D2.3 First study subject approvals package

Mobilise-D

Connecting digital mobility assessment to clinical outcomes for regulatory and clinical endorsement

Grant Agreement No. 820820

[WP2 – First study subject approvals package]

Lead contributor	Kristin Taraldsen (P10 – NTNU)
	kristin.taraldsen@ntnu.no
Other contributors	Beatrix Vereijken (P10 – NTNU) Isabel Neatrour (P1 - UNEW) Kirsty Scott (P2 USFD) Claudia Mazzà (P2 USFD) Alison Keogh (P9 - UCD) Andrea Cereatti (P16 UNISS) Alison Yarnall (P1 - UNEW) Brian Caulfield (P9 – UCD) David Singleton (P9 – UCD) Lynn Rochester (P1 – UNEW)
Reviewer	Arne Mueller (999754557 – Novartis Pharma AG)

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1 Publishable Summary

This document details the protocol for the technical validation study in the Mobilise-D project, where specifically the design, recruitment, and data collection will be described. Ethical considerations at the three sites will also be described along with registration of the study protocol prior to inclusion of the first participant.

2 Introduction

The Mobilise-D technical validation study is a multisite validation study evaluating physical activity in real life settings. This study aims to verify and test the device-algorithm pair to be used in the further studies of the overall work of the Mobilise-D consortium. The technical validation study has an observational design that measures walking in both controlled, simulated and real-world settings, and evaluates the experiences of both participants and professionals that are using the device. In addition, the study will help us to understand several of the practical issues associated with using this type of technology in clinical research.

The full title of the study is “Validating digital mobility assessment using wearable technology – the Mobilise-D Technical Validation study”, with a short acronym: “Mobilise-D – Technical Validation Study”. The Mobilise-D – Technical Validation Study will be conducted in order to validate the system prior to the clinical validation trial, which is the next step of the Mobilise-D project.

The Newcastle upon Tyne Hospital NHS Foundation Trust (NuTH) will act as the Sponsor for the entire study, including sites based outside the UK. As sponsor, NuTH has the responsibility for ensuring the appropriate regulatory and ethical approvals are in place as required.

The technical validation study will be performed at five sites located in the UK (UNEW and USFD), Israel (TASMC), and Germany (CAU and RBMF). All test sites obtained ethical approvals in September 2019. An amendment to the protocol was submitted for approval in January, and at the time of this deliverable, the UK have received approvals

but are waiting for local approval at Sheffield and Newcastle before the recruitment can start.

We will describe how we will be registering the trial prior to inclusion and as this is underway, no formal id number from the trial registry has been obtained yet as the payment is ongoing.

2.1 Content of this deliverable

This deliverable reports on the first study subjects' approvals package, including the protocol for the technical validation study, ethics approvals, and study registration. We also include a short description of study progress at the end of this deliverable.

The deliverable starts with an introduction (Section 3). Section 4 continues with the study protocol, presenting the crucial parts of the trial. Section 5 presents the ethical considerations and section 6 reports on study registration. Section 7 contains the status prior to the inclusion of the first participant for the Mobilise-D technical validation study.

3 Background for running a technical validation study

The ability to move is a key contributor to "physical, mental and social well-being" which defines health[1]. However, the study of mobility has received little attention, except in diseases characterised by specific mobility dysfunction. The increasing longevity of the world's population together with prolonged survival in many chronic diseases means that more people are suffering from loss of mobility, which in turn is a major determinant of loss of independence. This has a considerable and growing personal, societal and economic impact. Efforts to mitigate this loss of mobility are an increasing priority and promising interventions are now under investigation. To target mobility loss effectively and thus be able to prevent it, we need valid tools that can detect and measure it. Mobility - how well someone walks, including speed, symmetry/efficiency, pain, and endurance - is considered 'the 6th vital sign' of health. This is because poor gait (especially slow walking) is associated with greater mortality, morbidity, cognitive decline, dementia and fall risk[2, 3]. Existing mobility endpoints are based on performance, patient self-reporting and one-off assessment, are resource intensive and lack sensitivity, which limits

therapeutic development and clinical management. A novel approach is needed that is low cost, simple, accurate and capable of use in the real world, including the home and the community. Wearable digital technology (small devices worn on the body that measure movement) has the potential for measuring and monitoring real-world walking speed (RWS) and other digital mobility outcomes (DMOs).

The EU-funded IMI2-JU consortium Mobilise-D aims to develop and implement a digital mobility assessment solution to demonstrate that real-world digital mobility outcomes can successfully predict relevant clinical outcomes and provide a better, safer and quicker way to arrive at the development of innovative medicines. At present, however, there are no robust validation studies to demonstrate that measurement of digital mobility outcomes in the real-world are accurate and acceptable to patients and professionals. A technical validation study is therefore needed as a first step to adopting this form of mobility assessment in clinical studies and healthcare.

We will carry out a technical validation of a wearable device (which includes sensors and an algorithm to derive outcomes) to measure real-world walking speed and other digital mobility outcomes. A total of 120 participants will be recruited from six different groups across five clinical sites. These groups include: Chronic Obstructive Pulmonary Disease (COPD), Parkinson's disease (PD), Multiple Sclerosis (MS), Proximal femoral fracture (PFF), Congestive Heart Failure (CHF) and healthy older adults (HA).

We have planned for validation both in laboratory settings and in the home environments. We aim to verify and test the algorithm to be used in a further study as part of the overall work of the Mobilise-D consortium. We have designed an observational study that measures walking in both controlled, simulated and real-world settings and evaluates the experiences of both participants and professionals of using the device. The study will also help us to understand several of the practical issues associated with using this type of technology in clinical research.

The final version of the study protocol was approved by first regulator/ethics committees in September 2019. An amendment to the protocol was submitted in January 2020. Study registration is underway. Approval from all ethical committees on the submitted amendments along with getting the official registration number from the study registry,

are needed prior to study start which is planned for beginning of April.

4 Preparations prior to study enrolment

4.1 Protocol for the Mobilise-D Technical Validation Study

The first version of the protocol was submitted to ethical committees in August 2019 and approved in September 2019. An amended version of the protocol with adjustments were submitted to ethical committees in January 2020. The version of the protocol reported here in D2.3 is the January 2020 version of the protocol which is the final version of the protocol and corresponds to the study registry information in ISRCTN.

4.1.1 Research question and objectives

The overall aim is to carry out a technical validation of a sensor and algorithm pair to measure real-world walking speed and other digital mobility outcomes. We will include assessments of wearability and human factors related to sensor and data collection protocols.

The primary objective is to evaluate the validity of the selected wearable device and algorithm pair to accurately measure digital mobility outcomes in the real-world in five clinical cohorts (COPD, PD, MS, PFF, and CHF) and in healthy adults. Secondly, we aim to establish the usability and acceptability of this pair from the perspective of the participants and the researchers conducting the assessments. Table 1 presents a study summary.

***Table 1**: Study summary.*

Study Title	Validating digital mobility assessment using wearable technology – the Mobilise-D Technical Validation Study.
Internal ref. no. (or short title)	Mobilise-D - Technical Validation Study
Study Design	Observational study
Study Participants	Participants will be recruited from the following disease cohorts: Chronic Obstructive Pulmonary Disease (COPD), Parkinson's disease (PD), Multiple Sclerosis (MS), Proximal femoral fracture (PFF), Congestive Heart Failure (CHF), as well as healthy older adults (HA).

Planned Size of Sample (if applicable)	120
Follow up duration (if applicable)	9 days
Planned Study Period	Six months
Research Question/Aim(s)	To carry out a technical validation of a devise and algorithm pair to measure real-world walking speed and other digital mobility outcomes.

4.1.2 Outcomes

The primary outcome measure is walking speed determined in real-world settings.

Secondary outcome measures will include right and left step duration, right and left stride duration and length, turning angle, cadence, distance walked, gait variability and symmetry, and other gait-related outcomes relevant for assessments in real-world settings.

4.1.3 Study design

Given the requirement to assess the reliability and robustness of the sensor device-algorithm pair both in and out of the lab, the testing protocol will include three different experimental conditions over nine days (see Figure 1).

The first day is an in-lab session lasting up to 5 hours with breaks in-between (day 1), followed by a seven-day unsupervised real-life validation in home and work environments (days 1-9). The assessors will visit participants at home/work on day 9 to deliver a reference multi-sensor wearable system to collect 2.5 hours of unsupervised real-world daily activity data. Participants will be asked to complete some assessments on usability prior to the 2.5 hours of data collection.

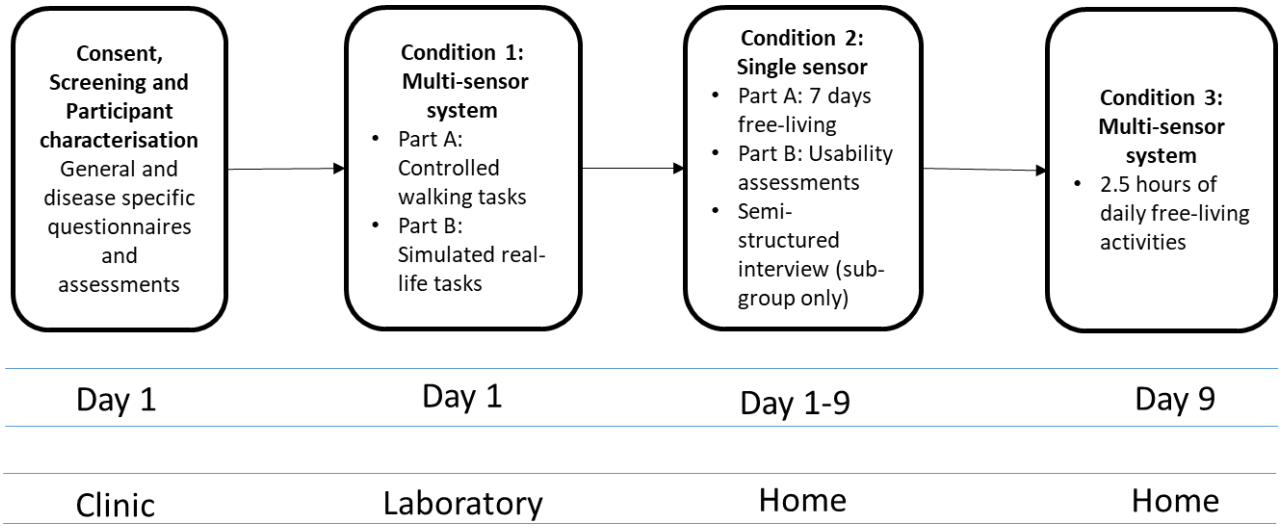


Figure 1: *Flowchart to illustrate study activities, time points and locations.*

All potential participants will receive information about the study and will need to complete an informed consent form prior to screening.

The screening assessment will consist of a review of the relevant inclusion and exclusion criteria. This will involve a checklist of questions and a review of the participants' medical notes to determine eligibility (see Assessment Manual). Participants will be required to complete the Montreal Cognitive Assessment (MoCA)[4] as part of the screening assessment to assess cognitive function.

Participants who meet the criteria for inclusion are invited to join the study and to continue with the in-lab testing on the same day.

4.1.4 Assessments

All participants will undergo a clinic/laboratory-based session to record generic and disease-specific characterisations. This will include participant reported outcomes, assessments and medical notes review.

The following participant reported outcomes will be collected: descriptive information (gender, year of birth, living arrangements, education), comorbidities, number of falls and injuries in the last 12-month, walking aid usage and current medication.

Cognitive status will be recorded from the **MoCA** (completed during screening). Participants will be asked to rate their general pain and pain during walking using a **Visual Analogue Scale** (0-10, from no pain to worst pain possible). Activities of Daily Living (ADL) function will be assessed by use of the **Late-Life Function and Disability Instrument (LLFDI)**[5,6]. The LLFDI is a comprehensive assessment of function and disability in community-dwelling older adults. The functional component (32 items) reflects a person's ability to perform specific actions or activities and the disability component (16 items) reflects a person's ability to perform socially defined life tasks within a typical sociocultural and physical environment.

Participants' height, weight, shoe size and waist circumference will be recorded.

Participants will then undergo additional disease-specific assessments, with the exception of healthy adults who will not complete additional assessments. All performance-based assessments will be completed in the laboratory with participants wearing a single Dynaport device and the INDIP system (see D2.2)

PD Cohort:

1. The MDS Unified Parkinson's Disease Rating Scale (MDS-UPDRS)[7] Part III (motor examination) will be undertaken as part of the characterisation assessment.

MS Cohort:

1. The most recent Expanded Disability Status Scale (EDSS)[8] score will be recorded from medical notes (if completed within last 6 months). If EDSS has not been completed within the last 6 months, this will be undertaken as part of the characterisation assessment.

COPD Cohort:

1. The COPD Assessment Test (CAT) will be undertaken as part of the characterisation assessment.

2. Lung function – Spirometry (under usual medication) results will be recorded from medical notes (if undertaken within last 3 months). If spirometry has not been completed within the last 3 months, this will be undertaken as part of the characterisation assessment.

3. Six minutes walking distance (6MWD) assessment will be undertaken using a 20-meter walking path.

CHF Cohort:

1. The Kansas City Cardiomyopathy Questionnaire (KCCQ) score will be recorded from medical notes (if completed within last 6 months). If KCCQ has not been completed within last 6 months, this will be undertaken as part of the characterisation assessment.

2. Six minutes walking distance (6MWD) assessment will be undertaken using a 20-meter walking path.

PFF Cohort:

1. The Short Physical Performance Battery (SPPB) will be undertaken. This consists of a static balance task, a five times chair-raise test, and a 4m walk test at preferred gait speed.

In addition, assessors will be described by their age, gender, highest educational degree, and years of assessment/research experience.

4.1.5 Training of assessors

The on-site assessors will complete training prior to conducting the assessments and sensor-setup to ensure participant safety and data quality. Training will be carried out by the University of Sheffield, supported by the University of Sassari who will oversee on-site deployment of the multi-sensor reference system. Assessors will be trained on all assessments and procedures for the data collection. Assessors will also be provided with information about the project and the different assessments, and how to communicate this information to participants. The on-site training is partly done already at time of submission of this deliverable and will be completed at all sites prior to starting the study.

4.1.6 Safety of participants

We include patients and healthy adults as participants in this study. Trained assessors will ensure the safety of participants during the in-lab sessions. The experimental

sessions when participants are wearing a full sensor set-up might take a few hours. Participants can have breaks between the sessions, or during testing, as needed, and they will be provided with a small meal or refreshments. If participants are tired, additional opportunities for rest will be given. The tasks are performed in order of increasing difficulty so that participants and researchers can opt to terminate the assessment at any appropriate level.

If the participant is tired at any point during the session, opportunities for rest will be given with the researcher confirming with the participant that they are ready to carry on after an appropriate amount of time.

4.1.7 Safety of assessors

When assessors attend a participant's home or place of work, the following precautions should be taken to ensure safety:

1) If possible, attend the venue in pairs.

2) Let someone else know where you are and what time you expect to be there.

3) Have a number you can call in case of emergencies.

4) Agree to contact someone by a specific time and agree a protocol if this does not occur.

4.1.8 In-Lab Tasks

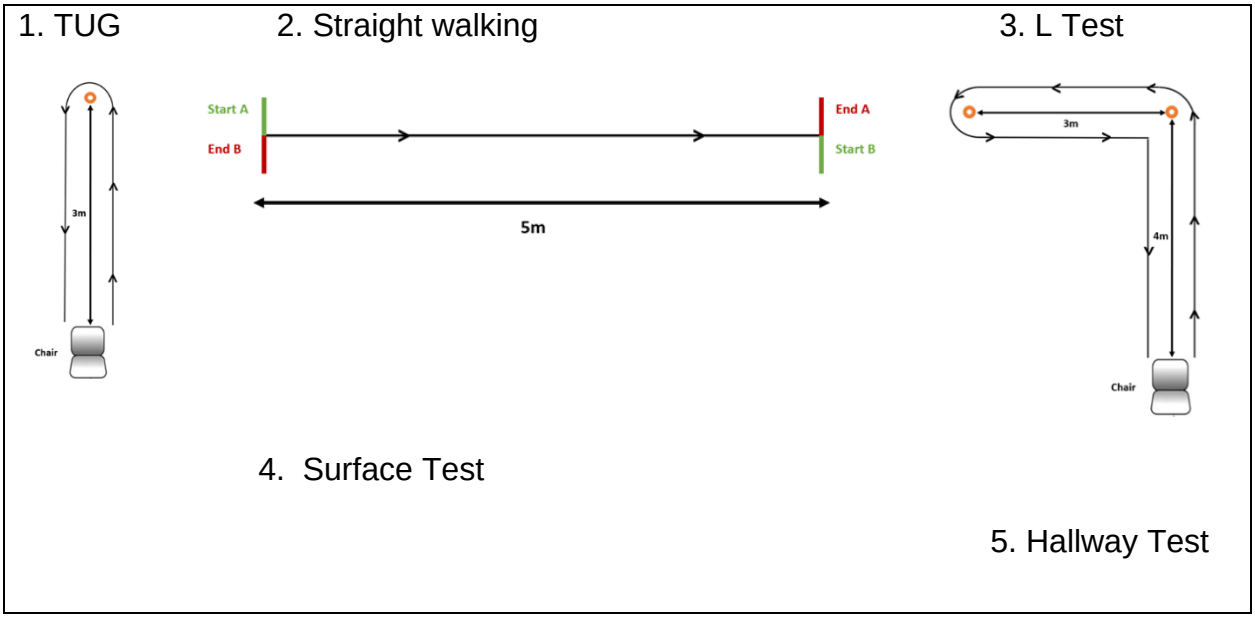
To determine the robustness and accuracy of the single device -algorithm pair in the real world, the system performances will be tested across a variety of movements and walking conditions using a stereo-photogrammetric system as reference.

As the sample population in the technical validation is widely distributed regarding their physical health, the safety and comfort of all participants during these tasks is crucial.

To ensure that the wellbeing of each participant is at the centre of the experimental session, the tasks proposed in the list below have been ranked in order of difficulty (easiest first and the most difficult last). The researchers will explain and demonstrate each task prior to verbal consent from the participant. By doing so, the participants/researchers can opt to terminate the assessment at any appropriate level.

1. **Timed Up and Go (TUG) Test** (3 meters)
2. **Straight Walking Test** (completed at three different walking speeds with two trials each).
3. **L Test**[9] (sit in a chair, stand up, walk straight, turn at a curved 90°, continue walking straight, turn again at a curved 180°, follow the circuit back to the chair and sit down).
4. **Surface Test** (walk the circuit by turning around the cones, completed twice and finish at the marked end point).
5. **Hallway Test** (including stair ascent and descent by step up and down off a step).
6. **Simulated Daily Activities*, level one (**a simplified version accommodating the participants who may find some of the tasks in Level two too physically demanding or uncomfortable).
7. **Simulated Daily Activities*, level two** (some complex movements that may not be suitable for all participants but will be useful for the development and validation of the single sensor system-algorithm pair).

***The researcher will indicate on the annotations which level was set for the participant, level one or two.



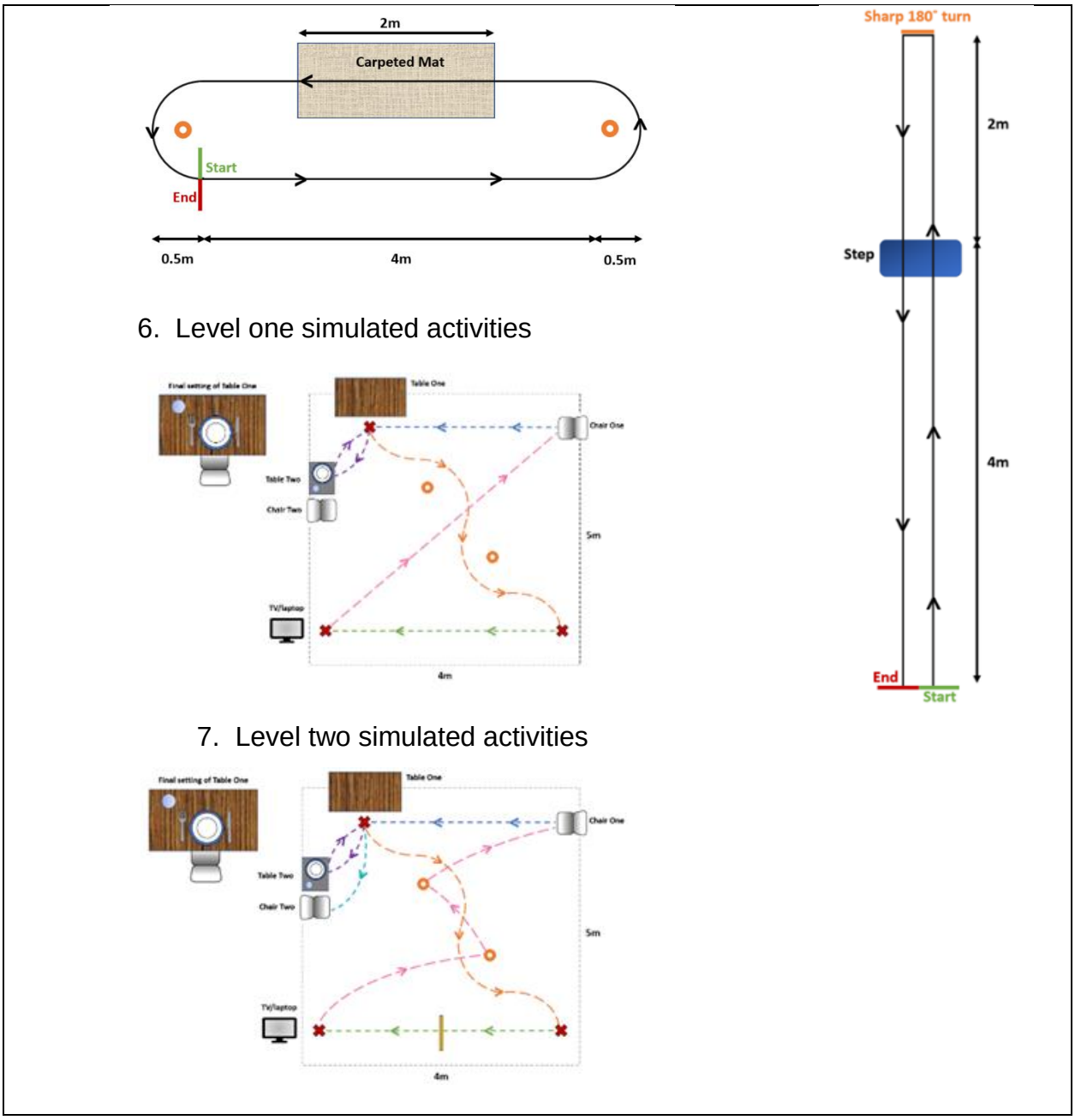


Figure 2. *Illustration of laboratory and procedures during all in-lab tasks.*

4.1.9 Seven days free-living activities

There are two parts to this condition. Firstly, participants wear a single device (Dynaport) to capture everyday activities over seven days (Part A) and, secondly, participants and the assessor will be asked their opinions on how user friendly they found the experience (Part B).

Part A: Monitoring free-living for a week

At the end of day 1, participants will return home wearing a single Dynaport device (worn on a provided belt at L7 on the back). This will be worn during their everyday life until day 9 (to allow continuous recording of free-living activities for at least seven days). The participants are asked to “Do what you usually do during a week”, without any further instructions. Participants will be provided with a mobile phone which will track their geolocation during the monitoring period. The phones will be provided with internal SIMs to avoid using Wi-Fi networks. A beacon sensor will also be attached to any walking aids normally used by the participants to detect whether and when these are being used. Beacon data will be collected automatically and stored on the mobile phone (when in the proximity of the device).

Part B: Wearability and compliance (usability)

Participant assessment

Participants’ wear-time of the Dynaport device will be collected from the device as a primary measure of compliance. Following the period of the seven-day, free-living data collection, participants will be asked to complete two usability questionnaires to assess acceptability of the Dynaport device: The 12-item Usability questionnaire from Rabinovich et al. (2013)[10] and the 6-item Comfort Rating Scale[11].

In addition, a sub-group of participants will be asked to complete a *semi-structured interview* which will be audio-recorded. All interviews and questionnaires will be administered by the local researcher, in either the participants home or place of work. Participants from each disease cohort will be asked to consent to an interview and will be recruited until data saturation is reached. The interview will explore participants’ opinions on the use of wearable and digital technology in healthcare, experiences of managing their condition, experiences of technology, and opinions on data privacy associated with the use of technology in healthcare. Additionally, participants will be asked about their experiences of using the Dynaport device, including comfort, perceived usefulness and ease of use, barriers and facilitators, and any other usability experiences that they may have encountered. All interviews will be audio-recorded, transcribed verbatim and checked locally. The transcribed versions will be checked by the researchers, by

comparing them with the audio-recordings (listening and at the same time reading the transcribed versions), before the final transcribed versions are translated to the English language locally. The four eyes principles will be followed, and final text can be uploaded to the platform for the coding/analysis to be done by UCD. UCD will also have access to the audio files, and UCD will be in charge of the data handling side of this part.

Assessor assessment

The assessors will complete the System Usability Scale[12], The IBM Computer Usability Satisfaction Questionnaire[13], along with intervention-specific questions about the Mobilise-D concept (including recruitment, data collection, project materials etc.) and the feasibility of the trial procedures. At the very end, an interview with the researchers/assessors will be completed to describe their experience with the Dynaport device, as well as their opinions and previous experiences with wearable sensors in general.

4.1.10 Daily free-living activities

The final condition will be a 2.5-hour session completed in the participant's home or chosen location on day 9. To be able to capture the 2.5 hours with highest activity levels and/or most variable activity patterns, each participant will be asked on day 1 to specify a convenient time of the day and location to capture active mobility. The protocol is free-living and unsupervised, but participants are provided with a list of activities that they should try to include during the 2.5 hour-session. The participants are instructed to "Go about your day as you usually would but try to include tasks such as:" (see list below for details).

Examples of activities to be performed in a self-chosen order
Walking indoors, both short and longer distances (e.g. within one room and then moving around in the house, including corridors if possible)
Rise from a chair and walk to another room
Walk to the kitchen to get something to drink
Walking up and down stairs (if possible)
Walking outdoors (if possible)
If walking outdoors, try including walking up and down an inclined path
Note: Participants are asked later to indicate what activities they did during this period

After the 2.5 hours, the assessors will return to the location chosen by the participant to collect the sensors.

4.1.11 Single device and reference systems

Several measurement systems will be used in order to validate the device-algorithm pair. The single device system and the different reference systems that will be used in each of the three test conditions in this trial will be presented briefly in the following.

The single device system consists of one inertial unit (MM+ Dynaport, McRoberts) attached to the lower back via an elastic strap. This device can be used to collect data for prolonged, remote (i.e. home, office, or other real-life scenarios) monitoring of the amount and quality of movement performed by an individual. As the goal of the technical validation is to validate a single device-algorithm pair, the Dynaport MM+ is used in all three protocol conditions (1,2,3) as well as during the performance-based disease characterisation assessments. The participants are asked to remove the single device system while bathing during condition 2, due to not being waterproof.

Reference systems will be used during the in-lab tasks, where reference data will be collected using simultaneously:

i) An optoelectronic stereo-photogrammetric system consisting of multiple infrared cameras that reconstruct the trajectories of non-invasive markers. Markers will be placed directly on the participants' shoes and on a rigid plastic fixture attached to the lower back using dermatological tape.

ii) A multi-sensor wearable system (INDIP) which includes two pressure insoles inserted into each of the participants shoes, two small distance sensors with one attached to each of the participants ankles, and four additional inertial sensors, two of which will be secured to the participants shoes, one attached to the non-dominant wrist by an elastic strap and one secured on the lower back.

During the daily free-living activities, only the multi-sensor wearable system will be used as reference.

To control possible confounding factors and allow for contextualization, it is planned to use a video-camera as one **additional system** for the in-lab tasks, whereas for the out-

of-lab conditions a mobile phone will be used to record geolocation data and, when relevant, a beacon sensor on walking aids to record their use by the participants.

4.1.12 Data collection

For each type of data in this study we will implement a standardised and secure data transfer pipeline, to ensure that all data can be integrated on the Mobilise-D data management platform. The Mobilise-D data management platform will be hosted on AWS secure services cloud platform. Data will be integrated on the platform by means of implementation of a standardised file nomenclature system. At point of capture, each file will be labelled in standardised format, including information on: Centre, Participant unique ID, Data source/ modality, and Time point. All data handling follows ALCOA+ principles.

4.1.13 Data analysis

We will follow COnsensus-based Standards for the selection of health Measurement INstruments guidelines for measurement properties (COSMIN, https://www.cosmin.nl/). Analyses will combine descriptive statistics, technical validation, wearability and compliance combining qualitative and quantitative approaches.

Technical (criterion) validity of the device algorithm pair to measure real-world walking speed and other digital mobility outcomes will be evaluated by comparing these outcomes to the same constructs obtained from single device system and reference standards. First, we will calculate the correlation between DMOs obtained with the sensor-algorithm pair and the reference standards. A r>=0.7 will be considered as acceptable. Second, we will use Bland–Altman plots to visually check for nonlinear or heteroscedastic distributions of error between digital mobility outcomes derived from the sensor-algorithm pair with the appropriate reference standard systems. Third, we will estimate the intra-class correlation coefficients (ICC) and limits of agreement (LoA) expressed both as absolute values and as a percentage of the mean. ICC values are expected to be >=0.7.

Quantitatively, all questionnaires will be reported using descriptive statistics. Qualitatively, interviews will be analysed using both deductive and inductive thematic analysis. An interview topic guide will be used to develop an initial draft codebook. Deductively,

transcripts will be assessed broadly for the themes of: participants' previous experiences with wearable devices and digital technology; barriers and facilitators to the use of wearable and digital technology within the management of participant's health condition; the perceived comfort, ease of use and usefulness of the Dynaport device; and barriers and facilitators to the use of the Dynaport device. Within these broad themes, subcategories will be inductively explored. Texts will also be inductively assessed for any further high-level themes that are present in the texts. To ensure that optimal analytical rigour is practised, a portion of texts will be double coded to assess for inter-rater agreement, following the guidance of previously published reports.

Additionally, the data collected allows us to complete a mixed methods analysis. Specifically, a concurrent design has been undertaken, therefore results will be listed both quantitatively and qualitatively, and finally triangulated to ensure a comprehensive report and a deeper understanding of participants' and assessors' satisfaction with the materials used in the Mobilise-D validation study. Results from both the qualitative and quantitative components will be included and reported for the participants and assessors independently. The data for the assessors and the participants will be triangulated independently using a matrix to facilitate comparison of the findings. This will involve presenting the quantitative data in a tabular format alongside summarised qualitative themes to establish convergence, discrepancy, or silence across the results. Convergence is defined as general agreement between the qualitative and quantitative data sets, discrepancy as a general disagreement between the qualitative and quantitative data sets, and silence when one data set arrives at results that the other does not.

4.1.14 Study setting

Five clinical sites in three different countries are involved in the technical validation study. All clinical sites have access to the populations of interest and have the capability to conduct technical studies. The sites are: Tel Aviv Sourasky Medical Center, Israel (TAMSC), Robert Bosch Foundation for Medical Research, Germany (RBMF), University of Kiel, Germany (CAU), The Newcastle upon Tyne Hospitals NHS Foundation Trust, UK (NuTH) and Sheffield Teaching Hospitals NHS Foundation Trust, UK (STH). The in-lab

tasks will take place in gait laboratories, see Table 2 for lab size and capture area of the optoelectronic stereophotogrammetric systems that will be used. As we are aiming to generate maximum variability in our data, protocol reproducibility is not necessary, and settings do not need to be identical. The 7 days of daily life recordings and the 2.5 hrs free-living activities condition will take place in participants' home or chosen location.

Table 2: *Lab size and capture area of the 3D motion capture system.*

	Manufacturer, cameras' model	# cameras	Gait lab size (length and width)	Mocap software version
STH	Vicon, T160	10	9.2x6.1m (usable capture volume: ~5.5x4m)	Nexus 2.6.1
NuTH	Vicon, Bonita 10	14	15×6.4m (usable capture volume at present: ~7×4m)	Nexus 2.7.1
CAU[1]	Qualisys, Miqus	12	10×5m (usable capture volume: ~5×4m)	Track Manager 2.16
RBMF[2]	Vicon, T10	8	20×4m (usable capture volume: ~15×4m)	Nexus 2.8
TASMC	Vicon, T10	8	14×5m	Nexus 1.8.5, Polygon 3.5.2

[1] *Treadmill AVAILABLE: manufacturer: Woodway; model: Slat Splitbelt*
[2] *8m GaitRite AVAILABLE*

4.1.15 Sample and recruitment

A convenience sample of 120 participants will be recruited to represent the disease cohorts of interest in Mobilise-D: Chronic Obstructive Pulmonary Disease (COPD), Parkinson's Disease (PD), Multiple Sclerosis (MS), Proximal Femoral Fracture recovery (PFF), Congestive Heart Failure (CHF), as well as healthy older adults (HA). A total of 20 participants will be recruited from each of these cohorts, covering a wide range of walking speeds and gait impairments. We will use a competitive recruitment strategy, where each site recruits a minimum of 4 and a maximum of 15 participants in multiple cohorts, until the total of 20 participants per cohort is reached. Table 3 presents which cohorts are planned to be recruited at each of the five clinical sites. Additionally, the assessors from each participating site who complete the data collection procedures will be recruited as part of the assessment of usability (minimum 1 at each clinical site).

Table 3: *Participants recruited at each clinical site.*

	PD	PFF	MS	COPD	CHF	HA	Total
CAU	✓	✓	✓	0	0	✓	24
RBMF	0	✓*	0	✓	✓	✓	24
UNEW	✓	0	0	✓	0	✓	24
TASMC	✓	0	✓	0	0	✓	24
USFD	0	0	✓	✓	✓	0	24
TOTAL	**20**	**20**	**20**	**20**	**20**	**20**	**120**

*at least 5 of the PFF will be a subgroup (defined as users of walking aids during testing)

The eligibility criteria (inclusion and exclusion) grouped by total cohort and disease cohort are summarized in Table 4 below. We aim to recruit comparable numbers of females/males within each cohort to ensure sufficient statistical power for gender. For assessors to be eligible to participate (final section in grey, Table 4), they must have completed the provided training procedures prior to data collection and have collected data by use of the McRoberts Dynaport device.

Table 4: *Inclusion and exclusion criteria for the participants and assessors.*

Group	Inclusion criteria	Exclusion criteria
All groups	-able to walk 4 meters independently with or without walking aids -able to give informed consent -willingness to wear the sensor set-ups during the study -shoe size 36 (3 UK) or above -able to read and write in first language in the respective country -MoCA >15[4] -available for home visit/office during study period	-occurrence of any of the following with 3 months prior to inclusion: myocardial infarction, hospitalization for unstable angina, stroke, coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), implantation of a cardiac resynchronization therapy device (CRTD) -current medical condition that could interfere with the patient's compliance
COPD	-≥45 years of age -Diagnosis of COPD (post-bronchodilator forced expiratory volume in the first second (FEV1) to forced vital capacity (FVC) ratio <0.70) -clinical stability, defined as at least 4 weeks without antibiotics and/or oral corticosteroids to treat either a moderate or severe exacerbation -current or ex-smokers with a smoking history equivalent to at least 10 pack years (1 pack year = 20 cigarettes smoked per day for 1 year)	-having undergone major lung surgery (e.g. lung volume reduction, lung transplant) -having a lung tumor -primary respiratory diseases other than COPD (e.g. asthma) - impaired mobility related to non-COPD causes, as judged by the investigator

PD	-aged 18+ years -Diagnosis of PD according to the Movement Disorders Society criteria	-impaired mobility related to non-PD causes, as judged by the investigator
MS	-aged 18+ years -Diagnosis of MS based on the revised McDonald's criteria	-impaired mobility related to non-MS causes, as judged by the investigator
PFF	-65+ years of age -surgical treatment (fixation or arthroplasty) for a low-energy fracture of the proximal femur (ICD-10 diagnosis S72.0, S72.1, S72.2) as diagnosed on X-rays of the hip and pelvis within last 12 months	-impaired mobility related to non-PFF causes, as judged by the investigator
CHF	-≥45 years of age -Diagnosis of chronic heart failure NYHA class II-IV	- history of COPD ≥GOLD III - impaired mobility related to non-CHF causes, as judged by the investigator
HA	65+ years of age	
Assessors	-Completed training procedures -Collected data by use of the McRoberts Dynaport device	

4.1.16 Sample size

No sample size calculation was performed for this study as no real-life validation data are currently available that would allow for a reliable power calculation analysis. We have established an initial sample size of 120 according to Consensus-based Standards for the selection of health Measurement Instruments guidelines for measurement properties (COSMIN, https://www.cosmin.nl/). This sample size allows for 'excellent' methodological quality of non-inferiority studies, and is the one endorsed by the COSMIN checklist, a standardized tool for assessing the methodological quality of studies on measurement properties (we will refine and adjust after 50% enrolment). For qualitative studies, sampling will continue until saturation is reached.

5 Ethics

5.1 Ethical considerations

We will take into account guidelines from the Clinical Trials Transformation Initiative: Recommended pathway for developing mobile-technology-derived outcome assessment. The McRoberts Dynaport device, study mobile phone, beacon sensors and the stereo-photogrammetric systems all have CE markings. The multi-sensor

system has been developed specifically for the present technical validation study by our academic partners and consequently does not have CE marking, but RoHS/REACH and electrical safety requirements have been satisfied. The Medicines and Healthcare products Regulatory Agency have confirmed that they will not need to regulate the study and a 'Notice of No Objection' is not required.

Informed consent will be taken by the Principal Investigator or a member of the research team who has been delegated this responsibility. That individual will have the necessary GCP training and regulatory approvals. At the beginning of the first appointment the researcher taking consent will confirm that the potential participant has read the participant information sheet before discussing the study further and answering any questions they may have. Provided that the potential participant agrees to participate, he/she will be asked to sign and date the informed consent form. This will be witnessed by the researcher taking consent, who will also sign and date the form. The informed consent process/discussion will be documented in the participants' medical records. The original consent form will be stored in the site file. A copy will be filed in their medical records and a copy will be provided to the participant.

5.2 Ethical application all sites

The study was submitted to the respective ethical committees for evaluation, and all sites have approved the first version of the study protocol (in September 2019). As we submitted an amended version of the protocol in January 2020, we are expecting responses from all ethical committees prior to starting recruitment.

The two UK sites received approval of the study in February 2020, and we expect Sheffield to be the centre to recruit the first study participant.

7 Study registry

As requested by the study sponsor, we will use the ISRCTN registry for registration of the protocol of the technical validation study. The ISRCTN registry is a primary clinical trial registry recognised by WHO and ICMJE where all clinical research studies are accepted, providing content validation and curation and the unique identification number necessary for publication.

At time of writing this deliverable, the payment to the ISRCTN is underway. We will not start recruiting any participants until we have received confirmation that we have the identification number ready with online information about the study.

8 Conclusions

This deliverable has provided an overview of the comprehensive protocol for the WP2 technical validation study that will be conducted within the Mobilise-D project in 2020. We have designed this validation trial to achieve a robust technical validation, including validation both on in-lab and real-world data. In addition, a range of human factors are included to be able to assess sensor and protocol acceptability. Trial registration is underway and will be completed prior to starting recruitment of participants.

In summary, we designed the study to guide the conduction of the clinical validation study that is planned to be conducted from 2021. The WP2 technical validation study will produce a validated “device-algorithm pair” and associated technical, clinical and patient-specific standards necessary for the clinical validation in WP4.

There is one appendix to this Deliverable, Appendix 1, where the reference system is described in detail in a Technical Validation Description document (see attached after the references).

9 References

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APPENDIX 1

Technical validation system description

Table of contents

Experimental setup

Measurement set-up IN-LAB experiments

The following devices/measurement systems will be used to collect movement data:

- Optolectronic stereo-photogrammetric system (CE marked);
- DynaPort MM+ (McRoberts) (for single device/algorithm pair validation) (CE marked);
- INDIP system (it includes 4 magneto-inertial measurement units (MIMU), 2 distance sensors and 2 pressure insoles).

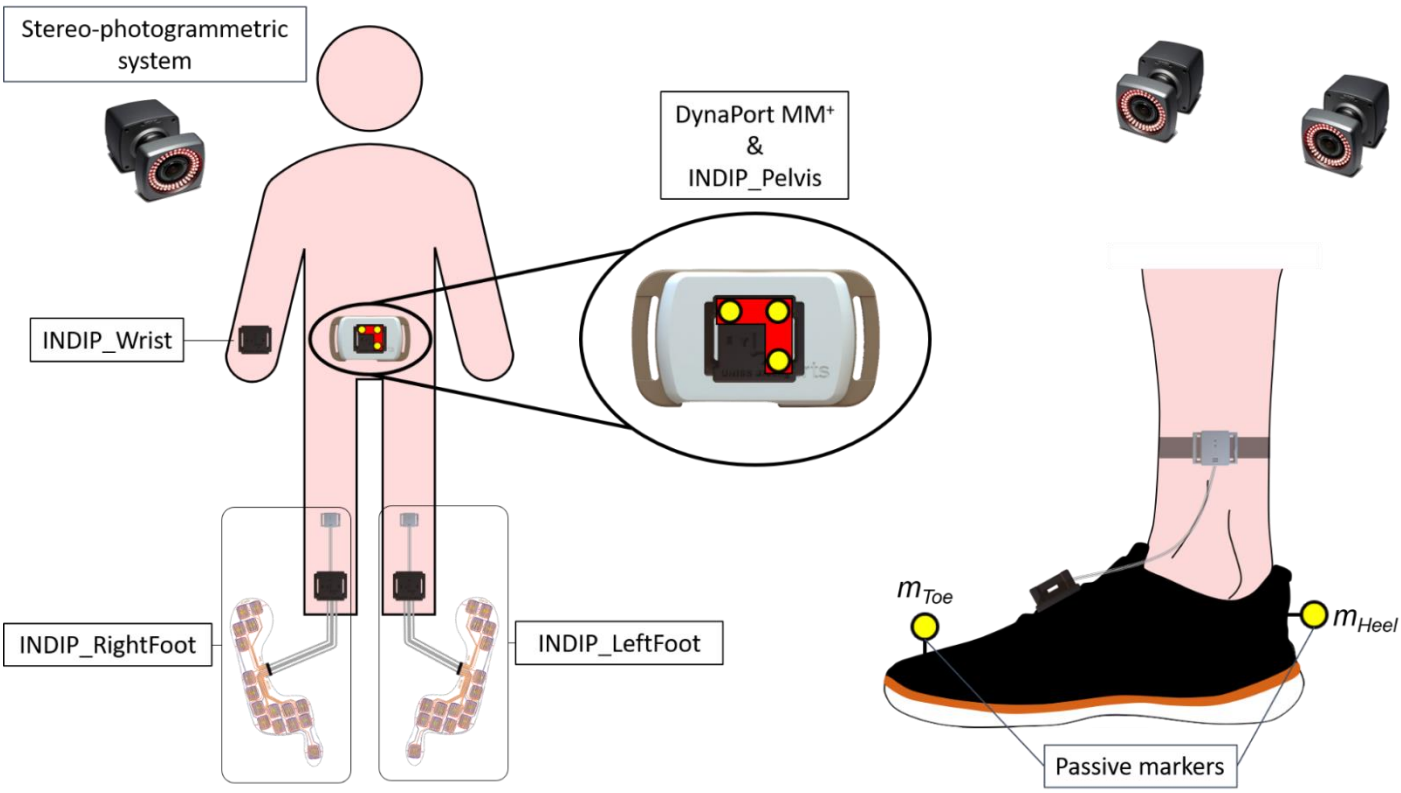


Figure 1: System overview for "laboratory settings".

Measurement set-up during FREE-LIVING DAILY LIFE ACTIVITIES (indoor and outdoor)

The following devices/measurement systems will be used to collect movement data:

- DynaPort MM+ (McRoberts) (for single device/algorithm pair validation);
- INDIP system (it includes 4 MIMU, 2 distance sensors and 2 pressure insoles);
- Smartphone (including GNSS).

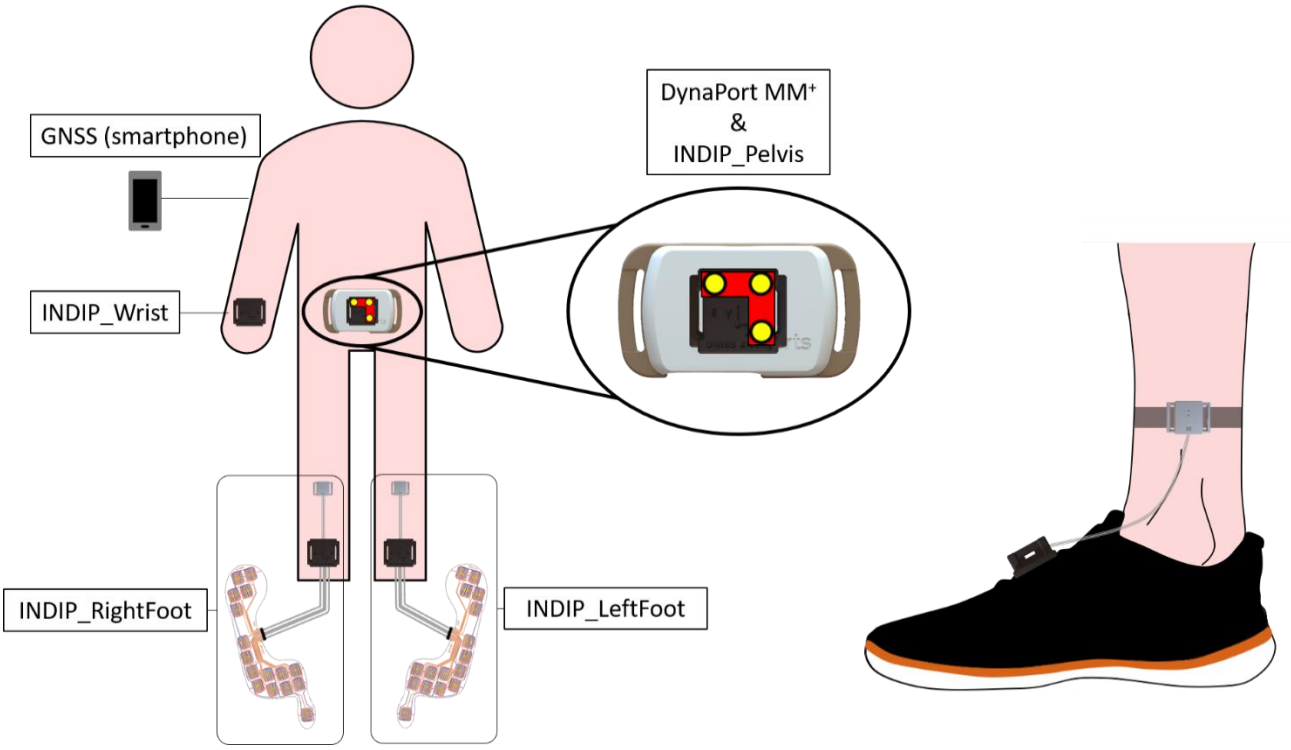


Figure 2: System overview for "free-living daily life activities".

Systems

Optoelectronic stereo-photogrammetric system (CE marked)

Characteristics of optoelectronic motion capture systems that will be used for the technical validation and that are already available in the clinical sites:
- Vicon Oxford metrics (https://www.vicon.com/), models: Vicon Bonita, Vicon T10.
- Qualysis (https://www.qualisys.com), model Miqus.

McRoberts DynaPort MM+ (CE marked)

https://www.mcroberts.nl/

Figure 3: DynaPort MM+.

INDIP (prototype system)

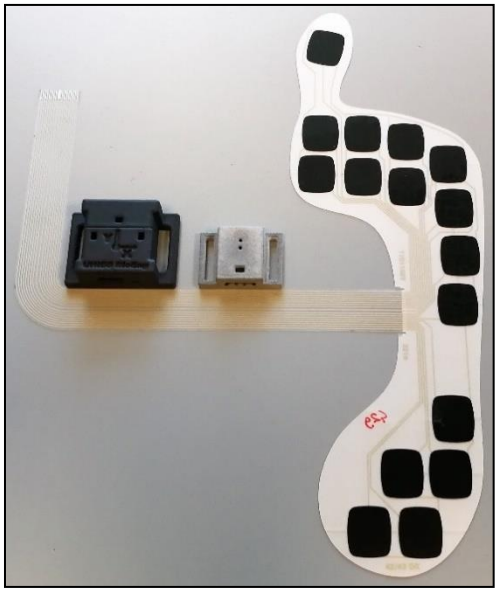


Figure 4: INDIP system.

System overview

INertial module with DIstance Sensors and Pressure insoles (INDIP) is a multi-sensor system which integrates an inertial module, up to two distance sensors and up to one pressure insole. The schematic representation of the INDIP system is reported in Figure 5. The inertial module includes an ultra-low-power microcontroller unit (MCU), a magneto-inertial measurement unit (MIMU → triaxial accelerometer, gyroscope, and magnetometer), a flash storage, and a wireless connectivity (Bluetooth LE). Each distance sensor integrates an infrared time-of-flight distance sensor that can be connected to the inertial module by cable. The pressure insole consists of sixteen resistive sensing elements and can be connected to the inertial module using a zif connector.

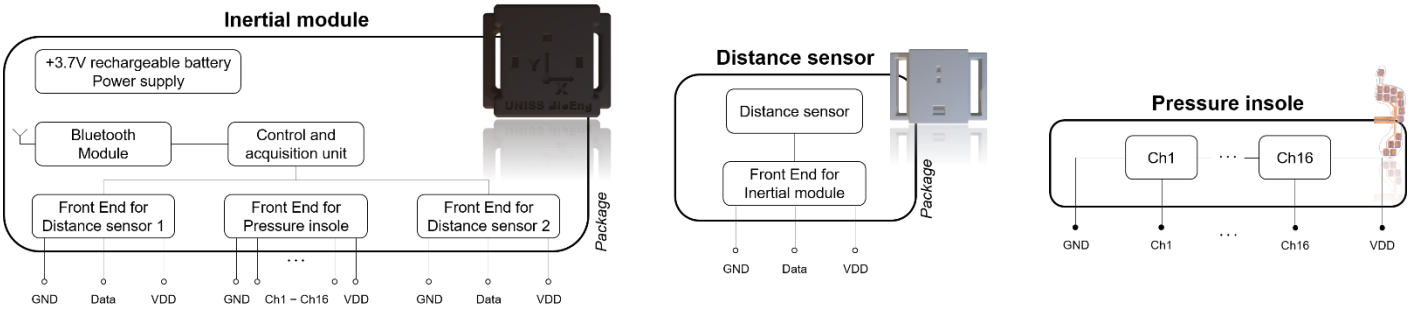


Figure 5: Schematic representation of the internal components of INDIP system: inertial module, distance sensor, and pressure insole.

An embedded sensor fusion algorithm, capable of computing the real-time device orientation in the three-dimensional space, is implemented in the firmware of the inertial module. The output data include linear accelerations, rate of turn, local magnetic field, orientation, distance, and tension/resistance for each sensing element of the pressure insole. For further technical description, please refer to INDIP datasheet (Attachment A).

Device description

The INDIP system will be used to collect reference data for the technical validation of a sensor and algorithm pair to measure real-world walking speed and other digital mobility outcomes (WP2). Experiements will be carried out in laboratory settings and during daily life activities for duration of acquisitions up to 150 minutes.
The INDIP device is **active** *("active means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices" [1]*) and **non-invasive** (*"invasive means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body" [1]*).
The electrical safety of the INDIP system is ensured by the fact that the system is powered through a self-contained battery which makes the system floating with respect to the power line mains and the ground. In addition, all circuits are enclosed by a plastic housing designed in accordance with the European Standard EN 60601-1:2006-10. Following this standard, the plastic case was designed to guarantee two means of protection: the means of operator protection (MOOP) and the means of patient protection (MOPP).
Preliminary measurements of the patient leakage currents and patient auxiliary currents in different conditions have been performed using a calibrated electrical safety analyzer (Rigel 288+, Rigel Medical, UK). All the measured values were smaller than the maximal allowed ones (and also smaller than the minimum current resolution of the Rigel 288+). Leakage currents were measured during both normal use and single fault conditions. Type body floating (BF) applied parts were considered for the measurements. Measurements of the insulation resistance and ground resistance are not applicable since, as stated earlier, the INDIP system is powered by a battery and consequently does not need a protective earthing system as defined by the EN 60601-1 standard. For further details, please refer to the INDIP electrical safety report (Attachment B).
The battery charging process is obtained by USB cable (max 5V and 0.9A).
In addition each component of the INDIP system satisfy RoHS/REACH Compliance and Declaration of conformity when sensible.
The INDIP system is not intended to be used for any specific medical purposes.

[1] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

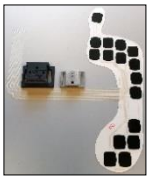
Available documentation

The full list of components with related documentation is reported in the following table and available in the *"INDIP system - Technical specification"* folder:

#	Component	Manufacturer	Description	Available documents				
				Product Specification/ Datasheet/ Reference sheet	RoHS	REACH	Reliability Report	Other
Inertial Module								
#1	204926-1103	Molex	USB Connector	•	•	•		Compliance declaration
#2	LSM6DSOTR	STMicroelectronics	Inertial Measurement Unit	•	•	•		Materials declaration
#3	S25FL512SAGBHVC10	Cypress Semiconductor	NOR Flash	•	•		•	
#4	XF3M(1)-1815-1B	Omron Electronics	FFC & FPC Connectors	•	•			
#5	MCS04020Z0000ZE000	Vishay	Thin Film Resistor	•	•			
#6	ERJ-2RKF10R0X	Panasonic	Thick Film Resistor	•	•	•		
#7	GCM155R71C104KA55D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#8	CC0402KRX7R8BB101	Yageo	Multilayer Ceramic Capacitor	•	•			
#9	ERTJ0EG103FA	Panasonic	Thermistor	•	•			
#10	GRM155C80J106ME11J	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#11	ERJ-2GEJ154X	Panasonic	Thick Film Resistor	•	•			
#12	GCQ1555C1H150FB01D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#13	ERJ-2RKF1004X	Panasonic	Thick Film Resistor	•	•			
#14	RT0402BRD071KL	Yageo	Thin Film Resistor	•	•			
#15	GRM152R60J105ME15D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#16	GRM155R60J225ME95D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#17	74479276222C	Wurth Electronics	Inductor	•	•			
#18	RT0402BRD07200KL	Yageo	Thin Film Resistor	•	•			
#19	CGA2B1X5R1C224K050BC	TDK	Multilayer Ceramic Capacitor	•	•	•		
#20	RC0402JR-07270RL	Yageo	Thick Film Resistor	•	•			
#21	GRM155R71C472KA01D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#22	GRM155R60J475ME47D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#23	ERJ-2GEJ473X	Panasonic	Thick Film Resistor	•	•			
#24	RT0402BRD074K99L	Yageo	Thin Film Resistor	•	•			
#25	74HC4051BQ	Nexperia	Multiplexer Switch	•	•			
#26	ABS06-32.768KHZ-1-T	ABRACON	Crystals 32.768KHz	•	•			
#27	AD8607ARMZ	Analog Devices	Precision Amplifier	•	•			Materials declaration
#28	214013	ERNI	Headers & Wire Housing	•	•			
#29	LIS2MDLTR	STMicroelectronics	Magnetometer	•				Materials declaration
#30	MAX17048G+	Maxim Integrated	Gas Gauge	•	•		•	
#31	MCS04020Z0000ZE000	Vishay	Thin Film Resistor	•	•			
#32	RT0402BRE0733KL	Yageo	Thin Film Resistor	•	•			
#33	SMLP36RGB2W3R	ROHM Semiconductor	RGB LED	•	•	•	•	ELV, ESD, MSDS, Material list
#34	SPBTLE-RFTR	STMicroelectronics	Bluetooth Module	•	•	•		Materials declaration, Test report, Test report2
#35	STC4054GR	STMicroelectronics	Battery charger	•	•	•		Materials declaration
#36	STM32L433RCI	STMicroelectronics	Microcontroller	•	•	•		Materials declaration
#37	TL4100AF240QG	E-Switch	Tactile Switch	•	•			
#38	TPD4E05U06DQAR	Texas Instruments	ESD Suppressor	•	•	•		Product summary
#39	TPS62740DSST	Texas Instruments	Voltage Regulator	•	•	•		Product summary
Additional part								
#40	LP382024	LiPol	Battery		•			Declaration of Conformity
Distance sensor								
#1	GRM152R60J105ME15D	Murata Electronics	Multilayer Ceramic Capacitor	•	•			
#2	CGA2B1X5R1C224K050BC	TDK	Multilayer Ceramic Capacitor	•	•	•		
#3	RT0402BRD0747KL	Yageo	Thin Film Resistor	•	•			
#4	214013	ERNI	Headers & Wire Housing	•	•			
#5	VL6180XV0NR/1	STMicroelectronics	Proximity Sensor	•	•			Materials declaration
Pressure insole								
#1	70	221e srl	Baropodometric Insole	•				
Connectors								
#1	839021	ERNI	Ribbon Cable	•	•			

Attachment A

INDIP - Datasheet



v1.2

System overview

INertial module with DIstance Sensors and Pressure insoles (INDIP) is a multi-sensor system which integrates an inertial module, up to two distance sensors and up to one pressure insole. The block diagram of the INDIP system full configuration is reported in Figure 6. The inertial module includes an ultra-low-power microcontroller unit (MCU), a Magneto-Inertial Measurement Unit (MIMU → triaxial accelerometer, gyroscope, and magnetometer), a flash storage, and a wireless connectivity (Bluetooth LE). Each distance sensor integrates an infrared time-of-flight distance sensor that can be connected to the inertial module by cable. The pressure insole consists of sixteen resistive passive sensing elements and can be connected to the inertial module using a zif connector. To ensure extra protection to the INDIP system from dust and water in outdoor conditions, a custom soft waterproof overshoes will be used.

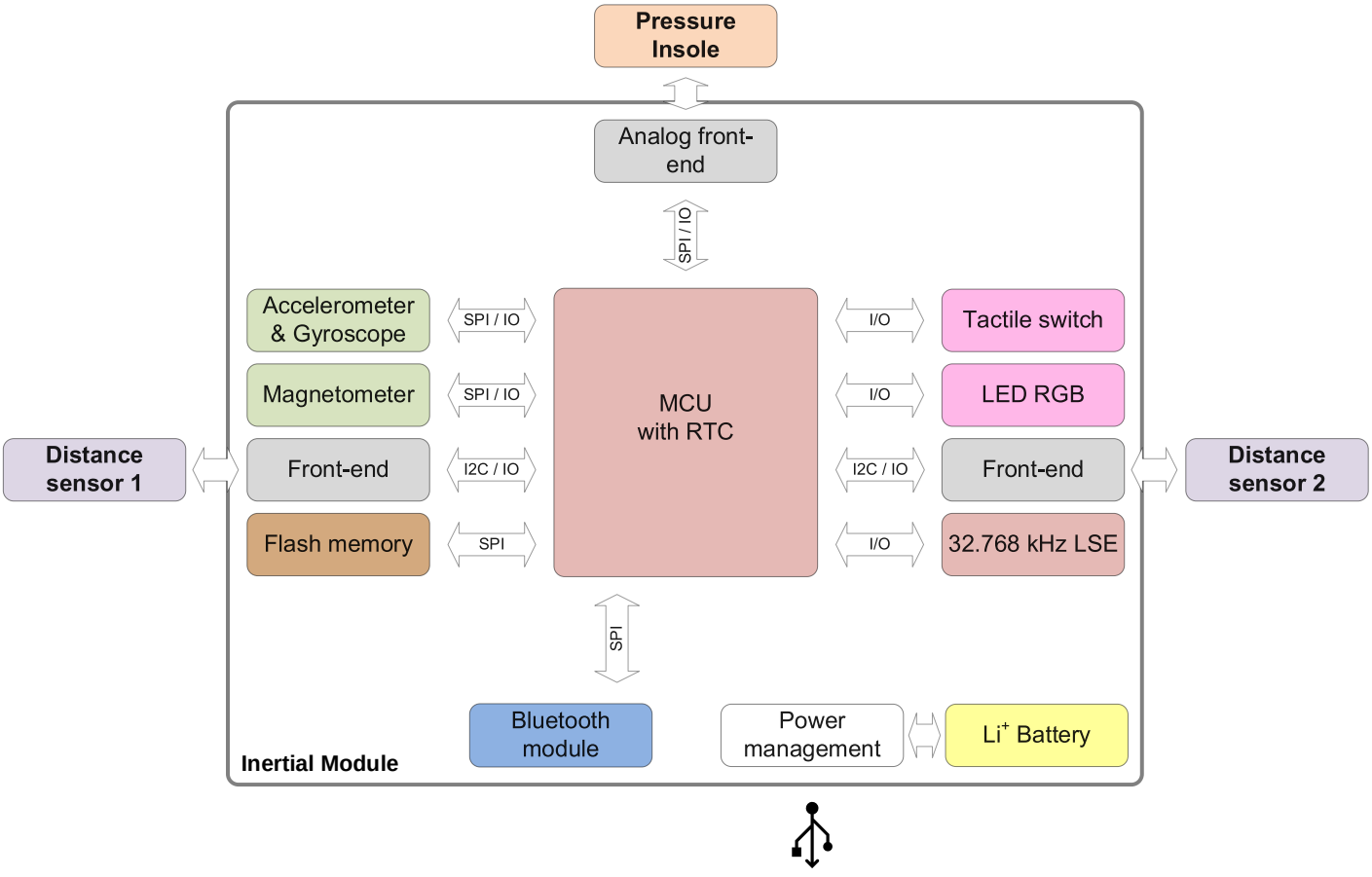


Figure 6: Block diagram.

An embedded sensor fusion algorithm, capable of computing the real-time device orientation in the three-dimensional space, is implemented in the firmware of the inertial module. The output data include:

- Linear acceleration:
  - Raw and calibrated XYZ measurements (up to ±16 g);
- Rate of turn:
  - Raw and calibrated XYZ measurement (up to ±2000 dps);
- Magnetic field:
  - Raw and calibrated XYZ measurement (up to ±50 gauss);
- Distance:
  - Calibrated distance (up to 600 mm);
- Pressure:
  - Output voltage for each sensing element (0 to V_{DD});
- Orientation:
  - Quaternions (qW, qX, qY, and qZ).

Hardware specifications

Inertial Module

MCU	
Architecture	ARM® 32-bit Cortex®-M4 CPU with FPU
Operating frequency	up to 80 MHz
Flash memory size	256 kB
Internal RAM size	64 kB
Temperature range	-40 to +85 °C

Sensors

ACCELEROMETER	
Axes	3 axes
Measurement range	±2 / ±4 / ±8 / ±16 g dynamically selectable full scale
Zero-g offset	±40 mg
Rate noise density	1.8 - 3.0 mg (RMS)
Output data rate	1.6 to 6664 Hz
Temperature range	-40 to +85 °C

GYROSCOPE	
Axes	3 axes
Measurement range	±125 / ±250 / ±500 / ±1000 / ±2000 dps dynamically selectable full scale
Zero-rate offset	±1 dps
RMS noise	0.075 dps
Output data rate	1.6 to 6664 Hz
Temperature range	-40 to +85 °C

MAGNETOMETER	
Axes	3 axes
Measurement range	±50 gauss
Zero-gauss offset	dynamically cancelled
Rate noise density	3 mgauss (RMS)
Output data rate	10 to 100 Hz
Temperature range	-40 to +85 °C

Storage

FLASH MEMORY	
Size	64 MB
Temperature range	-40 to +85°C

Connectivity

USB	
Standard	USB 2.0
Connector	Micro USB (type B)
Additional feature	INPUT for external trigger

BLUETOOTH	
Standard	Bluetooth v4.1
Range	≈10 m
Transmission rate	Up to 560 kbps with SPP / 250 kbps with iAP service
Features	• Supports master and slave modes • Multiple roles supported simultaneously
Temperature range	-40 to +85 °C

Power supply

BATTERY	
Type	Rechargeable Lithium Ion Polymer
Nominal voltage	3.7 V
Nominal capacity	155 mAh

Distance sensor

DISTANCE and AMBIENT LIGHT (up to 3)	
Measurement range	0-200 / 0-400 / 0-600 mm dynamically selectable full scale
Ambient range	<1 Lux up to 100 kLux

Sensitivity	±1 / ±2 / ±3 mm
Output data rate	up to 50 Hz
Temperature range	-20 to +70 °C

Pressure insole

PRESSURE INSOLE	
No. sensing elements	16
Size (shoe length)	• Small/Medium (23–27 cm) • Large (27–30 cm)
Output data rate	100 Hz

Attachment B

Electrical Safety Report

Test Information

Tester equipment: Rigel 288+ (Rigel Medical)
Operator: S. Bertuletti
Place: Sassari (Italy)
Date: 26/08/2019

LEAKAGE CURRENT (Device switched OFF)		Protective Earth Conductor (µA)	Max. Allowable Value (µA)	From the chassis (µA)	Max. Allowable Value (µA)	In the patient (µA)	Max. Allowable Value (µA)
WITHOUT GROUND	Direct Supply	Not Applicable	**1000 µA**	Not Applicable	**500 µA**	< 4µA	**500 µA**
	MAX (Main A, Main B)	Not Applicable	**1000 µA**	Not Applicable	**500 µA**	< 4µA	**500 µA**
	Transposed Supply	Not Applicable	**1000 µA**	Not Applicable	**500 µA**	< 4µA	**500 µA**

LEAKAGE CURRENT (Device switched ON)		Protective Earth Conductor (µA)	Max. Allowable Value (µA)	From the chassis (µA)	Max.Allowable Value (µA)	In the patient (µA)	Max. Allowable Value (µA)
WITHOUT GROUND	Direct Supply	Not Applicable	**1000 µA**	Not Applicable	**500 µA**	< 4µA	**500 µA**
	MAX (Main A, Main B)	Not Applicable	**1000 µA**	Not Applicable	**500 µA**	< 4µA	**500 µA**
	Transposed Supply	Not Applicable	**1000 µA**	Not Applicable	**500 µA**	< 4µA	**500 µA**

Test results:

Test Type	Status	Measured Value	Limit
Live Voltage	Info	2.8 V	-
Neutral Voltage	Info	229 V	-
Load Current	Info	0.0 A	-
Load Test	Info	0.0 kVA	-
Patient Lkg	Pass	< 4µA	100
Patient Lkg	Pass	< 4µA	10
Patient Lkg	Pass	< 4µA	500
Patient Lkg	Pass	< 4µA	50
Patient Lkg	Pass	< 4µA	500
Patient Lkg	Pass	< 4µA	50
Patient Lkg	Pass	< 4µA	100
Patient Lkg	Pass	< 4µA	10
Patient Lkg	Pass	< 4µA	500
Patient Lkg	Pass	< 4µA	50
Patient Lkg	Pass	< 4µA	500
Patient Lkg	Pass	< 4µA	50
Patient Lkg (F Type)	Pass	< 25µA	5000
Patient Lkg (F Type)	Pass	< 25µA	5000
Patient Lkg (F Type)	Pass	< 25µA	5000
Patient Lkg (F Type)	Pass	< 25µA	5000
Patient Lkg (Auxiliary)	Pass	< 4µA	100
Patient Lkg (Auxiliary)	Pass	< 4µA	10
Patient Lkg (Auxiliary)	Pass	< 4µA	500
Patient Lkg (Auxiliary)	Pass	< 4µA	50
Patient Lkg (Auxiliary)	Pass	< 4µA	500
Patient Lkg (Auxiliary)	Pass	< 4µA	50
Patient Lkg (Auxiliary)	Pass	< 4µA	100
Patient Lkg (Auxiliary)	Pass	< 4µA	10
Patient Lkg (Auxiliary)	Pass	< 4µA	500
Patient Lkg (Auxiliary)	Pass	< 4µA	50
Patient Lkg (Auxiliary)	Pass	< 4µA	500
Patient Lkg (Auxiliary)	Pass	< 4µA	50