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RESEARCH ARTICLE

Design of a Multi-Sensors Wearable System for Continuous Home Monitoring of People With Parkinson's

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ABSTRACT Parkinson's disease is a degenerative neurological disorder that impairs motor functions and is accompanied by a wide range of non-motor symptoms, such as sleep problems. Parkinsonism is assessed during clinical evaluations and via self-administered diaries and, based on these, the required medication therapies are provided to lessen symptoms. Tri-axial accelerometers and gyroscopes have the potential utility to objectively assess the patient's condition and aid clinicians in their decision-making. People with Parkinson's often have significant abnormalities in blood pressure due to comorbid age-related cardiovascular disease and orthostatic hypotension, which result in blurred vision, dizziness, and falls. Frequent blood pressure monitoring may aid in the evaluation of such events and differentiate Parkinson's disease symptoms from those originated by hypotension. In the present paper, a novel technology for the remote monitoring of Parkinsonian symptoms is presented: the WESAA system. It consists of two devices, worn on the wrist and ankle; its main function is to record accelerations and angular velocities from these body parts, together with photoplethysmograph and electrocardiogram data. This information can be elaborated offline to measure common Parkinson's disease motor symptoms (e.g., tremor, bradykinesia, and dyskinesia), as well as gait speed, sleep-wake cycles, and cuff-less blood pressure measurements. The overall system requirements, market overview, industrial design and ergonomics, system development, user experience, early results of the gathered inertial raw data, and validation of the photoplethysmograph and electrocardiogram signal waveforms are all thoroughly discussed. The developed technology satisfies all system requirements, and the sensors adopted provided outcomes comparable with gold standard techniques.

INDEX TERMS Cuff-less blood pressure, ECG, IMU, Parkinson's disease, Parkinson's disease motor symptoms, PPG, remote monitoring, telemedicine, wearable sensors.

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I. INTRODUCTION

Parkinson's disease (PD) is a chronic neurodegenerative disorder whose incidence increases with age and is expected to

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impact roughly 1.2 million people in the USA by 2030 [1]. Besides impairing motor functions (e.g., tremor, rigidity, and bradykinesia) [2], PD is also characterized by a broad variety of non-motor symptoms (e.g., sleep disturbances) [3] and by frequent orthostatic hypotension (reflecting autonomic dysfunction and also medication side-effects) [4]. Effective dopaminergic medications such as Levodopa can provide symptomatic relief and enhance long-term patient care [5]. However, unwanted motor symptoms are often related to the level of medication in the body system. The ''on'' and ''off'' phenomenon, in Levodopa-treated patients, describes symptom fluctuations that occur as the levels of the chemical in the body wear off; in fact, the duration of the response to a single drug intake may decrease with the progression of the disease: during the ''on'' state, the symptoms are well managed, while in the ''off'' state, the condition worsen again [6]. Levodopa-induced dyskinesia frequently manifests during the ''on'' state in People with Parkinson's (PwPD) who have been taking Levodopa for extended periods. Dyskinesia refers to involuntary abnormal muscle movements, such as tics or chorea [7].

To date, PwPD are evaluated using self-report of overall symptom burden, clinical assessments (e.g., the Movement Disorder Society - Unified Parkinson's Disease Rating Scale also known as MDS-UPDRS), and self-administered diaries [8], [9], [10]; nevertheless, due to the heterogeneity and complexity of PD features, clinical assessment are not always a reliable source of information [11]. In addition, PwPD may perform differently in clinical settings due to their awareness of being evaluated [12] or because their health condition at a clinic appointment may not be the usual [13]. Symptom diaries can also be an untrustworthy means of comparison for complex symptoms, such as self-evaluation of motor symptoms or sleep disturbance, and are challenging to complete in detail and accurately for a prolonged period. PwPD may not be capable of identifying their own symptoms (especially dyskinesia and hypotension) or may mis-record symptoms due to impaired cognition [14], [15], [16]. To summarise, sporadic clinical assessments and diaries are just a snapshot of the overall condition of a patient, giving clinicians little understanding of the day-to-day symptoms and functional status and consequently optimum medicine prescription.

Additionally, older adults are more likely than younger people to suffer from cardiovascular disease, with roughly 82% of people dying of coronary heart issues being 65 or older [5]. It is widely recognized that age-related changes in blood vessel structure predispose older persons to cardiovascular disease [17]; therefore, PwPD should obtain precise and regular blood pressure (BP) measurements to continuously check their health state. Apart from comorbid age-related cardiovascular disease, abnormalities in BP may present as orthostatic hypotension, which leads to blurred vision, dizziness, syncope, and falls [4]. Frequent BP monitoring may aid in the evaluation of such events and differentiate symptoms due to dopaminergic deficiency from symptoms due to hypotension [4].

Tri-axial accelerometers (acc) and gyroscopes (gyro), typically combined in an inertial measurement unit (IMU), can capture three-dimensional orientation, and linear and angular velocities and, recently, have offered a new approach to estimate motor symptoms, gait, and sleep parameters for a prolonged period of time in a home setting [18], [19], [20], [21], [22], [23], [24], [25], [26].

Concerning BP estimation, photoplethysmograph (PPG) and electrocardiogram (ECG) sensors can be utilized. This data must be merged through the use of smart algorithms in order to permit a comfortable measurement without the use of an inflatable cuff [27], [28]. PPG is a non-invasive technology that measures the volumetric variations of blood circulation [29], while ECG records the heart's electrical activity [30].

A number of commercially available devices designed specifically for PwPD include acc and gyro for the estimation of main motor symptoms, gait parameters, and sleep quality [31], [32], [33], [34], [35], [36]; nevertheless, according to the authors' knowledge, neither commercially available systems nor published works include PPG and ECG sensors that can be used for simultaneous cardiovascular monitoring, thus potentially differentiating between symptoms due to dopaminergic deficiency or hypotension, particularly where falls occur, or potential ''off'' symptoms are vague (e.g., fatigue or weakness) [37].

In this work, the WESAA (''Wearable Enabled Symptom Assessment Algorithm'') system is introduced as a revolutionary tool for the remote monitoring of PwPD. It is comprised of two devices, worn on the most affected wrist and ankle (external side), and its key purpose is to capture accelerations and angular velocities from these body parts, as well as PPG and ECG data. This information may be used offline to measure common PD motor symptoms (such as tremor, bradykinesia, and dyskinesia), walking speed, sleep-wake cycles, and cuff-less BP measures. This scientific paper focuses mostly on describing the hardware/firmware and industrial design development. The description of the offline techniques that might be used to calculate the parameters listed above is not provided and is out of the scope of the present work.

The design phase of novel prototypes typically focuses on technical performance, accuracy, and reliability, with less evaluation of the user experience of wearing monitoring devices, either for short-term assessment or for longer monitoring, which is essential for use and adherence [38]. Therefore, this study also aims to explore the user experience of the developed prototype device.

This paper presents the results achieved under the project (grant number: IP 2017 0625). The manuscript is organized as follows. Section II illustrates related works in the field covering both literature studies and off-the-shelf devices. Section III and Section IV demonstrate the market limitations

and proposed solution and system requirements, respectively. System architecture and industrial design concept are described in Sections V and VI, respectively, while Sections VII, VIII, IX, X, XI describe the system functional description, boards configuration, main component, system requirements vs achieved system specification, and WESAA system vs off-the-shelf solutions, respectively. Section XII, Section XIII, and Section XIV discuss the 24-hour data capture of inertial data, PPG and ECG validation, and user experience interviews, respectively. Finally, discussion and conclusions are presented in Sections XV and XVI, respectively.

II. RELATED WORKS

A. CURRENT STATE-OF-THE-ART

The last decade has seen significant attention toward the identification of PD motor symptoms using IMUs in unsupervised settings. Several reviews investigated the monitoring of PwPD who adopted body-fixed-sensors [18], [19], [20], [21], [22], [23], [24], [25]; where acc was mainly used [39], [40], [41], [42], [43], [44], also in combination with gyro [45], [46]. Device positions included waist [42], [44], most affected wrist [40], [41], and both wrists [39], [43], [45], [46]. To robustly assess multiple symptoms on different subjects and positions, a combination of several sensors may be more effective; in fact, a larger number of wearables used simultaneously enables the collection of multiple inertial signals and, consequently, depicts motion impairments from different body parts concurrently [18]. However, a single device on the wrist may facilitate the acceptability, wearability, and usability of the system [18], [47].

A number of papers adopted commercial wearable data loggers not specifically designed for a Parkinsonian cohort [39], [40], [42], [44], [45], [46], and, as a consequence, offline algorithm solutions. However, tailored hardware and firmware may contribute to the development of more personalized systems with real-time outputs that may have a substantial impact on the quality of life of PwPD, such as those living in remote areas [41], [43]. In both cases, raw data gathered at home allowed researchers to implement ad-hoc algorithms avoiding aggregated data (such as steps, distance, and energy expenditure) produced by the ''black box'' software of commercial wearables. In this context, pattern recognition and thresholds [41], [46], as well as supervised machine learning techniques including artificial neural networks [39], linear regression models [45], hidden Markov models [48], support vector machines [49], decision trees [50], and random forests [51], were utilized.

Similarly to PD motor symptoms, gait analysis in a free-living environment has been extensively studied [52], [53], [54], [55], [56], [57], [58], [59]. Kinematic parameters (such as gait speed) were extracted, by walking detection algorithms, and analysed with the goal of evaluating different mobility predispositions and habits. PwPD were differentiated from healthy subjects [52], [53], [57], or into fallers versus non-fallers [55], [59], via a reduction in walking speed, shuffling steps, and limited foot lifting. During gait monitoring in daily living, sensors were typically placed at the lower back [53], [54], [55], [56], [59] and also combined with IMUs at the top of each foot [52], [57], [58]; in terms of the device, acc was used alone [53], [55], [56], or in combination with gyro [54], [59] or along with gyro and magnetometer (mgn) [52], [57], [58]. Some researchers used a single sensor worn close to the centre-of-mass (waist and lower back) [52], [53], [54], [55], [56], [57], [58], [59]. In fact, PwPD may show an asymmetric gait characterized by different levels of impairment of the lower limbs. Consequently, a single device would collect data with large variations in gait characteristics (such as speed), resulting in a distorted overview of the patient's motion.

Wearable IMUs can also provide information on nocturnal postures and movements [60], [61], [62], [63] and, as a result, offer details on sleep-wake cycles and sleep quality in Parkinsonian syndromes. Actigraphy has been extensively used to study sleep over the last 30 years [60], [61], [62], [63]. ActiGraph (ActiGraph LLC, USA) [64] develops CE-marked wearables that embed inertial sensors; data are collected during night-time, downloaded, and analysed by dedicated proprietary software. Time over threshold, zero-crossing, and digital integration are the three methods that have traditionally been employed in actigraphy to quantify sleep-awake patterns. In particular, time over threshold considers the amount of time that the IMU signal exceeds a fixed value [65], [66], zero-crossing is a threshold-crossing technique [67], and digital integration computes the area under the inertial signal before applying thresholds [68]. Although ActiGraph did not design wearable solutions specifically for PD, its devices were extensively used to detect sleep-awake states in PwPD over the last decade [69], [70], [71], [72], [73], [74], [75], [76]. Consequently, this publication discusses actigraphy more in detail in the next sub-section as solutions specific to PD. Furthermore, the prototype system Night-Recorder [77], [78] has been developed to compute sleep parameters in a Parkinsonian cohort. It consists of a body-fixed sensor (worn on the sternum or the most affected limb) comprised of a 3-axis acc and gyro, used to monitor instances of rolling over and getting out of bed during sleep.

Finally, to the best of the authors' knowledge, there are no academic papers on the topic of measuring BP using ECG and PPG in a cohort of PwPD. In a single study, Ahn et al. [79] examined the accuracy of the Samsung SM-R850 [80] in PwPD. This smartwatch is described in the following sub-section and it has a PPG sensor and online algorithms for estimating BP. On a broader scale, considering studies on healthy subjects, basic features, such as dominant frequency, entropy, skewness, kurtosis, pulse transit time (PTT), and R-R interval (RR), were extracted and used to implement smart algorithms, based on thresholding [81], [82] or deep learning, to compute BP [83], [84], [85], [86], [87]. To measure the PPG signal, two different techniques were adopted: transmission and reflectance [29]. In transmission mode, light generated by an LED passes through various tissues and

is detected by a photodiode opposite the source, whereas in reflectance mode, the photodiode detects light that has been reflected from various tissues. The transmission mode is able to achieve the best signal between the two methods, but the measurement position is limited (e.g., fingertip). The reflectance mode removes the issues related to sensor placement, however, it is affected by pressure disturbances and movement artefacts [29]. Regarding ECG, dry electrodes are widely used in the literature with their performance comparable to that of gold standard wet electrodes, despite a number of drawbacks, such as higher impedance and motion artefacts [30].

B. MARKET PRODUCTS

The market of medical devices for daily monitoring of PwPD has the potential to be a suitable alternative to lab-based assessments [18], [19], [20], [21], [22], [23], [24], [25]. Currently, there are only five certified (e.g., FDA, CE, or TGA) wearable solutions specifically designed to detect PD motor symptoms and gait impairments at home, during daily living activities: Parkinson's Kinetigraph (Global Kinetics Corporation, Australia) [31], STAT-ON (Sense4Care, Spain) [32], Kinesia 360 (Great Lakes NeuroTechnologies, USA) [33], Apple Watch combined with StrivePD mobile app (Apple Inc., USA) [34], and PD Monitor (PD Neurotechnology, UK) [35], all described in Table 1.

Parkinson's Kinetigraph is a wrist-worn device (worn on the most affected limb) that provides continuous assessment of tremor, bradykinesia, dyskinesia, motor fluctuations, and time inactive/asleep. The device has a battery lifetime of up to ten days and, to detect symptoms, it implements a fuzzy logic approach using data collected from a 3-axis acc [88].

STAT-ON is a wearable device with advanced onboard algorithms that monitors bradykinesia, dyskinesia, motor fluctuations, and freezing of gait, as well as time inactive/asleep, number of falls, energy expenditure, and gait parameters (such as stride speed, cadence, time walking, step length, and number of steps). The device is worn on the waist (non-dominant side), has a battery lifetime of up to 7 days, and embeds a 3-axis acc, a 3-axis gyro, and a 3-axis mgn. The core of the algorithms for the detection of motor symptoms is based on a support vector machine classifier for walking detection and the adoption of multiple thresholds [89].

Kinesia 360 is a wearable solution designed to provide continuous assessment of symptoms such as tremor, bradykinesia, dyskinesia, and motor fluctuations. Other parameters measured are time active/rest and time walking. The system has a battery lifetime of up to one day and includes two devices, worn at the same time, on the most affected wrist and ankle. The quantification of PD motor symptoms is performed by means of linear regression models using data collected from a 3-axis acc and a 3-axis gyro [90], [91], [92].

Apple Watch Series 8 combined with the StrivePD mobile app offers a continuous assessment of tremor and dyskinesia. The device is usually worn on the non-dominant side, it has a 3-axis acc and a 3-axis gyro embedded and a battery lifetime of up to 60 hours. Symptoms calculations are based on results of comparing features extracted in time and frequency domains with feature thresholds [93].

Finally, PD Monitor is a system that consists of five devices worn simultaneously on both wrists, both ankles, and waist, with each of them embedding a 3-axis acc, a 3-axis gyro, and a 3-axis mgn. The system is able to record tremor, bradykinesia, dyskinesia, motor fluctuations, and freezing of gait, as well as time inactive/asleep, gait impairment (referred to as MDS-UPDRS item 29), and postural instability (referred to as MDS-UPDRS item 30). Tremor, bradykinesia, dyskinesia, and freezing of gait are detected with hidden Markov models, support vector machines, decision trees, and random forests, respectively [48], [49], [50], [51].

Concerning the market of wearables for the analysis of sleep in PwPD, MoveMonitor (McRoberts, The Netherlands) (Table 1) [36] and the ActiGraph products GT9X Link and wGT3X-BT (Table 1) are the only certified (e.g., FDA, CE, or TGA) solutions that estimate sleep patterns and quality of sleep.

MoveMonitor is worn on the lower back, has a battery life of up to 14 days, and embeds a 3-axis acc and 3-axis gyro; algorithms to quantify sleep-awake patterns are based on comparing features extracted in time and frequency domain with feature thresholds [94].

To detect sleep cycles, actigraphy was also extensively used and presented multiple correlations to subjective measurements [72], [73], [74]. K. Stavitsky et al. found a moderately correlated total sleep time between actigraphy and sleep diary ($r = 0.604$, $p < .001$) [72], while J.E. Maglione compared actigraphy and polysomnography, identifying multiple correlations (such as total sleep time, $r = 0.496$, $p < 0.001$) [74]. Currently, the two devices released by ActiGraph are GT9X Link and wGT3X-BT [64]. GT9X Link is a wearable device with a battery lifetime of up to 16 days, embedding two 3-axis acc, a 3-axis gyro, and a 3-axis mgn. Generally, it has to be placed on the non-dominant wrist to measure sleep parameters. wGT3X-BT is also used on the wrist (non-dominant side), contains a 3-axis acc, and has a battery lifetime of up to 31 days.

Regarding BP measurements, the Samsung SM-R850 (Table 1) was evaluated in a Parkinsonian cohort [79]. The wristwatch is equipped with a PPG sensor, is typically worn on the non-dominant side, and has a 31-day battery lifetime. The BP monitoring runs on the CE-marked Samsung Health Monitor app, although Samsung has not publicly released the approach used for estimating BP.

III. MARKET LIMITATIONS AND PROPOSED SOLUTION

As described in the above sections, a number of solutions, designed specifically for Parkinsonian syndromes, incorporate acc and gyro for the estimation of tremor, bradykinesia, dyskinesia, gait parameters, or sleep quality; however, to the best of the authors' knowledge, there are neither off-the-shelf systems nor studies in the literature that also incorporate PPG and ECG sensors for simultaneous BP calculation.

TABLE 1. Off-the-shelf systems.

Application	Device	Sensors of interest	Position and set up	Parameters of interest	Access to raw data	Battery life	Core algorithms
Motor symptoms and gait impairment	Parkinson's Kinetigraph	3-axis accelerometer	Wrist (most affected side)	Tremor, bradykinesia, dyskinesia, motor fluctuations, and time inactive/asleep	x	Up to 10 days	Fuzzy logic approach
	STAT-ON	3-axis accelerometer 3-axis gyroscope 3-axis magnetometer	Waist (non-dominant side)	Bradykinesia, dyskinesia, motor fluctuations, freezing of gate, time inactive/asleep, number of falls, gait parameters (such as stride speed, cadence, time walking, step length, and number of steps)	x	Up to 7 days	Support vector machine classifier for walking detection and adoption of multiple thresholds
	Kinesia 360	3-axis accelerometer 3-axis gyroscope	One wrist (most affected side) One ankle (most affected side)	Tremor, bradykinesia, dyskinesia, motor fluctuations, time active/rest, and time walking.	x	Up to 1 day	Linear regression models
	PD Monitor	3-axis accelerometers 3-axis gyroscope 3-axis magnetometer	Both wrists Both ankles and waist Waist (non-dominant side)	Tremor, bradykinesia, dyskinesia, motor fluctuations, freezing of gait, time inactive/asleep, gait impairment (referred to as MDS-UPDRS item 29), and postural instability (referred to as MDS-UPDRS item 30)	x	Up to 30 hours	Tremor: hidden Markov models; bradykinesia: support vector machines; dyskinesia: decision tree; freezing of gait: random forest
	Apple Watch Series 8 with StrivePD mobile app	3-axis accelerometer 3-axis gyroscope	Waist (non-dominant side)	Tremor and dyskinesia	x	Up to 36 hours (standard). Up to 60 hours (low power)	Feature extraction (frequency and time) and adoption of multiple thresholds
Sleep quality	MoveMonitor	3-axis accelerometer 3-axis magnetometer	Lower back	Going out of bed, night's rest detection, postures, movement time, movement intensity, and number of rotations	✓	Up to 14 days	Feature extraction (frequency and time) and adoption of multiple thresholds
	GT9X Link	2 x 3-axis accelerometers 3-axis gyroscope 3-axis magnetometer	Wrist (non-dominant side)	Total sleep time, sleep onset latency, wake after sleep onset, sleep efficiency, number of awakenings	✓	Up to 16 days	Time over threshold, zero-crossing, and digital integration
	wGT3X-BT	3-axis accelerometer	Wrist (non-dominant side)	Total sleep time, sleep onset latency, wake after sleep onset, sleep efficiency, number of awakenings	✓	Up to 31 days	Time over threshold, zero-crossing, and digital integration
Blood pressure	Samsung SM-R850 with Samsung Health Monitor app	PPG sensor	Wrist (non-dominant side)	Blood pressure	x	Up to 2 days	Not publicly released

MDS-UPDRS = Movement Disorder Society - Unified Parkinson's Disease Rating Scale, PD = Parkinson's disease, PPG = Photoplethysmograph.

The system proposed collects simultaneously inertial, PPG, and ECG raw signal waveforms that can potentially be used to estimate all the abovementioned parameters and, ultimately, might assist clinicians in their decision-making process and aid end-users in boosting their quality of life and safety.

IV. SYSTEM REQUIREMENTS

The authors interacted with various stakeholders, such as clinicians, PwPD, and caregivers, to gather their insights and opinions. Based on this guidance along with an exhaustive review of the existing state-of-the-art and the device market, system requirements were established and implemented.

The system should be able to collect raw inertial data (acc and gyro) useful for the estimation of gait speed, sleep-wake cycles, and main PD motor symptoms (bradykinesia, tremor, and dyskinesia), as well as PPG and ECG data for BP calculation. As the literature suggested, to measure the movements of different body parts, a combination of several devices is more effective; nevertheless, a reduction in the number promotes acceptability, wearability, and usability [18]. Concerning BP measurements, cuff-based devices can be uncomfortable and

difficult to be worn by a person alone, hence ECG and PPG signals should be collected to develop an indirect method for cuff-less BP estimation [81], [82], [83], [84], [85], [86], [87]. The authors, in agreement with the stakeholders, believed that dry electrodes should be adopted to acquire the ECG between the palm of the less affected hand and the wrist of the most affected hand, while the PPG measurement should be completely palm-based (less affected hand), to avoid movement artifacts during the acquisition due to tremor. In addition, according to the current literature, the reflectance PPG mode is more suitable for the palm position [29].

With the aim of collecting inertial, PPG, and ECG data at strategic positions and concurrently enhancing the acceptability, wearability, and usability of the system, we propose a configuration of two units, one placed on the wrist and one on the ankle (both on the external aspect of the limb), on the most affected side of the patient. Moreover, the enclosures need to be secured in such a way that the device does not move around and maintains adequate contact to allow proper readings without generating artefact data.

In accordance with stakeholders' recommendations and the off-the-shelf market norms, each device should be no bigger than 45mm $\times$ 80mm $\times$ 15mm, weigh less than 50 g, and be latex-free, BSE/TSE-free or inactivated, and biocompatible. To guarantee ease of use, the system should be powered by a replaceable and rechargeable battery and have a service life of four to seven days. The devices should embed adequate processing capabilities and memory space (7 days of data) to properly perform a secure, robust, and flexible data workflow. Furthermore, based on the current literature, IMU, PPG, and ECG sensors should be small-size, low-noise, and low-power, with a sampling frequency $>$ 30Hz, $>$ 100Hz, and $>$ 100Hz, respectively [18], [19], [20], [21], [22], [23], [24], [25], [27], [28]. The raw data should be uploaded to a computer for additional processing and analysis in order to provide clinicians with the necessary information in a usable format. To conclude, the system should also have indicators, such as LEDs or buzzers, to inform users about the condition of the devices, as well as a switch and a button to turn the unit on/off and initiate the BP measurement, respectively. All the above-mentioned requirements have been taken into consideration when developing the hardware and software components of the whole system.

V. SYSTEM ARCHITECTURE

In the WESAA system, two identical units are worn, on the most affected wrist and ankle (external side) (Fig. 1). Each device is powered by a replaceable and rechargeable battery (charging time: 2.59 hours) with a five-day service life (average device current equal to 6.5 mA and 15 mA with PPG/ECG monitoring off and on, respectively), and embeds an IMU to record accelerations and angular velocities as well as PPG and ECG sensors (Fig. 2). Inertial data is elaborated offline to estimate gait speed, sleep-wake cycles, main PD motor symptoms related to end-of-dose deterioration (bradykinesia and tremor), and those usually related to peak-dose concentration (dyskinesia). PPG and ECG data are also used offline to calculate a cuff-less BP measurement. The system does not require any physical connection between the two units (Fig. 2); accelerations and angular velocities are recorded from both devices continuously (sample rate 40 Hz), while PPG and ECG signals are measured only from the wrist device in windows of approximately 30 seconds (sample rate 167 Hz) at the user's request (e.g., by double pressing a push button). The system is able to gather, process, contextualize, and save 10 days of data from the abovementioned strategic positions with the aid of a low-power processing unit. Using a USB cable, the information (inertial, PPG, and ECG raw signals) is transferred over a personal computer (PC) and could be potentially further processed, analysed, and visualized using complex machine learning and data analytics techniques (Fig. 2). The current paper does not illustrate any offline or online algorithms as they are out of scope; instead, it focuses on describing the WESAA system and validating the raw signals acquired.



FIGURE 1. WESAA system - wrist and ankle.

Overall, the microcontroller of the units is the system's main constituent, so in addition to detecting and storing data, it also communicates with the PC to ensure access to files stored in the flash memory and engages with other elements to provide users with feedback (e.g., via buzzer and LEDs). The IMU, ECG sensor, PPG sensor, flash memory, power management components, buzzer, LEDs, and USB connector are among the additional primary parts available on each device (Fig. 2).

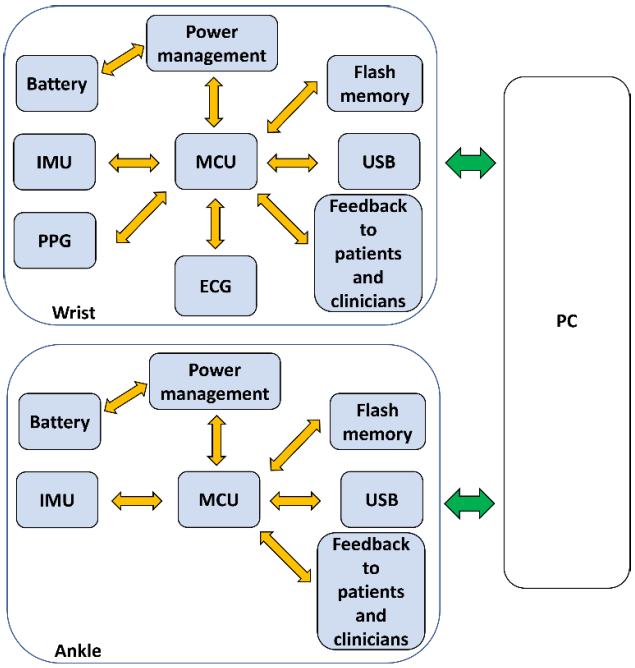


FIGURE 2. WESAA system architecture. ECG = Electrocardiogram, IMU = Inertial Measurement Unit, MCU = Microcontroller Unit, PC = Personal Computer, PPG = Photoplethysmograph.

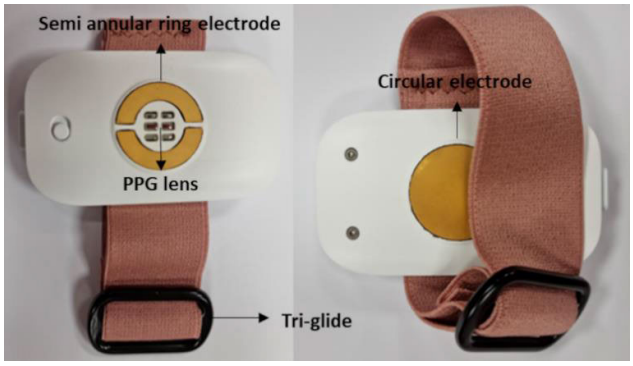


FIGURE 3. WESAA unit. PPG = Photoplethysmograph.

VI. SYSTEM INDUSTRIAL DESIGN

System industrial design was developed by a third-party partner (Design Partners, Ireland [95]), following the guidance of the authors. Each developed enclosure is 45.3mm × 76.8mm × 14mm, latex-free, BSE/TSE-free or inactivated, biocompatible (100% ABS), and weighs approximately 41g (including electronics, battery, and enclosure) (Fig. 3). Each device is fastened so that it does not move and keeps enough contact to permit accurate readings without producing artefact data. Tri-glide slides, used as buckles, work by using friction to secure the enclosure in place (Fig. 3). While the strap is held in tension, friction prevents the materials from sliding through.

The strap is 30mm wide, latex-free, BSE/TSE-free or inactivated, biocompatible (85% Polyester and 15% Polyurethane), and its weight is approximately 22g (Fig. 3).

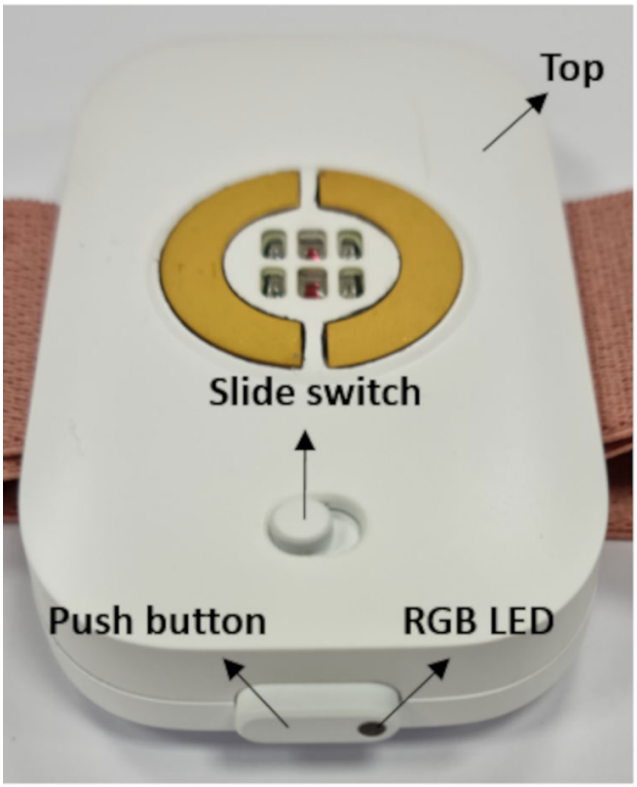


FIGURE 4. Slide switch, push button, and RGB LED. RGB = Red-Green-Blue.

To collect ECG signals, dry electrodes are used on the top and bottom of the device. The electrodes on the top have a semi-annular ring shape (25mm outer diameter and 15mm inner diameter), while the one on the bottom is circular (25mm diameter). They are manufactured with 302 stainless steel and coated with gold to improve the conductivity through the skin (Fig. 3).

The PPG measurement is carried out by means of LEDs and photodiodes (reflectance mode) located between the top electrodes. A transparent lens is placed to protect the components from external agents (such as water), as well as to improve the quality of the signal (Fig. 3). The lens is manufactured with Norland Optical Adhesive 68 (''NOA68'') liquid photopolymer (Norland Products, Inc., USA) [96], designed to adhere to many plastics and to be extremely transparent to green, red, and infrared light.

To turn the devices on/off, a slide switch is placed on the top of the enclosure, while a push button on the lateral side changes the device's mode or turns the BP monitoring on for approximately 30 seconds. Lastly, a USB-C connector on the other side of the push button is utilized to transport data to a PC. In addition, a red-green-blue (RGB) LED, placed next to the push button, and a buzzer provides feedback to the final users (Fig. 4).

VII. SYSTEM FUNCTIONAL DESCRIPTION

The present section will discuss the different modes in which the units can operate to acquire data from various sensing

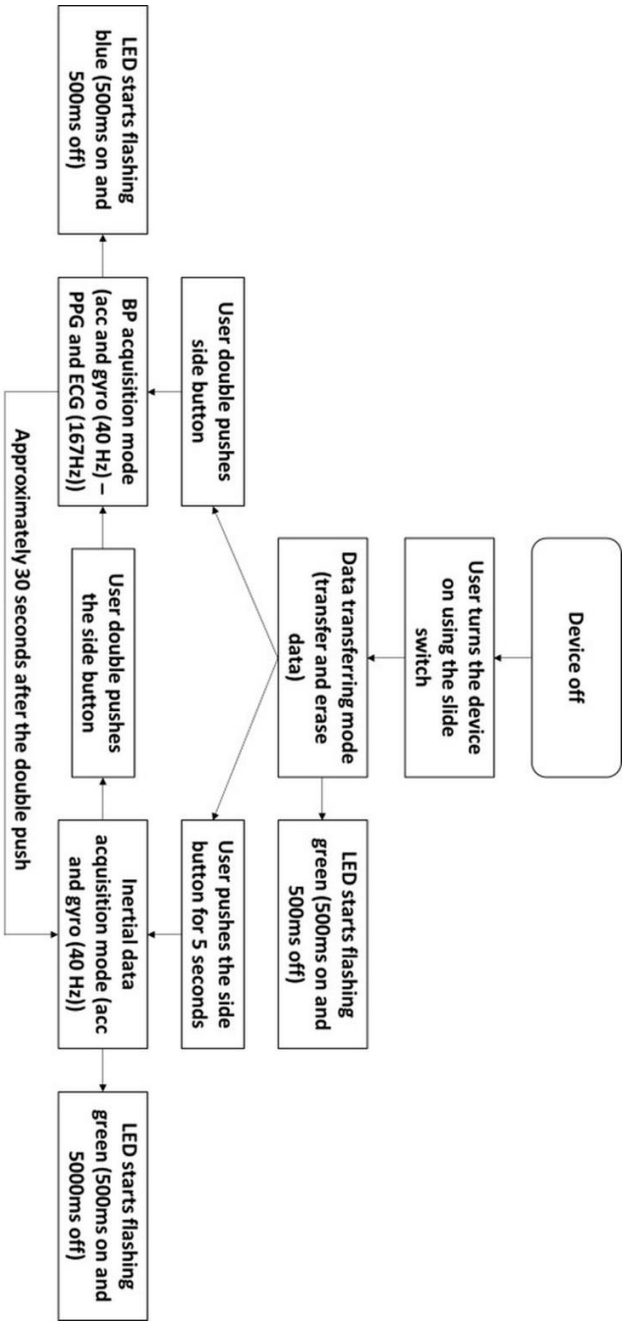


FIGURE 5. Functional description flow chart. Acc = Accelerometer, BP = Blood Pressure, ECG = Electrocardiogram, Gyro = Gyroscope, PPG = Photoplethysmograph.

sources and transfer that data. These modes are illustrated in Fig. 5.

A. DATA TRANSFERRING MODE

The user turns the device on using the slide switch, then the LED starts flashing green (500ms on and 500ms off). In this mode, it is possible to transfer data from the flash memory to the computer or erase the flash memory. When erasing the flash memory, a buzzer will activate before and after the task completion.

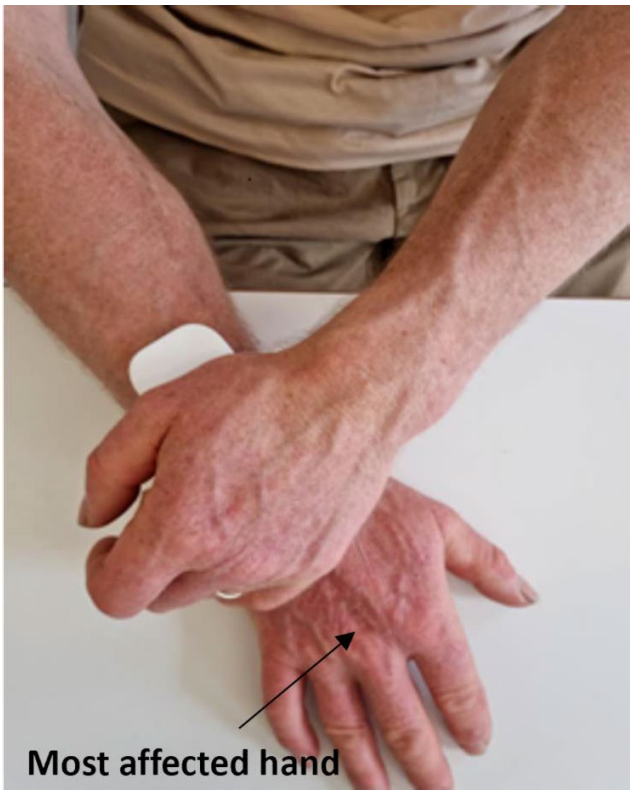


FIGURE 6. Blood pressure measurement– device worn on the most affected wrist.

B. INERTIAL DATA ACQUISITION MODE

From the data transferring mode, the unit passes into the inertial data acquisition mode by pushing the side button for five seconds, which is indicated by the LED flashing green (500ms on and 5000ms off). In the present mode, acc and gyro data are saved in the flash memory with a sampling rate of 40 Hz.

C. BP MODE

From data transferring or inertial data acquisition mode, the unit passes into BP mode by double pushing the side button, which causes the LED to start flashing blue (500ms on and 500ms off). In this mode, PPG and ECG data are acquired for a window of approximately 30 seconds with a sampling rate of 167 Hz. The unit switches to inertial data acquisition mode at the conclusion of that time window. A single BP measurement is performed using the PPG and ECG sensors concurrently. The ECG measurement is effectuated between the wrist of the most affected hand and the palm of the less affected hand using dry electrodes, by the wearer positioning their hands appropriately (Fig. 6). The PPG measurement is completely palm-based (on the less affected hand), it is effectuated by means of components placed between the top electrodes (Fig. 6).

VIII. BOARDS CONFIGURATION

Each unit's hardware consists of two boards, the main board and the BP board, which are connected by a flex cable and

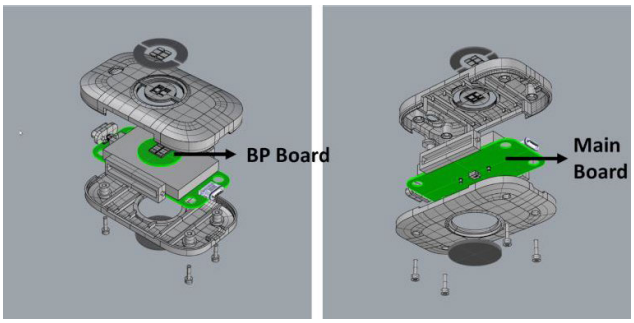


FIGURE 7. WESAA boards configuration (exploded view). BP = Blood Pressure.

separated by a battery (Fig. 7). The main board is designed with four layers and is 31mm × 68mm × 0.8mm in size, while the BP is six layers and 22mm (in diameter) × 0.8mm in size.

All the components in the main board, with the exception of the slide switch, were placed on the bottom side to maintain a clean surface with the battery. The main board embeds the majority of the components including microcontroller, IMU, flash memory, power management, LED RGB, slide switch, push button, and USB type C connector. The BP board embeds the parts used to measure the BP, including the PPG and ECG chip as well as LEDs and photodiodes used to measure PPG.

IX. MAIN COMPONENT SELECTION

A. MAIN BOARD

1) MICROCONTROLLER

The microcontroller adopted is the 32-bit STM32WBRGV6 (STMicroelectronics, Switzerland) [97]; the chip offers very high performance, real-time capabilities, digital signal processing, and low-power and low-voltage operations. External crystals are used (32 MHz and 32.768 kHz) to obtain a more accurate clock source.

2) IMU

The IMU used is the ICM-42670-P (TDK, Japan) [98]; it is a low-power (0.55 mA supply current), high-performance 6-axis device that combines a 3-axis acc and a 3-axis gyro.

3) FLASH MEMORY

MT29F8G01ADBFD12-IT:F TR (Micron Technology, USA) is used in each unit [99]; the present chip enables the software to load and save data from and to the device unit, allowing a secure, robust, and flexible workflow. The flash memory embedded is 8 GB, able to store at least 10 days of data.

4) POWER MANAGEMENT

The device is purely battery-operated. A Li-ion rechargeable battery from TinyCircuits (USA) [100] is used: voltage 3.7 V, capacity 850mAh, and dimension 48.0mm × 30.0mm × 6.0mm.

5) CHARGING CIRCUIT

The charging circuit is embedded in the WESAA system (for both units) and utilizes a type-C USB connector/cable and the BQ24070RHLR charger (Texas Instruments, USA) [101]. The circuit autonomously manages the power sources depending on availability: if the USB is plugged in, then this is the preferred source, otherwise, the battery is used, with a fuel gauge that monitors periodically the charge. A slide switch can be used to turn on/off the device, and an ultra-low power voltage monitor turns the power off whenever the supply voltage falls below a predetermined level.

6) ADDITIONAL COMPONENTS

A buzzer provides feedback to the users; a push button starts the BP measurement or is used to switch the device mode; LEDs give feedback to patients and clinicians; pogo pin connectors connect the main board with the bottom circular electrode; and flex cable connectors connect the main board with the BP board and the debugger.

B. BP BOARD

1) PPG AND ECG CHIP

The MAX86176 (Analog Devices/Maxim Integrated, USA) [102] is a complete PPG and ECG analog front-end solution for wearable applications that offers high performance with ultra-low power. The MAX86176 has a PPG data acquisition system supporting up to six LEDs and four photodiode inputs, which is fully synchronized with the ECG signal path.

2) MULTI-CHIP PACKAGE FOR PPG

SFH7072 (OSRAM, Germany) [103] is a multi-chip package that features one infrared emitter, one red emitter, two green emitters, and two photodiodes to measure PPG.

3) ADDITIONAL COMPONENTS

Spring-loaded connectors are used to connect the BP board with the two semi-annular ring-shaped electrodes, and flex cable connectors to connect the BP board with the main board.

X. SYSTEM REQUIREMENTS VS ACHIEVED SYSTEM SPECIFICATION

Table 2 compares in detail the system requirements with the achieved system specification. In particular, it is evident how the developed technology meets the system's initial requirements.

XI. WESAA SYSTEM VS OFF-THE-SHELF SYSTEMS

Table 3 provides a detailed comparison between the WESAA system and various off-the-shelf solutions. On one hand, systems like the Parkinson's Kinetigraph, STAT-ON, Kinesia 360, PD Monitor, and Apple Watch Series 8 with the StrivePD mobile app are capable of detecting relevant symptoms over extended periods. However, they do not offer sleep or BP monitoring. Similarly, the Samsung SM-R850 and

TABLE 2. System requirements vs achieved system specifications.

Title	System requirements	Achieved system specification
Device Locations	Wrist and ankle (most affected side)	Wrist and ankle (most affected side)
Size	Approximate measurements for guidance can follow that of a standard fitness tracker – 45mm x 80mm x 15mm	Each device measures 45.3mm x 76.8mm x 14 mm
Weight	Less than 50g	41g
Materials	The devices should be latex-free, BSE/TSE-free or inactivated, and biocompatible	All the materials are latex-free, BSE/TSE-free or inactivated, and biocompatible. In particular: • Enclosure: ABS • Band: 85% Polyester and 15% Polyurethane • Electrodes: 302 stainless steel and coated with gold • Lens: Norland Optical Adhesive 68
Visual indications	Display a visual indication of the device's status	An LED RGB is embedded
Data capacity	Each device shall have the capacity to retain at least 7 days of data	Flash memory embedded is 8 GB. Able to store at least 10 days of data
Data access	The data shall be accessible without disassembly of the device	Data are transferred via USB without disassembly of the device
Clearing the data	Clearing the old data is required	Erasable flash memory
PD symptoms data	Raw data useful for the estimation of tremor, bradykinesia, and dyskinesia	Tri-axis accelerometer and tri-axis gyroscope from wrist and ankle
Gait speed data	Raw data useful for the estimation of gait speed	Tri-axis accelerometer and tri-axis gyroscope from wrist and ankle
Sleep data	Raw data useful for the estimation of sleep	Tri-axis accelerometer and tri-axis gyroscope from wrist and ankle
BP data	Raw data useful for the estimation of BP	PPG and ECG from the device on the wrist
Internal Power Source	The device shall be powered by an internal electrical power source	Li-ion rechargeable battery: • 3.7 V Voltage • 850mAh Capacity
Battery Service Life	The device battery shall have an expected service life of between 4 and 7 days	Service life of approximately 5 days Average device current: 6.5 mA (without BP monitoring on) - 15 mA (with BP monitoring on)
Re-charging Power Source	The device battery shall be able to be replaced or recharged	Li-ion rechargeable battery (charging time: 2.59 hours)

BP = Blood Pressure, ECG = Electrocardiogram, PD = Parkinson's disease, PPG = Photoplethysmograph.

TABLE 3. WESAA system vs off-the-shelf systems.

Device	Sensors to measure motor symptoms, gait impairment and sleep quality			Sensors to measure blood pressure		Access to raw data	Battery life
	3-axis accelerometer	3-axis gyroscope	3-axis magnetometer	EMG	PPG		
Parkinson's Kinetigraph	✓						Up to 10 days
STAT-ON	✓	✓	✓				Up to 7 days
Kinesia 360	✓	✓					Up to 1 day
PD Monitor	✓	✓	✓				Up to 30 hours
Apple Watch Series 8 with StrivePD mobile app	✓	✓					Up to 36 hours (standard). Up to 60 hours (low power)
MoveMonitor	✓		✓			✓	Up to 14 days
GT9X Link	✓	✓	✓			✓	Up to 16 days
wGT3X-BT	✓					✓	Up to 31 days
Samsung SM-R850 with Samsung Health Monitor app					✓		Up to 2 days
WESAA system	✓	✓		✓	✓	✓	**Up to 7 days**

ECG = Electrocardiogram, PD = Parkinson's disease, PPG = Photoplethysmograph.

Actigraph technologies are tested on a PD cohort exclusively for BP and sleep quality, respectively. On the other hand, the WESAA system can simultaneously collect inertial, PPG, and ECG raw data. This information can be utilized to estimate main PD motor symptoms, gait speed, sleep cycle, and BP.

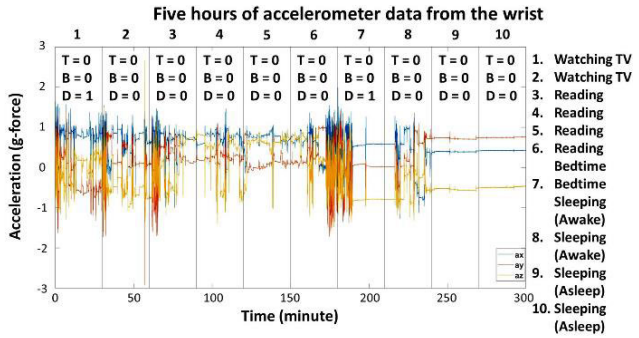


FIGURE 8. Five hours of acceleration data from the most affected wrist. T = Tremor, B = Bradykinesia, D = Dyskinesia.

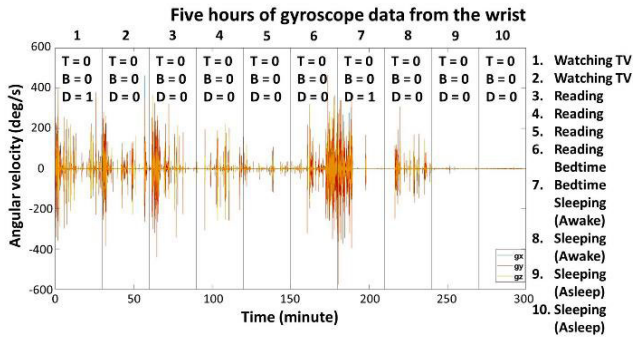


FIGURE 9. Five hours of gyroscope data from the most affected wrist. T = Tremor, B = Bradykinesia, D = Dyskinesia.

XII. 24-HOUR DATA CAPTURE OF INERTIAL DATA

Six participants (age: 69.83 ± 7.57 years; male: 2; female: 4) wore the system for 24-hours, on both the wrist and ankle, on the side of the body most affected by PD. Participants details such as age, sex, height (cm), weight (kg), most affected side (left or right), Hoehn and Yahr stage, MDS-UPDRS-III score (x/108), the 6-item Cognitive Impairment Test (x/28) [104], and PD duration (years) are available in the Appendix section.

During typical waking hours, participants were required to maintain a diary every 30 minutes to contextualise the sensor data collected; the information includes motor symptoms of the most affected side (severity 0-4 for tremor, bradykinesia, and dyskinesia), sleep-awake patterns, daily activities (e.g. sitting, walking), and PD medications. Volunteers were trained on how to properly remove and re-wear the devices as needed, such as during water-based activities like bathing and showering. At the conclusion of the 24-hour period, participants turned off the system and handed it over; data were retrieved using MATLAB software by researchers, and free-living activity segments were plotted offline.

Fig. 8, 9, 10, and 11 provide an example of five hours of accelerometer data from the wrist, gyroscope data from the wrist, accelerometer data from the ankle, and gyroscope data from the ankle, respectively. Each figure is vertically divided into 30- minute intervals, and for each of these, the activity performed and the severity of main motor symptoms (tremor, bradykinesia, and dyskinesia) were annotated.

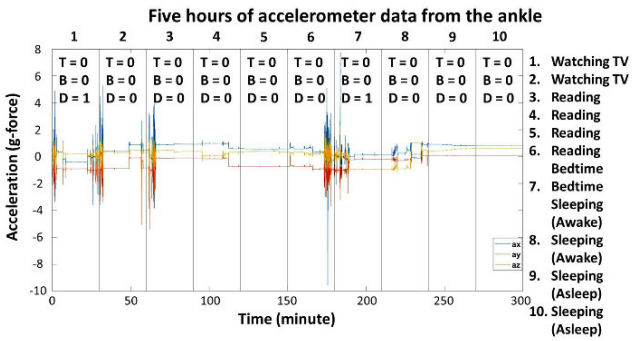


FIGURE 10. Five hours of acceleration data from the most affected ankle. T = Tremor, B = Bradykinesia, D = Dyskinesia.

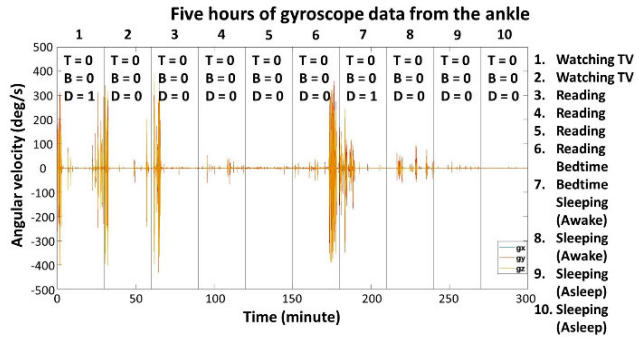


FIGURE 11. Five hours of gyroscope data from the most affected ankle. T = Tremor, B = Bradykinesia, D = Dyskinesia.

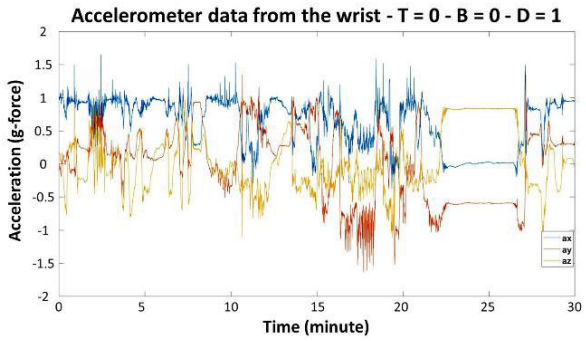


FIGURE 12. Accelerometer data from the wrist – Dyskinesia = 1. T = Tremor, B = Bradykinesia, D = Dyskinesia.

According to the diary, during the first hour, the subject watched television and exhibited mild dyskinesia in the first 30 minutes (Fig. 12); the figures illustrate a certain level of motion on both wrist and ankle. In the next two hours, the patient read a book and did not present any motor symptoms; given the nature of the activity, the wrist movement is coherently more active than the ankle. At the end of the aforementioned period, the person went to sleep. The final two hours reveal the sleeping awake-asleep inertial patterns; the signals' amplitude decreased gradually until the subject fell asleep. In the first 30 minutes of this period, a mild episode of dyskinesia was annotated.

Finally, Fig. 13 depicts the angular velocity around the z-axis over ten seconds of walking during free-living monitoring; gait patterns were manually segmented while toe-offs and heel strikes were marked.

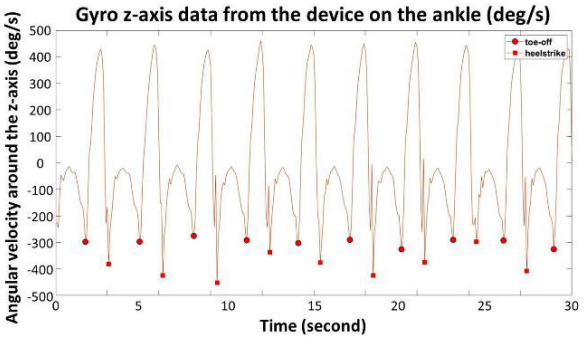


FIGURE 13. Angular velocity around the z-axis during walking. Gyro = Gyroscope.

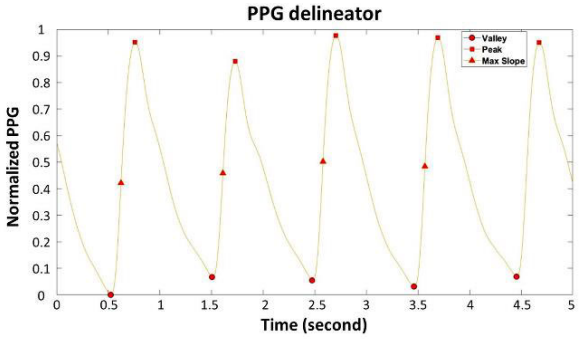


FIGURE 14. PPG delineator example. PPG = Photoplethysmograph.

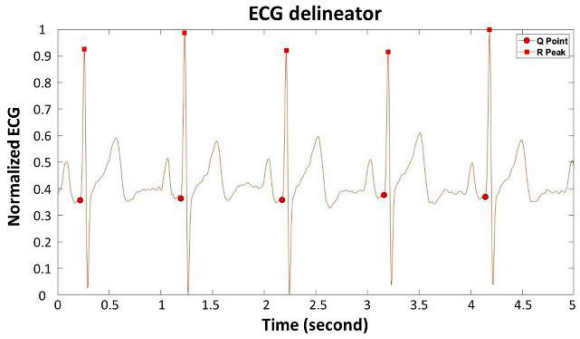


FIGURE 15. ECG delineator example. ECG = Electrocardiogram.

XIII. PPG AND ECG VALIDATION

In order to validate the PPG and ECG sensors of the prototype system, ten PD volunteers (age: 69.50 ± 5.89 years; male: 5; female: 5) attended a single session in which the signals were compared against the gold standard technology Biosignalplux (PLUX Biosignals, Portugal) [105]. Age, sex, height (cm), weight (kg), most affected side (left or right), Hoehn and Yahr stage, MDS-UPDRS-III score (x/108), the 6-item Cognitive Impairment Test (x/28), and PD duration (years) of each participant are available in the Appendix section.

Before starting the data acquisition, participants rested for 5 to 10 minutes, sitting on a chair next to a table, with their arm at heart level on the table to stabilize their heart rate. Measurements from the WESAA system and Biosignalplux were performed simultaneously for both PPG and ECG. For the PPG, the prototype measurement is completely palm-based (least affected hand) and is performed by components located beneath the lens, between the top electrodes, while for the gold standard, the PPG is acquired by means of a finger clip on the index (least affected hand). ECG is measured between the wrist of the most affected hand and the palm of the less affected hand in the WESAA system. The Biosignalplux employed three wet electrodes positioned 1) under the right clavicle, near the right shoulder, within the rib cage frame; 2) under the left clavicle, near the left shoulder, within the rib cage frame; and 3) on the left side below the pectoral muscles at the lower edge of the ribcage. Participants were encouraged to relax as much as possible while these readings were being taken. One single PPG and ECG prototype measurement lasted approximately 30 seconds; the validation was performed by acquiring five readings for each volunteer in conjunction with a single reading from the gold standard. After participation, raw data, from both the gold standard and prototype, were acquired and saved on a computer device. MATLAB software was used to analyse the collected signals offline. Data, from both Biosignalplux and WESAA system, went to preliminary post-processing, which included removing the signal mean, band-pass filtering (4th order Chebyshev II with low cut-off frequency at 0.5 Hz and high cut-off frequency at 5 Hz, and low cut-off frequency at 0.5 Hz and high cut-off frequency at 30 Hz, for PPG and ECG respectively), five seconds windowing, and rescaling into 0-1 values against maximum value [106], [107], [108], [109], [110], [111]. Then, a quality index capable of estimating the signal quality within each window was developed and windows with low quality were discharged consequently. To perform this, PPG and ECG delineators were implemented. Regarding the ECG, R peaks were detected by means of a threshold-based technique, while Q points were determined consequently as the local minimum ahead of the R peaks [112] (Fig. 14). For PPG peaks (systolic peak) and valleys detection, the well-known algorithm from Orphanidouet al. was used [113] and the PPG 'middle' was calculated as the maximum derivative point between two consecutive valleys [114] (Fig. 15). The window was classified as "good" if the time interval between consecutive R peaks/PPG middles fell between 0.35 and 1.5 seconds and the standard deviation (SD) of the amplitude of the R peaks, Q points, PPG peaks, PPG valleys, and PPD middles were below 0.1 [113], [115]. Once "bad" windows were discharged, PTT and RR were measured in each "good" window for both devices using the points generated via signal delineation. Currently, the association between BP, PTT, and RR has been widely examined, and a correlation has been established [116], [117], [118]. According to the original definition, PTT is the time interval between the R peak of the ECG and a characteristic point of the PPG within the same cardiac cycle; in particular, in the present study, it is assumed as the distance between the R peak and the PPG middle.

The following indicators were computed for PTT and RR: mean estimated value with related SD, mean absolute bias (MAE) (prototype vs gold standard), and mean absolute percentage error (MAPE), again prototype vs gold standard.

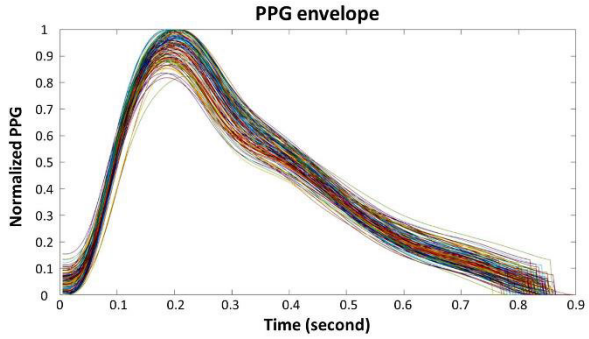


FIGURE 16. PPG envelope example. PPG = Photoplethysmograph.

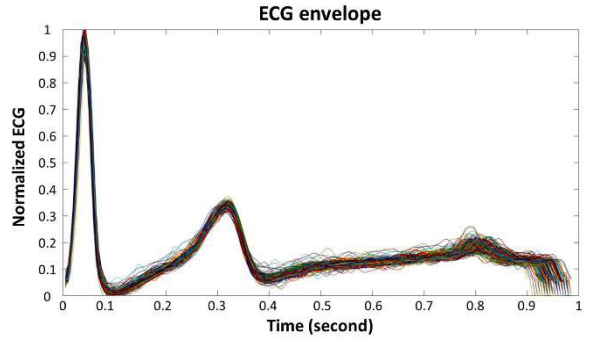


FIGURE 17. ECG envelope example. ECG = Electrocardiogram.

Intra-class correlation ICC[2,1] (prototype vs gold standard) was computed, and the corresponding 95% confidence intervals (CIs) were also calculated. ICC values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 are indicative of poor, moderate, good, and excellent reliability, respectively [119]. Bland-Altman plots were also obtained for both PTT and RR.

Finally, to compare similarities between Biosignalplux and WESAA system signals, the envelope was extracted from both devices for each individual (Fig. 16 and 17) and the all-pairwise dynamic time warping (DTW) distance was calculated between each wave of the gold standard and each wave of the prototype [120], [121], [122]. The all-pairwise DTW mean and SD were then determined. The same approach was adopted to estimate the all-pairwise DTW mean and SD between the same groups (gold standard vs. gold standard, and prototype vs. prototype) to provide a baseline when comparing the waves of different groups (gold standard vs. prototype).

Table 4 displays the mean and SD for PTT and RR for both Biosignalplux and WESAA system, as well as MAE, MAPE, and ICC[2,1] with the respective 95% CIs between the two devices. For PTT, the mean and SD are 0.267 ± 0.0.19 s and 0.275 ± 0.026 s for gold standard and prototype respectively, while MAE, MAPE, and ICC are 0.012 s, 4.519%, and 0.78 respectively. Concerning RR, the mean and SD are 0.673 ± 0.053 s and 0.657 ± 0.059 s for gold standard and prototype respectively, while MAE is 0.018 s, MAPE is 2.723%, and ICC is 0.93.

Table 5 illustrates the mean and SD of the all-pairwise DTW for PPG and ECG for the couples Biosignalplux vs. WESAA system, Biosignalplux vs. Biosignalplux, and WESAA system vs. WESAA system. In particular, for PPG, all-pairwise DTW is 3.3874 ± 1.5446, 1.8421 ± 0.5895, and 2.0324 ± 0.4812 respectively while, for ECG, DTW is 12.9181 ± 4.0341, 1.8144 ± 0.9830, and 4.6854 ± 4.5818 respectively.

Finally, the percentage discharge (e.g., the number of windows rejected as considered of "poor" quality) is 68.4% for the prototype and 13.03% for the gold standard. Bland-Altman plots are shown for both PTT and RR (Fig. 18 and 19). Bias is 0.009 s (upper LOA equal to 0.035 s and lower LOA equal to –0.017 s) and -0.015 s (upper LOA equal to 0.014 s and lower LOA equal to –0.045 s) for PTT and RR respectively.

TABLE 4. MEAN (SD), MAE, MAPE, and ICC (2,1) for PTT and RR.

Parameter	Device	Mean (SD) [s]	MAE [s]	MAPE [%]	ICC [2,1] (95% CI)
PTT	Prototype	0.275 (0.026)	0.012	4.519	0.78 (0.31, 0.94)
	Gold Standard	0.267 (0.0.19)			
RR	Prototype	0.657 (0.059)	0.018	2.723	0.93 (0.47, 0.99)
	Gold Standard	0.673 (0.053)			
Percentage Discharged	Prototype	68.400 (15.939)	-	-	-
	Gold Standard	13.029 (11.638)			

CI = Confidence Interval, ICC = Intraclass Correlation Coefficient, MAE = Mean Absolute Error, MAPE = Mean Absolute Percentage Error, s = second, SD = Standard Deviation.

TABLE 5. All-pairwise DTW distance for PPG and ECG.

Parameter	Signal	Device	Mean (SD)
All-Pairwise DTW distance	PPG	Gold Standard vs Prototype	3.3874 (1.5446)
		Gold Standard vs Gold Standard	1.8421 (0.5895)
		Prototype vs Prototype	2.0324 (0.4812)
	ECG	Gold Standard vs Prototype	12.9181 (4.0341)
		Gold Standard vs Gold Standard	1.8144 (0.9830)
		Prototype vs Prototype	4.6854 (4.5818)

DTW = Dynamic Time Warping, ECG = Electrocardiogram, PPG = Photoplethysmograph, SD = Standard Deviation.

XIV. USER EXPERIENCE INTERVIEW

The design phase of novel prototypes typically focuses on technical performance, accuracy, and reliability, with less evaluation of the user experience of wearing monitoring devices, either for short-term assessment or for longer monitoring, which is essential for their use and adherence [38].

Technology used in PD can play a significant role in care delivery if it is designed to increase the engagement of the person in their healthcare [47]. Therefore, in this study, we also explored the user experience of the WESAA system via online semi-structured interviews with six PwPD (age:

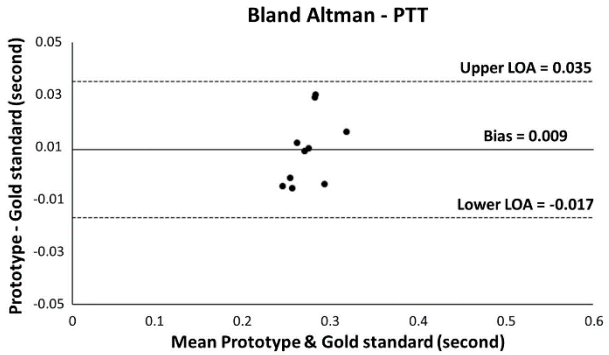


FIGURE 18. Bland Altman for PTT (Prototype & Gold standard). LOA = Limits Of Agreement, PTT = pulse transit time.

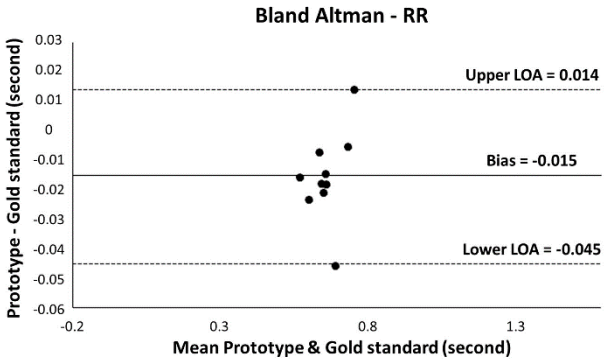


FIGURE 19. Bland Altman for RR (Prototype & Gold standard). LOA = Limits Of Agreement, RR = R-R interval.

65.25 ± 14.13 years; male: 3; female: 3), who wore the system for 24-hours at home. The Age, sex, height (cm), weight (kg), most affected side (left or right), Hoehn and Yahr stage, MDS-UPDRS-III score (x/108), the 6-item Cognitive Impairment Test (x/28), and PD duration (years) of each participant are reported in the Appendix section. All participants described having had an overall positive perception of wearing the system and it was considered comfortable, but there were some practical issues raised about its wearability. These included the individual devices being too bulky (e.g., outward projecting), and potentially hindering clothing (e.g., sleeves or pant legs), especially for a person with PD-related reduced dexterity, or affecting sleep, and being non-discrete, thus marking the person out as being different.

Fastenings to the wrist and ankle used a latex-free stretchy band, and in some instances, the strap became loose over time and affected device stability. Conversely, the ankle strap tightening was difficult to loosen, thus making it difficult to adjust and remove. The strap's plastic adjuster slider proved difficult for some individuals. Participants suggested more familiar options like a Velcro or watch-style strap. There were some strong negative associations of the ankle-worn device for some participants, being unfamiliar, potentially stigmatizing, or even reminiscent of a prisoner tracking system.

The prototype was not completely sealed and, as a result, not totally water resistant, which impacted robustness, as participants described being conscious of taking care of the device, and hence changing their movements or daily activities. The only feedback provided by the system to the wearer is power and BP mode on/ off, however, some participants would like feedback on whether the system is working, and the health-related data collected via a user interface. Volunteers were interested in getting feedback on gait, tremor, bradykinesia, dyskinesia, and sleep.

While this data indicates that aspects of the current WESAA system require refinement, most participants would still wear the system if it meant that their health condition could be improved through its use. Volunteers endorsed wearable technology in the future management of PD, where technology could have a positive influence on their day-to-day lives and support the management of PD.

XV. DISCUSSION

This paper investigated the development of a novel wearable solution for PwPD that records accelerations and angular velocities from wrist and ankle (on the most affected side) for prolonged periods of time, along with wearer-triggered PPG and ECG signals from the palm of the less affected hand. Inertial data collected might be used eventually to estimate gait speed, sleep-wake cycles, and primary PD motor symptoms, whereas PPG and ECG signals might be employed to assess BP without the aid of a cuff. This information can potentially assist clinicians in differentiating symptoms due to Levodopa deficiency from symptoms due to hypotension and, consequently, improve medication decision-making and patient safety [123].

The entire process has been depicted in the manuscript, including concept description, system requirements, industrial design and integration, hardware and firmware design, and user experience assessment. Additionally, preliminary data from the IMUs during a 24-hour acquisition were provided, as well as the validation of measured PPG and ECG signals.

The embedded inertial sensors on the wearable device provide information on motion patterns in a free-living scenario; data are downloaded on a computer device and, in the future, should be adopted to implement algorithms capable of recognizing the primary motor symptoms of PD, walking activities and consequently gait speed, and sleeping patterns. Using the patient's diary as labels, machine learning models could be implemented. However, as mentioned in the manuscript, loggers are not always a reliable means of comparison; indeed, self-assessing simple occurrences like resting tremor or more complex events, like symptoms during motion, can be extremely challenging. Nevertheless, artificial intelligence models might rely on large datasets to generalize the ''not-always-accurate'' data labelled by PwPD volunteers with the final aim of detecting motor symptoms, walking activities, and sleeping patterns accurately. In the future, a larger data collection would be required to accomplish this. This implies the need for a diverse group of participants, displaying a variety of symptoms from mild to severe, in order to offer a wide array of examples.

TABLE 6. Cohort characteristics – 24-hour data capture of inertial data.

Sex	Age	Height (cm)	Weight (kg)	Most Affected Side	Hoehn and Yahr (stage)	Years since diagnosis	Cognitive Impairment Test	MDS-UPDRS
F	83	153	60	Left	Two	5	0	75
F	73	171	70	Left	Two	9	0	78
F	67	152	73	Left	Two	3	2	70
M	70	183	92	Right	Three	6	4	71
F	62	162	63	Right	Two	3	0	40
M	64	173	82	Left	Three-Four	7	4	102

MDS-UPDRS = Unified Parkinson's Disease Rating Scale.

TABLE 7. Cohort characteristics - validation of the PPG and ECG sensors.

Sex	Age	Height (cm)	Weight (kg)	Most Affected Side	Hoehn and Yahr (stage)	Years since diagnosis	Cognitive Impairment Test	MDS-UPDRS
F	73	171	70	Left	Two	9	0	78
M	72	183	90	Right	Three	10	0	69
M	64	173	82	Left	Three-Four	7	4	102
M	78	172	69	Left	Three	7	4	87
F	70	165	70	Left	One	4	0	60
M	72	168	82	Left	Two	2	0	55
M	72	173	75	Left	Two	6	0	62
F	62	170	95	Left	One	9	0	38
F	59	175	70	Left	One	6	0	38
F	73	170	63	Left	Three	15	4	64

MDS-UPDRS = Unified Parkinson's Disease Rating Scale.

TABLE 8. Cohort characteristics – user experience interview.

Sex	Age	Height (cm)	Weight (kg)	Most Affected Side	Hoehn and Yahr (stage)	Years since diagnosis	Cognitive Impairment Test	MDS-UPDRS
F	83	153	60	Left	Two	5	0	75
F	73	171	70	Left	Two	9	0	78
M	56	175	70	Left	Two	17	0	73
M	70	183	92	Right	Three	6	4	71
F	62	162	63	Right	Two	3	0	40
M	52	178	107	Left	Two	8	0	38

MDS-UPDRS = Unified Parkinson's Disease Rating Scale.

The embedded sensing technologies for measuring BP were validated against gold standard devices, demonstrating overall good-to-excellent reliability. For PTT, the WESAA system presented a good correlation (ICC = 0.78) with the Biosignalplux and a MAPE of 4.519%; meanwhile, when comparing RR, the correlation was excellent (ICC = 0.93) with a MAPE of 2.723%. All-pairwise DTW was also used to identify signal similarities with lower values found when comparing the PPG gold standard and prototype (DTW = 3.3874), rather than ECG (DTW = 12.9181). This result can be explained by the position of sensors on the skin; indeed, the PPG from Biosignalplux and WESAA system sensors are very close to one another (index fingertip and palm, respectively), resulting in a similar signal shape, while, in contrast, the three electrodes for the gold standard ECG measurement were placed far from the palm, resulting in a different signal shape and a larger DTW. Finally, the windows discharged with the Biosignalplux are less (13.03%) than those discharged for the WESAA system (68.4%); as expected the finger clip and the wet electrodes provided a more stable attachment and consequently a better signal quality. Regardless, approximately 32% of the signal was deemed "good" despite the movement artefacts caused by individuals often affected by tremor.

In the current version of the WESAA system, PPG and ECG raw data are transferred via cable to a computer device for offline elaboration, which includes pre-processing, delineation, and signal quality evaluation. The next generation of firmware should incorporate the aforementioned operations as well as additional algorithms capable of estimating BP from the processed signals.

This study aimed to apply a design-thinking approach by including PwPD in the design process to recognise how the WESAA prototype delivers value from the perspective of

intended end-users. By starting with research, then testing the device with PwPD, and receiving qualitative feedback, the hope is that designers can cumulatively refine this technology for future use. Preceding research on the views and needs of PwPD regarding non-specific wearable devices for disease monitoring by Kenny et al. [47] found that while the size and weight of a device were important, the aesthetics appeared less significant. This contrasts with our findings, based on actually wearing a device, where participants expressed preferences for function without being too conspicuous [39], [124]. Similarly to a research study by Botros et al. [38], some individuals in this study did not feel fully at ease when wearing devices in public, especially wearing the ankle-worn device. Previous research has already highlighted the stigma associated with PD [125], thus visibility and discretion will be key for the future design of wearable devices for PwPD.

The WESAA system developed is a novel remote monitoring technology for PD patients. Clinical evaluations and self-reported diaries provide only a fragmented picture of a patient's overall health condition, giving clinicians little guidance regarding the optimal daily dosages to prescribe. The proposed system is a promising alternative because it has the potential to assist specialists with medication and treatment decisions by providing them with useful data regarding their patients' motor symptoms and overall health status. Potentially, the proposed technology can reduce the need for in-clinic evaluations and aid geographically dispersed patients with limited access to medical services.

XVI. CONCLUSION

The WESAA system, a novel system for the remote monitoring of PwPD, was presented in this work. It comprises two identical devices worn on the wrist and ankle, and its primary purpose is to capture accelerations and angular velocities from these body segments, in addition to PPG and ECG data. This information can be elaborated offline to provide gait speed, sleep-wake cycles, and primary PD motor symptoms, as well as blood pressure without the usage of a cuff.

The system requirement, market landscape, industrial design and ergonomics, system development, user experience, and validation were described in depth, including a comprehensive description of the hardware and firmware architecture as well as the multi-sensing technologies utilized.

The developed technology satisfies the initial system requirements, and the adopted multi-sensing technologies yield results comparable to gold standards. The WESAA system, therefore, might represent a potential alternative for holistic remote monitoring of PwPD.

APPENDIX

Table 6 describes age, sex, height (cm), weight (kg), most affected side (left or right), Hoehn and Yahr stage, MDS-UPDRS-III score (x/108), the 6-item Cognitive Impairment Test (x/28), and PD duration (years) of each participant during 24-hour data capture of inertial data.

Table 7 illustrates age, sex, height (cm), weight (kg), most affected side (left or right), Hoehn and Yahr stage, MDS-UPDRS-III score (x/108), the 6-item Cognitive Impairment Test (x/28), and PD duration (years) of each participant for the validation of the PPG and ECG sensors.

Table 8 shows age, sex, height (cm), weight (kg), most affected side (left or right), Hoehn and Yahr stage, MDS-UPDRS-III score (x/108), the 6-item Cognitive Impairment Test (x/28), and PD duration (years) of each participant for the user experience interview.

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