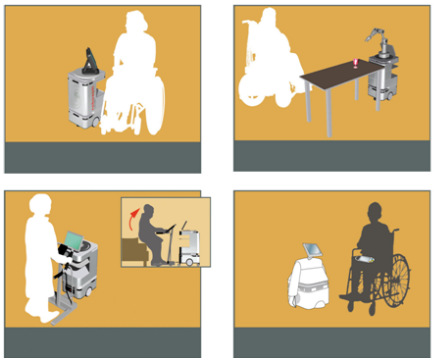
DOMESTIC ROBOT FOR ELDERLY ASSISTANCE



DOMEO Project
AAL-2008-1-159

D2.2 : Generic test description file and methodology

Document id: R-CHU-2_1-Generic_Test_Description

Document Information	
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Abstract:
This report is giving a frame to organise and describe tests with users as part of the iterative approach implemented in DOMEO Project.

Keyword List:
Tests with users, laboratory, field, description.

Summary

Generic description file relevance

Domeo project is a multidisciplinary project aiming at improving the daily life of home dwelling frail elderly or handicapped citizens. It is addressing the needs of mobility and communication trough two different robotized aids (Kompaï and Robuwalker) intermingling with communication technology and telemedicine. This holistic user-centred approach is driven by some underlying “tensions”: some of it is medical device and some is not, some of the technologies are more mature than others, some parts of the service model are better identified than others, cognitively impaired people have to be included but require a special approach. Therefore, we chose to provide a generic test description file rather than a traditional experimental logbook (needing a detailed and thence scoped format) that could not answer the adaptability requirements.

The tests with users are required to improve usability and better fit the needs of the users. They will help the “field” partners provide the “production” partners with the feedback information needed to improve the prototypes through the iterative approach we chose from the start of the project.

The “Domeo project, Test with users, Generic description file” has to:

- Help with the coordination and integration of tests (manages the differences in terms of maturity of technology tested in different places, help recognise the duplications of the same test in different locations, organise the tests at the different stage of iteration).
- Help the local responsible of a test with users manage the legal and ethical issues.
- Help the partners benefit from each other’s work when designing or duplicating a test.

The “Domeo project, Test with users, Generic description file” does not provide the results of the tests nor the methodology which will be provided by the corresponding work packages.

Definition

Tests with users are including all tests when a prospect user, either end-user or intermediate user, is involved.

Needs definition procedures, interviews, expertise and focus groups, even if they are involving end/intermediate users, or if demonstrations are included, are not considered as tests with users.

Laboratory or field testing for technical aspects, when only researchers are involved, are not considered as tests with users.

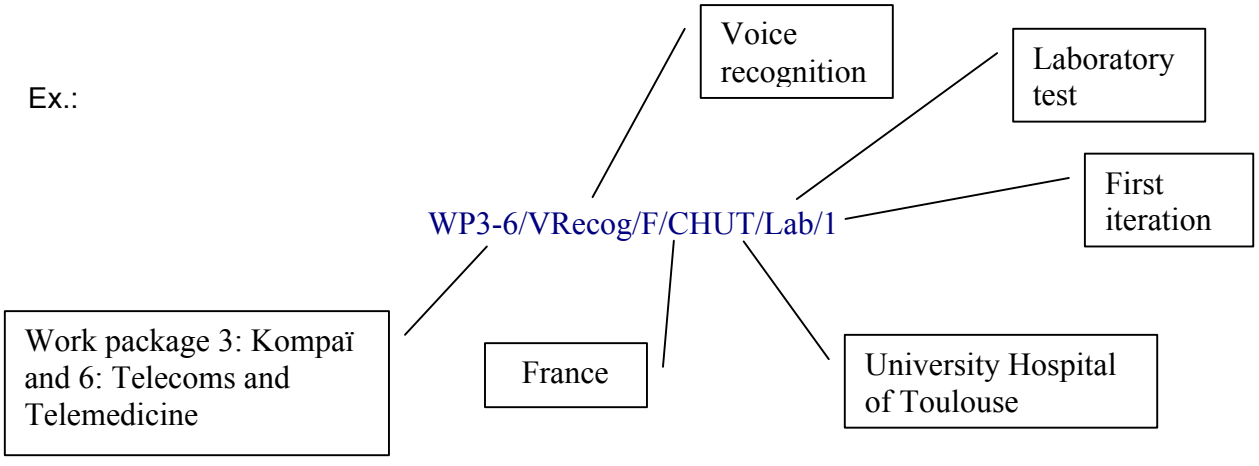
Laboratory or field testing, when researchers playing the role of prospect end/intermediate users are involved may be considered as test with users. Then, they would follow the procedure required for tests with users.

Form filling instructions

1.1. Test encoding

Each test will be encoded with the work package (or work packages), a code describing the test, the country, the place, if it is a laboratory of field test, the rank of iteration.

Ex.:



1.2. Type of test

A laboratory test is organised in a laboratory or, using laboratory conditions, in a different location. The users involved are closely monitored by the research personnel. The aim of those tests will more likely be to assess the functioning of a device regarding one aspect. The laboratory test will occur before field testing.

A field test is organised in a daily life location (home, nursing home…) or using daily life conditions (hospital, laboratory, club, living lab…). The aim of those tests will be to check functioning in real setting and assess usability and acceptance. The research personnel will attend the tests to observe the interactions of the user(s) and the device(s). Interactions between the research personnel and the user(s) will be restricted to a minimum during the test. Research personnel will have a major role assuring the security of the user(s), if needed medical or healthcare personnel will be involved. Field tests are the closest to field deployment when the robustness of systems still needs confirmation.

1.3. Country of test

This is the country where the tests are practically organised. It is of major importance as its regulations will apply and be abided. The same protocol applied in two different countries will be considered as two different tests.

1.4. Location of test

The location of test will be considered as the premises of the research personnel in charge of the test. If the tests are run outside those premises, under the responsibility of the corresponding partner, the actual location will have to be fully described in the research protocol. In the case of field tests located at the home of a user, then the research protocol will have either to describe the home or describe the related inclusion and exclusion criteria.

1.5. Local main responsible for the test

This is the person who will be in charge of the tests and be legally and ethically responsible, with a major stress on safety. She or he will be in charge of sharing the tasks between the technical and healthcare research personnel, selecting the volunteers, organizing the informed consent, running the tests and the writing of the results, according to the protocol.

1.6. Background of local main responsible for the test

The background of the local main responsible (LMR) has to allow her or him to take charge of the tests both in terms of efficiency and security. She or he is not forcedly competent on all the aspects of the test but has to contribute significantly to the required capabilities for the test to succeed. Those competences will have an impact on the required competences of the other research personnel involved.

1.7. Local technical investigator(s)

This(these) is(are) the person(s) who will locally address technical problems that could occur during the tests. She or he will have a role in technical security.

1.8. Local healthcare investigator(s)

This(these) is(are) the person(s) who will locally address the medical issues or problems that could arise during the tests. She or he will have a role in medical security.

1.9. Test level

The test level is describing in terms of technology which part of Domeo is considered in the test. That level may be at full system level or at subsystem level. When a subsystem is considered, it is required to describe it and tell which version is tested.

1.10. The system or subsystem tested is considered as a medical device

The local main responsible for the test has to state whether the system or subsystem considered is or is not a medical device. This statement will be according to the agreed interpretation of the EU definition of a medical device (93/42/CEE directive) and national legal requirements. In case of uncertainty the manufacturer or producer of the system or subsystem will have the last word. He will have to be able to comment his decision. A non medical system may include medical subsystems if those subsystems may work independently and are not compulsory to the global system (ex.: the telemedicine devices in Kompaï may be considered as medical devices while Kompaï itself is not a medical device).

1.11. Dates

Date of start is the date when the first test with user of the considered series is launched and date of end is when the last test with user of the series is finished. Results management and interpretation may go on longer than the date of end of the test.

1.12. Required documents check list

This check list is seen as an aid for the Local main responsible for the test to make sure he doesn't forget any of the required documents or steps to ascertain that the test fulfils the ethical requirements of tests with users. It should also simplify the management of tests.

CE marking

The LMR will have to ask the manufacturer or producer of the system or subsystem tested whether it is CE marked and whether it is regular or medical CE marking. In case the system or subsystem is CE marked, the LMR, will ask for the relevant certificate before starting the tests.

Test protocol

The test protocol is applied under the responsibility of the LMR. It should describe precisely the test. It will include: objective(s) of test, test location description, user's description, inclusion and exclusion criteria, consent procedures, test procedures, analysis criteria. The same protocol with minor adjustments should apply to the same question in various iterations and in replications to a different country. The test protocol will be defined under the coordination of the corresponding work package leader.

Informed consent leaflet

The informed consent leaflet is provided to the end/intermediate user volunteering for the test with oral the presentation of the project and the test he will receive according to the protocol. The informed consent leaflet is including:

a general synthetically overview of Domeo project,

a description of the test in which the volunteer will participate,

if personal data will be kept and then how they will be managed (any declaration or approval by a legal authority),

the ethical committee approval (name of committee and date) if relevant,

the contacts of the LMR,

the possibility for the volunteer to withdraw consent at anytime during the test,

the name and dated signature of the volunteer,

the name and dated signature of the person in charge of collecting the consent,

the name, legitimacy, and date signature of the legal representative of the volunteer if so required (as in case of cognitive impairment).

In this description file, only the frame of the informed consent leaflet will be included, the filled informed leaflets of volunteers will be kept by the LMR at hers or his premises.

Different informed consent leaflets may be required if both end and intermediate users are involved; in that case the different leaflets will be provided.

Informed consent leaflets are provided in the form signed by the volunteers and in the language of the volunteers.

Test with users with cognitive impairment

In case of involvement of cognitively impaired users, the consent protocol has to be provided. It will describe: who will give the information, who has to receive the information, who may represent the volunteer to give informed consent.

Ethical committee

If the advice or authorisation of an ethical committee is legally required or considered advisable; this should be stated. A legal ethical committee is acting as part of a compulsory procedure required by national law. A local ethical committee is acting as part of a compulsory procedure required by the rules of the body employing the LMR. An optional ethical committee is not required as part of a compulsory procedure but may be involved if the LMR considers that the test may rise ethical issues and he needs help to address them at the best during the test.

Statements are provided in their original language, it is the responsibility of the LMR to cope with their requirements.

Nominative data

The LMR has, according to the test protocol and her or his national law, to state if a special procedure is needed for nominative data management. If a declaration to or authorisation by a legal body is needed, then provide the receipt or statement. Likewise, if the body needs a general agreement, then select “data storage needs approval by a legal authority” and provide agreement.

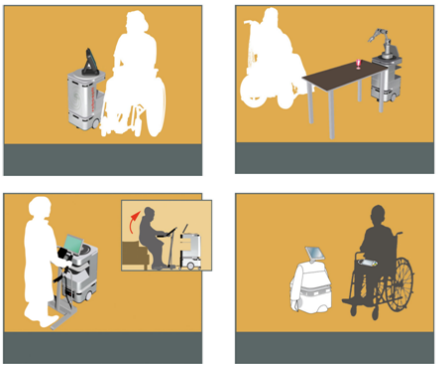
Description of file validation

The description file is validated is filled before the start of the test and validated at the end of the test (after end of test date can be provided). The validation of the description file is under the personal responsibility of the local main responsible for the test, apart from the test encoding which is agreed between the consortium members.

The validation part, at the very end of the file, is both in English for understanding by all the consortium partners and the AAL association, and in local language to be provided if required to local authorities, local researchers and local volunteers.

The signature of LMR and date of signature should be hand-written.

A copy of the file is forwarded to the project and the original is kept by the originating partner for the local main responsible of the test.



DOMEO Project
AAL-2008-1-159

Domeo project
Tests with users
Generic description file

Test encoding:

Type of test: Choose
Country of test: Choose
Location of test: Choose
Local main responsible for the test (full name and legal address):

Background of local main responsible for the test:
☐ MD, ☐ PhD, ☐ Eng, ☐ MSc, ☐ Other (please details there after)
Local technical investigator(s) (full name, profession and legal address):

Local healthcare investigator(s) (full name, profession and legal address):

Test level: Choose
In case of subsystem, describe it:
Development version tested:

The system or subsystem tested is considered as a medical device Choose.
Date of start (dd/MM/yyyy): Date of end (dd/MM/yyyy):

Required documents check list:

☐ CE marking is required Choose. If required attach the certificate from the manufacturer.

☐ Test protocol. Attach the protocol.

☐ Informed consent leaflet(s).

More than one category of user is involved in the test Choose. Provide the relevant informed consent leaflets How many (including end user) .

Cognitively impaired patients are involved in the test Choose. Provide the relevant informed consent leaflets How many (including end user) .

☐ Cognitively impaired patients are involved in the test Choose. Provide the relevant consent protocol for your country.

☐ An ethical committee agreement is required for the test Choose. Provide statement.

☐ A legal procedure is required regarding the saving and management of nominative electronic data Choose. In case of need of declaration or approval, provide the relevant receipt or statement.

I, first name, family name, main responsible for the afore mentioned test do attest that I took all due care to make sure that our national regulations on tests with users were obeyed, that the greatest care was taken to reduce any possible risk to users and testing personnel alike, that I checked both the manufacturer and Choose, in charge of the test, had the required insurance coverage in case of arm to volunteers or research personnel during the test,
Type here the above sentence in your language,then date and sign by hand