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Report on Second wave of pilots

Work Package 6: Large Scale Piloting and Validation

affecTive basEd iNtegrated carE for better Quality of Life: TeNDER Project

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The TeNDER consortium consists of the following Partners.

Table 1 - Consortium Partners List

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3	DATAWIZARD SRL	DW	Italy
4	UBIWHERE LDA	UBI	Portugal
5	ELGOLINE DOO	ELGO	Slovenia
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7	VRIJE UNIVERSITEIT BRUSSEL	VUB	Belgium
8	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	HOPE	Belgium
9	SERVICIO MADRILENO DE SALUD	SERMAS	Spain
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¹ **R**: Document, report; **DEM**: Demonstrator, pilot, prototype; **DEC**: Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.

² **PU**: Public; **CO**: Confidential, only for members of the consortium (including the Commission Services).

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Acronyms and Abbreviations

Acronym/Abbreviation	Description
EC	European Commission
#	Number of
WP	Work Package
SD	Standard Deviation
GDPR	General Data Protection Regulation
AD	Alzheimer Disease
PD	Parkinson Disease
CVD	Cardiovascular Disease
KPI	Key Performance Indicator
SUS	System Usability Scale

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1 EXECUTIVE SUMMARY

From November 2021 to June 2022, the second wave of pilots of the TeNDER study has been developed with 5 pilots in each of the user institutions involved.

During this time the organisation and coordination has been key, both among the user partners and with the technical partners, to achieve the development of the TeNDER tool and to adapt it to the real needs of the participants involved.

The development of the pilots has been carried out taking into account all ethical and legal considerations with respect to the rights and privacy of participants. In addition, it has required the establishment of recommendations and risk management related to the Covid 19 pandemic. Each pilot has incorporated these measures by adapting them to its own characteristics, to the settings and to the type of participants it involved.

In contrast to the first wave, this second wave has included new technological advances in the TeNDER tool. Extensive testing in large-scale pilots of the TeNDER ecosystem, together with continuous evaluation and feedback from all stakeholders, ensures efficient use of resources and coordination of care. The increased efficiency of these tools has been tested in prototypes (real environments) and the experience is applied at the core of TeNDER.

In this second wave, 410 user participants have been reached; 251 of them were patients, 104 carers and 55 professionals. The patients involved had one or more chronic diseases: 39.4% had dementia, 24.7% Parkinson's and 35.5% cardiovascular disease.

The TeNDER tool was installed in different real-life settings, such as homes, hospitals, day care centres and rehabilitation rooms.

To evaluate the degree of satisfaction of the different stakeholders participating in this wave of pilots and the usability of the system, a pre-pilot questionnaire and a post-pilot questionnaire were used, which included different questions on satisfaction, increased efficiency and usefulness of the system, as well as the System Usability Scale (SUS) to evaluate the usability of the TeNDER system. This deliverable presents the results obtained in this respect.

2 INTRODUCTION

The main objective of the TeNDER project is the creation of a comprehensive care system that facilitates the daily life of people suffering from chronic pathologies such as Parkinson's disease (PD), Alzheimer's disease (AD) and/or cardiovascular diseases (CVD), their carers and the professionals involved in their care. To this end, it is proposed to carry out 5 large-scale pilots on patients, their families, carers and professionals. These pilots will validate the toolbox of TeNDER services in several well-defined scenarios: TeNDER will provide 4 different scenarios according to the patient's pathways (home, day care centre, rehabilitation centre/rooms, and hospital).

The objective of the pilots is to verify TeNDER technological acceptance in real conditions within controlled pilots. As several technological components providing different services for different groups of users will be developed.

Specific objectives:

- To demonstrate the feasibility of implementation of the base solution of TeNDER, as a global ecosystem to support independent and healthy life.
- Lead practical field tests and user feedback/validation: setting up user groups: interview/filtering. Validating pilot.
- Application and prototype interfaces and issuing recommendations with regards to specific approaches more adapted to a senior public.
- To localize the project results into different languages and cultural environments.
- Gathering conclusions from users' feedback in order to make recommendations improving product design.

2.1 Purpose and scope

To achieve these objectives, in the second wave of pilots every effort has been made to get more users involved who could give feedback to the development of TeNDER. Testing has been carried out to verify and validate the robustness, performance, scalability and security compliance of the platform in preparation for the creation and production of learning material. Special consideration was given to the security of the resulting platform, integrating standard security countermeasures for the protection of personal data and other platform resources.

This deliverable reflects the magnitude of the pilot developed in the second wave through the number of participants involved, the devices and functionalities tested in each scenario, and adapted to the disease and condition of the patient.

It also shows the results of satisfaction and usability of the tool in patients, carers and professionals.

2.2 Contribution to other deliverables

The final result of the work developed in the WP2 tasks is a specification of the needs and requirements of the users to develop the scenarios to be used in the pilots.

Through the results and feedback from the pilots, all modules of the system (WP3, WP4 and WP5) will be evaluated for accessibility, usability improvement and user acceptance in both groups.

In the pilots, the platform will be tested according to the defined strategy and plans and based on the results of the tests as well as feedback from the pilots in WP7.

2.3 Structure of the document

The current document is the report on 2nd wave of Pilots of the TeNDER project (from November 2021 to June 2022). It details the progress, the activities and the outcomes achieved during the piloting phase are reported, stressing the risks management and outcomes.

The document is separated in:

- Statement on data collection for the second wave of pilots, that includes general guidelines for the Pilot execution and priorities.
- Overview of the progress, that describes the activity performed from November 2021 to June 2022, reporting the activities, the devices installed and integrated, the recruitment of users and the general usage of devices.
- Risk management related to the piloting execution, general and specific for each pilot sites, including the Covid19 pandemic impact on the Pilots.
- Description of expected outcomes and a comprehensive report for each Pilot, that describes scenarios tested, the users involved, the devices assigned and the functionalities tested. Moreover, the section 5 reports discrepancies with protocols described in D6.1, mitigation and integration plan in each Pilot sites.
- Conclusion section that reports the description of the achievement of the expected KPIs.

3 EXECUTION OF THE PILOTS IN THE SECOND WAVE.

The second wave of pilots started in November 2021 with the preparatory work and lab testing of devices and system integration.

The data gathering from real users started in fully in November 2021. The recruitment of users continued in all pilots' sites and has ended in June 2022.

As described in D6.1, all users involved will test the TeNDER system for 45 days-2 months in Rehabilitation room, and in home scenarios.

In Hospital scenario the length of monitoring depends on the length of hospitalization.

3.1 Overview of the progress

During the development of the pilots, the progress made in each of the institutions has been detailed and shared on a weekly basis in specific user meetings.

A weekly monitoring table has been used to supervise and control each of the pilots.

Table 2 shows the monthly summary of the progress made in each institution involved. We can see that in November the recruitment of participants had not yet started in most of the pilots. This is due to the fact that in that month the proposal began to be presented and the participants were invited, so work was carried out on the dissemination, installation and setting up of scenarios and recruitment began, collecting the informed consents. Some of the organisations participating in the pilots also took the opportunity to develop data collection circuits to assist in the creation and training of algorithms that allow the detection of events such as falls or freezing, among others. The table also shows how, in the following months, the number of participants involved increased exponentially.

Table 2- Monthly activity of the Second wave of Pilots

Date	Specs	Pilot 1	Pilot 2	Pilot 3	Pilot 4	Pilot 5
M25 (NOV 21)	Progress	Installation of devices in collaboration with UPM (0,0,0,0,0)*	Installation of devices in collaboration with UPM . Testing lab (0,0,0,0,10)*	Recruitment of patients. Installation of devices. (0,0,0,0,0) *	Installation of all devices used in SKBA. (0,0,0,0,0) *	Installation of devices in collaboration with ELG. (0,0,0,0,0) *
	Setting	Fit Bit, Sleep Tracker and high PC. In purchase: binary sensor, localization sensor, speaker, environmental, real Sense and highPC.	Fit Bit, Sleep Tracker, Kinect 2, Real Sense, Microphone and high PC	Fit Bit, Sleep Tracker and high PC. In purchase: Kinect 2	Fitbit, Sleep Tracker and high PC. For lab tests: Kinect 2	Sleep trackers, Mini and High-End PCs, Kinect Azures, Localization sensors, Binary sensors, Environmental sensors, Wristbands, Fitbits, Speakers, Microphones, Tablets, Smart Phones
M26 (DEC 21)	Progress	In progress with UPM support: 1) Fitbit and sleep sensor: done. 2) Binary sensors: pending after new updates from CERTH (0,0,0,0,0)*	Final technical adjustments and internal testing. Development of internal recruitment protocol. Pre-screening phase (0,1,0,0,0)*	Recruitment of patients. Installation of devices. (0,0,0,0,0) *	In progress with technical partners; waiting for pending updates *(0,0,0,0,0)	Recruitment of patients and presentation of TeNDER (0,0,0,0,0)*
	Setting	All devices received.	All operating devices	Fit Bit, Sleep Tracker and high PC. In purchase: Kinect 2	All devices received, waiting for update	All operating devices in testing at the SPO and ELG site
M27 (JAN 22)	Progress	In process: installation miniPC and binary / environmental sensors (UPM support) Recruited: 120 patients. (0,0,0,0,0)*	Beginning of the participation of the first patients of the round and development of the event identification loops (4,10,4,4,0)*	Recruitment of patients. Installation of devices. (0,0,0,0,0) *	In progress with technical partners; waiting for pending updates *(0,0,0,0,0)	Recruitment of the participants for TeNDER testing and presentation of TeNDER (0,0,0,0,0)*
	Setting	Fitbit and Sleep sensor installation completed.	Rhb Room ongoing	All devices received.	All devices received, waiting for update	All operating devices in testing at the SPO and ELG site, Recruitment of the participants

						for home scenario
M28 (FEB 22)	Progress	UPM coordination with Fitbit and Sleep Sensor Recruited: 120 patients. (23,0,0,0,0)*	Inclusion of new participants both in the rhb room and at home. (7,1,5,6,0)*	Recruitment of patients. Installation of devices. (0,0,0,0,0) *	In progress with technical partners; waiting for pending updates *(0,0,0,0,0)	Recruitment of the participants for TeNDER testing and presentation of TeNDER (0,0,0,0,0)*
	Setting	Home environment: Fitbit and sleeps sensor	Rhb Room and home set ongoing	Hospital environment ongoing	All devices received, waiting for update	All operating devices in testing at the SPO and ELG site Recruitment of the participants for home scenario
M29 (MAR 22)	Progress	UPM coordination with Fitbit and Sleep Sensor Recruited: 185 patients. (45,0,0,0,0)*	Inclusion of new participants both in the rhb room and at home. Completion of testing of the first included participants (2,0,2,5,0)*	Recruitment of patients. Installation of devices. (20,0,0,22,8) *	Arranging technical problems (HETRA) with technical support and internal setup/testing; (4,0,0,5,3) *	Piloting in home environment (2,5,0,2,2)*
	Setting	Home environment: Fitbit and sleeps sensor	Rhb Room and home set ongoing	Hospital environment ongoing	Fitbit and sleep sensor installation completed, waiting for mobile phone	Home environment: sleep trackers, localization sensors, wristbands; Kinect Azures, Binary sensors, Environmental sensors, Fitbits, Microphones in internal testing (SPO, ELG site)
M30 (APR 22)	Progress	UPM coordination with Fitbit and Sleep Sensor Recruited: 216 patients. (70,0,0,0,0)*	Inclusion of new participants both in the rhb room and at home. (8,1,0,10,0)*	Recruitment of patients. Installation of devices. (20,0,0,22,8) *	Set up of HETRA Server with technical partners; Inclusion of new participants; *(7,1,0,5,5)	Piloting in home environment (10,7,0,5,2)*
	Setting	Home environment: Fitbit and sleeps sensor	Rhb Room and home set ongoing	Hospital environment ongoing. Installation of the home-sets	Hospital environment: Fitbit, sleep tracker	Home environment: sleep trackers, localization sensors, wristbands; Kinect Azures, Binary sensors, Environmental

						sensors, Fitbits, Microphones in internal testing (SPO, ELG site)
M31 (MAY 22)	Progress	UPM coordination with Fitbit and Sleep Sensor Recruited: 230 patients. (80,0,0,0,0)*	Inclusion of new participants both in the rhb room and at home. (6,8,0,4,0)*	Recruitment of patients. Installation of devices. (20,0,0,22,8) *	Inclusion of new participants; *(20,6,0,13,6)	Piloting in home environment and recruitment in day-care centres (22,13,0,18,3)*
	Setting	Home environment: Fitbit and sleeps sensor	Rhb Room and home set ongoing	Hospital environment ongoing. home-sets ongoing	Hospital environment: Fitbit, sleep tracker	Home environment: sleep trackers, localization sensors, wristbands; Kinect Azures, Binary sensors, Environmental sensors, Fitbits, Microphones in internal testing (SPO, ELG site)
M32 (JUN 22)	Progress	UPM coordination with Fitbit and Sleep Sensor Recruited: 230 patients. (80,0,0,0,0)*	Last pilot weeks and finalisation of the last participants included in the second wave (0,0,0,0,0)*	Patients were asked to complete the questionnaires for the trial evaluation; 10 patients have returned the devices (20,0,0,22,8) *	Last pilot weeks and finalisation of the last participants included in the second wave (30,10,1,16,7)	Piloting in home environment and day-care centre environment, finalization of the 2 nd pilot wave (10,1,0,1,2)*
	Setting	Home environment: Fitbit and sleeps sensor	Rhb Room and home set ongoing	Hospital environment ongoing. home-sets ongoing	Hospital environment: Fitbit, sleep tracker Lab Test: Fitbit and Kinect 2 data collection	Home environment: sleep trackers, localization sensors, wristbands; day care centre environment: wristbands, localization sensors; Kinect Azures, Binary sensors, Environmental sensors, Fitbits, Microphones in internal testing (SPO, ELG site) Home scenario piloting; day care centre scenario piloting: wristband, localization sensor

* (PATIENT CASES, PATIENTS CONTROL, SIMULATION, CARERS, PROFESSIONALS)

3.2 Devices installed and system integration

The central components of TeNDER that were used in the 2nd wave was:

A. Mini-PC and Mini-PC light.

Two types of PCs have been chosen to cope with the TeNDER needs.

In addition, a wide set of sensors that communicate with the Mini-PC either through a HTTP GET method (they are first connected to the Wireless LAN) or through USB connection can be used for data collection and analysis purposes.

Sensors that are connected through a HTTP GET method (they are first connected to the Wireless LAN) are:

B. Sleep sensor

The Withing's Sleep Analyzer main features are:

- It allows us to capture sleep data through Withing API.
- It monitors the heart rate, respiration rate, sleep state and also has the ability to detect sleep apnoea.
- It doesn't require other devices to run (only a local wireless connection).
- It stores data on secure cloud positioned in the EU.

C. Fitbit Band Versa 2

The Fitbit band main features are:

- The creation of TeNDER app (code) that can be inserted directly in the band. This allows to control the data flow.
- It permits us to create a TeNDER scenario that includes only the band and the smartphone, skipping the pc.
- It allows extracting raw measurements data from the accelerometer which enables us to permit a procedure called re-association, which consists in matching the patient's band with the skeletons detected by the depth sensor, avoiding use of sensitive information while improving accuracy by using multiple modalities (skeletons, acceleration, patient's location).

D. Xiaomi Mi3

The Xiaomi Miband 3 main features are:

- Low price.
- Water and dust resistance.
- Long battery life.
- Compatibility with the position tracker system.
- It allows direct measurements transfer through Bluetooth (no cloud services are required).

E. Position tracker

The position tracker's main features are:

- It connects directly to the local wireless connection (no additional device is required).
- It measures the signal strength of all nearby Bluetooth devices and sends this data to the cloud.
- Cloud is located in the EU.
- Cloud supports API integration into the HeTra

F. Aqara Hub

The Aqara hub main features are:

- It is used as a gateway for the Environmental sensor and the Binary sensor.
- It connects to the local wireless connection.

- The EU version of this device sends data by default to a Cloud located in the EU.

G. Environmental Sensor -

The Environmental sensor main features are:

- Connectivity with the Aqara Hub.
- It measures the temperature and humidity of the environment.
- It sends the temperature and humidity of the environment to the TeNDER cloud.

H. Binary Sensor -

The Binary sensor main features are:

- Connectivity with the Aqara Hub.
- When placed at the entrance door, windows or other objects (box/drawer with pills), it sends data on whether a door/window/object has been opened/closed.

The sensors listed below are connected via USB connection

I. Kinect Azure

The Kinect Azure main features are:

- Its ability to connect to the Mini-PC (Mini-PC light does not meet the Kinect Azure requirements).
- Its ability to acquire RGB colour images and Depth images which are used to extract the skeleton using the body tracking SDK.
- The analysis results obtained from the acquired skeleton data is sent to the TeNDER cloud (the actual skeleton data are saved to the user's PC (only)).
- It can detect falls. In combination with Fitbit band (and additionally also microphone) we improve the performance of the fall detection results.
- In combination with Fitbit band, we can identify the skeleton.

J. Microphone

The Microphone main features are:

- The possibility of detecting falls and detecting end-user emotions (such as happy, sad).

K. Kinect v02

The Kinect v02 main features are:

- Its ability to acquire RGB colour images and Depth images which are used to extract the skeleton using the body tracking SDK.
- Kinect skeleton data can be used in order to detect human motion and more specifically, to evaluate the patients while performing rehabilitation exercises.

L. Real-Sense

Real-Sense main features are:

- It can be connected to the Mini-PC or Mini-PC light.
- It acquires RGB colour images and Depth images which are used to extract the skeleton using the body tracking module.
- The analysis results obtained from the acquired skeleton data is sent to the TeNDER cloud (the actual skeleton data are saved to the user's PC (only)).
- It can detect falls. In combination with Fitbit band (and additionally also microphone) we improve the performance of the fall detection results. This combined with Fitbit band, can be used to identify the skeleton.
- Real-Sense requires the body tracking module (for Real-Sense)

Sensors that are not ready due to various issues (technical or otherwise) and were therefore not used in the Second wave of pilots are as follows.

M. Speaker

Speaker main features are:

- The ability to connect to both the Mini-PC or Mini-PC light.
- The ability to provide vocal reminders and suggestions to users (primary users)

3.3 Software installation Procedure

TeNDER platform consists of two distinguished systems that host the services. The High-Level Subsystem (HLS) is deployed on the central cloud infrastructure of the project and the Low-Level Subsystem is deployed in the user's local computational infrastructure (i.e., personal computers in patient homes, hospitals, rehabilitation rooms, etc.) Especially, the installation on local pc is a challenging procedure because for each use case the system uses a different type of sensors/devices that requires the installation of different software and drivers. The hardware heterogeneity makes the installation challenging even for technical personnel. To minimize the complexity of the process the TeNDER consortium developed an automated installation procedure that installs all the necessary software (drivers and TeNDER tools) by executing some simple scripts which are provided with TeNDER GitLab repository. The platform follows a modular approach so it can easily adapt to the specific requirements of each use case by installing only the necessary components. The installation is divided into three phases in the system is prepared for TeNDER services by installing the appropriate hardware drivers and software frameworks (i.e., Kinect SDK, Docker engine, python, etc.), in the second phase, the latest version of the TeNDER tools and services are downloaded and finally, a performance monitoring service is deployed.

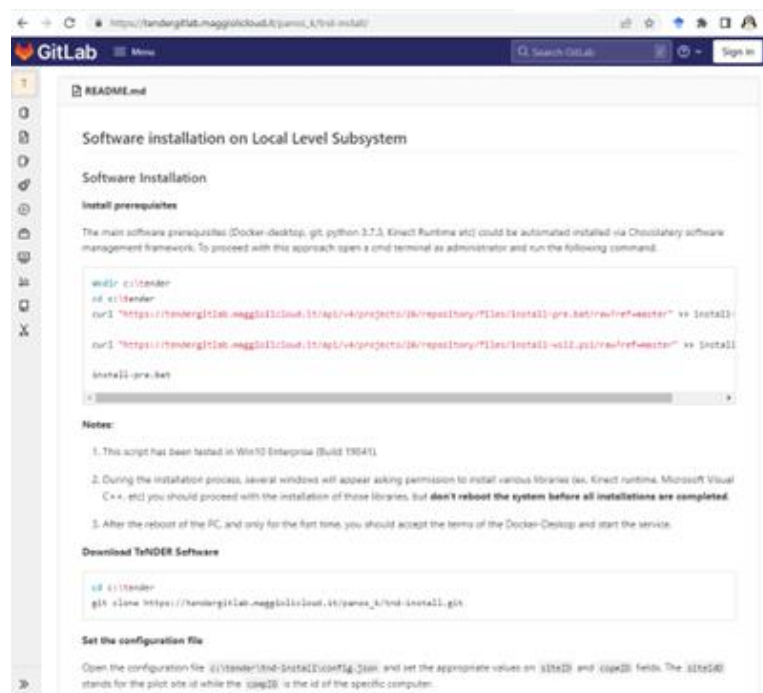


Figure 1- Installation Repository [1]

3.4 TeNDER Platform Prerequisites

TeNDER software platform is developed and tested under Win 10 operating system which is configured to support several tools and technologies. The prerequisites of the platform are the following:

- Windows 10 64bit (Pro, Enterprise, Education (Build 17134 or higher), Home (version 1903 or higher)
- Docker Desktop

- Python 3.7.3
- Kinect Runtime 2.0
- Visual C++ Redistributable Packages for Visual Studio
- Git

3.5 TeNDER software Installation

All software prerequisites are automatically installed by executing the following commands.

1. Prerequisites installation

```
mkdir c:\tender
cd c:\tender
curl
"https://tendergitlab.maggiolicloud.it/api/v4/projects/26/repository/files/install-
pre.bat/raw?ref=master" >> install-pre.bat

curl
"https://tendergitlab.maggiolicloud.it/api/v4/projects/26/repository/files/install-
wsl2.ps1/raw?ref=master" >> install-wsl2.ps1

install-pre.bat
```

Figure 2- Prerequisites installation

After the reboot of the PC, we can proceed with the second phase of installation as follows.

2. TeNDER Software installation

```
cd c:\tender
git clone https://tendergitlab.maggiolicloud.it/panos_k/tnd-install.git
```

Figure 3- Software installation 1

Before the deployment of the platform, we need to declare the pilot site and the specific id of the computer, to do so we open the configuration file `c:\tender\tnd-install\config.json` and set the appropriate values on `siteID` and `copmID` fields. Next, we start the services

```
cd c:\tender\tnd-install
install.bat
```

Figure 4- Software installation 2

3. Installation validation

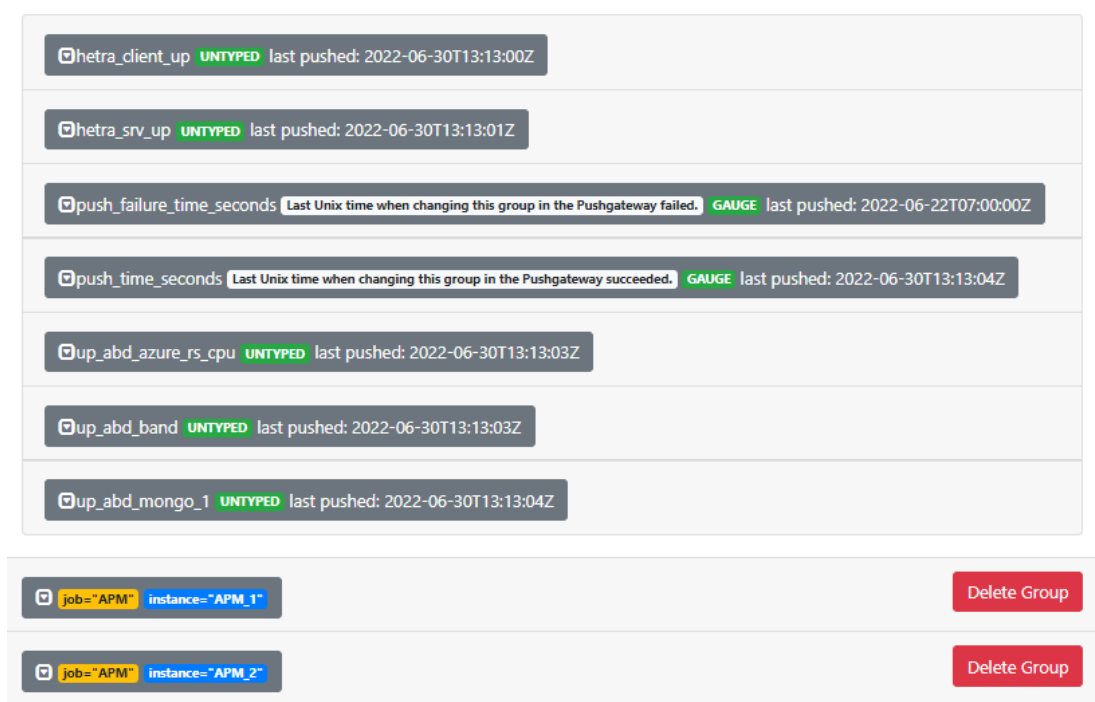
After the execution of the installation script the Hetra client and server processes should automatically start as also the AND and MongoDB containers.

```
docker ps
```

CONTAINER ID	IMAGE	COMMAND	CREATED
6e2d73c44e21	tenderhealth/tnd-abnorm-dtc:v1.0	"docker-entrypoint.s..."	10 minutes ago
Up 10 minutes	4369/tcp, 5671-5672/tcp, 15671-15672/tcp, 25672/tcp	tnd-abnorm-dtc	
0dccf82ae450	mongo	"docker-entrypoint.s..."	10 minutes ago
Up 10 minutes	0.0.0.0:27017->27017/tcp		

Figure 5- Installation validation

Furthermore, the performance status of the deployed services is monitored periodically and is reported to a dedicated monitoring server (Figure 2). Based on this mechanism the administrator of each pilot receives an alert notification each time that one of the services fails or in case of network failure. This approach is very useful, especially in home deployments where the system may stop sending data due to network or power failures. The first version of the monitoring framework is described in D5.4 and the final version will be presented in D5.5.



The screenshot displays a monitoring dashboard with several service groups. Each group is represented by a card with a status indicator (e.g., UNTYPED, GAUGE) and a last pushed timestamp. Below the main list, there are two specific instances of a service group, each with a 'Delete Group' button.

- hetra_client_up: UNTYPED, last pushed: 2022-06-30T13:13:00Z
- hetra_srv_up: UNTYPED, last pushed: 2022-06-30T13:13:01Z
- push_failure_time_seconds: GAUGE, Last Unix time when changing this group in the Pushgateway failed., last pushed: 2022-06-22T07:00:00Z
- push_time_seconds: GAUGE, Last Unix time when changing this group in the Pushgateway succeeded., last pushed: 2022-06-30T13:13:04Z
- up_abd_azure_rs_cpu: UNTYPED, last pushed: 2022-06-30T13:13:03Z
- up_abd_band: UNTYPED, last pushed: 2022-06-30T13:13:03Z
- up_abd_mongo_1: UNTYPED, last pushed: 2022-06-30T13:13:04Z
- job="APM" instance="APM_1": Delete Group
- job="APM" instance="APM_2": Delete Group

Figure 6- Current operational state of the deployed services in pilot sites

3.6 Recruitment and general usage of devices

Different devices have been implemented in each of the pilots carried out. Prior to each wave of pilots, a lab-testing phase is carried out. The lab-testing is a small-scale pilot, which was born as a contingency plan to address the difficulties of conducting large-scale pilots due to the COVID pandemic. After the first experience, we decided to maintain regular lab-testing prior to each wave of pilots. Thanks to lab testing in each scenario, the devices were tested individually and it helped us to prevent possible unforeseen events for the pilots.

Table 3 shows the devices used in all pilots, during wave 2 and the previous lab testing phase.

During the second wave 251 people affected by PD, AD or CVD participated in the pilot, using the TeNDER system in one of the four sets created (home, day care centre, hospital and

rehabilitation room). Participation in the trials lasted between 45 and 60 days. Prior to the pilot all participants underwent an initial interview and to complete the study a final interview was conducted. Of the 251 initial participants, 243 completed the final interview, which means a total of 8 drop-outs (3 in Spain, 1 in Germany and 4 in Slovenia).

The mean age of the patients participating in the second wave is 73,9 ($\pm 10,28$)

The percentage of female participants was slightly higher than that of male participants in the second wave.

Table 3- Main patient characteristics and use of devices by disease

CHARACTERISTICS	DISEASE			
	Total	AD	CVD	PD
	251	99 (39,04%)	89 (35,5%)	62 (24,7%)
Age Mean (\pm SD)	73,9 ($\pm 10,28$)	75,72 ($\pm 8,57$)	74,44 ($\pm 10,99$)	71,40 ($\pm 6,24$)
Sex				
MALE	115	23	54	38
FEMALE	135	76	35	24
OTHER	1*	0	0	0
Number of devices used				
FITBIT	112	29 (26%)	47 (42%)	36 (32%)
WITHINGS SLEEP ANALYZER	99	45 (45%)	35(35%)	19(20%)
KINECT AZURE	21	1 (5%)	-	20(95%)
XIAOMI MI BAND	20	20(100%)	-	-
MICROPHONE	1	-	-	1 (100%)
LOCALIZATION SENSOR	72	51 (71%)	-	21(29%)
KINECT 2	20	-	-	20(100%)
REAL SENSE	2	-	-	2 (100%)
BINARY DOOR	6	6 (100%)	-	-
ENVIRONMENTAL – TEMPERAT.	6	6 (100%)	-	-
ENVIRONMENTAL - HUMIDITY	6	6 (100%)	-	-
Mean duration of device usage in days Mean (\pm SD)				
FITBIT	15 \pm 13	20 \pm 23	15 \pm 14	13 \pm 5
WITHINGS SLEEP ANALYZER	23 \pm 17	24 \pm 17	17 \pm 18	12
KINECT AZURE	58 \pm 61	115	3 \pm 3	-
XIAOMI MI BAND	27 \pm 21	27 \pm 21	-	-
MICROPHONE	59 \pm 61	59 \pm 61	-	-
LOCALIZATION SENSOR	29 \pm 42	29 \pm 42	-	-
KINECT 2	13 \pm 5	-	-	13 \pm 5
REAL SENSE	0	-	-	0
BINARY - DOOR	161 \pm 1	161 \pm 1	-	-
ENVIRONMENTAL – TEMPERAT.	161 \pm 1	161 \pm 1	-	-
ENVIRONMENTAL - HUMIDITY	161 \pm 1	161 \pm 1	-	-

*This participant did not report his main disease when filling in the data.

The participation of caregivers in this second wave of pilots reached 104 participants. Of these, a total of 101 carers completed the study, which represents 3 drop-outs. The average age of the caregivers involved was 58,73 ($\pm 15,54$). There is a large difference in the percentage of female carers participating 64,42%, compared to 35.58% of male carers.

Table 4- Main characteristics of carers due to the illness of the person they are caring for

CHARACTERISTICS	DISEASE			
	Total	AD	CVD	PD
Total	104	51 (49,04%)	12 (11,54%)	41 (39,42 %)
Age Mean (\pm SD)	58,73 ($\pm 15,54$)	58,22 ($\pm 14,86$)	50,42 ($\pm 13,41$)	62,80 ($\pm 16,30$)
Sex				
Male	37	13	7	17
Female	67	38	5	24
Other				

The number of professionals involved in the second wave of pilots of the TeNDER Project was 55, with a marked female presence (78.18%). The average age of the participating professionals was 41,16 ($\pm 11,71$). Most of the professionals involved were health professionals (89,09%), although social workers and others were also present.

Table 5- Main characteristics of professionals by gender

CHARACTERISTICS	SEX			
	Total	Male	Female	Other
N=	55	12	43	0
Age Mean (\pm SD)	41,16 ($\pm 11,71$)	40 ($\pm 11,80$)	41,40 ($\pm 5,30$)	-
Profession				
Health professional	49	11	38	0
Social professional	2	-	2	0
Other professional	4	1	3	0

3.7 Technical upgrades

During the second wave, on a technical level, the implementation of several sensors and functionalities has been completed. On the one hand, the binary sensors and the environmental sensors for temperature and humidity have been incorporated into the home scenario. In addition, methods for detecting abnormal behaviour have been developed.

Improvements have also been made to sensors and functionalities already present in the first wave. In the case of the rehabilitation room, exercises have been added to the existing battery for the first wave, the voice control of the activation and deactivation commands and the different exercises has been improved and a tool has been implemented that allows programming the activation and deactivation of the Kinect 2 camera in each of the patients, so that professionals do not have to do it manually.

4 RISKS MANAGEMENT

This section includes a description of general risks management and measures applied for the pilots' activities and execution.

Besides the general approach adapted to all end user partners, this section describes also specific measures applied for the risk management in each Pilot.

4.1 Legal & ethical risk management in TeNDER pilots

Legal and ethical risk management in the TeNDER pilots was developed at the beginning of the project prior to the start of the first wave of pilots. Therefore, the following text is taken from D6.2, which first detailed the legal aspects, and is shared with the present deliverable.

Table 6- Legal and Ethical Risk Management Pilots (from D 6.2)

The legal and ethical framework, applicable to TeNDER pilots, was described in D1.1 Fundamental Rights, Ethical and Legal Implications and Assessment in more detail, and the impact of the pilots on fundamental rights in the first impact assessment (submitted in M22). In this subsection, we will briefly repeat its main findings regarding two important aspects; the data protection challenges and biomedical ethics aspects of the second wave of pilots.

In the pilots, the data of patients and caregivers will be processed in order to develop an integrated care model. These data are considered personal data in the sense of the GDPR, insofar they fall under its scope of application.

The GDPR applies to processing of personal data. These notions are defined in Art. 4(1) and (2), respectively as: '**personal data**' means any information relating to an identified or identifiable natural person ('data subject'). '**Processing**' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

In the TeNDER pilots, patients' health data will be processed. Due to their sensitivity and a higher impact on the data subject in case of a privacy breach, a stricter regime applies to processing of sensitive data. Their processing is not allowed unless restrictive criteria of art. 9 of the GDPR are met (such as processing with the explicit consent of the patient), and the regime may be further restricted by national legislation. '**Health data**' under the GDPR mean personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about their health status.

Various technologies, such as wearables and other sensorial devices and appliances, will be utilised in the pilots. The type of data that is currently intended to be collected includes identifying data (e.g.name, sex, age, place and date of birth, address, ID/social system number), geo-localisation data and data concerning health status. It is therefore safe to conclude that the data processed by the TeNDER project falls under the definition of personal data, and some under the definition of sensitive health data, and thereby will fall within the scope of the GDPR.

The partners involved in the pilots will be acting as either data controllers or data processors. '**Controller**' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; '**processor**' is defined as a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller.

The controller shoulders the burden of compliance with the obligations under the GDPR – it is responsible for and must be able to demonstrate compliance with data quality principles, as specified in art. 5 of the GDPR, inter alia the purpose limitation, data minimisation and accuracy principles. Moreover, the controller is obliged to implement appropriate technical and organisational measures to ensure and to be able to demonstrate that processing is performed in accordance with the rules of the GDPR, according to its art. 24. The processor carries out the processing under the authority of the controller and is not allowed to deviate from the controller’s instructions unless required to do so under national or European Union law.

In the pilots context, the user partners are acting as controllers and the technical partners as processors; therefore, they have signed respective data sharing agreements, which in accordance with art. 28(3) of the GDPR, set out the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the obligations and rights of the controller.

Data processing must be based on valid legal grounds. As explained above, in case of processing sensitive data, explicit consent is required. The term explicit relates to the manner in which consent was expressed by the data subject and means that “the data subject must give an express statement of consent”. Explicit consent may be obtained in writing as well as digitally and orally. However, like with consent, the controller has a duty to demonstrate consent was obtained. For that reason, documenting consent in writing holds clear benefits and TeNDER partners have obtained written consent from all the patients involved.

The right to data protection will be fully respected in trials. To this end, the consortium has taken steps to respect applicable legal and ethical frameworks, and several measures regarding the treatment of personal data have been adopted by the consortium partners. More specifically, our approach has been three-pronged:

1. **Definition of applicable framework in D1.1 Fundamental Rights, Ethical and Legal Implications and Assessment (First Version):** applicable legal and ethical frameworks, such as the GDPR, elemental principles of biomedical ethics, and regulation of medical devices. Based on our analysis, we defined the fundamental obligations of pilot partners vis-à-vis patients on protection of personal data, involvement of participants in pilots, ethical and social aspects, and safety requirements of medical devices deployed. Further, ethics compliance was demonstrated by our work in WP10.
2. **Support for pilot set-up and execution:** based on findings from step one, informed consent forms and information sheets for participants were drawn up. In this way, the consortium sought to fulfil the requirements of art. 13 and 14 of the GDPR and ensure the autonomy and informed consent as the fundamental principles of biomedical ethics. Data sharing agreements were circulated and signed by partners involved in specific trials, taking into account the roles of controllers and processors.
3. **Impact assessment and continuous legal and ethical monitoring:** in the impact assessment, we take into account the nature, scope, context and purposes of the processing in the TeNDER pilots in order to ascertain risks to the fundamental rights and freedoms of patients involved. The first impact assessment was carried out before the first wave of the pilots, and reflects the consortium’s risk assessment and risk response based on the current technical development. Our initial findings were reported in the D1.4 First legal/ethical monitoring report, submitted in M22, and will be revisited in D1.5 Final legal/ethical monitoring report (due M42) and D1.6 Final version of Fundamental rights, ethical and legal implications and assessment (also due M42).

Table 7 -Technical responsibility for each Pilot site

PILOT	END-USER PARTNER	PARTNER RESPONSIBLE FOR TECHNICAL SUPPORT
1	SERMAS	UPM
2	APM	UPM
3	UNITOV	DW
4	SKBA	CERTH
5	SPO	ELG

In addition, in order to minimize the risk of failure during the installation and integration of devices procedure, the consortium elaborated a tool named “Issue Tracker”, available for all researchers in TeNDER sharing and coworking platform. Issue Tracker allows prompt notifications addressed to partner involved in specific tasks: this tool was created in order to optimize and speed-up communication and coworking between partners, especially between end users' partners and technical partners during the piloting. In particular, this tool allowed a quick resolution of issues raised during the piloting. Issue tracker notify all activities required to respective partners, classifying them based on priority. In addition, Issue tracker allows an overview of calendarization and planning of the activities.

An important aspect related to the piloting phase is the COVID-19 pandemic and the impact of restrictions and safety measures during the piloting. The protocol concerning the safety measures to reduce transmission of COVID-19 was already described in D6.1, but it will be implemented throughout the entire project. In fact, both European and national directives are subject to changes based on changes of circumstances regarding COVID-19 transmission in each country. The safety measures for COVID-19 are also subordinated to national governments and local rules, depending on the typologies of facility. Therefore, the COVID-19 impact and related safety measures are different and described in each pilot section.

4.2 Risk Management in Pilot 1

SERMAS leads the Pilot 1 and involves for the second wave the home scenario. During the design of the second wave, we encountered difficulties that we had to overcome. As a result of the numerous waves of population reinfections by Covid, Spanish health centres have been overwhelmed by the demands of the population. This saturation of Spanish primary care has made it difficult to recruit participants, both in terms of the number of professionals and the number of patients and carers.

4.2.1 Covid19 pandemic impact and safety measures

As during the first wave of SERMAS pilot 1, patients were recruited through their health professionals in the health centres of the Community of Madrid. In order to involve the professionals and taking into account the delicate and overloaded workload they are going through; a series of premises were followed to include each actor:

Health professionals:

We presented the project via email to the health centre directors and only if they thought it was appropriate did, we go in person to tell them about it. If they did not come in person, we sent them as much information as possible.

In each health centre, a person in charge was assigned and through this person we communicated with the rest, to avoid face-to-face meetings. In addition to this, there was a support that we used to share material and information for the project: a content platform created exclusively for the project.

Given the effort of the professionals to get involved in the project despite the difficulties and work overload caused by Covid, it was decided to use the content platform to include them in a project training and accredited course. This was intended to encourage the participation of professionals.

Patients and carers:

Health professionals took advantage of consultations at the health centre to offer participation in TeNDER to those patients who met selection criteria. This reduced unnecessary contacts and gave patients more trust. Once they had signed the informed consent form, a health professional assigned to the project would telephone them and arrange an appointment with them, which could be at the health centre or at home, at the patient's choice. The installation was intended to be with a single person from outside the home, and if support was required, it was carried out by telephone to minimise contact. At all times, support was provided telematically.

4.3 Risk Management in Pilot 2

APM is leading Pilot 2 and during the second wave, our organization has had to face the new normality originated by covid and the recurrent waves of contagions that it has produced. As a result, we have had to face the fear of contagion of patients and their families, the suppression of the day care centre scenario (since we have not been able to reopen this service in our organization), a lower volume of patients treated in our rehabilitation centre, and the uncertainty and constant adaptations that have occurred.

4.3.1 Covid19 pandemic impact and safety measures

APM has had to adapt its care protocols to the health situation and to the regulations that the different health authorities have developed over time. Key measures include the use of masks, the use of alcoholic hydrogels for hand disinfection, increasing the distance between people in the association's activities, as well as a detailed protocol regarding disinfection, cleaning and ventilation of the facilities, and the use of air purifiers.

As a consequence of the measures implemented and the fear of many patients and caregivers of contagion, APM has had to make an extra effort to reach the agreed number of participants in the project. For example, we had to include in the pilot a larger number of therapy groups in the rehabilitation room setting due to, on the one hand, the smaller number of participants per therapy group and, on the other hand, the increased interpersonal distance, which meant that at most one therapy group could only cover the area occupied by 2 patients. All this has meant a notable increase in the use of human resources linked to the project.

On the other hand, we have been forced to dispense with the day care centre scenario with the need to include the number of patients initially planned in this set in other scenarios (rehabilitation room or home).

Likewise, the recruitment of patients for the home set has been complicated and has required an additional effort of information and awareness, since many families were not very receptive to the idea of people outside their usual circle of coexistence entering the home to perform the installations.

However, with all the efforts made, we have been able to overcome the difficulties and reach the expected numbers for the second wave.

4.4 Risk Management in Pilot 3

The impact of COVID-19 on Pilot 3 was carefully considered. This evaluation takes into account national recommendations and measures including restrictions and confinements of

trial participants and trial staff and the availability of trial staff to perform visits, enter data and, more generally, follow the protocol. The ability to confirm eligibility and to conduct key safety assessments and trial evaluations is of particular importance.

Priority was given to the impact on the health and safety of the pilot participant. Where a pilot participant is unable to attend the site, other measures, such as home nursing, if possible, given social distancing needs, or contact via phone were used to ensure continuous medical care and oversight.

The following risk were considered and mitigated: conversion of physical visits into phone or video visits, postponement or complete cancellation of visits to ensure that only strictly necessary visits are performed at sites; slowing down of recruitment of new trial participants (mitigated with an early start in the recruitment of participants and carers).

A risk assessment of each individual ongoing trial was done giving priority to trial participant safety and data validity.

4.4.1 COVID-19 pandemic impact and safety measures

In hospital scenario the compliance with AntiCOVID-19 national regulations defined by The Italian Ministry of Health was guarantee during the execution of the Pilots.

Then, each patient and caregiver underwent a triage assessment in which there is a section regarding COVID-19.

Also, technicians of DW that performed the installation of devices in hospital scenario underwent a triage assessment. The impact of the COVID-19 spreading in this setting regards mainly the reduced access of the patients to not emergency services and, therefore, there was an impact on the recruitment of patients (and caregivers).

The major impact of COVID-19 spreading concerning TeNDER in home setting regards the installation and uninstallation of devices in home scenario: UNITOV elaborated Safety measures guidelines for TeNDER home installation and deinstallation procedures, in accordance to DW. In particular, in order to follow these necessary guidelines, the timing of installations was significantly affected.

Guidelines prepared for UNITOV full home set installation:

“DW employees, patients and caregivers will need to follow and share the following safety measures:

- *During the sensor installation and deinstallation procedures, the environment must be ventilated and the windows must be open.*
- *The home environment must be cleaned and disinfected*
- *The patient and the caregiver must maintain a safety distance of at least 2 meters from the DW employees. In addition, the patient and caregiver must be in a different room from that of the DW employees during the sensor installation and uninstallation procedures.*
- *DW employees will carry out a molecular test (using a nose-pharyngeal swab) to detect the presence of Sars-Cov-2 in the 72 hours prior to the installation and deinstallation procedures of the sensors at the home of the participants in the TeNDER project.*
- *During the procedures, DW employees will wear suitable protective equipment during the installation and deinstallation procedures of the sensors at the home of the TeNDER project participants (FFP2 mask, disposable gloves, visor) and will sanitize their hands with disinfectant gel.*
- *The patient and the caregiver will also wear suitable protective equipment during the installation and deinstallation procedures (FFP2 mask, disposable gloves) and will sanitize their hands.*
- *Patient and Caregiver will provide a declaration in which they self-certify that:*
 - 1) *They are not positive for Covid19*
 - 2) *They're not in quarantine*

3) *Have no suspicious symptoms for Covid19 (e.g., fever, cough, shortness of breath, chills, muscle aches, headache, sore throat, loss of smell or taste)*

4) *They had no contact with people who then tested positive for Covid19 in the previous two weeks.”*

4.5 Risk Management in Pilot 4

SKBA leads the Pilot 4 involving hospital scenarios with stroke and Alzheimer patients. During the design of the second wave, we had to face and overcome new challenges of the pandemic. The main difficulties were, that only a small number of severely affected patients were admitted to the hospital and the Alzheimer therapy centre were partly closed for patients and caregivers.

4.5.1 Covid19 pandemic impact and safety measures

SKBA strictly followed the Covid-19 regulations by the Robert Koch Institute¹. Regarding vaccinations the instructions of the Paul Ehrlich Institute² were implemented. Furthermore, additional regulations considering the specific circumstances and factors at SKBA as a hospital with highly vulnerable patients and performing scientific work were developed in close cooperation by internal hygiene experts. At SKBA the general situation regarding Covid-19 was constantly evaluated. Possible risks were detected in regular meetings and respective actions were taken immediately, if necessary. This included restriction of visits to the clinic (completely or partly), wearing a specific face mask at all times, washing hands/using disinfectants when entering the hospital area or when engaging with patients, and keeping safe distances to others. Professional masks or FFP2 masks without a filter are still used according to the current guidelines and the recommendations of the hygiene experts at SKBA. Also, if possible, employees worked in home-office to keep the contacts at the lowest possible level. Furthermore, general Covid-19 tests are still required in specified intervals from each employee, in order to be able to work at the facility. All measures are constantly adapted to the current COVID-19 situation on a daily basis. Material used during the contact is disinfected according to a procedure approved from the hygiene experts. In case disinfection is not possible the material will be discarded.

At any time, all employees involved in the TeNDER project follow the recommendations and guidelines to protect the patients’ rights, safety, and wellbeing. In case a participant of the TeNDER trial cannot follow the safety and hygiene regulations and the medical project leader detects a risk increase, actions putting the respective person at risk were and will be stopped immediately.

Vaccination was offered to all employees of SKBA. All members of the TeNDER team had been vaccinated at least three times.

4.6 Risk Management in Pilot 5

Testing of TeNDER system in Slovenia involves the home scenario and in the day-care centre scenario. During the design of the second wave, we encountered difficulties that we had to overcome. The main difficulties were according to the bad epidemiologic situation in regards to covid-19 when the piloting started. Slovenia was on the world top by Covid-19 positive cases and had systemically bad situation in the social-care institutions and within the healthcare system. SPO has had to adapt its protocols to the health situation and to the regulations that the authorities have adopted over time. In addition, special care was taken considering the specific circumstances and factors at each piloting environment as working with highly vulnerable patients. When the general epidemiologic situation concerning Covid-19 was getting better in the Slovenian population, the problems in health care system persisted and professionals were still overloaded with the work and related procedures,

moreover, the postpones of the visits due to the pandemic issue has had delayed effect on the availability of the professionals to be involved in TeNDER. Even the cases were dropping in the whole population, there was still high virus spread among elderlies and many patients and carers that were already recruited in TeNDER had to be postponed with the inclusion process due to bad health conditions and also due to fear of infection. According to the delays and difficulties to perform the installation in home scenarios, but also in day care centres, SPO team used the mitigation plan as in the 1st wave and adapted the time of the testing accordingly. Moreover, the procedure was adapted to fit the safety measures and only fully vaccinated researchers that were also regularly self-tested performed TeNDER procedures. Moreover, only 2 people were at the same place when installing, interviewing and performing the TeNDER testing – so to minimize the potential spread of the virus.

4.6.1 Covid19 pandemic impact and safety measures

SPO follows protocol “SARS-CoV-2 Infection Control Plan (Covid-19) - protocols for the operation of institutional care providers”, defined by government of Slovenia . The general measurements have been constantly adapted according to the change of the Covid-19 situation. All the institutions that are having contract with SPO to participate with their residents in TeNDER testing have own protocols and follow the general guidance from NIJZ (National Institute of Public Health) and Slovenian Ministry of Health provisions and general and institutional rules for mitigation of Covid-19 risk spreading. All the rules and guidance form Slovenian government, Ministry of Health, NIJZ and institution, where the testing takes place, are followed by researchers form SPO and supporting technical partner ELG.

5 OUTCOMES PER PILOT

The results of each individual pilot are detailed below. It explains the characteristics of each scenario developed. A table and text provide a descriptive analysis of the users involved according to the disease. Afterwards, the devices and functionalities that have been implemented in each of them are detailed. Finally, the functionalities that have been left pending to be addressed in the testing lab and in the third wave are presented, as well as the planning to address possible discrepancies that have arisen and how to solve them for the next steps.

5.1 PILOT 1 (Madrid region, Spain)

5.1.1 Scenario

Home scenario

SERMAS primary care services provide patients to participate in the project. Patients are informed and recruited by their own primary care professionals involved in the TeNDER project. Once patients accepted to enjoy the project, they sign informed consent and arrange a meeting for the interview and device installation.

The setting in this pilot was the patients' homes. The devices were delivered and installed and the participants used them in their usual environment, their home, 24 hours a day.

5.1.2 Summary of relevant innovations

The advances in this wave with respect to the first have been notorious. Among the new functionalities incorporated are fall detection as a new functionality of the Well-being and those associated with the Sleep tracker such as Heart rate, respiration rate, sleep state, sleep score, snoring, detection, sleep duration and sleep quality.

In addition, the data collected has been transformed into a report for the participants through the TeNDER App.

5.1.3 Users involved in the Second wave of Pilot 1

SERMAS has had a total of 110 participants in the domestic setting. Of these, 74 were patients, with the majority being cardiovascular patients (94.7%). The carers involved were 10 and the professionals 25. With regard to the analysis by sex, it can be seen that the majority of CVD patients were men (60.6% vs 39.4%), while in the AD, on the other hand, women predominated (75% vs 25%). Both professionals and patients, the majority were women 84% and 80% respectively. The total number of participants includes one patient who did not provide socio-demographic data. An overview of users involved is described in Table 10.

Table 8- Participants involved in the Second Wave of Pilot 1

PILOT 1 (SERMAS)					
Characteristics	Participants Involved				
Total N= 110	Professionals n= 21	Caregivers n= 11	Patients n=74 *		
			AD 5(5.33%)	CVD 66(90.4%)	PD 2(2.7%)
Age Mean (±SD)	46 (±12.9)	51.2(±13.8)	87.2(±5.0)	74.7(±6.9)	83 (±4.2)
Male	4(19%)	6(54.5%)	2(40%)	39 (54.9%)	2 (100%)
Female	17(81%)	5(45.5%)	3(60%)	27(38.0%)	-
Other	-	-	-	-	-
Stakeholders screened, but not included	30	50	6		
Dropouts	-	1	1		

* The total number of participants includes one patient who did not provide socio-demographic data.

5.1.4 Devices assigned and functionalities tested

Under the technical support of the UPM, the second wave of piloting was carried out at SERMAS in the Home set.

The devices that are being tested in patients:

- Fitbit Versa + smartphone/tablet (in case of patient's personal smartphone was not compatible with TeNDER) for the patient;
- Whitings sleep sensor + smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER) for the patient;
- High MiniPC

Next steps for testing labs:

- Position Tracker
- Binary – Door
- Environmental – Humidity

- Environmental - Temperature

The functionalities to be tested:

Table 9- Functionalities to be tested after Second Wave in Pilot 1

DEVICE	DATA	FUNTIONALITY
Smartband Fitbit versa 2	Raw measurements from accelerometer	Well-being Fall detection
Sleep tracker Withings sleep analyzer	Heart rate, respiration rate, sleep state, sleep score, snoring detection, sleep duration	Quality of sleep
Smartphone	App interaction	Quality of sleep (feedback) Well-being (feedback)
TeNDER App	App interaction	Patients and caregivers are able to access to the information related to this functional through the TeNDER App and professionals through the TeNDER WebApp.

5.1.5 Discrepancies with planned protocols, mitigation and integration plans

Some functionalities such as Adherence to drug treatment and Emotional status were not ready for use. As far as possible they will be incorporated in the testing lab part in order to have them ready for the third wave. The caregiver communication module was not ready, so not many participants with the caregiver profile have been included.

Due to COVID-19 restrictions was decided to avoid using Position trackers as it was planned. The installation of this sensor involves the entry of multiple people into the patient's home that could generate rejection to the project development. Because of this the activity and room localization functionality will not be available.

5.2 PILOT 2 (Madrid city, Spain)

5.2.1 Scenarios

Rehabilitation Room

The Rehabilitation Room was set up in the association's two rehabilitation centres (Calle Poeta Esteban de Villegas 12 and Calle Andrés Torrejón 18, in Madrid City).

In this scenario the Kinect2 depth cameras have been tested with the rehabilitation room exercise tool that Hetra has and the FitBit Versa2 smart bracelets. Also, the users of this set have been able to test the mobile app, in the case of patients and caregivers, and web app, in the case of professionals.

The patients involved in this scenario have regularly attended their physiotherapy sessions, during which the exercises included in Hetra's rehabilitation tool have been performed. They also wore the FitBit bracelets continuously for the duration of the pilot (between 6 and 8 weeks).

The main objective of this scenario is to capture the dexterity when executing the exercises within the therapy sessions and thus be able to have objective information about the

evolution of the patients while being able to give them feedback on how effective the execution of their exercises is being, seeking to increase motivation and guide them on which movement patterns they should train more. On the other hand, thanks to the FitBit bracelet we can monitor the heart rate throughout the day as well as the average daily physical activity.

Home set

The domicile scenario has been divided into two sub-scenarios:

- The first one, has been composed of the FitBit smart wristband and the Withings sleep sensor.
- The second one is composed of Real Sense depth camera, Microphone and Fitbit smart bracelet.

During the duration of the pilot (between 6 and 8 weeks) the users involved in this scenario have continuously worn the Fitbit wristband, used the bed sensor on a daily basis or have been monitored by the depth camera and the microphone.

The main objectives of this scenario are:

- Increase the sense of security within the home itself, thanks to the depth camera and microphone placed in the room where users spend most of the day (usually the living room) and that allow to capture events such as falls or festination among others.
- Monitor heart rate and daily physical activity.
- Monitor sleep in terms of number of hours, fragmentation, depth, etc.

Simulation circuits

During the second wave, an additional battery of patients who participated in a series of circuits was included in order to identify events of festination, freezing or falls. For this purpose, a series of itineraries with obstacles were designed to provoke the events. During the circuit, patients were monitored thanks to the real sense depth camera and the FitBit Versa2 smart wristband.

In this scenario APM has included 11 participants, all of them affected by PD.

The main objective of this scenario is to collect data to train event recognition algorithms.

5.2.2 Summary of relevant innovations

Among the innovations tested, it is worth mentioning the voice functionalities incorporated in the rehabilitation tool that allow activating and deactivating the system with simple voice commands, as well as changing exercises or knowing the exercise in which the tool is activated. For this purpose, the MiniPC in the rehabilitation room has a microphone and speakers so that the interaction with the system is done through them.

Additionally, a task scheduler has been included to program which patient will be in each room and position, facilitating data collection and enabling the monitoring of patients to be done automatically.

5.2.3 Users involved in the Second wave of Pilot 2

APM has included in this second wave a total of 48 patients, 27 caregivers and 10 professionals.

Of the 48 patients included, 27 are cases and 21 are controls. Of the 27 cases, 7 have participated in the home setting and 20 have been included in the rehabilitation room. In addition to these 48 patients, APM has involved 11 patients in data simulation circuits to train the event detection algorithm with Fitbit and depth camera.

Table 10 - Participants involved in the Second Wave of Pilot 2

PILOT 2 (APM)					
Characteristics	Participants Involved				
Total N=	Professionals 10	Caregivers 29	Patients		
			AD	CVD	PD 48 (100%)(27 cases, 21 controls)
Age Mean (\pm SD)	30,8 (\pm 7,38)	63,07 (\pm 15,52)	-	-	76,74 (\pm 6,67)
Male	4 (40%)	12 (41,38%)	-	-	31 (18, 13) (64,58%)
Female	6 (60%)	17 (58,62%)	-	-	17 (9, 8) (35,42%)
Other	0		-	-	0
Stakeholders screened, but not included	0	1	0	0	6
Dropouts	2	1	-	-	1

5.2.4 Devices assigned and functionalities tested

APM received technical support from UPM for the installation of the devices.

Rehabilitation room scenario

- MiniPC
- Kinect 2
- Speakers³
- FitBit Versa2
- Smartphone

Home set scenario

- MiniPC
- Real Sense
- Withings Analyzer Sensor
- Microphone
- FitBit Versa2
- Smartphone

The functionalities tested:

³ The speakers used in the rehabilitation room are implemented in the voice assistant that incorporates the rehabilitation tool so that therapists can use it without the need for a keyboard or mouse to facilitate their work with patients.

Table 11 -Functionalities to be tested after Second Wave in Pilot 2

DEVICE	DATA	FUNTIONALITY
Smartband Fitbit versa 2	Raw measurements from accelerometer	Well-being
Sleep tracker Withings sleep analyzer	Heart rate, respiration rate, sleep state, sleep score, snoring detection, sleep duration	Quality of sleep
RGBD Sensor Kinect v2	RGB colour images and Depth images which are used to extract the skeleton	Well-being
RGBD Sensor Real sense	RGB colour images and Depth images which are used to extract the skeleton	Fall detection
Microphone	Sound	Fall detection
Smartphone	App interaction	Adherence to drug treatment Medical examinations Quality of sleep (feedback) Well-being (feedback) Fall detection (feedback)

5.2.5 Discrepancies with planned protocols, mitigation and integration plans

Due to the COVID-19 health crisis, APM has been forced to adapt its test scenarios. As happened in the first wave, APM has been forced to dispense with the day centre scenario, since as a consequence of the health crisis caused by COVID, the entity had to close this service and to this day continues to be unable to open it.

In relation to the rehabilitation room scenario, in addition to protective measures such as masks, we have been forced to increase the interpersonal distance between patients, so the number of patients who could participate in the test in each of the sessions has been reduced to a maximum of two, so it has been necessary to involve a greater number of therapy groups and consequently a greater number of hours of work of therapists to cover the target number of patients agreed in the agreement.

In relation to the home setting, we have had to adapt to the different waves of contagions that have occurred and reschedule on several occasions planned facilities as a result of contagions or close contacts. We have encountered some difficulties in getting those affected to agree to participate in this scenario due to the fear of contagion when people outside their usual living environment come to their homes.

At all times, the safety protocols established by the health authorities and the protocol developed by the association have been respected.

5.3 PILOT 3 (Rome, Italy)

5.3.1 Scenarios

Hospital and home scenarios

The hospital scenario has been performed at SLUCIA (Fondazione Santa Lucia IRCCS, Via Ardeatina 306-354, 00179, Rome, Italy) on the responsibility of UNITOV (University of Rome “Tor Vergata”).

Santa Lucia Foundation is a landmark institution in the field of highly specialized neurorehabilitation. Strong related health cares and research build its core activities. Neurorehabilitation programs affects patient with both, motor and cognitive deficits. Health services are provided under an agreement with the National Health Service (SSN) and also on a private patient basis³.

The hospital setting that has been evaluated for the Pilot 3 is the neurological practice for non-hospitalized patients: day-hospital, neurological examinations, routinely evaluations according to clinical practice.

UNITOV team planned to involve patients and caregivers by providing a system that can be used and tested both in hospital scenario and in home scenario. Therefore, all users involved in the Second wave of Pilot 3 tested the TeNDER system sets both in hospital scenario and in home scenario.

5.3.2 Summary of relevant innovations

The most relevant technical innovation is the use of localization tools and kinetic azure. An higher number of subjects were tested in the second wave of the pilot.

5.3.3 Users involved in the Second wave of Pilot 3

We reported data from 10 Fitbit sets and 10 homeset for a total amount of 20 patients (9 AD patients and 11 PD patients).

Hence, we are collecting data from 18 Fitbit sets both in Hospital and in-home scenarios.

We recruited a total of 20 patients, 22 caregivers, and 8 Health professionals.

During testing, one patient left the study (drop out); two fit-bit were accidentally broken by patients during the trial.

Table 12 - Participants involved in the Second Wave of Pilot 3

PILOT 3 (UNITOV)					
Characteristics	Participants Involved				
Total N= 28	Professionals 8	Caregivers (22)	Patients (20)		
			AD 9 (45%)	CVD	PD 11 (55%)
Age Mean (±SD)	42,5 (±3,5)	58 (±17.07)	71 (± 4,95)	-	68.7 (±4.76)
Sex					
Male	2 (25%)	12 (54.55%)	1 (11.11%)	-	5 (45.45%)
Female	6 (75%)	10 (45.45%)	8 (88,89%)	-	6 (54,55%)
Other	-	-	-	-	-

Stakeholders screened, but not included	-	1	7	-	3
Dropouts	-	-	2	-	-

5.3.4 Devices assigned and functionalities tested

The installation and deinstallation procedures were performed by UNITOV with the support of DW.

Hospital set:

- Fitbit Versa 02 + smartphone/tablet (in case of patient's personal smartphone was not compatible with TeNDER) for the patient (n=10 Fitbit; n=4 smartphone/tablet);
- Smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER)
- Mini PC low-end installed at SLUCIA hospital
- Kinetic azure installed at SLUCIA hospital (the finalization of the installation of the devices was done at the end of the second wave and has not been implemented yet).

The functionalities tested by using Fitbit sets are Health tracking and Reminders tested by 10 patients (4 AD patients and 6 PD patients), 10 caregivers, 8 professionals.

UNITOV's home set consists in:

- Fitbit Versa 02 + smartphone/tablet (in case of patient's personal smartphone was not compatible with TeNDER) for the patient (n=7 for homesets);
- Localization trackers (n=28 for homesets)
- Smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER) (n=2 for homesets)
- Mini PC low-end (n= 7 for homesets)

The functionalities tested by using UNITOV's home sets are Health tracking, Reminders, Nocturnal activities, Localization trackers, Emotional detection tested by 8 patients, 8 caregivers and 8 professionals.

Two out of the 10 patients tested with the home set broke their device accidentally, for this reason the localization tracker testing did not work for these subjects.

5.3.5 Discrepancies with planned protocols, mitigation and integration plans

As described above in Section 3, some sensors were not ready for the second wave of Pilots due to various issues. In particular:

Speaker: was not ready for the installation;

Real Sense: Technical issue due to the low-end PC that was unable to support the sensor;

Binary Sensors: huge delay in the delivery of the devices;

Binary sensor and Aqara hub: the device used for connection was delivered late during the pilot;

Microphone: was not ready due to technical issues.

Real Sense cameras (purchased for the UNITOV's home set) were not ready for the integration in TeNDER system, as mentioned in the Section 3

The position tracker has been installed in the Second Wave. The Kinect Azure, missing in the first wave, has been installed and integrated in the Second wave of Pilot 3, according to technical developments.

5.4 PILOT 4 (Bavaria, Germany)

5.4.1 Scenario

Hospital scenario

The Schön Clinic hospital in Bad Aibling (Kolbermoorer Str. 72, 83043 Bad Aibling, Germany⁴ and the Alzheimer's Therapy Centre of the hospital were the settings of the SKBA pilot scenarios. The pilot has been conducted under the responsibility of SKBA.

5.4.2 Summary of relevant innovations

The most relevant technical innovation is the use of the Fitbit and the sleep sensor. A higher number of subjects were tested in the second wave of the pilot.

5.4.3 Users involved in the Second wave of Pilot

Users involved for the 2nd wave of piloting at Pilot site 4 were patients hospitalised at Schön Clinic Bad Aibling, either in the main hospital or in the Alzheimer's Therapy Centre. Patients with AD, CVD and PD were included, as well as informal caregivers (family members) of AD patients. Professionals from SKBA were continuously involved in the second wave to support respective patients. In the 2nd pilot also control participants were recruited.

Table 13 - Participants involved in the Second Wave of Pilot 4

PILOT 4 (SKBA)					
Characteristics	Participants Involved				
Total N=40	Professionals 7	Caregivers 16	Patients 30 (+10 control patients)		
			AD 16 (+1)	CVD 14(+9)	PD -
Age Mean (±SD)	39,86 (±13,88)	71,56 (±8,35)	72,73 (±9,77)	78,14 (±9,05)	-
Male	2	5	7 (+1)	9 (+6)	-
Female	5	11	9	5 (+3)	-
Other	-	-	-	-	-
Stakeholders screened, but not included	-	-	4	13	-
Dropouts	-	-	1	1	-

5.4.4 Devices assigned and functionalities tested

Installation and deinstallation of devices have been performed by researchers of SKBA with the (virtual) support of CERTH. The following devices were installed at the hospital setting:

Hospital scenario for 2nd wave of piloting:

- Fitbit Versa 02 + smartphone/tablet for the patient
- Sleep tracker (Withing's Sleep Analyzer) sleep quality and according daily management + smartphone/tablet for the patient
- Smartphone/tablet for the caregiver (in case of caregiver's personal smartphone was not compatible with TeNDER)
- Mini PC low-end installed at SKBA hospital

- Kinetic azure installed at SKBA hospital (Lab testing)

The functionalities tested by using Fitbit and/or Sleep Tracker sets are Health tracking and reminders tested in the 2nd wave by 30 patients (16 AD patients and 14 CVD patients), 16 caregivers, 7 professionals. Additionally, we included 10 control patients (1 patient with AD (male, 78,5 years) and 9 patients with CVD (3 ♀; 72 ±16,07 years).

Table 14- Functionalities to be tested after Second Wave in Pilot 4

DEVICE	DATA	FUNTIONALITY
Smartband, Fitbit Versa 2	Raw measurements from accelerometer	Activity during the day
Sleep tracker Withings sleep analyzer	Heart rate, respiration rate, sleep state, sleep score, snoring & apnoea detection, sleep duration, constancy – sleep habits	Quality of sleep, well being
Smartphone, Tablet	App interaction	Getting feedback about their Quality of sleep & Well-being
Kinect Azure	Data of different activities of daily living from patients	Recognizing activities in daily living – could detect fall

5.4.5 Discrepancies with planned protocols, mitigation and integration plans

In SKBA we mainly used the Fitbit wristband and the Sleep Tracker due to various issues for other sensors, as described above in Section 3. Besides, we always adapted to the wishes of the participants and involved only the functionality testing accordingly. Therefore, some patients only got the Sleep Tracker or only the Fitbit wristband. In some cases, the participant with CVD had a severe hemiplegia or spasticity, therefore we decided to not give the watch to not further interfere the healing/training/casting process.

Due to difficulties to test the App that persisted through the most part of the 2nd Wave of piloting, carers were not very interested to check the app, but they were more like passive users accompanying their caretakers and checked the final result mainly of the sleep data, that we gave them after participating.

The position tracker Kinect Azure was set up in a Lab-Environment to gather movement data from patients during standardized Berg-Balance-Scale (activity of daily living) movement analysing.

5.5 PILOT 5 (Slovenia)

5.5.1 Scenario

Home environment and day care centres

During the 2nd wave SPO recruited patients with dementia, their family members /or informal caregivers in their home environments and in day-care centres. The participants were testing modular TeNDER services accordingly to their wishes and technical requirements.

5.5.2 Summary of relevant innovations

The most relevant technical innovation is the use of the indoor position sensor and the sleep sensor. Based on the insight concerning sleep quality and constancy of sleep patterns, the daily activities and daily management of the patient with dementia can be adapted.

Moreover, using the position sensor, the time spent for the activity can be managed. Therefore, the daily management for a patient and his/her carer can be personalized.

5.5.3 Users involved in the Second wave of Pilot 5

Users involved for the 2nd wave of piloting in Pilot 5 site were included in day care centre environment, in home set environment. SPO included patients with dementia and their carers (family members or informal caregivers that are not in relation with a person with dementia, but are providing support and care, according to the inclusion criteria) or formal caregivers, and the professionals (health professionals, social workers, other workers).

Table 15- Participants involved in the Second Wave of Pilot 5

PILOT 5 (SPO)					
Characteristics	Participants Involved				
Total N=	Professionals 9	Caregivers 26	Patients		
			AD 69	CVD -	PD -
Age Mean (\pm SD)	40,4 (\pm 9,8)	49,9 (\pm 11,7)	76,3 (\pm 6,6)		
Male	-	4 (15%)	12 (17%)	-	-
Female	9 (100%)	22 (85%)	57 (83%)	-	-
Other	-	-	-	-	-
Stakeholders screened, but not included	-	-	-	-	-
Dropouts	-	-	4	-	-

5.5.4 Devices assigned and functionalities tested

Each primary user (participant as a patient) had its own set of devices that were connected locally to the PC and a TeNDER App installed on smart device (tablet or phone) that could be tested accordingly. Researchers from SPO and ELG performed the installation and deinstallation of devices. ELG prepared the complete devices set-ups before handing over the sensors` set to SPO. All hygienic and privacy measures were taken into account when passing the devices and the system to a new user. Researchers from SPO and ELG partners were following the rules from National Institute of Public Health and Ministry of Health to ensure safety regarding Covid-19, but also the internal institutional procedures that were changing continuously due to the internal situations (namely in day-care centres). All sensors were connected to a Mini PC that was dedicated for a single user, essential information provided to the HeTRA system on the Mini PC and the TeNDER App set-up on a smart device, before providing the devices for usage to the participants. Usually, the setup consisted of 1-3 localization sensors, wristband, sleep analyser, tablet/phone and Mini PC. Each user and corresponding devices with essential identifications were registered in the TeNDER platform, activated and connected accordingly. Potential issues found were reported to issue tracker/Trello of the consortium and at the weekly Telcos or communicated by ELG to other technical partners. Kinect Azure and high-end PC were in the lab testing.

After the data gathering, the sensors are collected from the participants, disinfected and reset to factory setting. All sensors and participants needed to be deactivated in the TeNDER platform.

Home set scenario set for the 2nd wave of piloting

- Sleep analyzer – sleep quality and according daily management
- Localization sensors – activity and presence in the living environment
- Wristband – activity and presence in living environment
- Mini PC
- Smart device (tablet/smartphone) - communication

Day-care centre scenario set for the 2nd wave of piloting

- Localization sensors – activity and presence in living environment
- Wristband – activity and presence in living environment
- PC
- Tablet - communication
- Smartphone - communication

The functionalities tested:

Table 16- Functionalities to be tested after Second Wave in Pilot 5

DEVICE	DATA	FUNTIONALITY
Smartband, Localization sensors	positioning in the environment, time spent in precise environment, activity	Well-being
Sleep tracker Withings sleep analyzer	Heart rate, respiration rate, sleep state, sleep score, snoring detection, sleep duration, constancy – sleep habits	Quality of sleep, well being
Smartphone	App interaction	Quality of sleep (feedback) Well-being (feedback)

5.5.5 Discrepancies with planned protocols, mitigation and integration plans

Due to the epidemiological situation and difficulties in the Slovenian health and social care system, the piloting phase started late and the inclusion in the day-care centres was done by the end of the piloting wave. Moreover, there was poor interest to test the microphone, environmental sensors and other functionalities, so Spominčica adapted to the needs and wishes of the participants and designed the functionality testing accordingly in the 2nd wave. Due to persistent difficulties to test the TeNDER App by the carers, carers lacked the interest to be included, but they were more in the role of the passive users accompanying and assisting their caretakers.

6 OVERALL RESULTS

6.1 Description of participants

6.1.1 Patients

The sample size captured to start the pilots was 251 patients. The 45.8% were male. Table 17 show disease distribution by gender.

Table 17- Main disease by gender

	TOTAL N(%)	MALE N(%)	FEMALE N(%)
TOTAL N(%)	251(100)	115(45.8)	136(54.2)
AGE*		74.4(7.9)	73.5(11.9)
MAIN DISEASE			
- AD	99(39.4)	23(20)	76(55.9)
- CVD	90(35.9)	54(47)	36(26.5)
- PD	62(24.7)	38(33)	24(17.6)

*Mean (SD)

Patients were distributed in the scenarios described in table 18. Of the patients with AD as the main disease, they participated in day centres, homes and hospitals; for patients with CVD, the settings were homes and hospitals; for PD, they participated in homes, hospitals and rehabilitation rooms. Homes were the most frequent for AD and CVD while for PD it was the rehabilitation rooms. Of the total number of patients, 2 (0.8%) did not complete their participation in the TeNDER intervention.

Table 18- Pilot results by scenario

SCENARIO	TOTAL, N(%)	DAYCARE C N(%)	HOME N(%)	HOSPITAL N(%)	REH. ROOM N(%)	N/A N(%)
TOTAL, N(%)	251(100)	10(4)	147(58.6)	50(19.9)	42(16.7)	2(0.8)
AGE*	73.9(10.3)	78.5(4.1)	75.5(7.1)	71.6(14.9)	71.6(6.3)	-
MALE	115(45.8)	3 (2.6)	61(53)	25(21.7)	26(22.6)	-
COUNTRY						
-Spain	122(48.6)	-	79(64.8)	-	42(34.4)	1(0.8)
-Italy	20(8)	-	10(50)	10(50)	-	-
-Germany	40(15.9)	-	-	40(100)	-	-
-Slovenia	69(27.5)	10(14.5)	58(84.1)	-	-	1(1.4)
MAIN DISEASE						
-AD	99(39.4)	10(10.1)	67(67.7)	21(21.2)	-	1(1)
-CVD	90(35.9)	-	66(73.3)	23(25.6)	-	1(1.1)
-PD	62(24.7)	-	14(22.6)	6(9.7)	42(67.7)	-

* Mean (SD)

6.1.2 Caregivers

In the second wave of pilots, 104 caregivers participated. The mean age was 58.5(SD15.3) The majority were women (64.4%). Most of the carers were caring for relatives affected by dementia and Parkinson's disease, with dementia being the most frequent with 49%. Of the female carers, 56.7% cared for AD, 35.8% for PD and 7.5% for CVD.

Table 19- Caregivers-Socio-demographic characteristics

	TOTAL N(%)	MALE N(%)	FEMALE N(%)
TOTAL N(%)	104(100)	37(35.6)	67(64.4)
AGE*	58.5(15.3)	57.5(16.7)	59(14.5)
MAIN DISEASE			
- AD	51(49)	13(35.1)	38(56.7)
- CVD	12(11.5)	7(18.9)	5(7.5)
- PD	41(39.4)	17(45.9)	24(35.8)

*Mean (SD)

6.1.3 Professionals

In the second wave of pilots, 55 professionals participated. 78.2% were women; the majority were doctors, with lower percentages for social workers and other professionals involved.

Table 20- Professionals-Socio-demographic characteristics

	TOTAL N(%)	MALE N(%)	FEMALE N(%)
TOTAL N(%)	55(100)	12(21.8)	43(78.2)
AGE*	41.2(11.7)	40(11.9)	41.5(11.8)
OCUPATION			
- DOCTORS	49(89.1)	11(91.7)	38(88.4)
- SOCIAL WORKERS	2(3.6)	-	2(4.7)
- OTHERS	4(7.3)	1(8.3)	3(7)

Although professionals were informed about TeNDER, registered on the platform and were involved in the participation of patients and their carers, the tool was not ready for use by professionals. Therefore, the analysis below has not been conducted on professionals, as they have no say in the use of the TeNDER tool.

6.2 Autonomy

6.2.1 Patients

The adaptation of the scenarios, the devices and the functionalities used have been adapted to the diseases and severity of the participating patients, as well as to their level of autonomy. This level of autonomy also implies a greater or lesser burden on the caregiver. Table 18 details the autonomy of the participating patients according to their illness. Data were collected in the form of PROs (patient-reported outcomes), so some patients chose not to answer the questions.

The autonomy results were studied through 6 questions with a Likert-type response scale from 1 to 5 to which an option of N/A was added to offer the option of "no response". The scale ranges from 6 to 30, the higher the score, the greater the autonomy. The low score obtained by all participating patients is striking. This is due to the fact that they are an older population, with one or more chronic diseases.

Table 21- Autonomy by disease

	Total n(%)	AD n(%)	CVD n(%)	PD n(%)
1) How often do you require help from other persons in your daily activities?				
1. Always	14(5.6)	4(28.6)	8(57.1)	2(14.3)
2. Often	25(10)	10(40)	9(36)	6(24)
3. Sometimes	38(15.1)	10(26.3)	13(34.2)	15(39.5)
4. Rarely	74(29.5)	45(60.8)	12(16.2)	17(23)
5. Never	75(29.9)	7(9.3)	47(62.7)	21(28)
N/A	25(10)	23(92)	1(4)	1(4)
2) How often do you postpone doing things as you don't feel confident?				
1. Always	8(3.2)	3(37.5)	3(37.5)	2(25)
2. Often	30(12)	10(33.3)	12(40)	8(26.7)
3. Sometimes	50(19.9)	17(34)	11(22)	22(44)
4. Rarely	66(26.3)	39(59.1)	15(22.7)	12(18.2)
5. Never	72(28.7)	8(11.1)	47(65.3)	17(23.6)
N/A	25(10)	22(88)	2(8)	1(4)
3) How often do you confidently go out of your apartment/house?				
1. Always	124(49.4)	29(23.4)	63(50.8)	32(25.8)
2. Often	32(12.7)	10(31.3)	8(25)	14(43.8)
3. Sometimes	36(14.3)	24(66.7)	6(16.7)	6(16.7)
4. Rarely	17(6.8)	9(52.9)	4(23.5)	4(23.5)
5. Never	14(5.6)	3(21.4)	6(42.9)	5(35.7)
N/A	28(11.2)	24(85.7)	3(10.7)	1(3.6)
4) How often do you feel lost?				
1. Always	2(0.8)	2(100)	-	-
2. Often	6(2.4)	1(16.7)	5(83.3)	-
3. Sometimes	21(8.4)	13(61.9)	3(14.3)	5(23.8)
4. Rarely	16(6.4)	7(43.8)	4(25)	5(31.3)
5. Never	147(58.6)	20(13.6)	76(51.7)	51(34.7)
N/A	59(23.5)	56(94.9)	2(3.4)	1(1.7)
5) How often do you call services to help you?				
1. Always	-	-	-	-
2. Often	23(9.2)	2(8.7)	18(78.3)	3(13)
3. Sometimes	55(21.9)	18(32.7)	35(63.6)	2(3.6)
4. Rarely	45(17.9)	17(37.8)	17(37.8)	11(24.4)
5. Never	73(29.1)	12(16.4)	18(24.7)	43(58.9)
N/A	55 (21.9)	50 (90.9)	2(3.6)	3(5.5)
6) How often do you feel safe at home?				
1. Always	142(56.6)	14(9.9)	78(54.9)	50(35.2)
2. Often	22(8.8)	7(31.8)	6(27.3)	9(40.9)
3. Sometimes	16(6.4)	13(81.3)	1(6.3)	2(12.5)
4. Rarely	13(5.2)	11(84.6)	2(15.4)	-
5. Never	4(1.6)	3(75)	1(25)	-
N/A	54(21.5)	51(94.4)	2(3.7)	1(1.9)
TOTAL SCORE*	16.2(6.5)	12.1(7.9)	18.5(3.6)	19.4(3.2)

*Mean (SD)

The following image provides a summary of the average level of autonomy of patients by disease group. It can be seen that patients with AD have a lower level of autonomy compared to the rest.

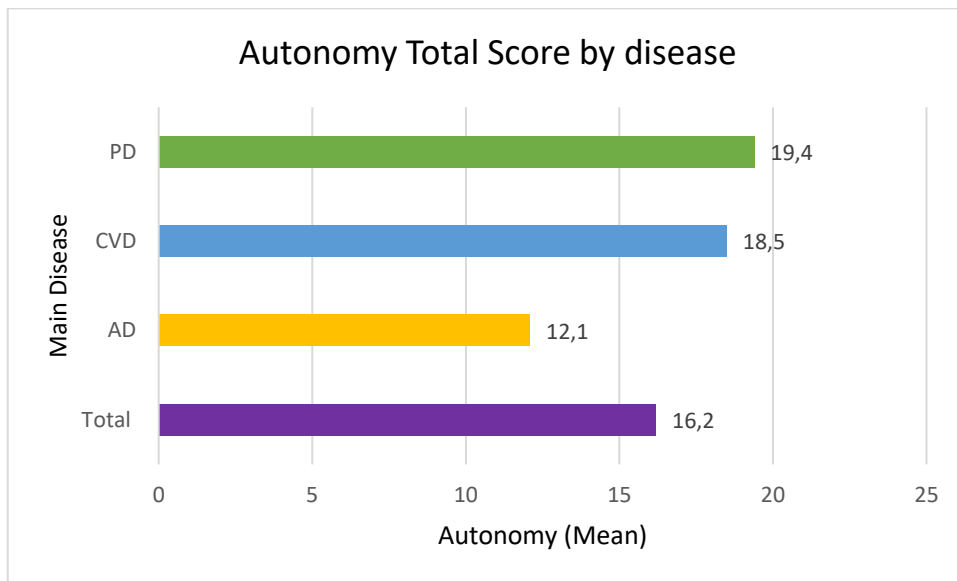


Figure 7- Total Autonomy Score by disease

The study of autonomy by gender shows that men had a higher level of autonomy. This may be due to how the disease is distributed by gender, as the most prevalent disease in female participants was AD, which explains why they have less autonomy than men, whose main condition was CVD.

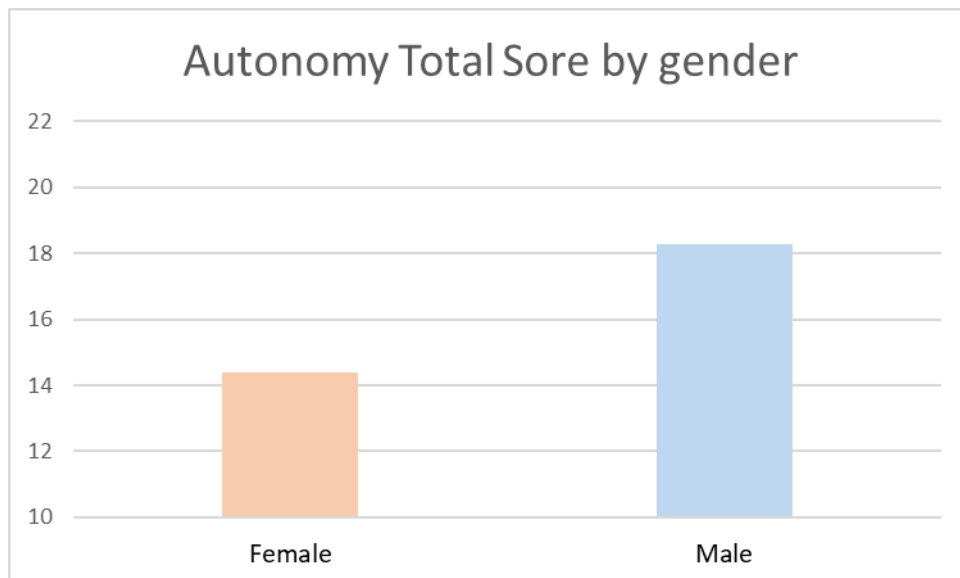


Figure 8- Total Autonomy Score by gender

6.3 Usability

6.3.1 Patients

The usability study was carried out on the participating patients by means of an ad hoc questionnaire made up of 10 questions whose answers corresponded to a Likert-type scale from 1 to 5, where 1 was totally agree and 5 was totally disagree. An "N/A" sub answer option was included for those who did not want to or did not know how to answer. It can be seen that the percentage of this option tends to come from the AD.

Regarding usability, a lot of variability can be observed in the answers. Most of them show a neutral position, without using extremes to qualify the tool. This opinion may be due to the fact that the tool is not sufficiently developed in this second wave to respond to participants. In addition, it should be taken into account that these are older people, who in many cases have no affinity for technology. This means that their opinion of it is not very highly valued. Despite this, it is noted that many participants do not consider it complex and are able to use it on their own.

Table 22- Usability by disease

	Total n(%)	AD n(%)	CVD n(%)	PD n(%)
1) I think that I would like to use this system frequently				
1. Slightly agree	10(4)	-	8(80)	2(20)
2. Agree	15(6)	2(13.3)	10(66.7)	3(20)
3. Nor agree or disagree	45(17.9)	27(60)	10(22.2)	8(17.8)
4. Disagree	54(21.5)	3(5.6)	36(66.7)	15(27.8)
5. Strongly disagree	16(6.4)	3(18.8)	11(68.8)	2(12.5)
N/A	111(44.2)	64(57.7)	15(13.5)	32(28.8)
2) I found the system unnecessarily complex				
1. Slightly agree	20(8)	4(20)	13(65)	3(15)
2. Agree	57(22.7)	4(7)	38(66.7)	15(26.3)
3. Nor agree or disagree	74(29.5)	50(66.7)	15(20.3)	9(12.2)
4. Disagree	20(8)	4(20)	6(30)	10(50)
5. Strongly disagree	9(3.6)	2(22.2)	3(33.3)	4(44.4)
N/A	71(28.3)	35(49.3)	15(21.1)	21(29.6)
3) I thought the system was easy to use				
1. Slightly agree	6(2.4)	-	4(66.7)	2(33.3)
2. Agree	23(9.2)	4(17.4)	6(26.1)	13(56.5)
3. Nor agree or disagree	70(27.9)	48(68.6)	13(18.6)	9(12.9)
4. Disagree	64(25.5)	6(9.4)	41(64.1)	17(26.6)
5. Strongly disagree	16(6.4)	5(31.3)	10(62.5)	1(6.3)
N/A	72(28.7)	36(50)	16(22.2)	20(27.8)
4) I think that I would need the support of a technical person to be able to use this system				
1. Slightly agree	21(8.4)	2(9.5)	18(85.7)	1(4.8)
2. Agree	32(12.7)	10(31.3)	20(62.5)	2(6.3)
3. Nor agree or disagree	37(14.7)	15(40.5)	7(18.9)	15(40.5)
4. Disagree	35(13.9)	2(5.7)	17(48.6)	16(45.7)
5. Strongly disagree	56(22.3)	35(62.5)	13(23.2)	8(14.3)
N/A	70(27.9)	35(50)	15(21.4)	20(28.6)
5) I found the various functions in this system were well integrated				
1. Slightly agree	3(1.2)	1(33.3)	1(33.3)	1(33.3)

2. Agree	8(3.2)	2(25)	6(75)	-
3. Nor agree or disagree	91(36.3)	50(54.9)	26(28.6)	15(16.5)
4. Disagree	67(26.7)	4(6)	39(58.2)	24(35.8)
5. Strongly disagree	11(4.4)	6(54.5)	3(27.3)	2(18.2)
N/A	71(28.3)	36(50.7)	15(21.1)	20(28.2)
6) I thought there was too much inconsistency in this system				
1. Slightly agree	8(3.2)	2(25)	5(62.5)	1(12.5)
2. Agree	74(29.5)	7(9.5)	43(58.1)	24(32.4)
3. Nor agree or disagree	92(36.7)	54(58.7)	21(22.8)	17(18.5)
4. Disagree	5(2)	-	5(100)	-
5. Strongly disagree	1(0.4)	-	1(100)	-
N/A	71(28.3)	36(50.7)	15(21.1)	20(28.2)
7) I would imagine that most people would learn to use this system very quickly				
1. Slightly agree	5(2)	1(20)	2(40)	2(40)
2. Agree	22(8.8)	4(18.2)	8(36.4)	10(45.5)
3. Nor agree or disagree	75(29.9)	43(57.3)	13(17.3)	19(25.3)
4. Disagree	62(24.7)	5(8.1)	46(74.2)	11(17.7)
5. Strongly disagree	7(2.8)	1(14.3)	6(85.7)	-
N/A	80(31.9)	45(56.3)	15(18.8)	20(25)
8) I found the system very cumbersome to use				
1. Slightly agree	17(6.8)	3(17.6)	13(76.5)	1(5.9)
2. Agree	57(22.7)	3(5.3)	37(64.9)	17(29.8)
3. Nor agree or disagree	77(30.7)	51(66.2)	16(20.8)	10(13)
4. Disagree	20(8)	4(20)	6(30)	10(50)
5. Strongly disagree	9(3.6)	2(22.2)	3(33.3)	4(44.4)
N/A	71(28.3)	36(50.7)	15(21.1)	20(28.2)
9) I felt very confident using the system				
1. Slightly agree	6(2.4)	1(16.7)	4(66.7)	1(16.7)
2. Agree	19(7.6)	4(21.1)	11(57.9)	4(21.1)
3. Nor agree or disagree	80(31.9)	46(57.5)	15(18.8)	19(23.8)
4. Disagree	51(20.3)	4(7.8)	32(62.7)	15(29.4)
5. Strongly disagree	23(9.2)	7(30.4)	13(56.5)	3(13)
N/A	72(28.7)	37(51.4)	15(20.8)	20(27.8)
10) I needed to learn a lot of things before I could get going with this system				
1. Slightly agree	11(4.4)	1(9.1)	9(81.8)	1(9.1)
2. Agree	65(25.9)	10(15.4)	44(67.7)	11(16.9)
3. Nor agree or disagree	70(27.9)	46(65.7)	11(15.7)	13(18.6)
4. Disagree	20(8)	4(20)	6(30)	10(50)
5. Strongly disagree	13(5.2)	2(15.4)	4(30.8)	7(53.8)
N/A	72(28.7)	36(50)	16(22.2)	20(27.8)

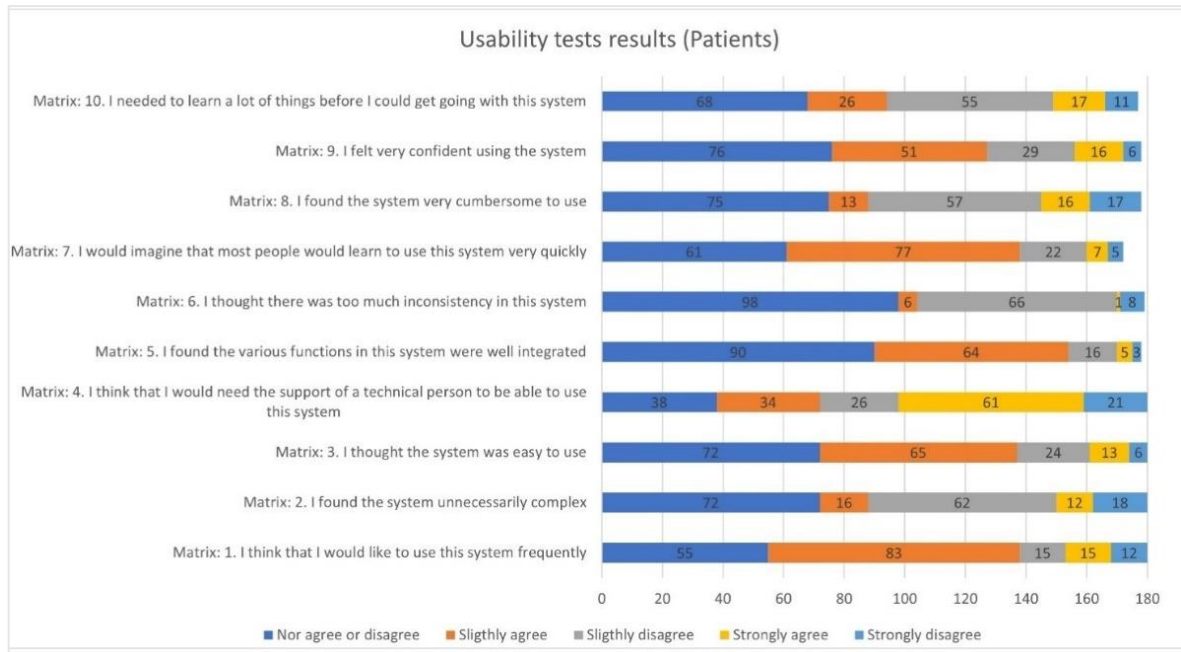


Figure 9- Patient utility results with the TeNDER tool.

6.3.2 Caregivers

Usability data on caregivers show a neutral or low rating. This is due to the limitation found in the second wave, because many of the functionalities related to caregiver involvement with the TeNDER tool were not yet ready.

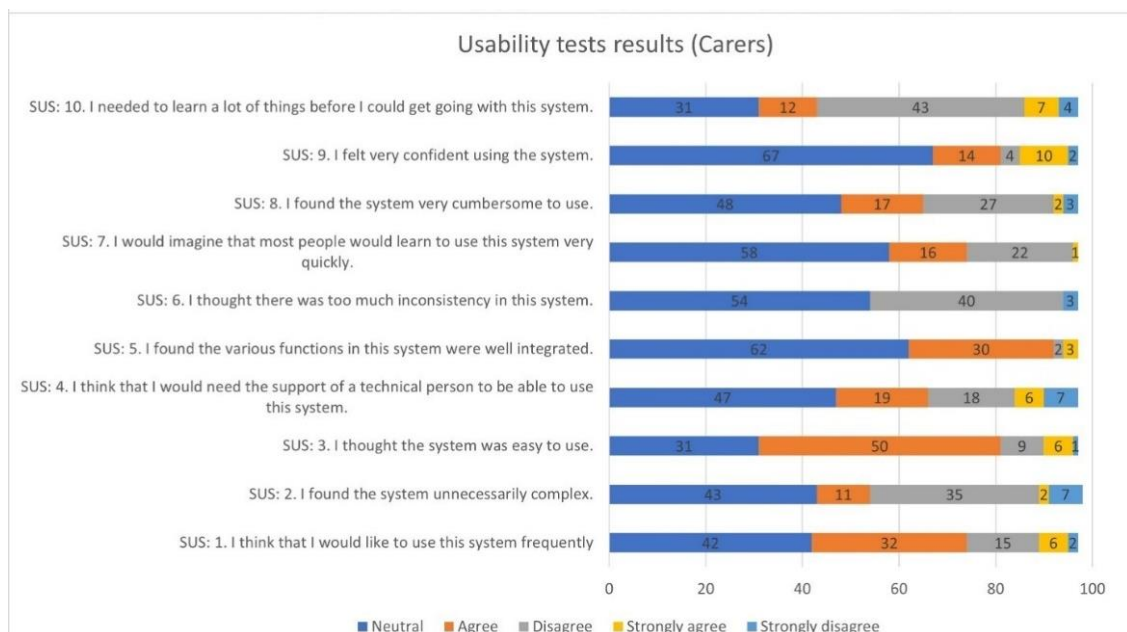


Figure 10 - Carer's utility results with the TeNDER tool.

6.4 Reduction of medical visits

6.4.1 Patients

One of the objectives of the TeNDER tool is to support the care of these patients with chronic diseases. They are therefore asked whether they believe that the TeNDER system can help in this respect.

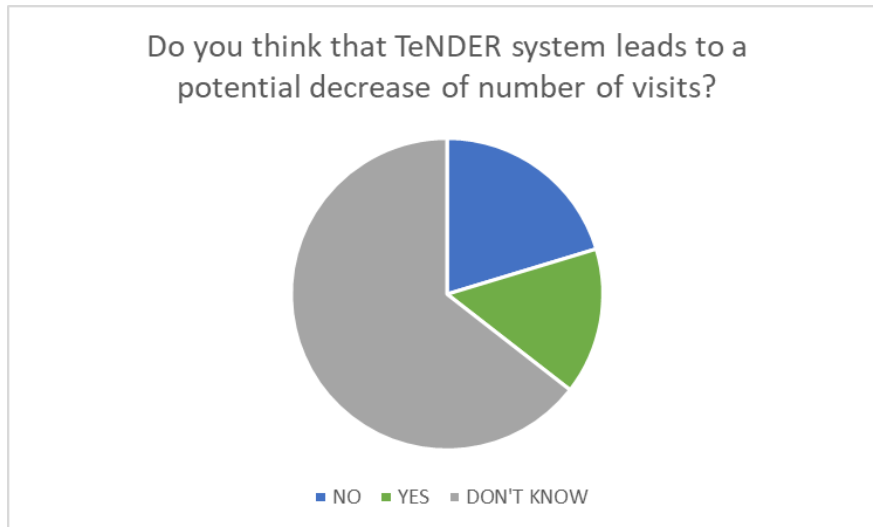


Figure 11- Patients-Potential decrease in medical visits

Although the tool was not fully developed in the second wave and offered little communication between patient, carer and practitioner, 15.5% of patients said that TeNDER had the potential to reduce their medical visits. Of these, 3.2% felt that it could reduce them by 10% and 2% by 20-40%, the rest were unable to make an approximation of the potential reduction.

6.4.2 Caregivers

For carers, TeNDER has great potential to help them with their care and monitoring of their health. When caregivers were asked if they saw potential for reducing medical visits, 32.7% said YES. Of these, 59.6% felt they could reduce them by 10%; 4.8% by 20-40%; and 2.9% by more than 50%; the rest could not make an approximation of the potential reduction.

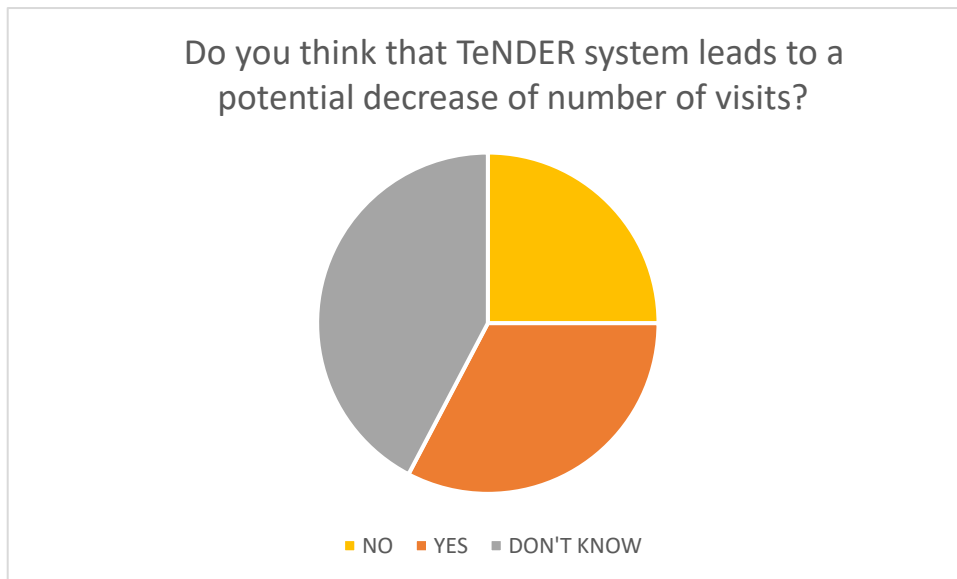


Figure 12- Caregivers-Potential decrease in medical visits

6.5 Satisfaction

6.5.1 Patients

The analysis of patient satisfaction after the end of the second wave in relation to the use of some functionalities of the Tender system shows that the majority of patients rate their experience with the system as satisfactory or neutral.

Figure 11 shows that none of the respondents are "very dissatisfied" with the use of TeNDER. Notably, 45,6% of CVD patients and 43,5% of PD patients report being "satisfied" with the use of TeNDER.

In figure 11 we report the outcome of some of satisfaction rates questionnaires performed after the end of the second wave concerning the use of some functionalities of Tender system by patients. The most of the patients rate as satisfying or neutral their experience with the system.

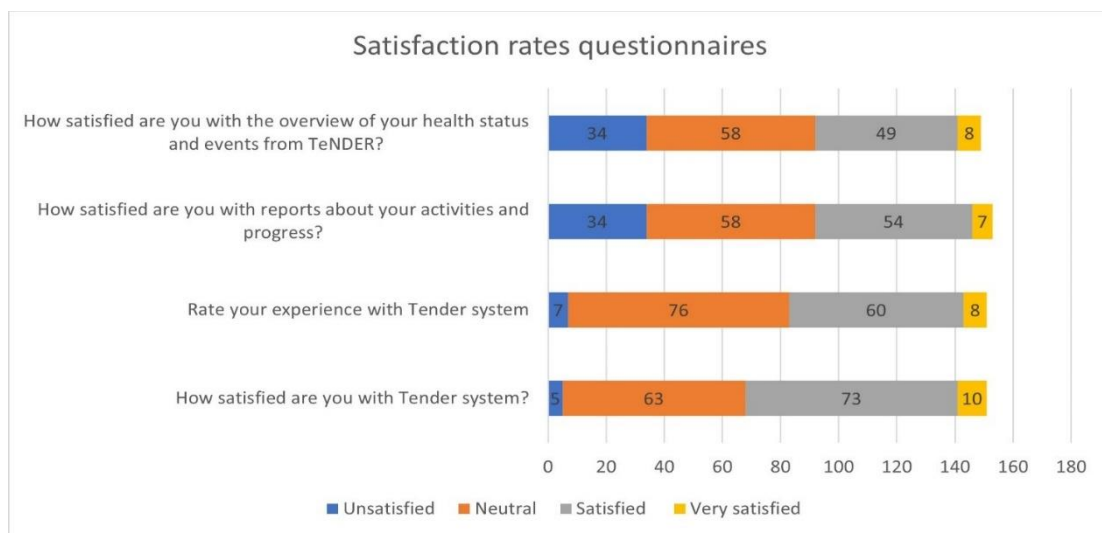
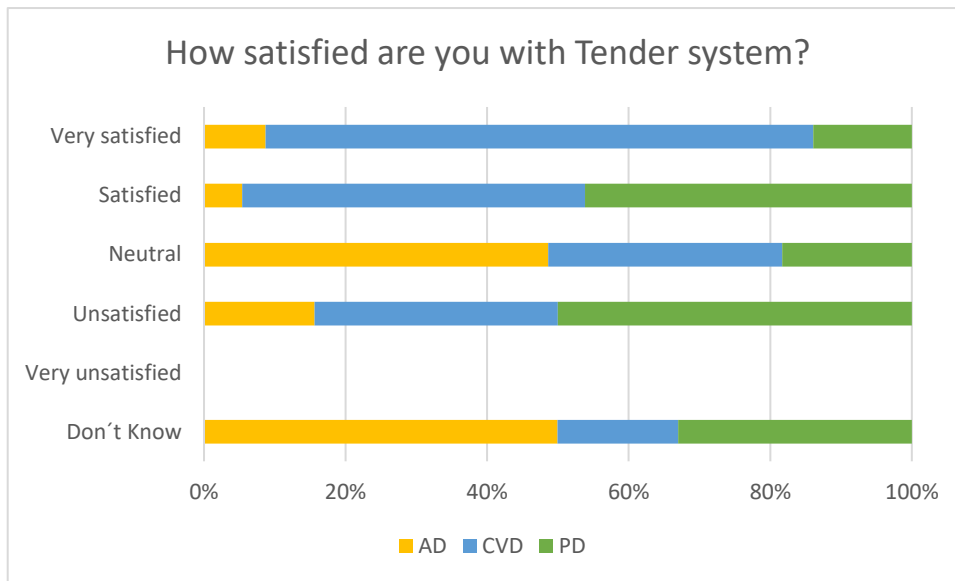


Figure 13- Patient-Satisfaction with TeNDER use

Although the functionality of reports and overview was not yet fully operational, figures 12 and 13 show that 42,2% and 37,8%, respectively, of CVD patients were "satisfied".

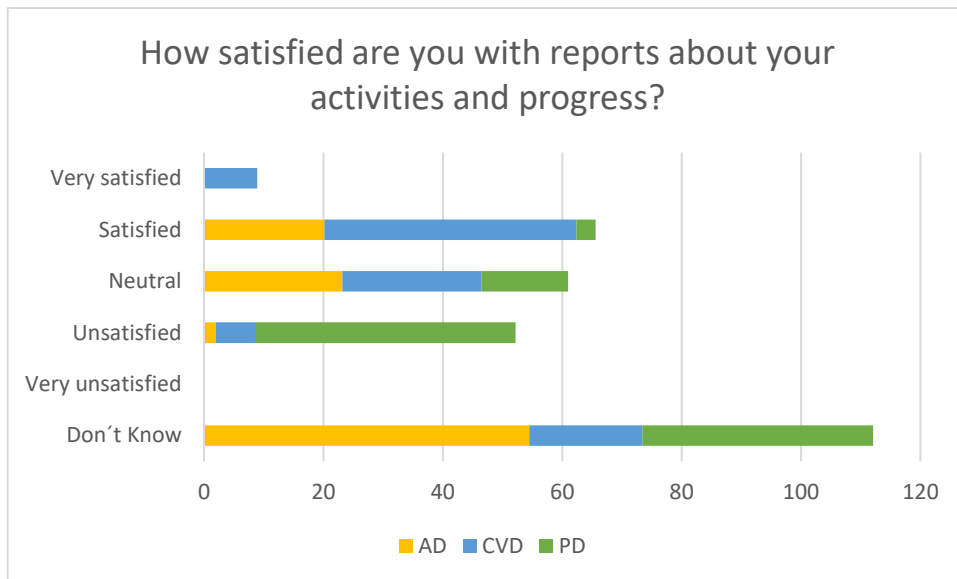


Figure 14- Patient-Satisfaction with TeNDER reports

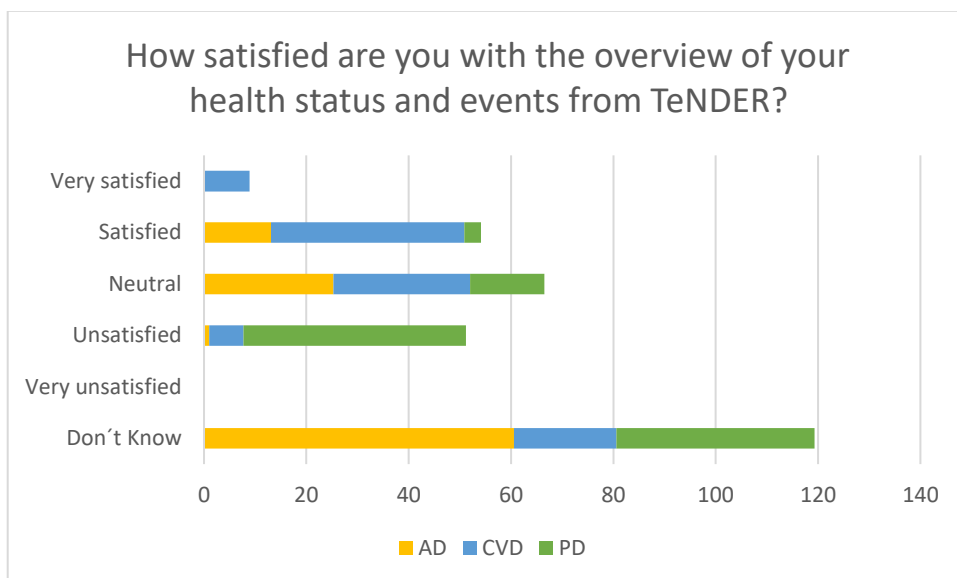


Figure 15- Patient-Satisfaction with TeNDER overview

When asked to provide a rate for evaluating the TeNDER tool, the majority of AD patients offered a low rating. While the majority of CVD patients rated it as "great". This is shown in figure 13.

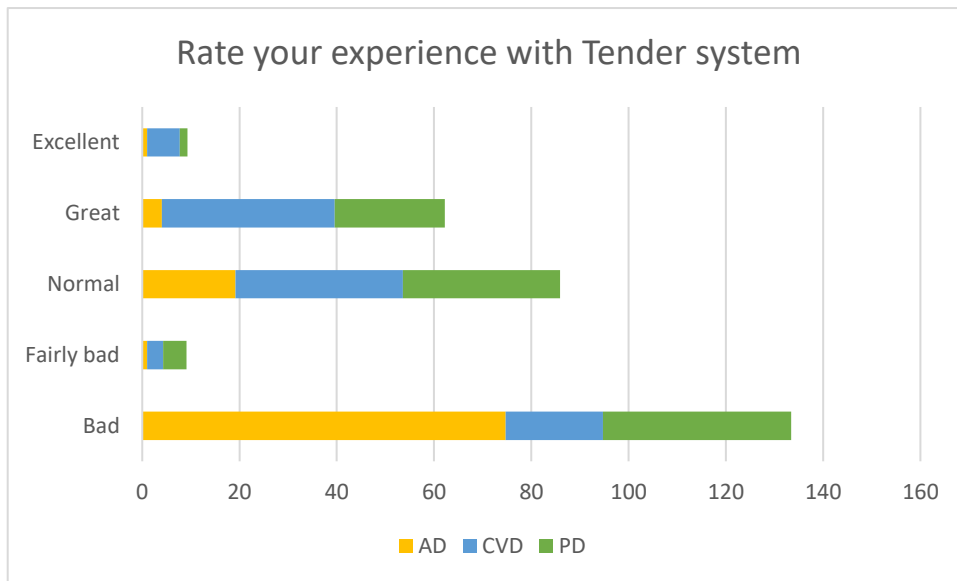


Figure 16-Rate Patient-Satisfaction with TeNDER

6.5.2 Carers

Carers' satisfaction with the use of the TeNDER tool has been similar by gender, with 31.3% of women and 35.1% of men rating it as satisfied. With regard to reporting and overview, around 30-35% rated it as dissatisfied. Despite being dissatisfied with the functionalities that were not developed, 60% of women and 67.6% of men gave a rate of "great". The most of the carers rate as satisfying or neutral their experience with the system. Nevertheless, reports of activities progress and overview of patient’s health status left most of the carers unsatisfied.

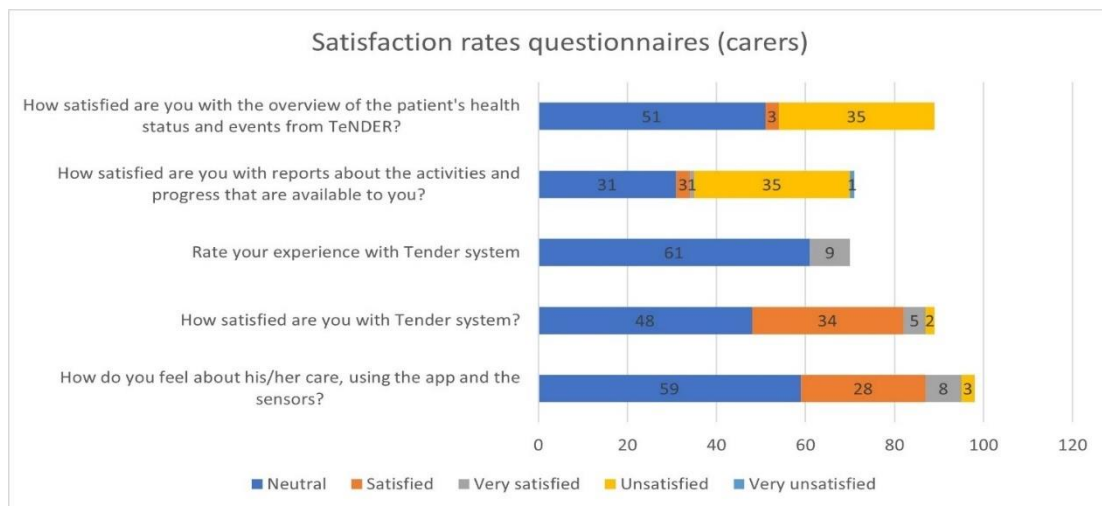


Figure 17- Caregiver-reported satisfaction results with the TeNDER tool.

In figure 12 we report the outcome of some of satisfaction rates questionnaires performed after the end of the second wave concerning the use of some functionalities of Tender system by carers. The most of the carers rate as satisfying or neutral their experience with the system.

Nevertheless, reports of activities progress and overview of patient’s health status left most of the carers unsatisfied.

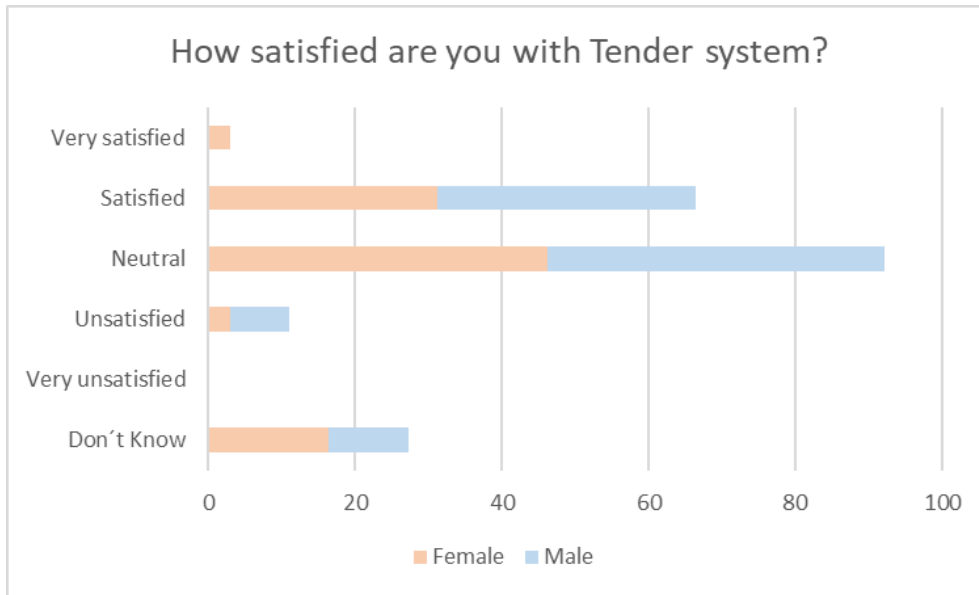


Figure 18- Caregivers-Satisfaction with TeNDER use

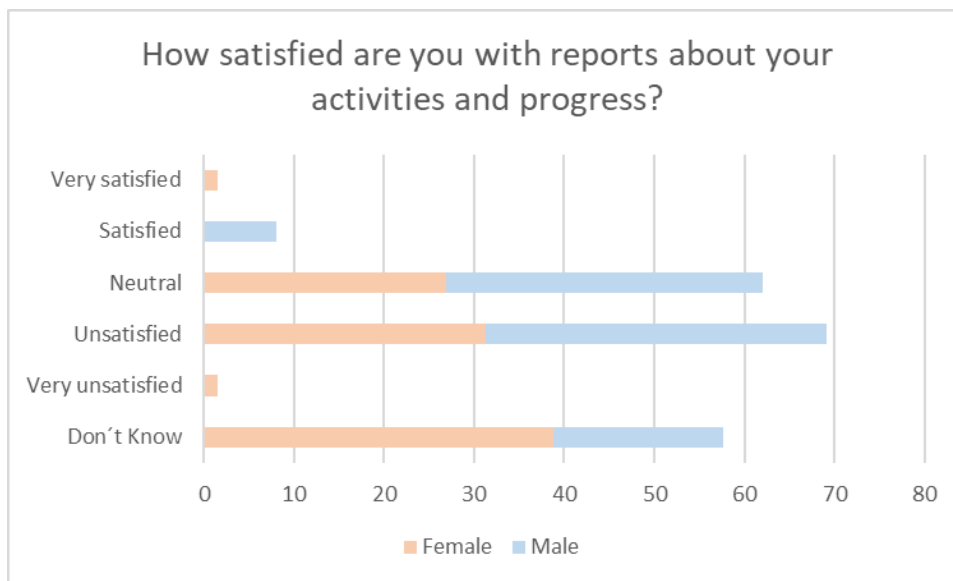


Figure 19- Caregiver-Satisfaction with TeNDER reports

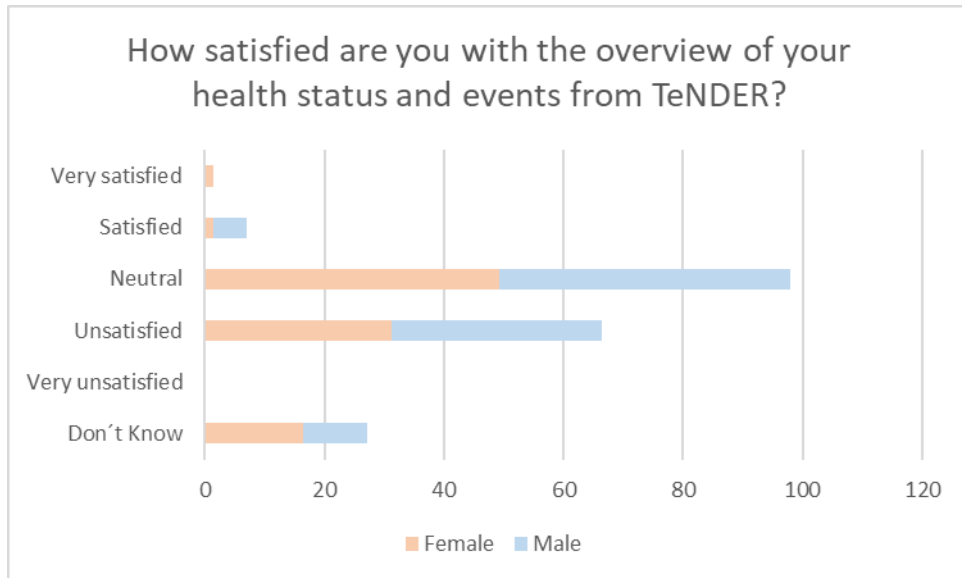


Figure 20- Caregiver-Satisfaction with TeNDER overview

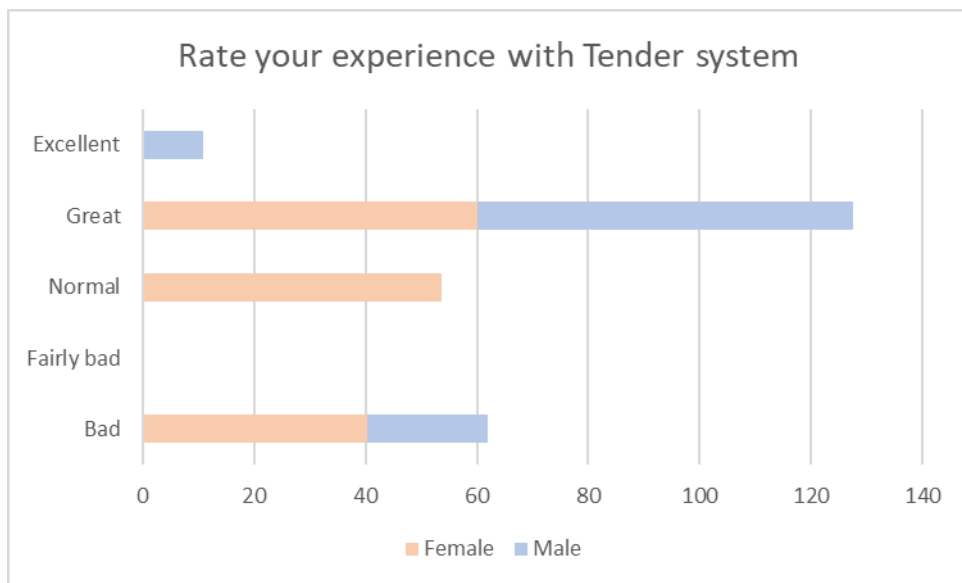


Figure 21- Rate Caregiver-Satisfaction with TeNDER

7 KPIs STATUS

Table 23-KPI Status

STAKEHOLDER	KPIs	STATUS
General	Number of diseases: at least 3	ACHIEVED
	Number of pilot sites: at least 5	ACHIEVED
	Number of pilot users in the entire project: at least +1500	ONGOING

Patients	Patient satisfaction of speed-up attention perception (>90% Questionnaire's satisfaction)	ONGOING
	Reduction of average number of visits to the hospital of at least 12%.	ONGOING
	Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate	ONGOING
Caregivers	Carer satisfaction of speed-up attention perception (>90% Questionnaire's satisfaction)	ONGOING
	10% increase satisfaction care of relatives.	ONGOING
	Time saving for carers in waiting while patient is going to be attended (>10%)	ONGOING
	Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate	ONGOING
Health and social professionals	Reduction of time in access to clerical patient information at least 10%.	ONGOING
	Improved interaction paradigms (User Experience Questionnaire) with >90% satisfaction rate	ONGOING

8 CONCLUSIONS.

The development of the second wave of pilots was marked by the obstacles posed by the pandemic in the first pilot. This caused a delay in the implementation of the pilots and in the development of some functionalities. Among them, those related to the role of carers and professionals in the participation of the TeNDER system. This has marked the responses of the participants with respect to the results obtained in the scores of this wave, as carers and professionals did not have a full experience of the system with the communication tool. Despite this, many more functionalities have been implemented and incorporated in the second wave than in the first wave.

This deliverable reflects the achievement of many of the KPIs. Among them, the incorporation of the adapted real scenarios in which patients spend real time based on their chronic condition stands out. Furthermore, it is important to note that although not all of the system's functionalities are active, satisfaction with the TeNDER tool is good and both patients and caregivers value it as having the potential to improve patients' health care.

The evaluation of usability has been established through the SUS questionnaire, a validated psychometric scale whose objective is to determine user satisfaction with the use of a technological tool. However, the results obtained have been quite heterogeneous among users. For this reason, from pilot 1 as leaders of the WP6 and responsible of the task of measuring usability, a study will be carried out that cover this concept in a broader way. Different properties will be measured in the execution of tasks defined according to the characteristics of the users of the TeNDER tool, as well as their satisfaction through the SUS questionnaire.

With a view to the third wave of pilots, work is underway to improve pending functionalities and incorporate more devices to meet the needs of patients, carers and professionals.

9 REFERENCES.

[1] [Online]. Available: https://tendergitlab.maggiolicloud.it/panos_k/tnd-install/.

10 ANNEXES.

10.1 Prepiloting Usability Assessment

10.1.1 AFFINITY FOR TECHNOLOGY

I like testing the functions of new technical systems.

Completely disagree	Largely disagree	Slightly disagree	Slightly agree	Largely agree	Completely agree
---------------------	------------------	-------------------	----------------	---------------	------------------

10.2 Postpiloting Usability Assessment

10.2.1 SUS QUESTIONNAIRE

1)I think that I would like to use this system frequently.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

2)I found the system unnecessarily complex.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

3)I thought the system was easy to use.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

4)I think that I would need the support of a technical person to be able to use this system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

5)I found the various functions in this system were well integrated.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

6)I thought there was too much inconsistency in this system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

7)I would imagine that most people would learn to use this system very quickly.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

8)I found the system very cumbersome to use.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

9)I felt very confident using the system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

10)I needed to learn a lot of things before I could get going with this system.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree
(1)	(2)	(3)	(4)	(5)

10.3 Open ended questions.

- 1) How do you feel with TeNDER sensors?
- 2) What do you like less about TeNDER sensors?
- 3) What do you like more about TeNDER sensors?

10.4 Satisfaction in patients

10.4.1 Reduction in the number of visits

Using TeNDER system:

	Yes	I don't know	No
--	-----	--------------	----

Do you think that TeNDER system leads to a potential decrease of number of visits?			
--	--	--	--

	No reduction (0%)	Small reduction (10%)	Moderate reduction (20-40%)	High reduction (>50%)
How much do you think the number of visits has decreased?				

10.4.2 Satisfaction Rate

1) How satisfied are you with Tender system? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

2) Rate your experience with the Tender system. Please circle one number

Bad	Fairly bad	Normal	Great	Excellent
(1)	(2)	(3)	(4)	(5)

3) How satisfied are you with reports about your activities and progress? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

4) How satisfied are you with the overview of your health status and events from TeNDER? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

10.4.3 Modular set

FUNCTION: ENTRANCE DOOR AND/OR WINDOWS STATUS (safety and wellbeing)

	Yes	I don't know	No	I don't want to answer
Does the information about the door and/or windows open/closed status increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of "Entrance door and/or windows status": think if this sensor has had an influence on your daily life

	Less	About the same	More	I don't know	I don't want to answer
Do you worry about having left the door open?					

How satisfied are you with "Entrance door and/or windows status" function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: INDOOR ENVIRONMENTAL MONITORING (safety and wellbeing)

	Yes	I don't know	No	I do not want to answer
Does the information on the Indoor air quality increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of "Indoor environmental monitoring": think if this sensor has had an influence on your daily life

	Less	About the same	More	I don't know	I don't want to answer
Do you feel comfortable with knowing the temperature and air quality?					

How satisfied are you with "Indoor environmental monitoring" function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ADHERENCE TO DRUG TREATMENT (The person is notified to take the medication on a predefined schedule.)

	Yes	I don't know	No	I don't want to answer
Does the reminder of medication increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of adherence to drug treatment (reminder for medication intake): think if this function has had an influence on your daily life

	Less	About the same	More	I don't know	I don't want to answer
--	------	----------------	------	--------------	------------------------

Do you forget to take your medication?					
--	--	--	--	--	--

How satisfied are you with “Adherence to drug treatment” (reminder for medication intake) function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: MEDICAL EXAMINATIONS (CALENDAR FOR, Reminders of medical therapies and exercises, appointments to MD)

	Yes	I don't know	No	I don't want to answer
Does the calendar for medical examinations increase your perceived quality of life?				
Do the reminders on important events and appointments help you in your daily living?				

How satisfied are you with the calendar for medical examinations? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ROOM-LEVEL LOCALIZATION (in which room, for how long)

	Yes	I don't know	No	I don't want to answer
Does the localization information (for instance wristband/bracelet that determines the room-level position) increase your perceived quality of life?				

How satisfied are you with “Room-level localization” function (sensors for localization)? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: EMOTIONAL STATE DETECTION

	Yes	I do not know	No	I don't want to answer
Does the emotional state detection increase your perceived quality of life?				

Do you feel that early detection of unwanted emotions by the system helps you to prevent them?				
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How satisfied are you with emotional state detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: QUALITY OF SLEEP

	Yes	I don't know	No	I don't want to answer
Does the information on your quality of sleep increase your perceived quality of life?				
Are you more comfortable during the day with your activities, emotions and events as you have the information about your sleep quality for the night before?				

How satisfied are you with sensors for quality of sleep? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: WELLBEING (for instance: sensors for health status, calendar, communication services, applications to use games)

	Yes	I don't know	No	I don't want to answer
Do these TeNDER sensors increase your perceived quality of life?				
Do you feel more autonomous by using these sensors?				

How satisfied are you with sensors for safety and wellbeing? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: FALL DETECTION (safety)

	Yes	I don't know	No	I don't want to answer
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Does the information on falls increase your perceived quality of life?				
Do you feel safer due to the monitoring of your health?				

How satisfied are you with sensors for fall detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

10.5 Satisfaction for carers

10.5.1 Questions regarding time-saving.

	Yes	I don't know	No
Do you think that TeNDER system leads to a decrease of waiting time while patient is going to be attended?			

	No reduction (0%)	Small Reduction (10%)	Moderate reduction (20-40%)	High reduction (>50%)
Can you quantify the reduction of waiting time?				

10.5.2 Satisfaction Rate

1)How satisfied are you with Tender system? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

2)Rate your experience with Tender system. Please circle one number

Bad	Fairly bad	Normal	Great	Excellent
(1)	(2)	(3)	(4)	(5)

3)How satisfied are you with the reports about activities and progress of the patient? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

4) How satisfied are you with the overview of the patient's health status and events from TeNDER? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

10.5.3 Modular Set

FUNCTION: ENTRANCE DOOR AND/OR WINDOWS STATUS (safety and wellbeing)

	Yes	I don't know	No	I don't want to answer
Does the sensor on the door and/or the windows increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of "Entrance door/and or windows status", think if this function has had any influence on your care work.

	Less	About the same	More	I don't know	I don't want to answer
How often does he/she forget to close the (entrance) door and/or the windows?					

How satisfied are you with "Entrance door and/or windows status" ? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: INDOOR ENVIRONMENTAL MONITORING (safety and wellbeing)

	Yes	I don't know	No	I don't want to answer
Does the information on the Indoor air quality increase your perceived quality of life?				

Here we are going to ask you a question about the perception of usefulness of Indoor environmental monitoring: think if this sensor has had an influence on your care work.

	Less	About the same	More	I don't know	I don't want to answer
Do you feel comfortable with knowing the temperature and air quality of the place where the person you are caring for is?					

How satisfied are you with Indoor environmental monitoring function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ADHERENCE TO DRUG TREATMENT (The person is notified to take the medication on a predefined schedule.)

	Yes	I don't know	No	I don't want to answer
Does the reminder for medication increase your perceived quality of life?				
Do the reminders on medical examination and other important events help you in your care work?				
Do the reminders on Adherence to drug treatment increase your perceived quality of life?				
Do the Adherence to drug treatment in form of reminder for medications and/or pill dispenser help you in your care work?				

Here we are going to ask you a question about the perception of usefulness of Adherence to drug treatment (reminder for medication intake), think if this function has had any influence on your care work.

	Less	About the same	More	I don't know	I don't want to answer
How often does he/she forget to take his/her medication?					

How satisfied are you with “Adherence to drug treatment” function (reminder for his/her medication and/or pill dispenser)? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: MEDICAL EXAMINATIONS (CALENDAR FOR, Reminders of medical therapies and exercises, appointments to MD)

	Yes	I don't know	No	I don't want to answer
Does the calendar for medical examination schedule help you in your care work?				

Do the reminders on important events and appointments help you in your daily living because he/she can act more confident?				
Does the calendar for medical examinations increase your perceived quality of life?				

How satisfied are you with Calendar for medical examinations? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: ROOM LOCALIZATION MONITORING (sensors for localization inside the house, which room and for how long)

	Yes	I don't know	No	I don't want to answer
Does room localization help you in your care work?				
Do you feel safer with room localization functionality the person is using?				
Do you have more freedom due to room localization functionality the person is using?				
Does this function increase your perceived quality of life?				
Does it help monitoring activity recognition and path-tracking?				

How satisfied are you with "Room localization monitoring" function? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: EMOTIONAL STATE DETECTION

	Yes	I don't know	No	I don't want to answer
Do you feel that early detection of unwanted emotions by the systems helps you to prevent them?				
Does the emotional state detection of a person you are caring for help you in your care work?				
Does the emotional state detection increase your perceived quality of life?				

How satisfied are you with emotional state detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: QUALITY OF SLEEP

	Yes	I don't know	No	I don't want to answer
Are you more comfortable during the day with your activities, emotions and events as you have the information about his/her sleep quality for the night before?				
Does having the information about sleep quality increase your perceived quality of life?				

How satisfied are you with quality of sleep monitoring? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(0)	(1)	(2)	(3)	(4)

FUNCTION: WELLBEING (for instance: sensors for health status, calendar, communication services, applications to use games)

	Yes	I don't know	No	I don't want to answer
Does monitoring of the health and wellbeing of a person you are caring for help you in in your care work?				
Do the reports on wellbeing help you in your care work?				
Do these reports increase your perceived quality of life?				

How satisfied are you with the reports about wellbeing (for instance: sensors for health status, calendar, communication services...)? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

FUNCTION: FALL DETECTION (safety)

	Yes	I don't know	No	I don't want to answer
Does these TeNDER alerts/reports increase your perceived quality of life?				
Do you feel more peace due to the monitoring of possible falls of a person you are caring?				

How satisfied are you with sensors for fall detection? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

10.6 Satisfaction for professionals

10.6.1 Questions regarding number of visits and time-saving

Using TeNDER system:

	Yes	I don't know	No
Do you think that TeNDER system leads to a potential decrease of number of visits?			

	No reduction (0%)	Small Reduction (10%)	Moderate reduction (20- 40%)	High reduction (>50%)
How much do you think the number of visits has decreased?				

	Yes	I don't know	No
Do you think that TeNDER system leads to a potential decrease of time in access to patient clerical information?			

	No reduction (0%)	Small Reduction (10%)	Moderate reduction (20- 40%)	High reduction (>50%)
How much do you think the time in access to patient clerical information has decreased?				

10.6.2 Satisfaction Rate

1) How satisfied are you with Tender system? Please circle one number

Very unsatisfied	Unsatisfied	Neutral	Satisfied	Very satisfied
(1)	(2)	(3)	(4)	(5)

2) Rate your experience with Tender system. Please circle one number

Bad	Fairly bad	Normal	Great	Excellent
(1)	(2)	(3)	(4)	(5)

10.6.3 Usefulness

1) Do you get more information about him/her and find this useful?

Yes	I don't know	No
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2) Does TeNDER system improve your approach to the patient?

Yes	I don't know	No
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3) Have you found something new that improves your knowledge of him/her using TeNDER system?

Yes	I don't know	No
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4) Do you feel that you can apply better or more specific therapies to the patient because of the system?

Yes	I don't know	No
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