issues are discussed.

Person-issues refer to the aim that POSEIDON should have a benefit to the society by increasing the quality of life. We try to increase the quality of life by enhancing the self-determination, the social participation as well as the safety and security of people with DS. Therefore, we discuss issues like mobility, structure and support in daily life, friendships and leisure time activities, as well as education and work and how this can be enhanced while meeting safety, privacy and ethical standards.

Furthermore, we focus on technology-related issues like usability and design aspects which should be considered. We discuss, how people with DS can be supported by technical assistants regarding their independence and autonomy in compliance with safety and ethical standards and without violating their privacy.

Safety, privacy and ethical issues should also be considered when pilots with primary users are conducted. For that reason, the procedure of the pilots is discussed from a safety, privacy and ethical perspective.

When revising this document in M21 and M31, we added screenshots of the current developmental status and explained the progress achieved as well as the technical implementation of safety, privacy and ethical considerations regarding the POSEIDON app, the CapTap and the Home Navigation system.

1 Overall aim of POSEIDON

POSEIDON aims to support both existing competencies and to regulate experienced challenges in the everyday life of people with Down`s Syndrome (DS[1]). It will be developed to improve the autonomy and self-determination of people with DS and by that to increase their quality of life. It will not be developed to replace personal contact.

Developing assistive technologies for people with some kind of cognitive disabilities requires to determine the views, opinions and needs of those people (Gilbert, 2004). It is in general unanimously agreed that the wellbeing of the participants (in interviews, field trials or focus groups) and of their carers is of greatest importance to the project partners' interests.

The development of assistive technologies is not legitimate without regarding ethical questions (e.g. Manzeschke, 2013; Rauhala & Topo, 2003; Raskind & Higgins, 1995). According to these ethical issues, three dimensions seem to be important:

1) Person, including the areas with need for support and targeted aid given
2) Technology, including requirements for a successful and safe use
3) Research, including modalities for involving people with special needs.

Please note that the deliverable is not a literature review, as there are other literature reviews available (e.g. Jones, Hara & Augusto, 2014) written by members of the consortium.

POSEIDON was developed and evaluated in accordance with the regulations of the Charter of Fundamental Rights of the European Union (ECFR)[2] and the Convention on the Rights of People with Disabilities (CRPD)[3].

2 Person-related

Referring to Ikonen, Kaasinen and Niemelä (2009) a technology should have a benefit to the society by increasing the quality of life. POSEIDON as an assistive technology addresses this issue by increasing the autonomy and social participation of people with DS.

2.1 Self-determination

Autonomy means self-dependence, self-determination and independence in daily life. Due to their cognitive impairments people with DS usually experience a big extent of dependency on significant others, like relatives, teachers or general caregivers. Although the range of abilities among people with DS is big, almost everyone needs more or less help in everyday life.

POSEIDON addresses different ways of supporting the autonomy of the target group in giving back some freedom of decision-making.

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[1] In the following text we use DS instead of Down’s syndrome. This is purely done for ease of reading and does not constitute a discrimination.

[2] http://www.europarl.europa.eu/charter/pdf/text_en.pdf

[3] http://www.un.org/disabilities/convention/conventionfull.shtml

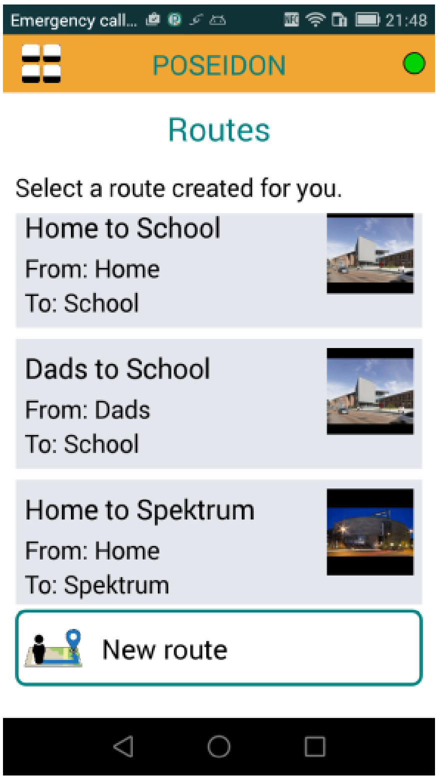
2.1.1 Mobility

One big issue for people with DS is that most of them need help to get from A to B at least for travelling routes for the first time. Difficulties occur, for instance in finding correct routes or the way on maps, but also in tackling changing plans for familiar routes, e.g. if a train is coming later or if the route needs to be changed. This can lead to some insecurity for the person itself, but also for the carer, who might be afraid that this person gets lost.

It was explored if POSEIDON can effectively address this insecurity by giving access to context-related information. In the navigation part of the POSEIDON app photos are inserted and written and recorded messages with reminders, suggestions and warnings which can be attached to specific segments of the travel plan. The system based on GPS knows where the user is and can high this information. This holds an option for carers to track the user's position. Tracking a position could lead to specific help given by the carer, if the user has problems finding his/her way. In the end, it also supports a safe travel, as the person can be found almost anywhere using GPS, even if he/she got lost and is not able to say, where he/she is. Overall POSEIDON was developed to take away some of the carers insecurity and helps to encourage a user to find his own way.

Supporting the mobility does not only affect the autonomy, it also has an impact on the social participation (see 1.2 social participation).

The screenshots display the current status of the development of the POSEIDON app and one of the main functions: the navigation. The navigation aims to increase the mobility of people with Down's syndrome and to help them travel safely.



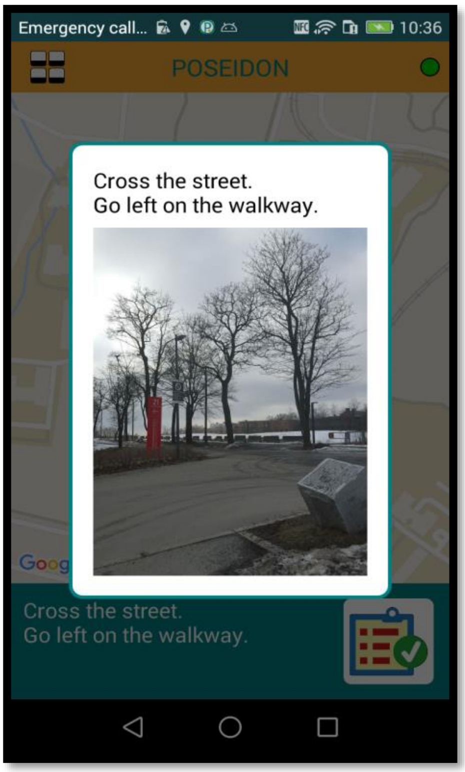
Routes

Select a route created for you.

Home to School
From: Home
To: School

Dads to School
From: Dads
To: School

Home to Spektrum
From: Home
To: Spektrum



Cross the street.
Go left on the walkway.

Cross the street.
Go left on the walkway.

Routes for the navigation can be created in the Route Creator app. It is a carer application for the secondary users. Routes can be created by walking, taking photos and entering instructions. The app has different functionalities:

- Log in with username & password.
- List and edit existing routes.
- Create new routes.
- Route editing on map, showing route with decision points and current position.
- Add decision point on current position or clicking on map.
- Move, insert and delete points.
- Write instruction or record voice information for decision point.
- Set photo for decision point from camera or files.

Select an existing route, or create a new one.

To School
From: Home
To: School

Home
From: School
To: Home

From: School
To: Home

Go to the other side of

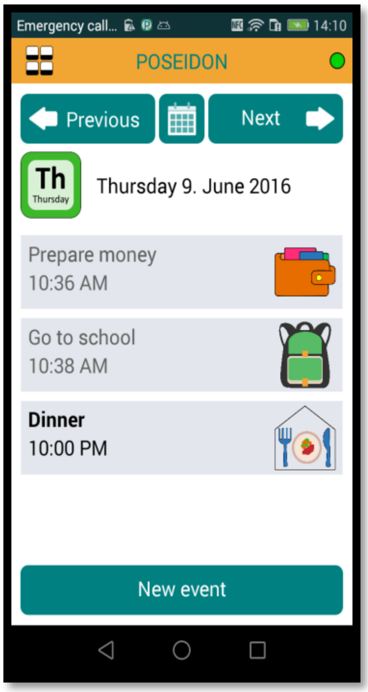
When selecting Routes from the main menu in the POSEIDON app, a list of planned routes transferred from the Route Creator app appears. A planned route has a specific start and end point and can only be used when starting from the planned location. When selecting one of these planned routes, the navigation starts. When selecting a new route, all destinations chosen for the user will be listed. Below the map there is a field with written instructions. The arrow indicates the direction.

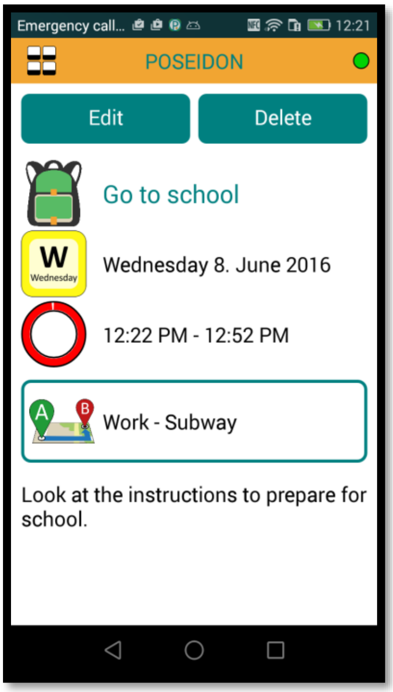
Routes can be trained with the help of the Home Navigation system on a PC, a program to be downloaded on a PC. It provides several functionalities for training for the person with DS. The person with DS can train by going through the different steps in the route where there are pictures and written and oral instruction at decision points and playing a kind of a game where more than one picture is shown at each decision point and the correct picture should be selected. The third option is to select the correct direction to walk at decision points. It is possible to move 360 degrees around in Google Street View. The carer can configure an address book with the addresses to be used for routes. These routes are again described by a start and an end address. The carer can customize the steps of a journey by adding photos and/or text. The user can rehearse a route made by the carer and consolidate knowledge about it at home.

2.1.2 Structure and support in daily life

Many people with DS struggle with time orientation and need help to remember tasks, event and or appointments. POSEIDON provides a technical solution, which includes a task/event overview and reminders before tasks/events as well as instructions, e.g. on how to perform specific tasks or what to remember to bring to appointments. By that the technology gives a chance to complete tasks and prepare for appointments independently without the need for personal assistance.

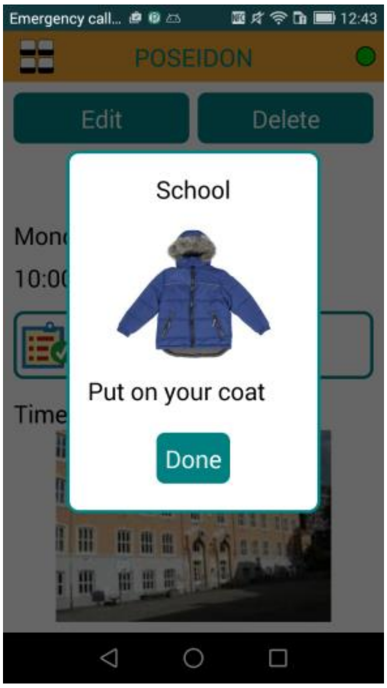
The screenshots display the current status of the development of the POSEIDON app and one of the main functions: the calendar.





Look at the instructions to prepare for school.

The calendar gives an overview of the events on the current day with title and time. Previous and Next can be used to see the events of other days. Passed events are displayed with less contrast, the current event is highlighted. The time left until the start of an event is indicated with a colored bar for the last half hour before the start. An event can be pressed to see any description entered for the event. Images and an instruction list can be added to an event. Each instruction is a short text and may also have an image and/or voice message or a planned route for navigation. It is also possible to have a link to a YouTube video or a small video uploaded to an event. When an event is upcoming, the user is given a notification with the event details and how long it is until the event starts. A notification appears in the notification bar of the phone if the application is currently not open. A full reminder is shown in the application when it is opened. The notification gives a sound and vibrates until the app is displayed. A weather based message to remind the user to wear appropriate clothes comes up if the event or task is a travel for which a travel route is made.



School

Put on your coat

These functions encourage the user to structure daily life more easily. If possible, the user can add and delete appointments on his or her own in the calendar app. If the person with DS cannot enter appointments himself/herself or if images, videos, voice messages or routes should be inserted into events an appointment can be added via the Poseidon web.

2.2 Social Participation

As it is the aim of other assistive technologies not merely to replace but to facilitate inter-personal contacts (Schülke, Plischke & Kohls, 2010), POSEIDON will be developed to foster the inclusion of people with DS. DS is a well-studied condition which affects a substantial number of European citizens directly (one of 700-800 newborns having this condition; Schaner-Wolles, 2000), or indirectly (their family, carers, teachers, etc.). Although being such a well-known condition by science, it is still surrounded by negative preconceptions which make inclusion of these citizens harder.

2.2.1 Friendships and leisure time activities

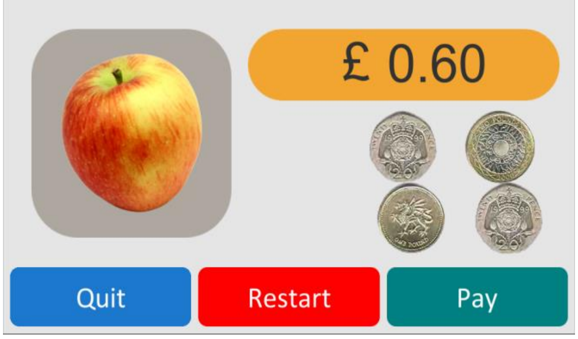
Giving the opportunity to travel independently from one location to another can have an impact on the opportunity to build up and maintain friendships outside school or work. The dependency on parents, other relatives or carers with regard to the need for help to visit somebody affects friendships and also the possibility to attend general leisure time activities. It seems to be difficult for people with DS to extend friendships from one setting (e.g. school) to another (leisure), if these friends are located in another area, unless they are helped to visit friends or go to the same leisure activities. It is more difficult to participate in popular leisure time activities, if the opportunity to get there is not given by family members.

Providing support for independent travelling POSEIDON could help to overcome this gap and can contribute to the possibility to visit friends and to go to leisure time activities, cinemas etc. for people with DS.

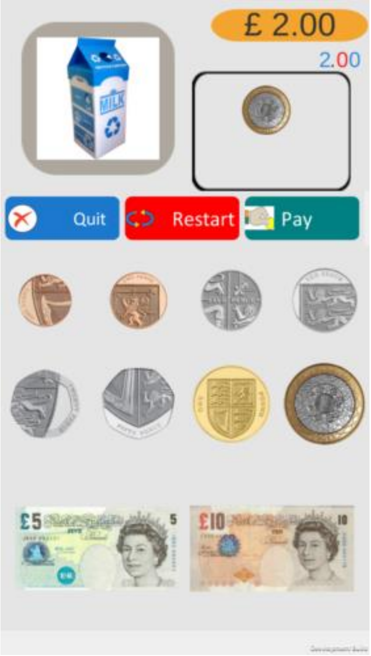
2.2.2 Education

POSEIDON also helps to deal with educational requirements. As already mentioned it was developed to help travelling more independently, e.g. to school. By using the calendar POSEIDON can support that homework is done by entering details for the homework as calendar appointments. The calendar can also help to organize specific elements of the day (transport, prepare for school, like bringing everything needed like equipment for physical exercise lessons, food and drinks (if not provided at school), pencil case with content, giving information about which classroom to use for different lessons, etc.).

POSEIDON tried to enhance the competencies of persons with DS regarding money handling with the help of an interactive table/CapTap and a Money Handling Game. The screenshot to the left shows the overlay for the Money Handling application to be used on interactive table. Real money could be used in connection with the training on the interactive board. The products which needed to be payed are displayed on a PC as shown to the right.



After pilot 1, the Money Handling Game was no longer played via the interactive table, but a Money Handling Training app was constructed to play the game via smartphones. This Money Handling Training app was integrated into the POSEIDON app. In pilot 2 only the app, not the interactive table was tested.



Moreover, a shopping assistance function was created after pilot1 and integrated into the POSEIDON app. Carers can create shopping lists with images of products and add prices in the POSEIDON web. When a shopping list is created in the web, options about creating calendar reminders that will remind the user to bring the exact amount needed or an extra amount of money for the shopping trip, appear. The user uses the shopping assistance part of the POSEIDON app in the shop to find the right products. The app also contains a virtual wallet with the money needed to buy the products. When the user ticks the products from the shopping list he/she has found the total price is calculated and displayed. When the user presses "Pay" in the app, the amount of money in the virtual wallet decreases and the app suggests which coins and notes he/she should use to pay.

With the help of the Money Handling Game and the Shopping Assistance part of the app the user can learn the value of different products, how to pay the right amount of money and to find the correct items to buy. It also helps to Learn the value of coins and bills in daily life.

2.2.3 Work

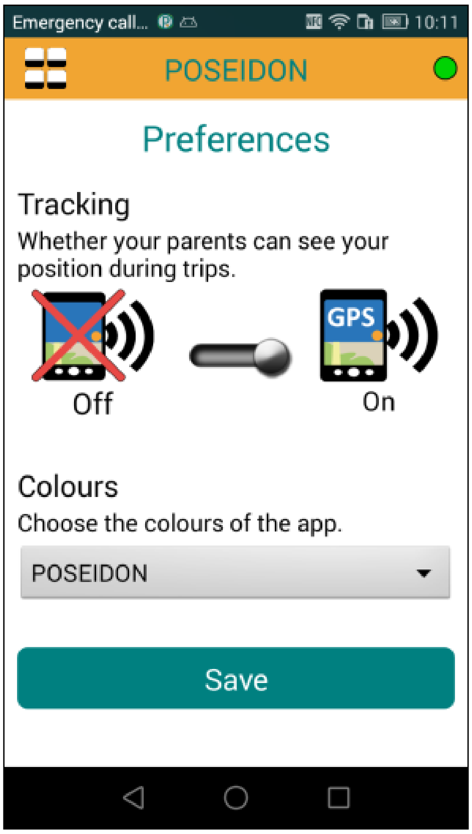
POSEIDON not only tries to support the capabilities, but also to raise awareness about the competencies of people with DS. For instance, the project webpage (http://www.poseidon-project.org/) highlights several biographies of people with DS from all over the world who achieved maybe more than anyone ever would have expected. It is important to emphasize, that the provided pictures and stories don't represent a deficit-oriented perspective, but rather want to underline the strengths of people with DS. It is intended to take away the attention on the deficits and point out the abilities instead. Underestimation of people with learning disabilities like DS has also an impact on their working opportunities. POSEIDON wants to raise the awareness for the abilities people with DS have. That means that POSEIDON might increase their chances of employment indirectly.

Apart from underlining the great spectrum of skills and competencies people with DS have, POSEIDON can directly support the independency and autonomy in daily life and facilitates managing daily and work tasks by providing functions like the calendar and the shopping assistance. Both this and the support from POSEIDON for travelling to work can support managing a work situation. As mentioned by Wehmeyer et al. (2006) employment of people with intellectual disabilities can benefit from technology use.

2.3 Safety and security

POSEIDON was developed to support the feeling of safety and security, both for carers and users. Furthermore, by giving the opportunity to track the user's position outside home, carers will always be informed where this person is when the navigation app is used and the primary user has allowed tracking. This is important, if he/she might get lost and needs guidance on how to get back home or even needs to be located to be picked up. People with DS must consent to this, when this kind of surveillance is done in other than private settings (e.g. by a health or care service) if they have consent competence; if not their legal guardian must consent. In Norway special conditions apply for the use of tracking technology for persons with intellectual disabilities by public health and care services or other service providers or helpers who are not within the family. A coercion decision has to be made for the use of tracking technology giving continuous information to others about the position. Other measures should have been tried before a coercion decision is made. Tracking the position should be in the interest of the user. The person in charge of the service providers should make this decision, but it should be granted by the County Governor before action is taken (that is: tracking is started). It is necessary that the user has a legal guardian, and both the user, the family and the legal guardian should get information about what is planned and have the opportunity to comments upon this. Also the specialist health service should be involved.

The screenshot shows the screen in the POSEIDON app where primary users can change their preferences. Here persons with DS have the opportunity to switch on and off the tracking function of the POSEIDON app on their own. There is no option for carers to change this setting on the POSEIDON website, which means the user won't be tracked without the tracking function being switched on in the app.



Preferences

Tracking

Whether your parents can see your position during trips.

Colours

Choose the colours of the app.

POSEIDON

As safety is very important for disabled people good interfaces should provide a quick and reliable communication channel in order to call someone for help (Abascal & Nicolle, 2005).

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In pilot 1, if the user deviated far from the route, this would be detected and three choices would be given: A new route could be produced automatically from the current position to the original destination, the carer could be called if his/her telephone number had been entered on the POSEIDON web or the navigation could be ended. In pilot 2, the user received a message if he/she wants to call the carer if he/she deviates far from the route. Currently some work remains before it works stable on the current POSEIDON system.

This features helps the user to tackle difficult situations, where insecurity or the feeling of being unsafe might occur I This feature helped the user to tackle a difficult situation, where insecurity or the feeling of being unsafe might occur.

3 Technology-related

Assistive technology in general aims to help in daily life, to give support and make some aspects of life a bit easier. From the ethical point of view the technology must provide a useful, reliable, safe, easy to use and non-stigmatizing solution.

3.1 Usability and design

3.1.1 Ease of use and usefulness

As assistive technology aims to be a support in daily life and not a challenge, it is necessary to keep it easy to use. Particularly when it is made for people with special needs a simple to operate user interface must be provided. Therefore, people with DS as possible users are involved into the developmental process and as proposed by Jones et al. (2014) their wishes, ambitions and values are taken into account.

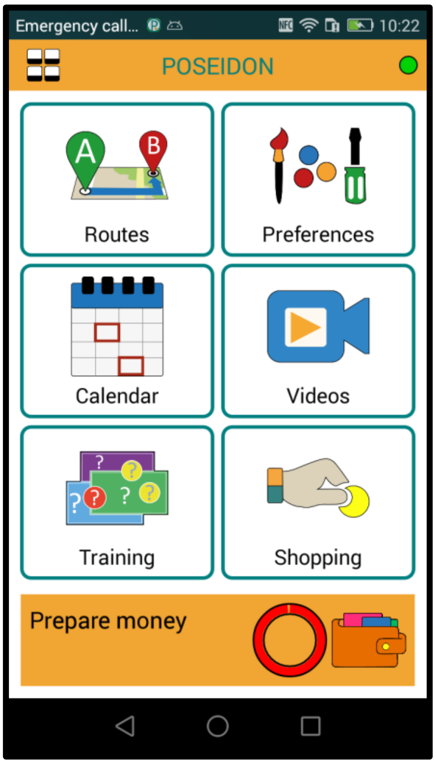
People with DS is a very special target group. They are easily getting frustrated (see pilot 1 and 2), so POSEIDON needs to motivate to use it and to avoid end-user frustration, which can be caused by difficulties in operations. It must allow and compensate errors, when it is used, so it needs to be an intelligent and stable system.

POSEIDON is adjustable to individual preferences and backgrounds (e.g. regarding the language and colors on background and letters) to ensure, that it is easy to use. The correct language is set at the POSEIDON webpage, and the choice for colors on letters and background in the app itself.

The calendar option contains many ways of helping persons with DS. In addition to written text, it is possible to use pictures, videos/link to YouTube videos, instructions (with voice records, text and images), all this entered by the SU. In addition, links to navigation routes and shopping lists can be used. Images and videos of familiar things are considered very important for persons with DS. In the project a lot of signs were developed to insert into calendar appointments for persons with DS who cannot read. Persons with DS will benefit from the use of pictures of actual items they should buy in the shop in the Money Handling Game and the Shopping List. Also for the navigation training and the navigation itself the use of real pictures from the routes and individual message at decision points made the SUs (both written and oral) can ease the use.

3.1.2 Design and joy of use

To support the wish for using POSEIDON it should have an attractive user interface. The screenshot below shows the last version of the POSEIDON app (start screen). As can be seen it provides the right balance of necessary information/features and a simple interface. There are only six options displayed on the start screen: Routes, Preferences, Calendar, Videos, Training (Money handling) and Shopping. This ensures that the user is not overwhelmed by too much information and that he or she can easily navigate through the menu. In addition, the main menu is easy to understand as the six main options are arranged in a squares. Furthermore, all six options are not only displayed with the help of text but also with an icon which helps the user to better understand what is written or even helps users who cannot read.



POSEIDON should not cause the feeling of being stigmatized and must not influence the felt dignity of the person using it in a negative way. POSEIDON gives support when help is needed. Technology must not bother people when they are able to deal with problems on their own. In addition to being useful the POSEIDON app should be appealing and make the user proud to use it. Most of the POSEIDON functions are developed so that they can be used on ordinary smartphones and tablets.

For more information about the design principles have a look at deliverable 2.3 Designing technology for people with DS.

3.2 Reliability

Tackling changes of any kind is difficult for people with DS, so POSEIDON must give a reliable and stable guidance in daily life.

“At a basic level, the protection of people starts with the safety and reliability of the equipment.” (Hoof, Kort, Markopoulos, & Soede, 2007, p. 158) It must be avoided that the system crashes when it is used. That particularly applies to the use outside home.

To ensure the reliability of all POSEIDON systems two four weeks’ pilot studies were conducted in the UK and Germany and Norway. In total, 18 families (two times three in each country) have tested the POSEIDON systems with regards to usefulness, usability, etc. During these testing weeks, the users were observed by researchers and developers. The aim was to collect as much meaningful data as possible. This included identifying bugs as well as usability problems. After analyzing the data, the information was used to improve the systems and the apps to ensure a reasonably reliable and stable product provided at the end of the project.

3.3 Transparency

POSEIDON is developed to support people with DS in their everyday life. It is essential for potential users to know how a technical device can affect their life in a positive as well as in a negative way (Jones et al., 2014). For that reason, all functions and known weaknesses, for example system operations, data collection, surveillance activities and limitations provided by POSEIDON was explained to the users as best as possible. During the project insights of how persons with DS and their parents used the web and the apps, what they think about the different parts of the POSEIDON system and how the functionality affect the users with DS was gained. This knowledge provided basic information for further periods of the project or for coming to the market. This knowledge will be published to foster the ethical discourse.

3.4 Privacy

When it comes to the market, POSEIDON needs to collect a lot of data to provide appropriate options and tools for different situations (e.g. tracking the position). On the other hand, it should just concentrate on relevant information, which is collected and stored. It must be guaranteed, that no third party has access to the collected data.

There were five main areas, which needed to be considered regarding data protection in connection with the pilots:

1) Consent: Informed consent must be given, before any data is collected.
2) Collection: Just necessary data shall be collected, avoid collecting any data just because one is able to do.
3) Storage: Just necessary data should be stored; this should be done timely limited. Data should be deleted, 12 month after the project is completed.
4) Transparency: It should be obvious at any time, which data are collected, used and stored.
5) Security: Data transfers should be made in safe technical environment. No third parties should get access to these data.

When conducting the two pilots in Germany, Norway and the UK, these five privacy issues regarding data collection had to be considered on beforehand. This means primary and secondary users had to give informed consent to take part. Furthermore, it was agreed to only collect data which is meaningful and which will be used at the end of the pilot to improve the POSEIDON systems. Participants were explained which data are collected when. Data is stored timey limited. Information will be kept for 12 months after the project officially ended as the period of reporting extends beyond the end date of the project. After this date individual identification and contact details will be destroyed in a permanent way by each of the data holders. It was ensured that no third parties should get access to the data collected.

3.5 Safety and autonomy

Technology can never be a substitute for real social contacts, especially regarding the safety of a person. Therefore, it should be possible to check technical information about the system from anywhere. This enables a carer to give personal help, if the system is – for any reason – not able to do so. POSEIDON aims to make communicating for people with DS more simple instead of being a substitute for communication. Furthermore, it tries to make the organization of daily life easier. This might increase the quality time with relatives and carers.

Using technology autonomously is a key requirement for any system (Jones et al., 2014). It includes the opportunity to turn off the system if one feels bothered by it (Jones et al., 2014). This requires good knowledge about the technology and how to control it. The user needs to be in control of the system, needs to understand it's (re)actions, feedback and provided opportunities.

3.6 Multiple user groups

The challenge which arises when different users share the same technology has to be considered. As a result, the need to identify the preferences and requirements of *multiple user groups* and stakeholders in any number of different settings has to be prioritized (Jones et al., 2014). These requirements may compete with one another, and may need to be accommodated and balanced by prioritising the preferences and needs of some stakeholders over others. It was will be carefully considered who these stakeholders are (primary/secondary/tertiary users) and how ethical issues might be affected by multi-user environments where the requirements of each user may be different and may change dynamically (Jones et al., 2014). We agreed that under consent age decision-making is on the Secondary User, after that it depends on the capability of the individual. We implemented mechanisms which allow to switch decision-making on whether the Secondary User should know where the person with DS is at a given moment.

4 Project- and research-related

Especially during the process of experimentation and validation of a new technology ethical aspects have to be considered (Ezeiza, Garay, Lopez-de-Ipiña, & Aitzbier, 2008): Although the POSEIDON-project does not include medical or health-related research, but research on assistive technology development the consortium is well aware of ethical issues, which arise when persons with cognitive impairments are part of a research project.

If one wants to develop technology which meets user's needs and abilities, it is a common technique to involve possible end users into the developmental process. As our target group is a very vulnerable user group, several ethical principles were drawn up and will implemented within the project. The main aim was, as mentioned by Schülke et al. (2010) to realize a meaningful balance between privacy, security and safety and thereby to enhance the autonomy and self-determination of people with DS.

4.1 Procedure of pilot tests

Two pilot studies were conducted to gather detailed feedback of the system. For that POSEIDON was given to the families at two different stages of evolution.

Each pilot involved testing nine families at the same time for an uninterrupted period of a month (three families in each country). The primary users were schoolboys/schoolgirls or and younger adults in sheltered workplaces or in labour- and activity centers. There were pre-pilot studies conducted by the development teams as part of their formal software development process (testing and validation) for the applications developed early enough before the pilot to do undergo such testing

Pilot 1 was an initial basic collection of services. It included some context awareness services and some of the interface functionalities. POSEIDON was improved according to user feedback gained from pilot 1.

Pilot 2 was the final collection of confirmed and consolidated services. It also incorporated more ambitious services than in Pilot 1, that secondary users and the project team felt were needed and which were considered as feasible by the technical team. However, suggestions for new additions will be valuable to encourage a growing developing market in this area by the commercial partners of the project and also by independent external partners who are interested in this project.

There are different approaches of how data were collected:

1. Statistics of use and preference were collected through logs embedded in the technology (what inclusive services are used, in which contexts, when, how often, for how long, etc.). Usage of the mobile app was logged in SmartTracker, and Tellu provided these logs at the end of the pilot.

2. Feedback was collected from the secondary users through questionnaires and dairy sheets/user protocols during the pilots from both the primary and secondary users by interviews.

3. Video recordings and/or voice recordings were done when allowed by the users and considered useful for collecting data about the use of the different applications during monitoring visits under the pilots. Observation sheets completed by the monitors were written during the use of the different applications during visits by the monitors. For some applications, also smiley faces (from sad to happy) appeared and should be ticked by the primary user each time the application was used during the first pilot. For this pilot, also the so-called “again-again” table was used where the primary users should indicate if they would like to use the application again.

POSEIDON was improved according to user feedback gained from pilot 1 and 2.

4.1.1 Participation and informed consent

According to Perry, Beyer and Holm (2008) the issue of consent is one of the most challenging ethical questions in the case of people with intellectual disabilities. It is likely that some of them have consent competency and others not (Fisher, 2003). This raises the question how can be guaranteed that a person really wants to participate (Stalker, 1998) This means that appropriate information for the different competencies of users had to be created. Information about how the research should be conducted, possible outcomes, how personal information would be kept and the person’s rights (Dalton & McVilly, 2004) was also provided. All project members will respect the person’s right to self-determination especially with regard to initial decision to participate (Magnusson & Hanson, 2003). It was also reassured to all participants that there would be no adverse consequences if they declined to participate or later withdrew (Dalton & McVilly, 2004). Specific information sheets and consent forms in easy-to-understand-language were provided to all people with DS. A lot of illustrations were used to explain what was meant.

Informed consent was also obtained from the secondary users. Trials and user group workshops involved different users for each technology set being examined and as a consequence more than one set of information sheets and consent forms were required.

4.1.2 Autonomy, well-being and dignity in participation

Every participant (person with DS and carer) could quit the participation in the project any time without giving a reason.

All appointments for monitoring visits in the pilots were at a date and time most suitable for the participants, not for the monitor and/or developer visiting. It took place in the home of the person with DS so that he/she did not need to leave and could feel as comfortable as possible in a well-known friendly environment. If it was not possible to conduct interviews or observations in people's homes (e.g. when there were workshops abroad, where people with DS and their relatives were invited), the project consortium ensured an appropriate and not-overwhelming environment and gave the opportunity to leave the situation at any time. In addition, the consortium aimed to provide an atmosphere, in which the persons with DS could feel comfortable, valuable and honored. The main focus in research activities was on the persons and their well-being, not on collecting data.

The research instruments, which were chosen for the different parts of the project were in line with the specific abilities and requirements of the person, who was asked for information. All instruments were discussed and developed together with the National Down Syndrome associations in the consortium to ensure an appropriate approach.

All the interviewers tried to respect the participant's needs, to keep the participant's dignity as well as to avoid confusion, frustration or harm. The principle was that if it became obvious that the participant was stressed or frustrated by his/her participation, the researcher should - after consultation with the participant and their parents/relatives/caregivers -stop the participation. In the pilots and the workshops this did not happen. However, the researchers ensured that after all interviews and observations the participants were left with a feeling of success and were thanked for their contribution.

Attention was paid to the need to fully support the project participants to enable them to fully communicate their needs and to ensure that the project was carried out with as little intrusion as possible to minimize possible stress. The project team ensured that they had the full support of the participants and their carers at all times.

To ensure autonomy, well-being and dignity in participation all these points were considered by the researchers and the developers during our first pilot. To support our participants as best as possible a first line and a second line support was established and offered during both pilots. This ensured that participants knew who to call if something went wrong or they experienced problems and didn’t know how to deal with them.

4.1.3 Involving children

Our project is aimed at the part of the population which has more potential for independence. It aimed at teenagers and young adults, who are generally more active (in connection with education, work, exercise and socialization) and at the same time more technologically prepared and interested in than children and older adults. There are other issues like safety and health around very young or elderly people. Hence we carefully selected young users for the pilot within reasonable limits of safety in connection with the families and the social services related to the family. We selected families for the pilots where the users had quite a high level of technology knowledge and the persons with DS were living with their families (except for one use in the UK in the first pilot).

4.1.4 Privacy

Since privacy is the ethical issue of greatest concern (Jones et. al, 2014), our aim was to ensure that no one’s privacy is violated neither by participating during the project nor by future usage of POSEIDON. There are different steps within the project, where information was gathered. This was done in an online survey, in interviews with persons with DS, in group discussions in workshops and in pilot-tests.

Information gathered by the online-survey was given anonymously, the form was completed at the internet by clicking a link. The project team didn't not know who completed the questionnaire, as it also did not include any question where conclusions could be drawn about specific persons. IP-addresses were not linked to answered questionnaires.

All other steps included personal contact, so this could be done anonymously. After confirmation to take part, the personal data (name, address, contact information) and identifiable person data was stored safely and the participant got a number. Therefore, no conclusions could be drawn concerning individual persons, for example when the participant completed questionnaires. Both kinds of information (a: identifiable personal data, b: information that was given in interviews and questionnaires and from observations) were stored separately. Just a limited and authorized circle of people got access to them. It was transparent for the users what kind of data was stored and for what purpose and how data was used and stored.

The participation of primary users less than 18 years of age also required parent consent.

For the use of POSEIDON, it was essential to collect and analyze data coming from different persons. It was assured that only relevant data was recorded and that the data was used appropriately. We also asked for permission to use voice recording and photos/video recordings of persons with DS and their carers for being able to see all details about what was happening when they used the POSEIDON applications. However, consent to this was not required to participate in the pilots. When photos were planned to be distributes so that they could be seen by third parties, we asked for permission to use them.

4.1.5 Reliability

As user trust and confidence were necessary aspects of successfully interacting with a technical device, the functional capability of the technology (both Hardware and Software) was tested several times before starting the trials, so that the participants can use a reliable and stable version of the system at any stage. Furthermore, the user should completely understand to what extent he/she can rely on POSEIDON (Ikonen et al., 2009). There was a technical support in every country, which could be called and solved problems as fast as possible. If technical problems were experienced, the technical team ensured that the participants were aware that it is the fault of the project not theirs.

4.2 Equality of access

As proposed by Jones et al. (2014) aspects of equality were considered. POSEIDON designed simple enough so that it can be used by the widest possible range of users. For this reason, "different potential levels of cognition, competence and cognitive ability of primary users" (Jones et al., 2014) were considered. Regarding these individual differences, users were able to personally customize POSEIDON with regards to language used and if they should be tracked or not when using the navigation part of the app. There are many options for making different functionalities within POSEIDON user friendly for each user with all the photos, voice recording, prizes of items etc. inserted by the seconday user. This makes more equality of access for users with different capabilites than without.

If it comes to the market, there is a need for different marketing strategies (for example leasing or paying a monthly amount instead of paying the whole amount at one time) to avoid the financial exclusion of those who do not have much money but would definitely benefit from using the system. This approach follows the principle of equality which prohibits irrelevant differentiation and realizes a fair access to POSEIDON (Schülke et al., 2010)

For the research period, all technological equipment which was needed for testing and piloting was provided by the consortium to avoid excluding persons, who did not own their own technology devices.

4.3 Advisory committee: Experts on ethics, data protection and target group

Ethics advisor:	Dr. Juan Carlos Augusto (Middlesex University, United Kingdom)
Research-related data advisor:	Dr. Eva Schulze (Berlin Institute for Social Research, Germany)
Country specific data advisor:	Christine Schniersmeier (Arbeitskreis Down-Syndrom e.V., Germany) Lars Erik Brustad (Norwegian Network for Downs Syndrome, Norway) Vanda Ridley (Downs Syndrome Association, United Kingdom)
Technology-related data advisor:	Lars Thomas Boye (Tellu AS, Norway)
Experts on target groups:	Arbeitskreis Down-Syndrom e.V. (Germany) Norwegian Network for Downs Syndrome (Norway) Downs Syndrome Association (United Kingdom)

4.4 State-level ethical issues

4.4.1 Germany

The German work in connection with user involvement in surveys, field trials or workshops followed accepted international ethical practice.

High standards related to data protection issues and human ethics are based on the suggestions of the German Research Society.

The project was reported by the Berlin Institute for Social Research to the National Data Protection Agency in Berlin (Dr. Alexander Dix). All requirements for data protection, user involvement and dignity issues followed in regard to every person being part of the evaluation.

The relationship between researcher and participant was based on the ethical codex of the German Society of Nursing Sciences. This codex includes basic issues, e.g. the necessity of a research project, information about the aim of the project, possible exit strategies, prevention of stress and harm, which followed with respect to the participant's rights and meant to maintain a good mental and physical health of these volunteers. Participants with reduced consent competence were only involved, if he/she agreed to participation and in addition to a parent agreed.

4.4.2 Norway

The work in Norway in connection with testing followed accepted international ethical practice. For primary test users with reduced consent competence the guidelines from 2005 made by The Norwegian National Research Ethics Committee for Medicine and Health (NEM) for persons with reduced consent competence was used. In addition to international ethical guidelines and practice the Norwegian Guidelines for Natural Science and Technology were followed as good as possible;

(http://www.etikkom.no/Forskningsetikk/Etiske-retningslinjer/Naturvitenskap-og-teknologi/). These guidelines are supplemental to existing international ethical research guidelines.

The project was reported by Karde to the Norwegian Data Protection Agency. International and Norwegian requirements for data protection and confidentiality were followed both for persons with DS and secondary users and collection and storing of data. The Personal Data Act for Norway required that the controller ensures satisfactory information security with regard to confidentiality, integrity and treatment of information: http://www.ub.uio.no/ujur/ulovdata/lov-20000414-031-eng.pdf. The project team leader Terje Grimstad in Karde AS was the controller of the data for Norway.

This project is mainly a technological project. There was no treatment of medical nature. The primary test persons with DS have a medical diagnosis of intellectual disability. One of the criteria for this diagnosis is problems with adaptive skills in functions/abilities of daily life. In the project, we tried to help persons with DS in mastering certain aspects of daily life. A request weather the project team should send a notification/submission or not was sent to the appropriate Norwegian regional committee for medical research ethics. If the committee should be of the opinion that a full evaluation was required, the appropriate information would be submitted for review and guidelines for medical research ethics should be followed. The committee found that the project was not health research, so no submission was required.

Karde has conducted several projects involving persons with reduced cognitive functions. These projects have primarily involved elderly persons with intellectual disabilities and memory problems/dementia. In connection with these projects Karde has gained considerable experience in communicating with persons with intellectual disabilities, their next of kind and helpers. Karde also has great experience creating easily understandable information sheets and consent forms for test of persons with intellectual disabilities. They used this experience to ensure that test persons understood the meaning and principles of the study and that they were as comfortable as possible with the information given before participating.

The involvement of The Norwegian Network for Down Syndrome in planning, making Norwegian information sheets and testing, further ensured the use of good methods.

4.4.3 United Kingdom

The work in the United Kingdom followed accepted ethical practice with respect to the work with the volunteers with disabilities and their carers and also with respect to the collection and storing of data on the participants.

Approval for the research was sought from the Middlesex University Ethics Committee and followed the Middlesex Code of Practice for Research (http://www.mdx.ac.uk/Assets/Code%20of%20Practice%20for%20Res-July2011.pdf).

The research made use of the existing best practice with respect to the participants' rights (http://www.eis.mdx.ac.uk/research/groups/Alert/Ethics_Research/forms.html).

The Middlesex Guidelines closely followed the code of the British Psychological Society (http://www.bps.org.uk/sites/default/files/documents/code_of_human_research_ethics.pdf) and are most suitable for the non-invasive research to be carried out on this project.

1 Middlesex University has a record of carrying out participative research with people with disabilities and other vulnerable people. They used the knowledge from this work to ensure that

all the volunteers are enabled to participate only if they want to and that the research is an enabling enjoyable experience for all who take part.

Particular attention was paid to the need to communicate with the volunteers in a suitable way and to ensure that the tests do not put any volunteer under undue stress. Middlesex University had through its work in the EDeAN: European Design for all eAccessibility Network links to the National Disability Authority of Ireland, we therefore followed their Ethical Guidance for Research with People with Disabilities (http://www.nda.ie/cntmgmtnew.nsf/0/D6EFA30A02A47B14802570660054EC16?OpenDocument), particular attention will be paid to the advice on working with people with intellectual disabilities.

The attention that Middlesex University payed to the need to work with people with disabilities in an ethical way can be seen by the talk given at Middlesex, 'The Practical Application of Ethical Guidelines for Participative Research' Workshop held at Middlesex University, London, UK on Monday 23rd January 2006, (http://www.humanity.org.uk/articles/politics-culture/ideologyprofessionalism-research-disabled). We followed the ideas presented in this research and acted in a professional and supportive way with all the project staff and volunteers.

5 Framework

Deliverable D2.4 Safety, Privacy and Ethical Considerations is a document compiling all safety, privacy and ethical main considerations that were followed during the project. The document has an emphasis on:

- Person, including the areas with need for support and targeted aid given
- Technology, including requirements for a successful and safe use
- Research, including modalities for involving people with special needs.

We have created a framework to guide development of technology in this area with ethical considerations embedded in the development process. The framework is based on the eFRIEND ethical framework, which was created for Intelligent Environments in general.

> Jones, Simon and Hara, Sukhvinder and Augusto, Juan Carlos (2014) *eFRIEND: an ethical framework for intelligent environments development*. **Ethics and Information Technology**, 17 (1). pp. 11-27. ISSN 1388-1957. Springer Verlag.

The considerations are mapped to requirements to the POSEIDON-system:

- 7 Framework requirements,
- 20 Functional requirements,
- 10 Non-functional requirements,
- 4 Hardware constraints
- 6 Design constraints

These principles are given by the Intelligent Environments Manifesto proposed by Augusto et al (2013a) that advocates the development of systems in a manner that is aligned with a number of explicitly defined user-centered principles:

- P3—deliver help according to the needs and preferences of those who are being helped
- P5—preserve the privacy of the user/s
- P6—prioritize safety of the user/s at all times

- P9—adhere to the strict principle that the user is in command and the computer obeys

  Augusto, J.C., Callaghan, V., Kameas, A., Cook, D., Satoh, I. (2013) *Intelligent Environments: a manifesto*. **HumanCentric Computing and Information Sciences**, 3:12, Springer. DOI: 10.1186/2192-1962-3-12 URL: http://www.hcisjournal.com/content/3/1/12

General principle 1: Non-Maleficence and Beneficence

- *The system should avoid causing harm to any of the users.*
- *The system should proactively seek for opportunities to assist users.*
- *The system should actively benefit users by enhancing their welfare and quality of life.*

POSEIDON aims to enhance the welfare and quality of life of its target users by enhancing their autonomy, independence and social inclusion. It incorporates measures to avoid any risk of harming the user.

The project has an Ethics Advisory Committee, comprised of experts on ethics, data protection and on the target users (representatives of Down Syndrome associations in the participating countries).

General principle 2: User-Centricity

- *Users should be placed at the centre of the development process.*
- *The type of technology and associated services should be agreed with users in advance.*
- *The system should be designed and implemented in accordance with users' wishes, ambitions and values.*
- *The systems should be customisable to dynamically evolving individual needs, preferences and requirements.*

The POSEIDON project aims to develop assistive technology in joint collaboration with primary users and their carers at every stage of the development process.

Primary and secondary users' wishes, values and needs are taken into account through detailed requirements gathering and analysis via surveys and face-to-face interviews with secondary and primary users in addition to questionnaires to secondary users in connection with the pilots.

From this information, a clear understanding has been gained of primary users' living situations and daily living competencies, levels of proficiency using existing technology, together with the range of physical, sensory and cognitive difficulties they experience, including areas such as motor skills, speech, writing and learning disabilities.

The POSEIDON system aims to address these challenges by providing context-specific help, information and intelligent assistance which is appropriate for different situations.

General principle 3: Multiple users

- *The system should be aware of the different needs and preferences of all individuals in a multi-user environment.*
- *The system should consider how to balance the competing rights, preferences and requirements of different users.*

POSEIDON is specifically designed for a multi-user environment and incorporates the needs and requirements of various stakeholders, including:

- primary users (people with Down´s Syndrome),

- secondary users (parents / carers) and
- tertiary users (for example, personal assistants, support workers, specialist teachers, and employers).

The project acknowledges that these requirements and preferences may need to be balanced and/or prioritized, and that they may change dynamically over time.

General principle 4: Privacy

- *Users can specify privacy levels and preferences for different services.*
- *Users decide on, and can change, levels of acceptable recording, monitoring and tracking of activities.*

The results of the requirements analysis confirm that privacy is of high importance to potential users of POSEIDON and must be guaranteed in usage outside the home. POSEIDON accordingly aims to ensure that no user's privacy is violated. Users have the ability to adjust whether the secondary user should be able to see their position when they are using the navigation functionality and to choose between different color settings. Data entered directly into the calendar in the app by the primary users are not seen in the calendar part of the POSEIDON website.

So, a general principle in our system is that when live, it should support the privacy of end-users, and provide optional user privacy settings to enable customization. Users also should be able to decide on, and vary, the level of privacy at a specific point in time.

General principle 5: Data protection

- *Users have access to the sensitive information stored about them and can decide what can be done with this information.*
- *Users can determine levels of information-sharing and disclosure.*
- *The system should seek informed consent to secondary uses of personal data by 3rd parties.*
- *The system should adhere to recognised principles and good practices of data protection.*

While the effective use of POSEIDON makes it necessary to collect and analyze personal data to provide appropriate tools for different situations. Data protection principles would be adhered to regarding informed consent for data collection, controlled access to secondary uses of personal data, and storage of (un)necessary data according to specified time limits.

Examples on how this can be materialized in our project are: safeguarding user data at the server-side with appropriate backup, providing optional user settings to customize data storage requirements, protecting users' information security, limiting context-related data storage period, and allowing users to decide the type of information stored in the devices used.

General principle 6: Safety and security

- *The system should protect users and their information.*
- *The reliability and stability of systems must be ensured.*
- *The security of data transfer must be ensured.*
- *Adequate security measures and standards, appropriate to different environments, must be provided.*

The use of a tablet device in a public setting by vulnerable users raises potential safety issues. Location and context awareness features help the user to tackle difficult situations where they feel insecure or unsafe. Interfaces should provide a quick and reliable communication channel in order to call someone for help. Location-tracking via GPS and emergency connectivity enable carers to know the current whereabouts of their protégés, their previous locations, and enable them to check that they had reached their destination safely. Primary users are able to contact the carer if they get lost or have problems finding their way and need help

Our system should support the safety of the end users, for examples by aiming to provide immediate access to phone call, keep track of user's position when travelling outdoors, and carers should have the possibility to request location of primary user and to contact the primary user.

Specific consideration on Reliability

Given that users may be dependent on the POSEIDON system outside the home, it must be robust, stable and reliable.

Hence it is expected that when live, framework components should have robustness and fault-tolerance comparable to non-vital commercial systems, that the system should be available 24/7, except for short periods of downtime for maintenance such as system upgrades, and reliable enough so that its services are working and available at least 95% of the time. When live, maintainability should be such that the time to get the system restored after major failure is less than one day and technical support should be available. The system is expected to provide comprehensive outdoors navigation services.

General principle 7: Autonomy

- *The system should support and enhance the independence and autonomy of its primary users.*
- *Users should have the freedom to override or "switch off" the system at any time if its performance is negatively perceived.*
- *Users should be trained to operate the system to the extent they wish.*
- *Users can determine for themselves degrees of protection, privacy and information-sharing.*

The survey and interview data suggested a strong wish from the majority of the target users to be more independent, and less reliant on carers and relatives. A high priority for POSEIDON, therefore, is to provide context-specific assistance to support autonomy and independence in the above areas. Enabling tasks to be completed independently without the need for assistance are potentially boost users' self-esteem and confidence.

Autonomy, however, as previously discussed, also means users being able to control technology. POSEIDON is adjustable to individual preferences and personal needs. Users are able to customize the system, within their framework of capabilities or with the help of their carers. While default settings are provided, POSEIDON includes the ability to override those defaults. The system allows the tracking option to be switched on or off, in line with different needs and competencies. Functions do not have to be used all the time, or in situations where support is not needed. It is recognized that too many choices and functions working at the same time could make it difficult for the user. Users, ultimately, thus have the ability to scale back or turn off the system if they feel bothered by it.

The system should promote user's autonomy and independence, support for optional interface customization to suit the end-user's needs, functionality should be customizable, should assist with activities supporting independence and inclusion, with special consideration given to the way time is represented and communicated. Third User-level contexts to be considered are: socializing, organizing the day, managing money.

General principle 8: Transparency

- *All users should be clearly informed of the pros and cons of the services offered by the system, including system capabilities, potential weaknesses, vulnerabilities and negative consequences.*
- *Users should be given notice of the existence of intelligent environment activity in an open manner.*
- *Background data processing, monitoring and surveillance should be made visible to users, where possible.*

To be in the control of the system, users' needs to understand it's (re)actions, feedback and possible uses.

Potential weaknesses, limitations and vulnerabilities in the POSEIDON system will be made transparent to users, including system operations, data collection and use, and surveillance activities.

The system should be open and transparent to users with respect to expected system functionality and weaknesses, and documentation must be provided to enable project participants and third parties to develop POSEIDON components. The system should be extensible, allowing integration of new functionality not yet foreseen. It should also provide confirmation that system has processed a request so users are informed about the inner processes of the system.

General principle 9: Equality, dignity and inclusiveness

- *The system should provide help regardless of age, technical background and ability.*
- *Affordability, fair provision, accessibility of technologies should be ensured.*
- *The system should accommodate different levels of cognition and competence.*
- *The system should reduce social isolation and not substitute for human care.*

POSEIDON is designed simply enough so that it can be used by the widest possible range of users with different potential levels of competence and cognitive ability. The system kits will be financially affordable and available in various price categories with different payment options.

Accessibility and inclusiveness also inform design and usability. In accordance with user requirements, the system avoids the need for fast reactions, fine motor skills and manual dexterity. It is generally symbol-based, rather than text-based, using gestural interaction where appropriate. POSEIDON have an attractive design and user interface that is fun and simple to operate.

The system should provide help regardless of age and technical ability, have an affordable cost, be motivating to use, with interface preferably based on symbol, icons and animations, taking into consideration aesthetical features (colors, fonts, contrast, etc.), and consider design heuristics.

Specific consideration on Social inclusion

One of the most important requirements to emerge from survey data was the facilitation of communication and socializing with others, in order to reduce the risk of social isolation that people with DS face, and increase their independence. Social inclusion was in turn found to be closely related to mobility and travel independence, a major factor in feeling independent and less reliant on others.

The system should be proactive (instead of reactive) in the following situations: issuing reminders in the areas where the primary user has indicated more help is welcomed (candidates: planning trips, during travelling from A to B). First User-level contexts to be considered are: travelling, communicating.

Second User-level contexts to be considered are: studying, working, well-being.

When live, ‘safety net’ plan for foreseeable situations (e.g. bus does not arrive and no connection) should be in place.

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Appendix A

Information sheets for primary users (people with DS) used for interviews in January 2014

Example: United Kingdom

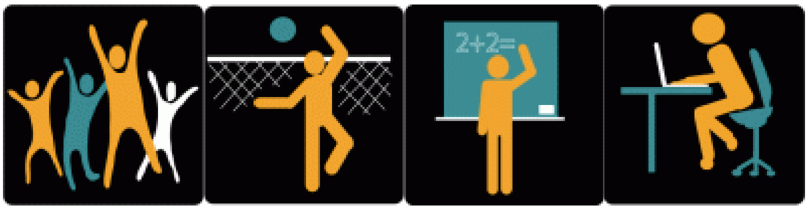
Easy Read Information Sheet

Our Project

We are looking for people with Down’s syndrome to help us with our project.

What the Project is about?

- We want to develop technology to be used for smart phones, ipads, tablets and PCs to help you in your daily routines.



- We want you to tell us where you most need help and support.

- Ask your parent/carer to explain more about the project if you need to. Then think about if you want to help us.

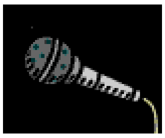
- You can also ask Vanda Ridley from the DSA who is member if the project team for more information.

Why I am asking you to help?

- We are asking for your help because you have Down’s syndrome.
- We want you to tell us about the things you do every day and where you need most help and support.
- We will give your information to inventors who want to make phone and iPads that can help you with the things you do every day.
- You don’t have to say yes to help.
- It’s ok to say no.

If you want to help what happens next?

- If you decide to help we will set up a time to meet you. At the meeting we will ask you questions about things that you do every day.
- You can ask for a parent or carer to be present.
- The meeting will take 1 ½ hours.
- We will record your answers.



- It’s ok to say you don’t want to answer a question.
- It’s ok to say you want to break for a pause.

- It’s ok to say you want to stop the interview.
- It’s ok to say you don’t want your answers recorded.
- We will write a report about the information we collect.
- We will show you what we have written and you can change anything you do not like.

- We may write about the project in magazines.
- We will change your name so no one will know what you have said.
- We will not share your personal information with anyone.
- Your personal information will be kept in a safe place and only one person from the project team will have access to it.
- One year after the project is finished your personal information will be destroyed.
- You can tell us if you don’t want us to use your answers.
- If you are unhappy about anything you can tell us.

☹

- You can ask us any questions about the project. ?

Appendix B

Consent forms used for interviews in January 2014

Consent Form

Poseidon Project

Please tick the appropriate box:

I am participating in this project as a

- ☐ Primary User (person with Down's syndrome)
- ☐ Secondary User (parent or carer of person with Down's syndrome)
- ☐ Tertiary User (professional supporting people with Down's syndrome)

---Thank you for considering taking part in this research. If you have any questions, please ask a member of the project team before you decide whether to take part. You will be given a copy of the Consent Form and Information Sheet to keep and refer to at any time.

Please tick or initial each box to agree to below.

- ☐ I confirm that I have read and understood the information sheet dated…… (version….) for the above study
- ☐ I have had time to consider the information, ask questions and have had these answered satisfactorily.
- ☐ I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason, without my care or legal rights being affected.
- ☐ I understand that if I withdraw from the study, the data collected up to that point will be destroyed.

- ☐ I understand that my personal data will be safely stored and destroyed one year after the end of the project.
- ☐ I understand that the data may be published but this will be without reference to my personal details.
- ☐ I agree to the interview being audio recorded if necessary so that my comments can be typed up and used for research data after I have verified a summary of the interview
- ☐ I agree to take part in the study

Participant ____________________________________

I am over 16 years of age [ ] *tick*

Signature_______________________________

Date______________________________

Parent/Guardian, please sign here (if the participant is under 16 or unable to sign) **:**

Name ____________________________________

I am over 18 years of age [ ] *tick*

Relationship to participant

____

Signature_______________________________

Date__________________________________

Name of Researcher/Interviewer (please print):

____

Signed________________________ Date_________________________

Appendix C

Guidelines for inclusion of adult people with missing or reduced competence to consent in health research[4]

1. It is presupposed that the requirements that generally apply to research that includes people, also form the basis for research that includes people with reduced or lack of consent competence, to the extent that they are relevant.

2. Persons who are not able to give informed consent should generally only be included in the research if:
a) it cannot be performed on individuals who are able to consent, and

b) It can be substantiated that the research is of direct and significant benefit to the individual or group being studied.

3. In research where knowledge can benefit the group in question, but the direct benefit to the individual that is included is absent, uncertain or in the distant future, it is essential to include people who cannot give informed consent, the risks and load entailed by the study are negligible for the person being included.
4. When people who communicate pain, discomfort or well-being in a peculiar manner, are included in the research, it is important that the study uses methods that take into account the subject's specific communication means. It is particularly important that the expression of pain and discomfort is captured. A person with a good knowledge of the relevant person's ways of expression should be consulted, so that one can best interpret the person's speech and sign and side effects.
5. The greater the risk or discomfort a project entails, the more stringent the requirements to the subject's understanding of what the project means, should be.
6. An assessment of consent should not be based on group identity. People with the same disease or the same intellectual disability may have different consent competence. Whether a person is competent to give consent or not, must be shown through an individual assessment of each potential participant.
7. If the tests are used for the assessment of consent, it is important that these are not be used mechanically, but only as a means to identify people who are in a situation where consent competence need careful consideration. When a person's skills may be situational and project dependent, the person´s under-standing ability always must be considered in relation to the current study.

The Responsibilities of the Project Manager
8. The project manager should always consider on an individual level if potential subjects / informants are consent competent in relation to the current research project. If there is doubt about consent competence for any of those considered as possible participants, the project will include in the protocol / application to the REK (Regional Committee on Research Ethics) a plan for how consent competence should be considered.

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[4] These guidelines are made by The Norwegian National Committee for Research Ethics for Medicine and Health Research for information and consent procedures for persons with reduced consent competence. It is based on the health research law in Norway and the OVIEDO convention. These guidelines are often used also for other research than health research. These guidelines will be adopted in POSEIDON unless the local government requires something different or additional. All partners of POSEIDON are experienced on using consent and information sheets from previous projects they have participated from.

9. Since consent competence is not only depending on personal circumstances, but also on how the current project is presented, the project manager must always consider whether special information facilitation and information procedures can make persons more able to consent to participation on their own behalf.
10. Although a potential test subject does not have sufficient understanding capacity to give consent, it is essential that the project manager is doing everything possible to explain what the current project involves (purpose, risks and potential benefits), if the trial subject or informant is not is completely without the ability to understand.
11. If a person with limited ability to understand is considered competent to give informed consent to participate in a particular study, the project manager should consider whether a person who is independent of the research project, should be present at the information and consent process.
12. Any expression, both verbally and non-verbally, from a subject who opposes participation, both prior to and during the trial must be respected.
13. Where there is doubt about the person considered for inclusion in a project, understands enough of the project and can safeguard his/her own interests, the project manager to the greatest extent possible, and as long as the person does not oppose this, consult with next of kind about what can be in accordance with his or her interests. A reservation of the next of kind should be given considerable weight. Although the next of kind accepts that a person with reduced or lack of consent competence is included in the project, this never makes redundant a thorough and independent review by the project manager's about the interests and welfare of this person is dealt with in a satisfactory manner. An acceptance of next of kind never invalidates expressed reluctance to participation from the relevant subject, whatever mental condition and competence of the person.
14. If next of kind does not exist or for other reasons is not natural to contact next of kind, the project manager should check if there is another person who knows the research subject or informant well (family, friends, caregiver / health care personnel), who can be consulted on the advisability of to include him or her in the current study.
15. When it can be questioned whether the person considered included in the project is competent to give consent, and he/she is a patient and has a person being responsible for the treatment who is another than the researcher, the project manager should consult the treatment responsible person to discuss the appropriateness of including the patient in research. Or they should then discuss how to provide information and conduct the project in a satisfactory manner.
16. When it should be decided whether the current research project purposes can be said to have a clear positive impact on the individuals or groups being studied, the project manager should consider consulting relevant user groups. Their potential advice must however be regarded only as a guide and cannot replace an individual assessment of the risk / benefit for the individual subject or informant.
17. In studies without potential direct benefit of the person being included, and it is therefore presupposed that research participants only are exposed to insignificant risk /load, the project manager should consider the use of a person who knows the person well. This person must be independent of the study and should be able to decide whether the risk / load the study may expose the individual for, really is insignificant to him/her.
18. If the subjects or informants during the study will be able to give consent, the project leader should again provide information about the study and obtain consent for continued participation. If he/she wants to withdraw from the study, all data about that person deleted unless there are compelling reasons not to do this.