PORTABLE MEDICAL ELECTRICAL EQUIPMENT FOR PARKINSON'S DISEASE MOTOR IMPAIRMENT AND MEDICATION RESPONSIVENESS EVALUATION

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Abstract: This article describes aspects of the development and testing of a portable Parkinson Disease (PD) resting tremor data-logger, able to monitor up to 48 hours of upper limbs' movements. The equipment aims to objectively evaluate effectiveness of drug treatments and/or therapeutic procedures, supporting clinical neurology decisions with motor system relevant data regarding tremor frequency and time. Frequency response tests results, simulating PD resting tremor conditions, show 0,011Hz maximum tendency between the frequency values collected using our equipment and a digital tachometer simultaneously with maximum absolute difference value of 0,0205Hz between samples. Tendency below 0,05Hz of tolerance and ANOVA gauge repeatability and reproducibility of 1% RR indicate that, the measurement system is considered acceptable or recommended and the equipment is ready for the next steps toward clinical trials in PD patients.

1 INTRODUCTION

Until now, to the best of our knowledge, the clinical assessment of motor impairment, medication and treatment responsiveness in PD patients is mainly done through subjective methods, in which a clinician assesses the subject's condition and ability to perform a range of tasks resulting in metrics. According to National Parkinson Foundation some of most used evaluation scales are the characterization by Hoehn-Yahr stages scale, The Unified Parkinson's Disease Rating Scale (UPDRS), the modified Columbia Scale, The Schwab and England Disability Scale and Abnormal Involuntary Movement Scale (AIMS). Webster scale and the Tremor Rating Scale (TRS) are also present in literature (Mansur, 2007). Those are all qualitative and subjective methods, based on history, questionnaire and clinical examination.

Nearly 40 medicines are being developed to treat or diagnose Parkinson's Disease (PD) and related conditions. In the last decade, five new medicines were approved to treat motor and non-motor symptoms. Current medicines for PD are approved to treat the symptoms, such as mobility problems and tremors, but do not replace lost nerve cells or halt the progression of the disease itself (PhRMA, 2014).

Levodopa is the leading drug used in PD treatment and is especially effective in managing the initial symptoms. Over time, its effectiveness is reduced, resulting in motor fluctuations and dyskinesia, which can affect quality of life and may cause disability (AAN, 2014). Around 50% of the PD patients treated with levodopa develop dyskinesia within five years (Toulouse and Sullivan, 2008).

There is a great need for methods that can precisely measure the patient's commitment and responsiveness to treatment, in order to help physicians define an optimized individual drug posology for patients in clinical neurology care.

The PARKIGLOVE (PG), is a simple and user friendly portable medical electrical equipment that uses accelerometers fixed in the subject's upper limbs, to intermittently measure PD tremors during every-day life and store information data into a memory card. Working as a data-logger, similar to a

HOLTER heart exam (Holter,1961), after 24 or 48 hours the collected data can be used to objectively evaluate the patients motor impairment and medication responsiveness, based on tremor dynamics and fluctuation during the day.

In this paper, we describe PG's technical aspects its development and testing.

2 MATERIALS AND METHODS

The PG architecture consists of two 3-axis accelerometers sensors connected to the analog inputs of a processing unit, which saves pre-formatted text data into a micro-SD storage card and generates sound alarms through a medical standardized sound unit. A long lasting battery unit powers the equipment. The system architecture is illustrated in Fig. 1.

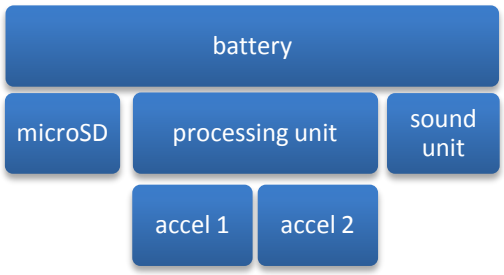

Figure 1: PG architecture.

2.1 Architecture details

We used the Sparkfun ADXL335, a 3-Axis accelerometer breakout board module. A light weighted (1.45g), small sized (20mm×20mm×2mm), with a plastic lead frame chip scale package (LFCSP_LQ), low powered (350μA), single-supplied (1.8V to 3.6V), with excellent temperature stability (-40°C to +85°C) and three signal conditioned analog voltage outputs, one for each axis, which measure acceleration with a minimum full-scale range of $\pm 3g_n$.

The module contains a poly-silicon surface-micro-machined sensor and signal conditioning circuitry to implement open-loop acceleration measurement architecture. The output signals are analog voltages proportional to the acceleration in each axis, making it possible to measure the static acceleration of gravity in tilt-sensing applications as well as dynamic acceleration resulting from motion, shock, or vibration.

The ADXL335 module includes capacitors (C) on its outputs in order to select operation bandwidths to best suit the user application, with a range of 0.5Hz to 1,600Hz for the X and Y axes, and 0.5Hz to 550Hz for the Z axis. Bandwidth is calculated as:

$$\text{Bandwidth}=1/(2\times\pi\times32\text{k}\Omega\times C) \quad (1)$$

We adjusted the module capacitors to 0.1μF, resulting in a 50Hz electronic filter and a suitable operation range considering PD. The decision considered the typical PD resting tremor frequency range between 3Hz to 6Hz (Bhidayasiri, 2005) and regarded the Nyquist's sampling theorem, in which the minimum sample rate should be limited to double of the maximum frequency of interest to avoid the aliasing effect, which compromises data interpretation (Pelgrom, 2013). In this case, for better results, we are working with four times Nyquist's suggested frequency.

The accelerometer modules were powered by a 3.3V power supply pin provided by the processing unit.

Current prototype was developed using mBed™ LPC1768. A small sized (14mmx14mmx1.4mm), single-supplied (4.5V to 9V), USB enabled, 32KB RAM, 512KB FLASH, 32-bit high performance 96MHz ARM® Cortex™-M3 processor based board, with eight 12-bit resolution ADC-Analog to Digital Converter input channels.

The outputs of two accelerometers were connected to the ADC inputs available in the processing unit using a 1.5m flat cable. The real-time collected data is transferred via SPI-*Serial Peripheral Interface Bus* to a Sparkfun microSD breakout board, capable of handling a 2GB flash-based memory card, in a maximum 50MB/sec data transfer rate.

The equipment generates beeps during its operation in accordance to IEC 60601-1-8, international standard that defines general requirements, tests and guidance for alarm systems in medical electrical equipment. The beeps have a 975±24Hz fundamental frequency with four harmonic peaks within (1kHz to 4kHz) and a sound level of 85dB at 10cm typical, following IEC's technical requirements that describes characteristics for burst and pulse of auditory alarm signals, the beeps must have a "on" time of 170ms arranged in three different signal priorities as follows:

- **Low Priority**: Beep, Pause 200ms, Beep; Repeat every 20 sec

- **Med Priority**: Beep, Pause 200ms, Beep, Pause 200ms, Beep; Repeat every 7.5 sec
- **High Priority**: Beep, Pause 100ms, Beep, Pause 100ms, Beep, Pause 370ms, Beep, Pause 100ms, Beep, Pause 500ms, Beep, Pause 100ms, Beep, Pause 100ms, Beep, Pause 370ms, Beep, Pause 100ms, Beep; Repeat every 2.5 sec

The equipment beeps when starting to capture data and keeps beeping Low priority until the configured capturing time ends. The beeping is accomplished by connecting the processing unit to a Mallory Sonalert MSS5M1 speaker (8Ω; 0.25W), designed to meet IEC 60601-1-8 medical applications requirements.

The complete system is powered by a TAUE-cjw 3.7V; 5,200mAh Li-ion - Lithium Ion rechargeable battery, that can provide up to 47 hours of continuous operation or up to 57 hours of operation considering for instance, 30sec of data capture every 30 minutes. Thus to the fact that current consumption measurements showed 90mAh being drained during sleep-mode and 110mAh while capturing tremor data.

Electronic design and simulation were performed using LabCenter® Electronics Proteus (7.1 version) ISIS and ARES software. The equipment mainboard design is shown in Fig. 2.

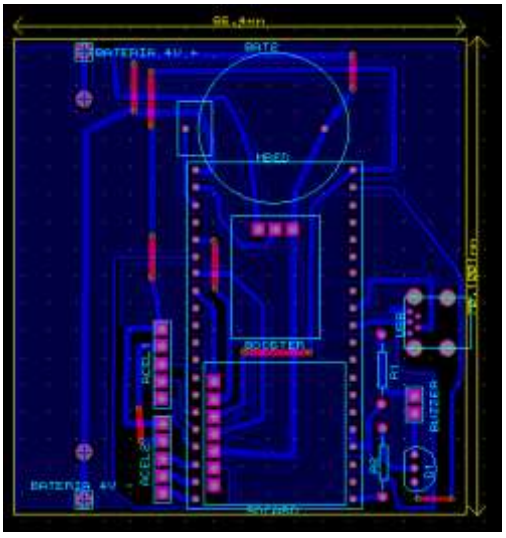

Figure 2: PG mainboard design.

All the electronics is housed by a small size (80mmx62mmx35mm) enclosure, designed in Google SketchUp (8.0 version) software and 3D printed in a MakerBOT Replicator2 printer using PLA (Polylactic Acid) material, a biodegradable thermoplastic ali-phatic polyester, as shown in Fig. 3.

Available connectors to the outside world are power plug to recharge battery and USB connector to download data or operate the equipment in real-time mode directly connected to a computer.

Figure 3: PG box showing its components; PG open enclosure on the left; cables at the center; battery and charger on the right side.

Final result is a 200g equipment that can be fixed to patient's waist or arm using a belt as shown in Fig. 3.

2.2 Firmware software

A firmware software was developed using mBed's web-based C/C++ programming environment. The system runs on power-up and during the start-up it checks for a configuration file and then creates a new data-storage file with ".PG" extension on every boot.

A configuration file is created and updated with user input information, once the equipment is connected to a computer. Data-storage files (.PG) contain pre-formatted text information arranged in a

XML-Extensible Markup Language. The information includes patient's name, date of birth, sampling rate, wait interval and capture interval.

The sampling rate defines the sampling frequency for each analog input channel (accelerometer axis); wait interval stands for the time interval the equipment will stay in sleep mode waiting until the next capture; and capture interval stands for the time interval the equipment will actually record tremor data.

Although the system can operate and record tremor data continuously for periods up to 47 hours, it was designed to work intermittently by means of time windows; recording, for example, 30 seconds of data every 30 minutes. The user can freely adjust these values in the software when the equipment is connected to a computer.

Considering two accelerometers (3 axis each), producing an average of 14 bytes (14 characters) of data per sample per axis, on a maximum sample rate of 50Hz (cycles/sec), results in an average of 4,200 Bytes/sec stored in the memory card.

Considering this storage rate running for 30 seconds of capture intervals every 30 minutes, one whole day of data results in a ".PG" file of approximately 346MB, much less than the 2GB limit available in the card. This way, one can consider performing up to five 24 hours exams before having to download the data from the equipment.

2.3 Computer software

For the data analysis and user interface a computer software was developed using Embarcadero RAD Studio Delphi (6.0 version) environment. The system automatically detects when the equipment is connected to any computer USB port, allowing the user to download data files stored in the memory card and save them in a local or remote folder.

The saved files are processed and the user can choose to see time-based or frequency-based graphics for each accelerometer axis. Frequency-based graphics are generated using FFT-Fast Fourier Transformation of the data. Our software FFT outputs were validated comparing the results with MatLab (R2009b version) similar analyses.

The resulting graphics can be printed out along with clinical description/annotation of events making it possible to track tremors "on" and "off" moments during the day, as shown in the Appendix.

Another available option is to connect the equipment to the PC and operate the system in a real-time fashion, in which the collected data is transferred directly to the USB port and plotted in real-time in either a time-based or frequency-based graphic.

3 RESULTS

In order to validate the equipment, frequency response tests were ran by attaching the device to a rotating machine, simulating PD resting tremor conditions, with adjusted frequencies at 1.6Hz, 4.8Hz, 5.3Hz, 6.3Hz and 8.3Hz.

A Minipa MDT-2238A digital photo tachometer with laser sight, 0.1RPM resolution and ±0.05%+1 precision, was fixed to a tripod distant 300mm from the rotating machine. Data collections were ran registering 20 samples for each configured rotating frequency, both with tachometer and PG at same time. *Grubbs* statistical test was applied in order to discard possible data outliers. Table 01 shows information on the collected data.

Table 01: Frequency response test results

Machine Expected Value (Hz)	Digital Tachometer		PG	
	Avg (Hz)	StdDv	Avg (Hz)	StdDv
1,6667	1,7830	3,9%	1,7776	1,1%
4,8333	4,9616	3,6%	4,9566	0,6%
5,3333	5,3713	3,4%	5,3666	0,4%
6,3333	6,4360	3,3%	6,4264	0,5%
8,3333	8,8419	4,6%	8,8536	0,3%

Differences between sampled frequency values collected with the PG and the digital tachometer had a maximum absolute value of 0,0205Hz.

All statistical analysis were performed using *Action Statistical Software* which is based in QS-9000 MSA- Measurement Systems Analysis 4th edition. Results for Tendency T-test are presented in Table 2.

Table 02: Tendency T-test statistical results

Information	Results	Results	Results	Results	Results
Ref. value	1,783	4,9616	5,3713	6,436	8,8419
Average	1,77756	4,95658	5,366585	6,426445	8,85355
Tendency	-0,00544	-0,00502	-0,004715	-0,009555	0,01165
T Statistics	-119,4613	-86,0922	-84,4156	-145,0261	174,6925
P-value	8,55E-29	4,271E-26	6,201E-26	2,157E-30	6,300E-32
Lower limit	-0,005535	-0,005142	-0,004831	-0,009692	0,011510
Upper limit	-0,005344	-0,004897	-0,004598	-0,009417	0,011789
VE %	2,443810	3,129217	2,997472	3,535742	3,578885

Standard Dev.	0,000203 651	0,000260 768	0,000249 789	0,000294 645	0,000298 24

Considering 5 different frequencies (parts) each being measured 20 times for planes X-Y the ANOVA gauge repeatability and reproducibility was calculated and a 1% RR was obtained considering no operator relevance. Graph results are shown on Figure 4.

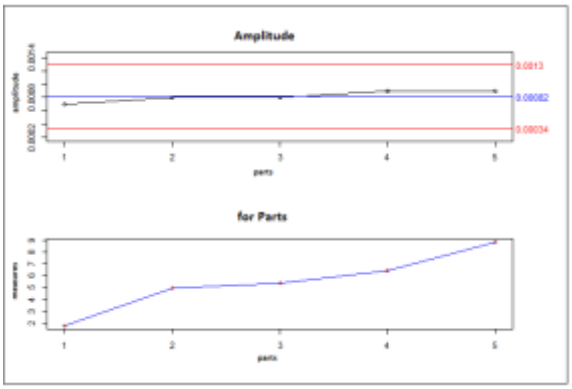

Figure 4: ANOVA gauge R&R graph results

Continuous 48 hours trials were performed to make sure hardware, firmware software and computer software could handle long time operations and files as big as the resulting 484MB files generated when considering configured operation parameters of 35Hz sampling rate, 30sec capture duration and 30 minutes capture interval.

When leaving the sensors resting over a non vibrating environment white noise levels showed to be around 0,02Hz.

4 DISCUSSION

In the United States, between 1.5–2.5% of people over 70 years of age are carriers of PD. The estimated prevalence is 150 to 200 per 100,000 inhabitants. Some works reveal that 1% of people over 65 years of age are carriers of PD, and this index doubles among the population over 85 years of age (Mansur,2007).

The main methods used for the measurement of the tremors in the laboratory are accelerometry, electromyography (EMG), and the spirogram, with the latter used in smaller proportion. The current state of the art does not allow for identification of which strategy of tremor measurement is more efficient or more suitable, or which of the analysis methods is more necessary or effective as published works possess different samples (geographical area, age group, aggravation of the pathology, etc) and they use different methodologies (protocol) for the measurement of the tremor (Mansur,2007).

Long-term PD EMG recording was proved possible, although usually not very portable due to equipment size and weight limitations (Bacher, 1988).

The quantitative assessment of frequency in PD using a data-glove was first proposed by Warner et al., although no actual measurement were demonstrated. Electromagnetic position sensors applied to upper limbs was also able to record tremor and bradykinesia in a data-glove fashion, although not portable at all (Yu, 2013).

Accelerometer signal data showed able to classify PD “on” and “off” states (Keijsers, 2006). Accelerometers were also applied to objectively evaluate adverse side effects of drug therapy. (Keijsers, 2000).

Considering a drug therapy strategy that can enhance cognitive function but has the drawback of amplification of movement disorder, such as tremor, the accelerometer signal can enhance diagnostic acuity being used to elucidate in an objectively quantified manner (Gurevich, 2006).

Accelerometer data can be coupled with numerical methods and spectral analysis of the signal have contributed to ascertain medication efficacy (Schrag, 1999) and also applied to discern the efficacy of deep brain stimulation (Obwegeser, 2001).

Recent accelerometry-based studies showed to possible to record PD lower and upper limb tremor (Blake, 2013), in a continuous at-home monitoring fashion (El-Gohary. 2010) and even applying wireless techniques (Robert, 2013), although most were performed with non specific/validated equipment.

The aim of this study was to design, develop and validate a portable PD resting tremor data-logger in order to address the need to perform long time tremor measurements under patient daily life condition, being able to support clinical neurology decisions with motor system relevant data regarding effectiveness of drug treatments and/or therapeutic procedures.

The Frequency response test results showed in Table 1 indicates a possible tendency of the PG collected data considering the tachometer as golden reference. The tendency T-test statistical results showed in Table 2 proved that the tendency really exists and is statistically relevant considering P-value very low and zero not being between the lower

and upper limit for all the results for a 95% of confidence interval.

Absolute average tendency is 0,0072Hz and maximum tendency is 0,0116Hz. Considering an absolute tolerance of 0,05Hz as being acceptable for the process the tendency can be considered not relevant for the information being measured and therefor the system is acceptable or recommended.

The ANOVA defined as a Measurement System Capability Analysis also known as R&R study, is a technique that uses an analysis of variance to assess a measurement system (Burdick, 2003). This method allows the individual sources of variation in the measurement data to be identified; the part-to-part variation, the repeatability of the measurements, the variation due to different operators; and the variation due to part by operator interaction.

ANOVA gauge repeatability and reproducibility graph results shown in Figure 04 present almost linear representation, additionally RR below 10% indicate that, according to MSA QS-9000 standards, the measurement system is considered acceptable or recommended, especially useful when trying to order or sort parts or when tight control of the process is required.

The equipment is not limited on issues of unilateral versus bilateral disease, as we have two accelerometers being able to capture bilateral signals at the same time.

No information concerning non-motor aspects of PD is provided and at this moment the presence or absence of postural reflex impairment is not addressed, thereby leaving some specific aspects of motor deficit un-assessed.

Tests were focused on the PG ability to correctly determine the subject's tremor frequency and sustain registration quality during long lasting exams. Frequency response tests results, simulating PD resting tremor conditions, showed minor differences between the frequency values collected using our equipment and a digital tachometer simultaneously.

The equipment ended up being very simple and easy to use, and so far appropriate engineering frequency response tests were successfully conducted. Next steps to be taken are toward clinical trials in PD patients, and we are at this moment requesting and waiting for authorization of the Professor Edgar Santos University Hospital ethics committee in order to proceed.

Our long shot is to make the PG a useful tool in the clinical PD treatment being able to precisely measure the patient's commitment and responsiveness to treatment, in order to help physicians define an optimized individual drug posology for patients in clinical neurology care.

A diagnostic accuracy study will soon be performed with PD patients that will use the PG equipment along with surface electrodes electromyography as our golden reference standard and in compliance with STARD-Standards for the Reporting of Diagnostic accuracy studies. Final goal is to produce an expression of how well the PG results correspond with the presence or absence of typical frequency target condition, as established by PD patients electromyography reference standards.

Figure 5 shows the equipment being weared by one of our researchers and ready to be tested together, but most important, not interfering in electromyography's surface electrodes being fixed in the upper limbs area.

According to IEC 60601-1 mechanical strength tests for hand held and mobile devices must be ran in such equipment before going commercial. This tests include push test, impact test, drop test, rough handling test and mould stress relief test in conditions such as a minimum 70°C for 7h with no shrinkage or distortion, and a drop test from a height of 1m with test being repeated 3 times.

The current 3D printed housing prototype was developed only to validate dimensional aspects for a future final version of the enclosure as it is known that the PLA material does not comply with IEC 60601-1 mechanical strength requirements in terms of flammability classification, force and impact resistance and mould stress relief test for thermoplastic materials.

Considering the need for minimal mechanical resistance during the future diagnostic accuracy study when PD patients will go home wearing the equipment for periods up to 48 hours, we decided to temporally house the electronics inside a Sparkfun 2mm-thick aluminium enclosure (112x60x31mm). This enclosure is force and impact resistant, can be submitted to really rough handling conditions and is rated IP54 against dust and splashing water.

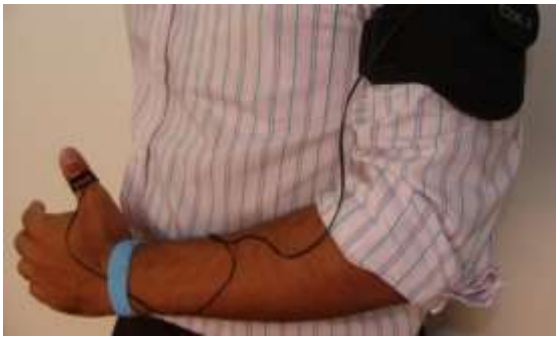

Figure 5: PG in human.

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APPENDIX


Janela de Dados
Resultado Exame
Desenhar Gráficos
Imprimir
Exame Sensor 1
Exame Sensor 2
Exame Sensor 3
Data
Amplitude
Paciente:
João Braga
Codigo:
Data:
EQUIPAMENTO OFFLINE