

# ENGAGEMENT OF TEST PERSONS AND CONSIDERATION OF LEGAL ASPECTS

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Deliverable D.T3.3.2

Version 1  
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## 1. Introduction

This document, the engagement of test persons and consideration of legal aspects, presents the most important information regarding the selection of residents from the Social Care Centre Petržalka and their involvement in “Output O.T3.2 - Pilot testing of AP-NURSE - persons suffering from Parkinson’s disease in Care Centre in Bratislava”. It is also one of the deliverables in thematic work package WP T3, D.T3.3.2.

## 2. Methodology

The deliverable deals with the engagement of minimum 10 residents of Care Centre Petržalka upon the consultation with the STU team, initial meeting, explanation of principles and benefits of pilot action, contact with care givers and Written Consent with the representative of the Social Care Centre in Petržalka. The initial meeting between the STU team and the representatives of the Social Care Centre Petržalka (SCC) took place on 23th April, as part of the briefing and training of test persons, home care givers and nurses using the online MS Teams platform. The meeting served to identify the clients of the SCC Petržalka for the pilot testing, select the version of AP-NURSE devices to be deployed in SCC Petržalka and to discuss the details of Written Consent between STU and SCC Petržalka. This deliverable includes the meeting minutes and the scan of the signed Written Consent in ANNEX 1.

## 3. Meeting minutes

### Attendants:

Štefan Čerba (STU,PP4), Jakub Lüley (STU,PP4), Branislav Vrban (STU,PP4), Soňa Chanečková (SCC - PP1 associate partner) and Stanislava Šrenkelová SCC - PP1 associate partner).

### Selection of the patients for the pilot action:

- Monitoring of clients’ rooms
  - 2 rooms with 2 mobile clients per each room
    - Monitoring of the patient in the room
    - Monitoring of the door to the toilet
  - 6 rooms with 2 or 1 immobile patient per room
    - Monitoring of the patient in the bed
- Monitoring of common areas
  - Monitoring of the staircase and the corridor of the second floor
    - Monitoring of activity patterns and passage
    - Focus on monitoring the potential activity over night
    - All mobile clients and all caregivers involved (approx. 50 people)
  - Monitoring of the kitchen
    - Monitoring of gas, heat, smoke and humidity
    - All mobile clients and all caregivers involved (approx. 50 people)

- Monitoring of forbidden areas for clients
  - Monitoring of the caregivers' cloakroom
    - Monitoring of potential passage of clients
  - Monitoring of the laundry
    - Monitoring of potential passage of clients
    - Monitoring of gas, heat, smoke and humidity
- Monitoring of emergency exits
  - Exit to the terrace on the first and the second floor
    - Monitoring of potential passage of clients

#### **Selection of the versions of the AP-NURSE**

- AP-NURSE Home platform
  - Using with the Information system
  - No AP-NURSE wearables used
  - Monitoring from the nurses' desks using standard internet browser
  - Deployment of the following versions:
    - AP1-H
    - AP2-H
    - AP6-H
- AP-NURSE Care M5stack platform
  - Using with the Information system
  - Monitoring from the nurses' desks using standard internet browser
  - Deployment of the following versions
    - AP2-M
    - AP4-M
    - AP6-M

#### **Content of the Written Consent**

- Purpose
  - Comprehensive explanation of the purpose of the Pilot Testing
- Procedures
  - Preparation of testing
  - Installation of devices
  - Operation of devices and collection of data
  - Analysis of data
  - Collection of feedback



- Risks
  - COVID-19
  - Violation of privacy
  - Reduced care
- Benefits
  - Using a modern modular monitoring tool for free
  - Easing the day and night duties of caregivers
  - Gathering of experience with an IoT to easy caregiving
  - Providing fast alerts on possible danger
  - Easy traffic light logic used to monitor the conditions of clients
  - Availability of devices after the pilot testing
  - AI (artificial intelligence) based evaluation of sleep patterns of the clients
- Confidentiality
  - Anonymous assignment of patients to the tested devices
  - No voice and video recording applied
  - Sending of encrypted data
  - No data provision to third parties without additional written consent of the subjected party
- Consent
  - Who should sign

#### **Time Schedule of the Pilot Action**

- According to the procedures in the Written Consent

## **4. Conclusion**

The Briefing with the representatives of Social Care Centre Petržalka has met its objectives and the work on Output O. T3.2 - Pilot testing of AP-Nurse - person suffering from Parkinson's disease in Care Centre in Bratislava as well as in the related deliverables is in a very good way. The representatives of the SCC Petržalka were informed about all aspects of the pilot testing and helped to select the clients of the centre as well as the versions of AP-NURSE for the Pilot. The logistics and the details on testing procedure were discussed in details and the Written Consent including all necessary information and legal aspects was created and signed by the representatives.



## ANNEX 1: Written Consent between STU and Social Care Centre Petržalka



## **TITLE OF STUDY**

**Testing of the AP-NURSE digital tool in Social Care Centre Petržalka**

## **PROJECT SUPERVISOR**

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## **PURPOSE**

The purpose of this study is to perform the testing of the AP-NURSE modular platform in the pilot action of the Intereg CE niCE-Life CE1581 project, especially as part of Output O.T3.2 "*Pilot testing of AP-nurse - persons suffering from Parkinson's disease in Care Centre in Bratislava*". This pilot action tests AP-NURSE for persons suffering from Parkinson's disease, Alzheimer's disease and frail elderly by utilizing ambient sensors preventing events endangering the health of clients, like falling from bed or stairs, fire, gas leakage or leaving the area of care center. Its aim is to simplify work of home caregivers or nurses by monitoring basic interactions of the patient with environment during night or job duties and provide fast alert about possible dangers when abnormal patterns would be observed. The pilot action is performed in Social Care Centre Petržalka (SCC) with the technical support of the staff of the Slovak University of Technology in Bratislava (STU).

## **PROCEDURES**

The pilot testing of AP-NURSE in Social Care Centre Petržalka includes the following procedures:

### *1. Preparation of the testing*

- The preparation of the pilot testing started in January 2021 and includes the development of prototypes, their production, software implementation, 3D print of the casing, laboratory testing of devices and management of the installation and data collection activities. Some of the preparatory actions were performed under the work package WP2 of the project. The last step of this procedure collection and categorization of devices for implementation to the IS and their transport to Social Care Centre Petržalka by 26<sup>th</sup> April 2021

### *2. Installation of devices*

- The installation of devices is in line with the project deliverable D.T3.3.1 – Design of the pilot action in Bratislava. It includes information about the



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type of clients treated in the center, the deployment of devices in dedicated rooms and common areas and the physical installation including their connection through the local WiFi network to the information system (IS).

This phase of the pilot action is scheduled between 26<sup>th</sup> and 7<sup>th</sup> May 2021

### 3. *Operation of devices and collection of data*

- The operation of devices starts after their connection to the information system. The IS provides notifications, which could be evaluated as alerts to abnormal or critical conditions of pre-defined scenarios. More information on the IS and the types of AP-NURSE devices can be found in D. T2.2.5 of the project. The Status of connected devices as well as the notifications from the IS are available for the caregivers at SCC Petržalka and the STU staff. This procedure starts directly after the installation of AP-NURSE devices and will be performed while the devices are operational and do not required significant maintenance.

### 4. *Analysis of data*

- Notifications and operation data from the connected devices are stored in the information system and are available for subsequent analyses. The collected data are anonym, therefore they cannot directly identify the test persons and are in line with GDPR and the data protection policies of interested parties. Data related to sleep patterns and frequency of notifications will be made available only to partners of the Integer CE NiCE-Life project and the staff of SCC Petržalka for the purpose of the deliverable D.T1.2.3 – “Analysis of the statistical data and interoperability of data”. Sharing of data beyond the scope of the Intereg CE niCE-Life project cannot be done without the written consent of SCC Petržalka and STU.

### 5. *Collection of feedback*

- Feedback from caregivers and the staff of SCC Petržalka will be collected after the data analysis has been finished. It will be through dedicated meetings and electronic survey prepared by the STU staff.

## RISKS

During the pilot testing several risks may occur, some can be predicted, but some cannot. Based on the analysis of planned actions in the pilot testing, the following risks were identified.

### 1. Risk of COVID-19 infection

- Severity: High
- Probability: Low
- Corrective measures taken by the members of the STU staff performing the pilot action:
  - i. vaccination by the first dose of a EU certified vaccine (Astra Zeneca)
  - ii. entering the building only with negative antigen or PCR COVID-19 test not older than 7 days

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- iii. use of FFP2 respirators and protective gloves
- iv. minimization of the contact with the clients
- v. avoiding contact with unknown people outside of the center, household and workplace

### 2. Violation of client's privacy

- Severity: Low
- Probability: Moderate
- Corrective measures taken by the members of the STU staff performing the pilot action:
  - i. minimization of contact with clients
  - ii. installation devices in the absence of clients in the rooms
  - iii. placement of devices in places, which do not attract the attention of patients

### 3. Reduced care of client

- Severity: Moderate
- Probability: Low
- Corrective measures taken by the members of the STU staff performing the pilot action:
  - i. minimization of contact with clients
  - ii. installation of devices in the absence of clients in the rooms and in line with daily routines of caregiving
  - iii. selection of those clients for testing, who may not significantly suffer if this risk occurs

## BENEFITS

AP-NURSE is a modular platform developed for home and medical use, tailored to the needs of caregivers and patients. The AP-NURSE devices as well as the pilot testing were designed in a way that the benefits significantly outweigh the associated risks. The main benefits of the AP-NURSE pilot testing are:

1. Using a modern modular monitoring tool for free
2. Easing the day and night duties of caregivers
3. Gathering of experience with an IoT to easy caregiving
4. Providing fast alerts on possible danger
5. Easy traffic light logic used to monitor the conditions of clients
6. Availability of devices after the pilot testing
7. AI (artificial intelligence) based evaluation of sleep patterns of the clients

## CONFIDENTIALITY

In order to preserve the confidentiality of clients and caregivers during pilot testing, the following measures will be taken:

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1. Anonymous assignment of patients to the tested devices
2. No voice and video recording applied
3. Sending of encrypted data
4. No data provision to third parties without additional written consent of the subjected party

### CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I understand that participation of clients and employees of the Social Care Centre Petržalka, for who I am responsible, is voluntary and anonym and the collected data will be used only as stated. I understand that I will be given a copy of this consent form. I am aware of my right to withdraw this consent at any time, which however shell not affect the lawfulness of processing based on consent before withdrawal. I agree to engage the clients and the staff of the Social Care Centre Petržalka in the pilot testing of AP-NURSE devices.

Chanečková Soňa, Mgr. \_\_\_\_\_

Date 05/05/21

Director of the Social Care Centre Petržalka

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\_\_\_\_\_ Date 05/05/21

Project Supervisor