

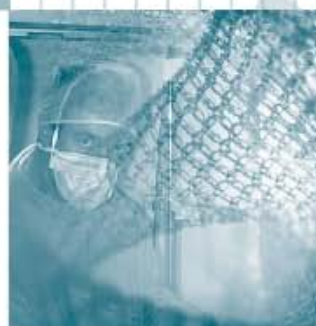


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**Design and construction of a portable kit
for the assessment of gait parameters
in daily rehabilitation**



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Design and construction of a portable kit for the assessment of gait parameters in daily rehabilitation

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Design and construction of a portable kit for the assessment of gait parameters in daily-rehabilitation.

Daniele Giansanti, Sandra Morelli, Giovanni Maccioni, Andrea Giordano, Federica Tamburella, Marco Molinari, Salvatore Silvestri, Sergio Calabrese, Velio Macellari, Mauro Grigioni
2010, 34 p. Rapporti ISTISAN 10/16

To daily monitor the gait improvement of a subject, during a motion exercise and in rehabilitation care, it is necessary the assessment at least of the path length, velocity, time duration, number of steps. The report presents a novel approach for gait monitoring based on: one step counter; two couples of photo-emitter-detectors (at the initial and final path position, to detect the start and the end of the gait exercise); one central unit for collecting and processing the telemetrically transmitted data; a software interface. A case study for one subject at the 1st level of the Tinetti test, showed the clinical feasibility. The kit can be used with different rehabilitation tools and ground rugosity. The kit shows the following advantages: a) very low costs, when compared to optoelectronic solutions or other portable solutions (such as LifeGait or GAITRite); b) very high accuracy, also for subjects with unbalance problems, when compared to other commercial solutions.

Key words: Wearable device; Step counter; Daily-rehabilitation

Istituto Superiore di Sanità

Progetto di un kit portatile per la misura di parametri del cammino nella riabilitazione giornaliera.

Daniele Giansanti, Sandra Morelli, Giovanni Maccioni, Andrea Giordano, Federica Tamburella, Marco Molinari, Salvatore Silvestri, Sergio Calabrese, Velio Macellari, Mauro Grigioni
2010, 34 p. Rapporti ISTISAN 10/16 (in inglese)

Per il monitoraggio quotidiano del miglioramento dell'andatura di un soggetto durante l'esecuzione di un compito motorio in fase riabilitativa è generalmente usata la valutazione quotidiana della distanza percorsa, della velocità, del tempo impiegato e del numero dei passi. È stato proposto un nuovo sistema, basato su: un contatore di passi; due coppie fotoemittitore/rivelatore (poste nella posizione iniziale e finale del percorso, per rilevare l'inizio e la conclusione dell'esercizio di riabilitazione); un'unità centrale per la memorizzazione e l'elaborazione dei dati trasmessi via telemetria; un'interfaccia software. Uno studio di un caso clinico su un soggetto al primo livello del Test di Tinetti ha mostrato le potenzialità cliniche del sistema proposto. Il sistema realizzato può essere usato con differenti strumenti di riabilitazione e diversa rugosità del suolo. Il sistema mostra i seguenti vantaggi: a) costi molto bassi, sia quando confrontato con soluzioni optoelettroniche che con altre soluzioni portatili (quali LifeGait e GAITRite); b) accuratezza molto elevata, anche per soggetti con problemi di disabilità, quando comparato a soluzioni commerciali.

Parole chiave: Dispositivo indossabile; Conta-passi; Riabilitazione giornaliera

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INTRODUCTION

The present study is focused on the daily-rehabilitation for gait in and outside the hospital; it is proposed in the form of a technical report provided within the mainframe of the Project “Messa a punto di nuove metodologie per la teleriabilitazione neuromotoria: linea di ricerca Sistema di rieducazione neuromotoria al cammino basato sull’uso di percorsi tra parallele o su scale” (31-1-2010) (Set-up of new methodologies for the neuromotory telerehabilitation: research neuromotory rehabilitation system based on the use of walkways on stairs or hand-rails) funded by the MURST (Italian Ministry of University and Scientific and Technological Research), today MIUR (Italian Ministry of Education, Universities and Research), and faces the sensorization aspects of mechanical tools used in rehabilitation. The global aim of this study is to allow to perform the rehabilitation exercise by using measurements obtained thanks to the sensorization of both the patient and the rehabilitation tools currently available. The paradigm of this project has arisen from the consideration that a patient, a physician, a therapist could benefitate from a sensorization of the used rehabilitation tools for furnishing easy-to-process performance parameters in order to carry out quantitative information useful for gait assessment and to be added to a qualitative interpretation of clinical exercise. The solution must be simple and useful to qualify the daily assessment of the physical and physiological conditions of a patient during a care therapy, whenever he performs its own trial (hospital, gym or physiotherapy rooms, home). The general idea is thus (as the focus is the gait) to design a simple kit alternative to the complex and expensive instruments already used, with an easy way to be interfaced or integrated within the clinical framework both for patient monitoring with their own aids and clinical reporting needs. The kit herein presented should be implemented on a variety of settings and particularly for extensive use.

The requirements for the proposed kit should be:

- *simplicity* (both to use and to set-up);
- *low-cost* (both in terms of prototype design and construction and maintenance);
- *adaptability* to different environmental characteristics (hospital, home, outside, etc.);
- *integrability* of different rehabilitation and measurement tools, from the hospital LAN to the WAN;
- *portability*.

The complete system presents itself as a portable set up, able to furnish useful parameters with a feedback for the patient, aimed at quantitatively assessing and constantly monitoring the progress in the rehabilitation care; the implementation must be simple to be integrated within the standard set of exercise provided by a clinical settings, generally a patient with wearable devices, using aids and supports, in a prescribed pathway. In this case the system can be used also in external areas, with specific path (curved, roughed, shaped surface, multipath) or internal areas (home room with or without obstacles) to allow monitoring of daily motion exercise.

Since the today most used parameters for motion rehabilitation and health promotion in the field of cardiology, obesity, diabetes care are the ones focused on the step counting and derived parameters such as distance, velocity, step length, we have proposed the methodology capable to reach the above mentioned objective based on a kit comprehending at least a step counter and a couple of photocells.

The system, as it is, can be also integrated into specialized contexts, in clinical or daily life environments, through wearable devices (e.g. activity monitor) or fixed instrumented appliances (devices for domotics).

Figure 1 elucidates the final scenario as it has been planned in the project: a Tele-Rehabilitation Government (TR-GOV) monitors the walkways sensorized with the portable kit.

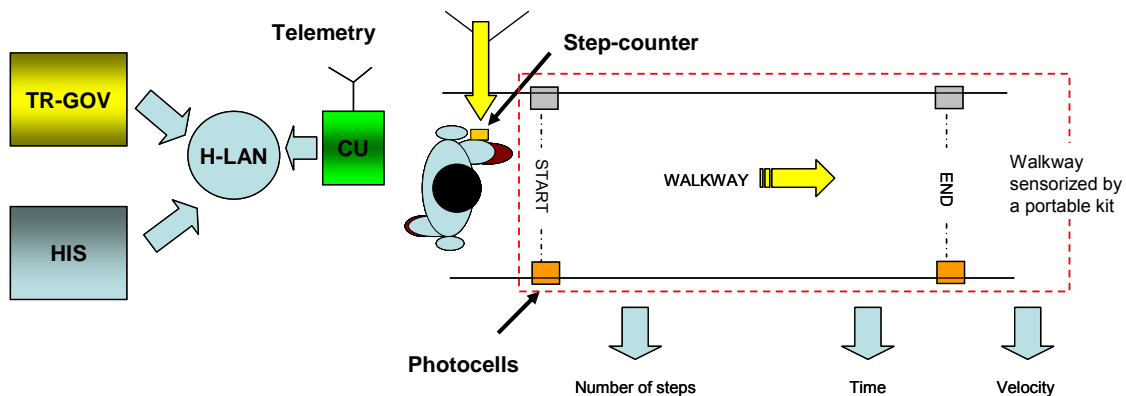


Figure 1. General block scheme of the rehabilitation and assessment system

The system allows the accessing to the virtual-directory of the patients available in the Hospital Information Server (HIS) for the clinical use.

Chapter 1 reviews technological solutions starting from the optoelectronic solutions up to emerging wearable and portable solutions.

Chapter 2 highlights mechanical tools used in rehabilitation potentially available for sensorization purposes

- assistive devices (canes, crutches, walkers);
- walkways (handrail systems, staircases, equipped walkways);
- ankle foot orthosis devices.
- Reciprocating-Gait-Orthosis (RGO) and Advanced Reciprocating-Gait-Orthosis (ARGO) (initially accompanied by a generalized clinical enthusiasm these tools are not widely used today; however they have been inserted in the review because their sensorization could lead to a renewed interest in these tools).

The chapter also shows a cane sensorization as an example that fulfils with the previously stated keywords of the project.

Chapter 3 faced thus in details the design of the portable kit in terms of the hardware and software components and the model used for the analysis.

The main specification is the environmental integration of the proposed portable kit with:

- every mechanical equipment used in rehabilitation (as those listed above);
- different grounds (ground rugosity, walled shaped, etc.).

This specification must allow the monitoring of the step counting and other relevant derived parameters such as distance, velocity, step length performed during a rehabilitation task on the basis of a predefined protocol and an assigned walkway of a defined length.

Chapter 4 described the validation of the portable kit and faced the future developments of the technologies. It also faces the integration in cascade of different rehabilitation walkways to constitute a complex and heterogeneous pathways. In the following we will thus use the term walkway in the case of a single rehabilitation path (eventually assisted or equipped); we will use the term pathway in the case of a multiple rehabilitation paths (eventually assisted or equipped) in cascade connection.

1. TECHNIQUES USED FOR FURNISHING GAIT PARAMETERS

This chapter reviews the most used techniques furnishing gait parameters. In particular the optoelectronic and wearable solutions based both on accelerometers and rate-gyroscopes have been analyzed with consideration to the gait parameters. Also other wearable methodologies have been considered such as the so called activity monitors and other easy portable solutions. Particular care has been devoted to the step counter devices in terms of evolution, medical perspectives and applications on subjects with motion disability. The chapter ends facing the limits of the solutions reviewed.

1.1. Optoelectronic and wearable sensor solutions based on both accelerometers and rate-gyroscopes

The traditional approach used in movement analysis is based on the measurement of the position of markers affixed on body segments by means of optoelectronic technology. The same result can be achieved by means of ultrasound technology based on ultrasound emitting point-markers and microphonic sensors. This approach is currently taken in literature as golden standard (1). The main limitation of this approach is the encumbrance and costs of the equipments. As an alternative to the optoelectronic/ultrasound approach in the seventies both Morris (2) and Padgaonkar (3) showed the potentiality of the accelerometric techniques. Padgaonkar used an analytical model aimed at reconstructing the 3-D Position and Orientation (P&O) of a body segment using the signal provided by nine accelerometers for the angle measurement of the rigid body (2), Morris used a model based on the signals from six accelerometers (3). A systematic analysis on the propagation of the measurement errors that may affect Accelerometer (ACC) sensors when estimating the 3-D P&O of a rigid body segment for the 6-ACC and the 9-ACC assembly has been reported in (4). In this paper the authors found no substantial advantages in using a 9-ACC system rather than a 6-ACC system and concluded that none of the two systems were suitable to reconstruct the P&O showing that the predominant cause of error was due to the accelerometers sensitivity to gravity. Other types of kinetic sensors, such as gyroscopes, rate-gyroscopes are reported in the literature. The gyroscopes and rate gyroscopes have the advantage of being insensitive to gravity, the last one seem to be suitable for the timely dependent applications but have the disadvantage of the thermal drift (5).

Miyazaky (6) used gyroscopes for monitoring joint angle rotations. Kataria and Abbas (7) used rate-gyroscopes for the estimation of body segment orientation. Williamson and Andrews (8) proposed a device for the measurement of the knee angle, composed of two clusters, each one arranged with one rate-gyroscope and a 2D accelerometer. Wu and Ladin (9) introduced a single sensor assembly consisting of one triaxial rate gyroscope, one triaxial accelerometer and multiple optoelectronic markers, and conducted an error analysis to determine the relative contribution of the accelerometer and of the rate gyroscope to the determination of the centre of mass acceleration in clinical applications. They found that in practical kinesiological applications, the addition of accelerometers or rate-gyroscopes can remarkably increase the accuracy in the determination of the segmental centre of mass acceleration. The brief literature analysis showed that while accelerometers and rate-gyroscopes alone or combined in a single

assembly were amply used the problem of the feasibility of the P&O trajectory reconstruction was not completely faced.

This is a basic problem, especially to date, thanks to the decreasing of production costs and to the increasing of the performance of the developing technologies we are assisting to a renovated interest to these systems.

This was demonstrated by the interest of the industry in manufacturing motion sensors based on inertial sensors, such as for example the MT9-A sensor (Xsens Motion Technologies, USA), which by means of three rate-gyroscopes, accelerometers and magnetic sensors reconstructs the orientation of the point in which it is affixed by means of a dedicated algorithm. In previous papers we have designed, constructed and validated a wearable sensor based on three accelerometer and three rate-gyroscopes (Figure 2) in motion analysis and demonstrated that they were principally suitable for the assessment of transitory tasks and not for example for the monitoring of gait properties (1, 10).

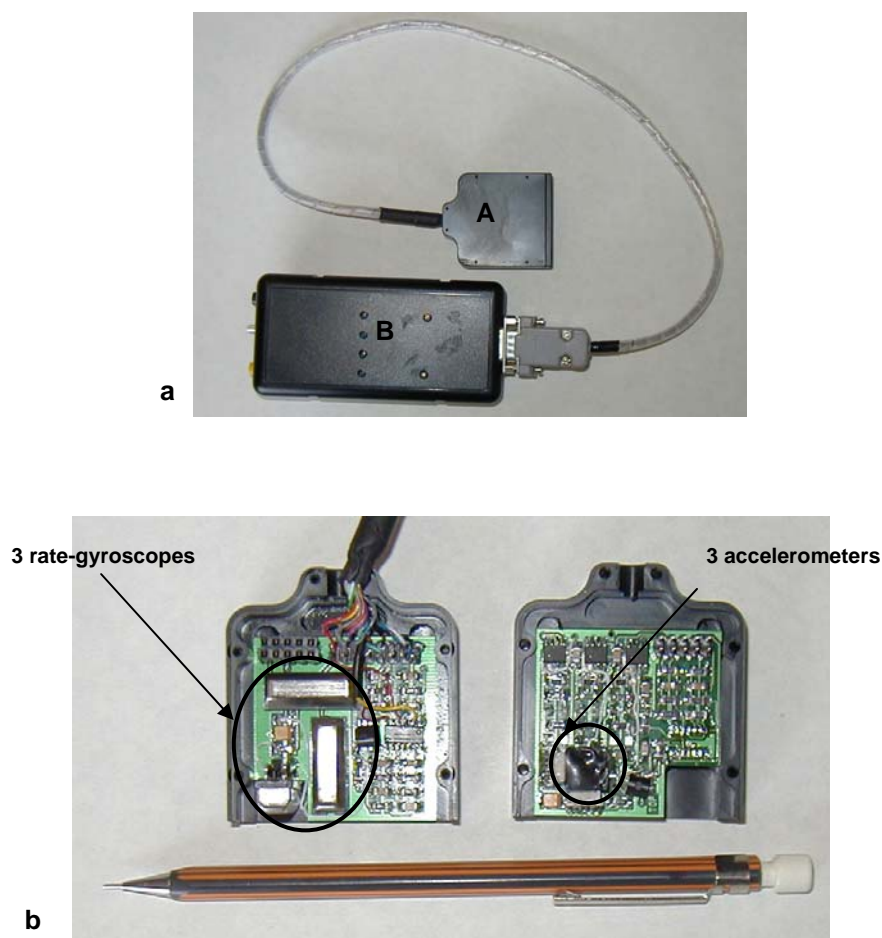


Figure 2. Example of wearable device with 3 accelerometers and 3 rate-gyroscopes:
(a) the part A is the case containing all sensors and the part B is the control unit;
(b) details of the assembly of the sensors' case

1.2. Solutions based on step counters

1.2.1. Step counters

The number of steps performed during a day changes with age. Figure 3 shows the mean value performed in a mean life in USA (11).

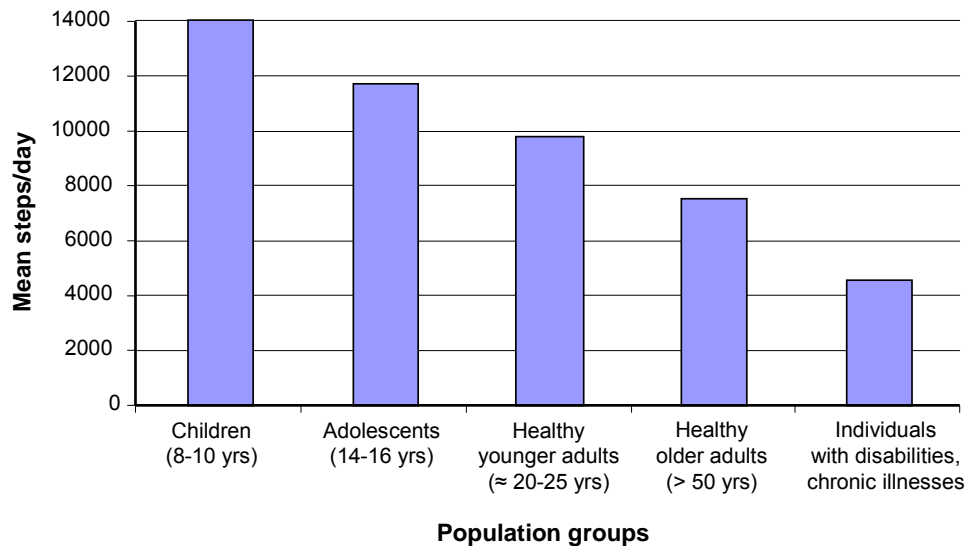


Figure 3. Expected values of steps/day for different populations

The number of steps is strictly correlated (at every age) to wellness and to the concept of promotion of health; this is the reason that deployed the widely spreading of interest of governmental institutions in the world (11) in the diffusion of the culture of step counters.

Although the invention of the step counters or pedometer is commonly attributed to U.S. President Thomas Jefferson, drawings from the 15th century indicate that Leonardo da Vinci was the conceptual originator (12). His early design appeared to be a gear-driven device with a pendulum arm to move back and forth with the swinging of the legs during walking. Thomas Jefferson did enjoy the use of a pedometer he purchased in France, and enthusiastically introduced it in America (13).

The step counter or pedometer is conceptually very simple in design and requires no additional software or expertise to access or interpret data. The internal mechanism of a pedometer typically includes a horizontal, spring suspended lever arm that moves up and down with normal ambulation (e.g., walking, running). An electrical circuit closes with each movement detected and an accumulated step count is displayed digitally on a feedback screen. Pedometers do not, however, record velocity of movement, restricting their use to measures of total accumulated steps/day, or accumulated steps taken over a specific time frame (e.g., during physical education class). Some of the newest pedometers count "time in activity". Pedometers with a time feature have a clock that starts with the initiation of stepping and stops with inactivity. We must await research findings to determine the value of this feature.

Pedometers display good agreement with accelerometers ($r=0.80-0.90$) (14-16), indicating that the two types of motion sensors measure approximately the same total accumulated daily activity. Accelerometers can be also used; the cost of accelerometers (\$ 50-400 per unit), costs for additional software and calibration hardware, and the associated demands of personnel expertise and time, make widespread use of accelerometers prohibitive outside the realm of research (17).

More and more, researchers are beginning to acknowledge that, in terms of practicality, pedometers offer the better solution for a low cost (\$ 10-30 per unit), objective monitoring tool that is accessible to both researchers and practitioners (14, 18-20). A common measurement tool and collection protocols would help bridge the gap between research and practice.

Most pedometers record and display movement as steps taken (a simple, raw or pure measure of ambulatory activity). Some have also features to estimate expended energy (kcal), user must manually enter a number of variables (including any manufacturer-defined combination of gender, stride length, weight and/or age) into the pedometer's program in order to obtain a running estimate of caloric expenditure or distance travelled. The manufacturer's actual mathematical formula used is usually proprietary, thus it is not readily available for public or scientific scrutiny. Further, this process of manipulating the raw step data could introduce possible error.

1.2.2. Step counters on subjects with motion unbalance problems

The step counting is an important index of motion activity and it is currently used in the prevention of the obesity, in applications for the prevention of cardiovascular problems, in diabetes care and more in general in motion rehabilitation (21-26); however, there are still opened problems about their accuracy.

Schneider *et al.* (24) tested 13 models of pedometers on healthy subjects, performing a high number of steps, and had shown that many of them underestimated (of about 25%) or overestimated (of about 45%) the number of steps. Keenan and Wilhelm (25) enlightened that pedometers could be confounded by movement style, as in the case of the Parkinson's disease and found that for this specific pathology accelerometers performed better. We have also investigated the feasibility of the integration with elaborators of the same commercial solutions analysed by Schneider *et al.* (24) and found that many of them (especially the cheapest ones) were closed systems, not permitting the integration with elaborators for the data-uploading/downloading, basic aspect for telemonitoring applications in telemedicine.

There is a great interest to investigate the performance of pedometers on subjects with a high degree of unbalance caused by different diseases. In particular there are mainly two reasons to study subjects with unbalance disease. The first reason is that, for these subjects, commercial devices do not show suitable performances because are confounded by the motion style (25). The second reason is correlated to the aspect that for these subjects with a high degree of unbalance it is not possible to test pedometers for an adequate (of about 10000) number of steps as in the case of healthy subjects (27). Subjects with the Parkinson's disease, for example, could usually perform only some hundreds of steps a day. This second reason means thus the need of a highly specific design to investigate the performances of step counters system on these subjects. For these subjects, for example, it is important to appreciate also very little improvements. In previous papers we have investigated novels solutions in step counters design and constructions.

1.2.3. Two examples of novel step counters for subjects with unbalance problems

In previous papers we have investigated novel solutions in step counters design and constructions that we report here by means of two examples. The first solution is based on the sensorization of commercial and/or made in orthopaedic laboratory Codivilla springs (28).

A Codivilla spring with sensors has been proposed to obtain a Sensorized COdivilla SPring (SECOSP) for tele-monitoring/daily-rehabilitation in order to track step count. The system is based on two Force Sensing Resistors (FSRs) (CP0152 by Interlink, USA) affixed in the plantar area of the Codivilla spring (foot-tip and heel), and a wearable unit with the conditioning electronics and a μP PIC 16F877 microprocessor (Microchip, USA). While ambulating, the two FSRs detect the pressure of the foot-tip and the heel. This information is used by the PIC to increment the step count based on an algorithm. The system is calibrated before being used. The calibration is obtained by three consecutive trials of loading of the heel and the foot-tip of the foot with the body weight. The algorithm calculates the step count by recognizing the sequence foot-heel to foot-tip, which is used to increment the step count. When the subject is still and standing, both FSRs are active, and this information is not used by the algorithm to increment the step count. Small oscillations are eliminated using thresholds obtained during calibration. When the subject is sitting, the pressure is not sufficient to activate the calibrated FSRs which run as foot-switches. The power-supply is assured by 4 NI-MH rechargeable batteries with 3.6 V and capacity $I = 160 \text{ mA} \times \text{h}$ (Extracell, USA). Figure 4 shows the electronic components of the SECOSP.

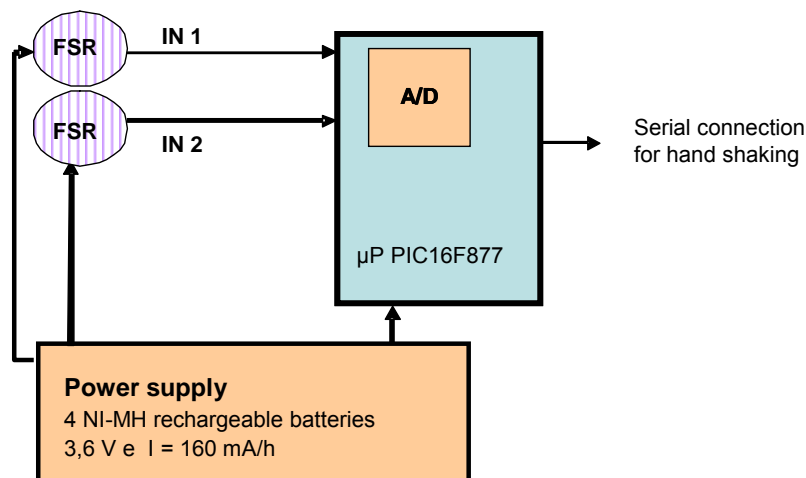


Figure 4. SECOSP electronic components

Figures 5 and 6 show respectively FSRs affixation in the SECOSP and the final assembly.

The second example is appropriated for subjects with complex models of walking (not fluid) caused by a high degree unbalance. The component of the system used to monitor the step count at this stage is a Gastrocnemius Expansion Measurement Unit (GEMU) (29). Commercial pedometers fail to furnish suitable performances in subjects with a high motion disability (caused by their more complex model of gait).

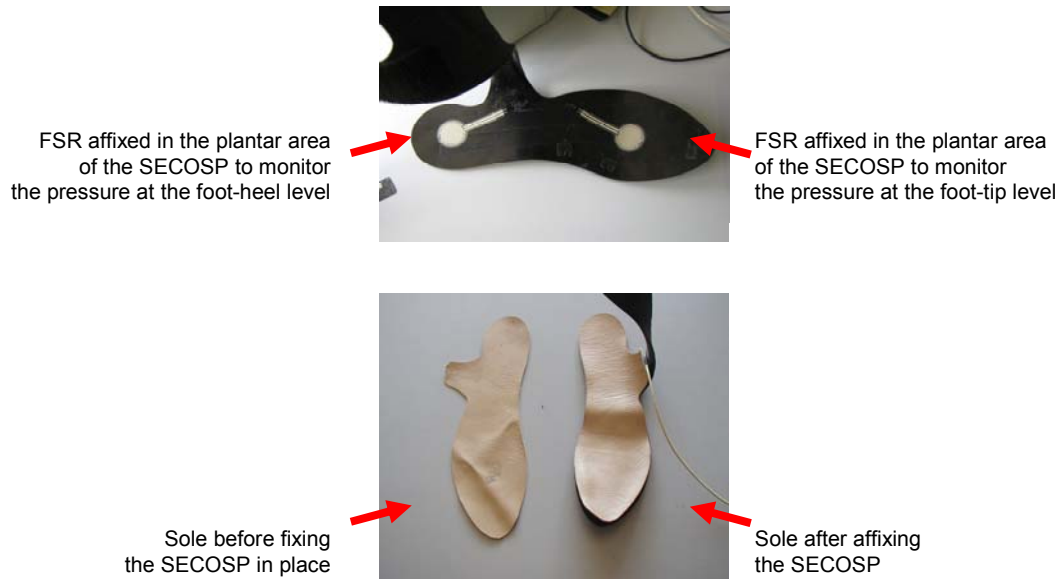


Figure 5. Details of the affixation of the couple of the FSRs at the level of the plantar area of the SECOSP



Figure 6. Final assembly of the SECOSP

Furthermore, in most cases, commercial pedometers are not easily integrable to a telemedicine system designed for daily-rehabilitation. A full description of the GEMU can be found in (29) where it is available the description of a full telemetric version of the unit. For the sake of clarity, we report here a brief description. The GEMU consists of a wearable device sensor with a belt (Figure 7) to monitor the force exerted by the gastrocnemius against the device sensor during muscular expansion.



Figure 7. GEMU with belt

At the fixation point, we refer to the horizontal slice delineated by the vertex of the pit between the two gastrocnemius muscles (Figure 8). The wearable system is based on a FSR CP0152 (Interlink, USA) and a microcontroller PIC μ P PIC 16F877 (Microchip, USA). The μ P is programmed in order to facilitate step counting (Figure 9). Once a variation of pressure is detected by the FSR, the step count is incremented by a trigger mechanism based on a threshold (50% of the supervised maximal signal excursion mediated on three consecutive steps). The power is supplied by three Extracell NI-MH rechargeable batteries that provide 3.6 V and a capacity $I=160 \text{ mA} \times \text{h}$.

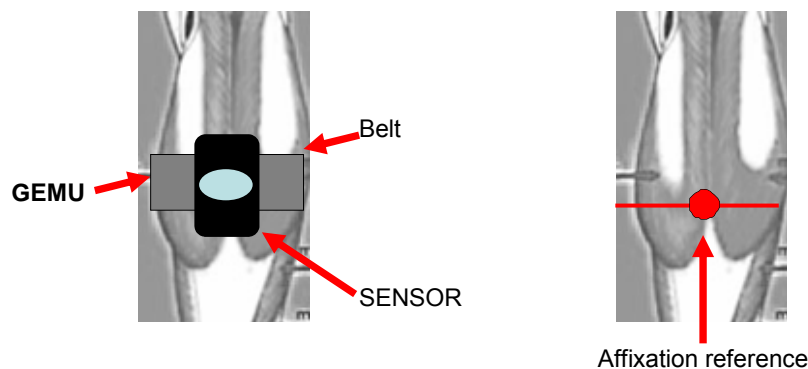


Figure 8. Affixation of a GEMU

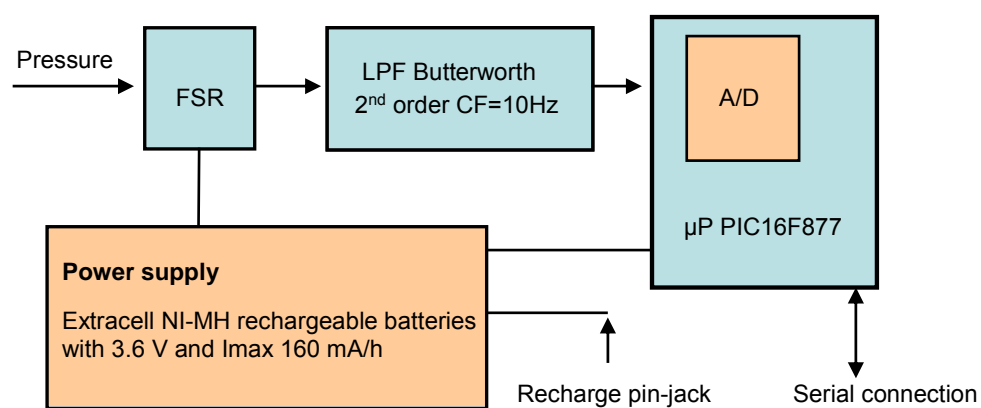


Figure 9. Electronic components of GEMU

Both GEMU and SECOSP once validated with a gold standard showed high performances when compared to an accelerometer based solution (28-29).

1.3. Solutions based on wearable systems for the activity monitor

A person while activating muscles for the control of motion and postures can change and configure a high number of positions as elucidated by posture and motion sciences. The monitoring of the type of position is an important target in motion daily analysis; however, it obviously should be limited to a finite category of motion tasks such as gait, sitting, standing, lying; from the monitoring of these tasks, it is possible to determine the amount of daily activity and estimate the energy expenditure. The ability to accurately monitor the amount of daily physical activity is particularly important in older adults as regular physical activity is associated with both physical and mental health (30-34) and is a primary determinant of quality of life. The use of accelerometers to objectively measure body movement is recorded as early as the 1970s (35).

Veltink *et al.* (36, 37) investigated the feasibility of detecting postures and movements using accelerometers, and five healthy subjects followed a strict and supervised activity protocol of sitting, standing, lying and walking at various speeds. Veltink concluded that using a minimum of two accelerometers, one mounted on the trunk and another mounted on the upper leg, was sufficient to distinguish postures from movements and to discriminate between the postures of sitting, standing and lying. Veltink used posture thresholds to identify which posture a person had but did not describe the posture threshold method or the values used. Following Veltink's work, other researchers developed similar accelerometer-based mobility monitoring systems (37-52).

Like Veltink, Busser *et al.* (39), Uiterwaal *et al.* (49) and Aminian *et al.* (38) also used predetermined fixed threshold levels to define each activity classification. These monitors used trunk accelerometers and a single thigh accelerometer and activities were classified based on an analysis of the mean and deviation of the acceleration signal. However, in these cases, the posture threshold method or values used were not described in detail. Lyons *et al.* in (53) proposed an accelerometer-based mobility monitoring technique, which can distinguish between static and dynamic activities and can detect the basic postures of sitting, standing and lying. The technique allows thresholds for these postures to be set and two different posture threshold methods are described: mid-point and "best estimate". The evaluation of the technique was carried out over the long-term (>29 h) in an uncontrolled environment and the method used to carry out the evaluation was described in detail. The two different posture thresholding methods were tested on long-term mobility data from one older adult subject. The subject did not have to follow a specific activity protocol during the recording period (4 days) and was shadowed by an observer in order to evaluate the accuracy of this technique. The monitoring hardware consisted of two accelerometer devices, one on the trunk and the other on the thigh and a pocket-sized ambulatory data-logger. Applying "best estimate" thresholding, as opposed to mid-point thresholding, improved sitting-detection accuracy by 18%, to 93% and lying detection accuracy by 5%, to 84%.

Referring to Lyons' experience (53), an activity monitoring solution is based on a wearable kit (based for example on accelerometers sensors) and properly designed algorithm to assess the different motion tasks in an interval of time (Figure 10). Many commercial solutions are today available designed according the experience shown in literature.

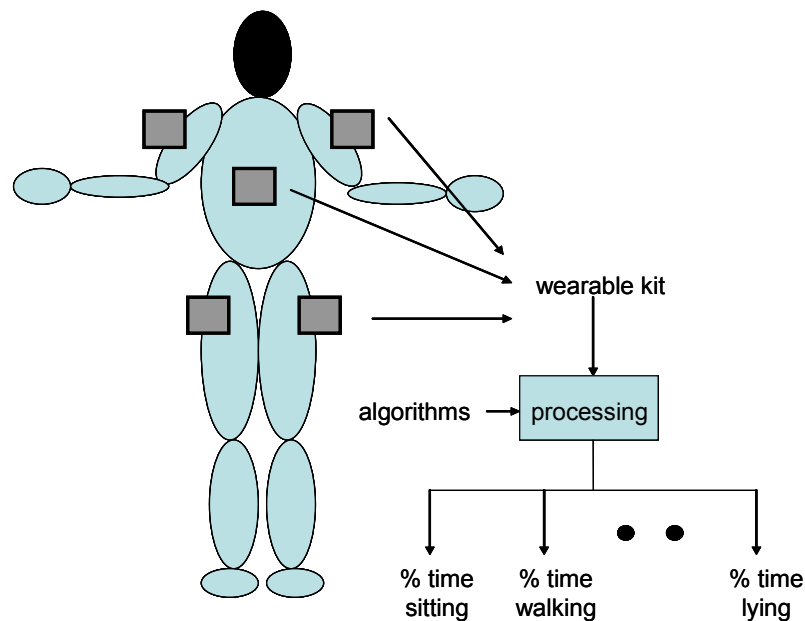


Figure 10. Activity monitoring technique

All the showed solutions are more adequate (29) for the assessment of a percentage of a motion task than other characteristics; more specifically they are not appropriate for the step counting in subjects with problems of unbalance because they have been planned with other objectives; also the costs are not right for a high diffusion of the technology. A not exhaustive example is LifeGait (www.portablegaitlab.com/default.asp): the performances and the acceptance of this system recently commercially available are expected to be shown by the laboratories of motion analysis for applications of pattern recognition and/or classification.

1.4. Portable walkway systems: the GAITRite

There is a lot of portable walkway systems that could be cited, however the description would need a special review out from the aims of this report. We will thus limit to one of the most used systems in motion laboratories, very frequently cited in international meetings, i.e. the GAITRite system.

The GAITRite system (<http://www.gaitrite.com/>) automates measuring temporal (timing) and spatial (distance) gait parameters by means of an electronic walkway connected to the serial port of a Windows® 95/98/ME personal computer.

The standard GAITRite electronic walkway contains six sensor pads encapsulated in a roll up carpet to produce an active area 61 cm wide and 366 cm long. In this arrangement the active area is a grid, 48 sensors by 288 sensors placed on 1.27 cm centres, totalling 13824 sensors. The walkway is portable, can be laid over any flat surface, requires minimal setup and test time, and needs no placement of any device on the patient.

As the patient ambulates across the walkway, the system captures the geometry and the relative arrangement of each footfall as a function of time. The application software controls the functionality of the walkway, processes the raw data into footfall patterns, and computes the

temporal (timing) and spatial (distance) parameters. The software's relational database stores tests individually under each patient, and supports a variety of reports and analyses. Testing patients with or without shoes, including those patients using assistive devices and ambulatory aids such as: crutches, walkers, or canes. In addition, testing patients pre- and post-treatment is quickly, and easily performed when utilizing this versatile and ingenious measurement tool.

The system is capable to produce temporal timing and spatial parameters:

– *Temporal timing parameters*

- *Step time*

It is the time elapsed from the First Contact of one foot to the First Contact of the opposite foot.

- *Gait cycle*

It is the elapsed time between the First Contact of two consecutive footfalls of the same foot.

- *Ambulation time*

It is the time elapsed between the First Contacts of the first and the last footfalls.

- *Velocity*

It is obtained after dividing the Distance by the Ambulation time.

- *Mean normalized velocity*

It is obtained after dividing the Velocity by the Average Leg Length and it is expressed in Leg Length per second (LL/s). The Average Leg Length is computed $(\text{left leg length} + \text{right leg length})/2$.

- *Single support time*

It is the time elapsed between the Last Contact of the current footfall to the First Contact of the next footfall of the same foot. This is equal to the Swing time of the opposite foot.

- *Double support time*

It is the time elapsed between First Contact of the current footfall and the Last Contact of the previous footfall, added to the time elapsed between the Last Contact of the current footfall and the First Contact of the next footfall.

- *Stance time*

It is the time elapsed between the First Contact and the Last Contact of two consecutive footfalls on the same foot. It is also presented as a percentage of the *Gait cycle* of the same foot.

- *Swing time*

It is the time elapsed between the Last Contact of the current footfall to the First Contact of the next footfall on the same foot. It is also presented as a percentage of the *Gait cycle* of the same foot. The Swing Time is equal to the Single support time of the opposite foot.

– *Spatial distance parameters*

- *Step length*

It is measured on the horizontal axis of the walkway from the heel point of the current footfall to the heel point of the previous footfall on the opposite foot. The step length can be a negative value if the patient fails to bring the landing foot heel point forward of the stationary foot heel point.

- *Stride length*
It is measured on the line of progression between the heel points of two consecutive footfalls of the same foot (left to left, right to right).
- *Step/extremity ratio*
It is Step Length divided by the Leg Length of the same leg.
- *Toe in/Toe out*
It is the angle between the line of progression and the line connecting the heel point to the forward point of the footfall. This angle is reported positive for Toe out and negative for Toe in.
- *H-H base of support*
It is the perpendicular distance from heel point of one footfall to the line of progression of the opposite foot.
- *Distance*
It is measured on the horizontal axis from the heel point of the first footfall to the heel point of the last footfall.

1.5. Considerations

An overview on the solutions available to obtain parameters relevant to the gait and useful to be integrated in the design of rehabilitation walkways has been given together with the relevant emerging limits. In particular, the methodologies up to now available are:

- very expensive and thus not adequate for the daily monitoring (as the optoelectronic or ultrasound based methodologies).
- mainly suitable for the monitoring of the duration in a percentage of time of a motion task (as the activity monitoring techniques).
- mainly suitable for the assessment of transitory tasks (as the wearable systems based on accelerometers and rate-gyroscopes).
- not adequate to be integrated with a walkway (staircases, slides, etc) or to assess the performance on a ground with different rugosity (as many portable walkway systems).
- not appropriate for the monitoring of subjects with unbalance as in the case of the Parkinson's disease.

2. MECHANICAL TOOLS USED IN REHABILITATION

The chapter reviews the mechanical tools used in Rehabilitation with the potentialities to be integrated in the sensorization process.

2.1. Aids for assisted walkways

The assignment of a proper rehabilitation program in gait-rehabilitation and the choice of the assisting devices and supports is a function of the degree of the unbalance of the patient, assessed by appropriate tests, coming from the databases of medical knowledge. This process involves at different levels the medical therapist and the physician, who can strictly and continuously interact for assuring the most appropriate rehabilitation path and the best patient progress. Figure 11 schematically depicts a possible process of the assignment of a tool for rehabilitation. The process involves the medical therapist and the physician; they assess the degree of unbalance using properly designed tests coming from a on a database of tests of unbalance used in motion ability assessment. Usually these partially quantitative tests assign a score. On the basis of the reached scores, an appropriate rehabilitation walkway or aid is thus assigned. For assessing the degree of the unbalance, different tests may be adopted. One of the most used methods for investigating the fall tendency or motion unbalance are based on the pure qualitative or partially qualitative observation. The most used method is the Tinetti test (54).

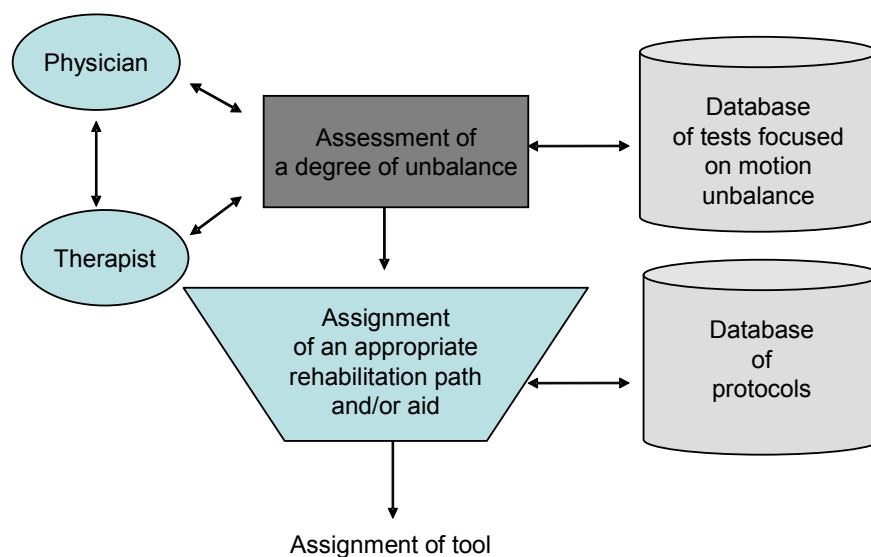


Figure 11. Process of assignment of rehabilitation path and/or aid

This test consists of a subministration of a series of motion tasks to a subject and on a scoring methodology based on the medical observation of the execution of these tasks. By means of the Tinetti test it is possible to categorize the subjects into four classes, with increasing

unbalance problems and fall-risk on unbalance. Once assessed the right motion unbalance of the patient and designed the appropriate rehabilitation program, different instruments, both devices and supports, are chosen for mainly assisting the patient in its walking. Different instruments, such as assistive devices and/or support walkways, are today used for the assisted walking in the elderly and/or disable peoples (55). Assistive devices to improve independence in the balance and in the walking (e.g. canes, crutches, walkers) are used to provide an extension of the upper extremities to help transmit body weight and provide support for the patient.

Besides, some walkways (e.g. handrail systems, staircases, platforms equipped or not with obstacles) are arranged in different manner, generally in laboratories, for creating suitable walking paths for rehabilitation/training in disable/elderly subjects. In some cases the patient is walking-assisted in scenarios reducing the gravity of the body, both using special supports for the body weight relief and/or environment decreasing the gravity (i.e. swimming pool). In addition, in some rehabilitation programmes, orthosis for the lower limbs are temporarily used in order to sustain the impaired leg, like as the AFO (Ankle Foot Orthosis) devices and the RGO (Reciprocating Gait Orthosis) or the ARGO (Advanced Reciprocating Gait Orthosis).

2.2. Assistive devices

The proper use of the assistive devices, also common referred as ambulatory aids, depends on the degree of the impairment of the subject. Generally, the more disabled the individual is, the greater the complexity required in the walking device.

In general, an assistive device helps to:

- redistribute and unload a weight-bearing lower limb;
- improve balance;
- reduce lower limb pain;
- provide sensory feedback.

The most common assistive devices (associated to different impairments) that aid in ambulation and mobility are as follows:

- *Canes*
 - single-point cane
(for mildly impaired balance/stability or unilateral lower limb pain/mild weakness)
 - quad cane (narrow or wide base)
(for moderate impaired balance/stability)
 - walk cane (hemiwalker)
(moderate-to-severe unilateral weakness/hemiplegia)
- *Walkers*
 - bilateral crutches or walker (pickup or front-wheeled)
(for bilateral lower extremity weakness/paralysis)
 - walker (pickup or front-wheeled)
(for severely impaired stability)
 - stair-climbing walker
(for difficulty in climbing stairs).

Many assistive devices for the walking could be sensorized for acquiring the most significant walking parameters, in order to carry out a more complete assessment of the posture and balance in ageing and disease and also for monitoring more efficiently the rehabilitation progress.

2.2.1. Example of cane sensorization

Moran *et al.* (56) showed the potentialities of the cane sensorization. They integrated an electronic system with a commercial cane in order to measure the axial cane forces while walking and furnish biofeedback information to both a subject and a physician. An audio alarm can be programmed to sound within adjustable limits according to the cane load magnitude. Cane load sensors provide input to a portable data acquisition system which is designed to perform analog to digital conversion and store the force data using a precalibrated look-up table. The audio alarm is controlled on the basis of sensor look-up table values with high and low thresholds set as a ratio of subject weight. High-speed CMOS (Complementary Metal-Oxide Semiconductor) technology and the Motorola 68HC11 microprocessor were used in the design to limit power consumption. Ten normal adult subjects were used to evaluate the system. Measurements were made using the system with and without audio feedback. The system is suggested for further use in the characterization of feedback on cane and lower extremity load metrics.

The authors retained that a more simple approach, to give a reliable evidence of cane use with feedback to both patient and physician, could be realized simply by using the audio feedback together with a pulse train related to the length of ground pressure, without load information as a first simple aid to the interpretation of the walking model avoiding the high amount of electronics and calibration needs for a internal/external environmental use of a simple portable kit. The information provided by this simple solution fits with the aim of the project to have a set of parameters to evaluate level of ability reached.

2.3. Assisted walkways

In the following we report a summary of the most common walkways used in laboratories in the assisted walking:

- *Handrail systems*

The most common handrail systems are of two types: 1) a system of a pair of parallel bars directly connected to the ground, to support the patient walking to the ground; 2) a system of a pair of parallel bars and a platform, where the patient walks. Both systems have the possibility of regulating the high of the handrail; the minimum length of the walkway is 2 meters and the systems of type 2 could be modular, in order to realize a longer walkway. If needed, a trolley to sustain the patient during the walking can be applied to the handrail systems.

- *Staircases*

There are platforms at different high that can be arranged in order to realize staircases in different configuration: at one, two or three ramps arranged by normal steps or by slide. These modular staircases with adjustable handrail and parallels bars could be adapted both to children and adult subjects. The staircases can be combined with ramps and platforms with high or low steps, offering thus the possibility to modify the difficulty of the therapeutic-rehabilitative exercise during the execution.

- *Equipped walkways*

Different objects can be placed in the platform of the handrail systems to create different types of rehabilitation walkways. The objects can be of different material (e.g. plastic

bags filled of sand or PVC granules), shape (e.g. concave/convex modules) and surface (e.g. modules with lines or hemispheres) for offering different difficulty and rugosity. Moreover the platform of the handrail system can be equipped with obstacles for incrementing the complexity of the walking exercise.

2.4. Ankle foot orthosis devices

An Ankle Foot Orthosis (AFO) is a hard brace worn on the lower leg to support the ankle and foot junction during walking furnishing elastic propulsion for those subjects with neuromuscular pathologies affecting the normal gait.

People suffering from a foot drop, or inability to raise the foot, often wear an ankle foot orthosis to assist clearing the toes during walking. In order to contain the foot in the functional position, it is used various orthoses, such as peroneal springs, Codivilla springs, and others, which are inserted in ordinary shoes and are fixed to the leg of the patient by means of appropriately provided closure systems, for example of the Velcro type.

An example of these AFO devices, used in case of paralysis of the extensor dorsal muscles, is the Codivilla spring for supporting the dangling foot. It is constituted by a steel foil vertically inserted in the posterior of the shoe and placed along the back calf, until the posterior convexity of the leg.

2.5. Recipro-gait orthosis and advanced recipro-gait orthosis

The RGO and its ARGO evolution (57) are orthoses designed in order to allow the gait with alternated footstep also to the paraplegic patients. This is possible because the hip joints are in block position only for the time necessary to the patient to catch up the erected position. The unblocking of the hip joints allows the alternated footstep, with the legs advancing in oscillation singularly and alternatively. Moreover the two hinges of these devices are connected through metallic cables in order to avoid a contemporary inferior limbs flexo-extension, in manner that to each joint hip extension corresponds the flexion of the contralateral hip joint and vice versa. Naturally the walking can only occur with the aid of the crutches or the walker, while the erected position can be maintained without other aids.

In order to optimize the deambulatory technique and to get better the aesthetic and dressing characteristics, various improvements have been carried out on the RGO, leading to the realization of other versions of orthosis, such as the ARGO. The mainly innovative element of this orthosis when compared to the previous one is the insertion of a pneumatic system to the level of the knee for supplying part of the required energy to reach the erected position. Moreover the structure of ARGO results lighter than the RGO.

The RGO or the ARGO, also remaining the only orthoses that allow the independent deambulation in the paraplegic patients, result no more used due to their encumbrance, weight and no pleasant aesthetic. For this reason many patients prefer to use the wheelchairs.

3. DESIGN AND CONSTRUCTION OF THE PROPOSED PORTABLE KIT

The methodological flow followed to design and construct the portable kit consisted of:

- definition of the architecture of the clinical system and modelling parameters.
- design and construction of the hardware solution;
- design and construction of the software interface.

3.1. Definition of the architecture of the clinical system and modelling parameters

The aims of the entire system designed at ISS are:

- monitoring the steps performed during a rehabilitation task on the basis of a predefined protocol and on an assigned walkway of a defined length and thus the determination of all the relevant parameters of velocity and time (Figure 12);
- pre-processing this information according to a model to obtain other useful gait parameters;
- formatting this information according to a textual file easy to send to a communication centre for post-processing purposes and archiving according to a database.

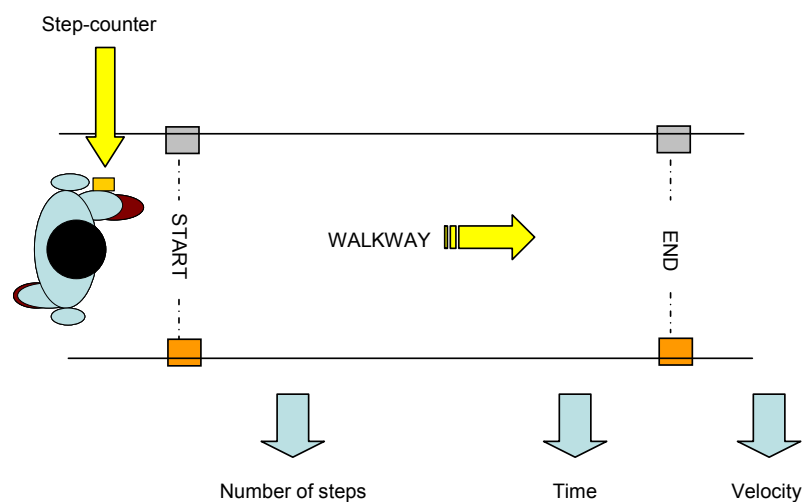


Figure 12. Monitoring of the steps during a rehabilitation task in an assigned walkway

The complete architecture (hardware and software) of the system is as follows: the hardware unit allows the telemetric acquisition of the row data from the subjects; the row data are sent by means of an acquisition card (NI-DAQ USB-6008 by National Instruments, USA) connected by USB connection to a PC; a software interface, designed by means of LabVIEW 8.2 (National Instruments, USA) pre-process the information in the PC according to a model, rearrange it in an

ASCII textual file easy to manage and upload it by means of a LAN or WAN connection for the final post-processing and archiving.

3.2. Design and construction of the hardware solution

The hardware solution is based on the following components (Figure 13):

- step counter;
- detectors positioned at the initial and final position of the path, to detect the start and the end of the gait exercise;
- one central unit for the collection of the row data.

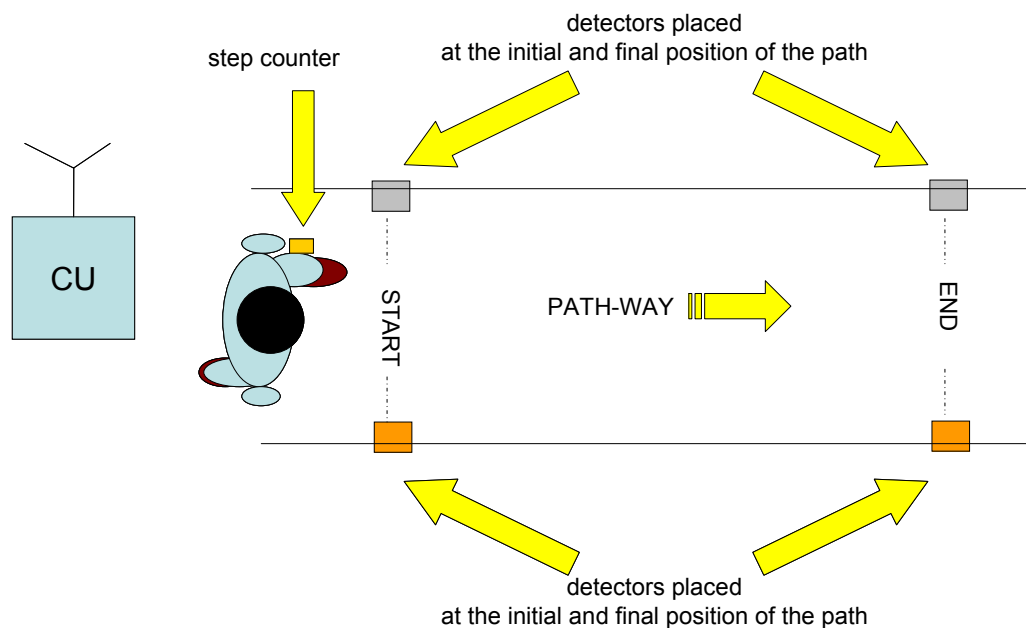


Figure 13. Components of the hardware solution in details

3.2.1. Step counter

Different step counters can be used in the hardware solutions such as sensors based on: accelerometers; FSR embedded in a sole; FSR affixed for monitoring the expansion of the calf (the cited GEMU). The step counter used in this bench test is based on a GEMU. In brief, the wearable system consists of a device sensor embedded in a belt to monitor the pressure variation during the muscular expansion at the calf level. The device sensor is based on a FSR (CP0152 by Interlink, USA) and the microprocessor (μ P PIC 16F877 by Microchip, USA). The μ P is programmed in order to allow the step counting. Once a variation of pressure is detected by the FSR at the level of the gastrocnemius, the step counting is incremented by a trigger mechanism based on a threshold. The device is telemetrically connected to a central unit for the integration

to the WAN/LAN by means of a couple of telemetric receiver-and-transmitter (RX-TX) devices XTR-434H (Aur^oel, USA), which works at 433.92 MHz. The connection to a central unit is also used for recharging this wearable component.

3.2.2. Detectors of the path

The assessment of the start and final position of the path is basic to determine the duration (in time) of the exercise. This timing also acts as a temporal mask for the step counting. Only the steps actually monitored, during this timing interval are used to increment the total number of steps. Two couples of photo-emitter/detectors PEM10D (Wellean, UK) and relevant mirrors have been used to be positioned respectively at the starting and the ending of the walkway on two couples of tripods.

3.2.3. Central unit

The central unit (Figure 14) is telemetrically connected with the other components of the equipment. It also provides the following functions:

1. assessment in real time of the number of steps;
2. recharging of the step counter;
3. elaboration of the row data (T_{start} , T_{stop} , Number of steps);
4. biofeedback representation of the data;
5. connection to a Pc to send the parameters T_{start} , T_{stop} , Number of steps.



Figure 14. The central unit of the proposed system

3.2.4. Parameters from the portable kit

Starting from the number of steps N_{step} during the masked interval of time and the $\Delta t = T_{start} - T_{stop}$ interval of time associated to the length of the rehabilitation walkway and the spatial distance d it is possible to obtain:

- the exact mean velocity V_m [1], knowing the distance d and the interval of time Δt masking the exercise:

$$V_m = \frac{d}{\Delta t} \quad [1]$$

- the approximated step length $l_{step \text{ measured}}$ [2]:

$$l_{step} = \frac{d}{N_{step}} \quad [2]$$

and thus

- as limits of errors; the superior and inferior ranges of step length $l_{step-sup}$ and $l_{step-inf}$ [3, 4] obtained in the case of the maximal range of errors at the moment of the end of the exercise, in consideration of a ± 0.5 step:

$$l_{step-sup} = \frac{d}{N_{step} + 0.5} \quad [3]$$

$$l_{step-inf} = \frac{d}{N_{step} - 0.5} \quad [4]$$

As a numerical example, in the case of a walkway of 10 m and in the case of $N_{step} = 15$ [5], from equation (Eq. 2-5) it is respectively obtained $l_{step} = 0.666$; $l_{step-sup} = 0.689$; $l_{step-inf} = 0.645$. This result shows that also in the case of the maximal errors at the end of exercise the estimated length of steps differs in a value about 2×10^{-2} m i.e the contour of a shoe. However repeated measures associated to statistical models gives satisfactory results as enlighten in the following.

$$l_{step-(sup/inf)} = \frac{10}{15 \pm 0.5} \quad [5]$$

The processing according to the equation [1-4] is obtained by the following described software interface.

3.3. Design and construction of the software interface

A software program was developed for monitoring the walkway of patients wearing the GEMU device and storing the parameters in text ASCII files containing also the patients' name and the length of the walkway. The program was developed in the LabVIEW programming language (*Laboratory Virtual Instrument Engineering Workbench*) version 8.2.

LabVIEW is a graphical programming language that uses icons instead of lines of text to build programs. A program generated with LabVIEW is named VI, or Virtual Instrument, to indicate a LabVIEW program imitating a physical instrument. The instruction and functions are represented by graphical objects, and the object representing a function is provided with terminals of input and output and correspond to a VI program. The subroutines created by the programmer are also generated as VIs program, with proper input and output terminals, and placed in the main VI and for this, they are denoted SUBVIs. Figure 15 shows examples of an instruction and a predefined function.

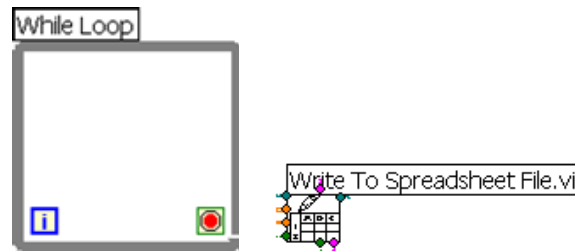


Figure 15. “While Loop” instruction on the left and the “Write To Spreadsheet File” function in the right

A LabVIEW VI consists of two windows:

- *Front panel*: constituted the user interface and contains objects representing the inputs/outputs parameters of the VI program (like as controls, indicators, charts) and other useful for the control of the execution of the program (like as buttons, LED). In some ways, the Front panel is similar to the Front panel of a physical instrument.
- *Block diagram*: constituted the “source code” of the program, represented by graphical functions linked by means of wires. This graphical source code is also known as G code or block diagram code. In some ways, the block diagram is similar to a flowchart.

Figure 16 shows the two windows (Front panel and Block diagram) of an empty VI.

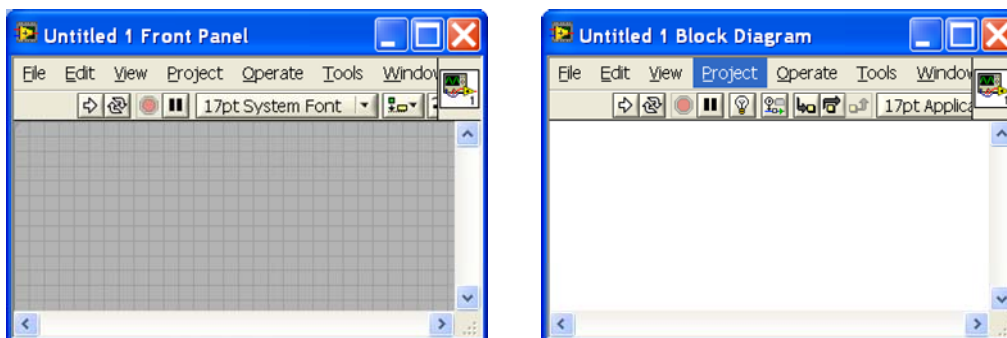


Figure 16. The two windows of the VI programs: the “Front Panel” on the left and the “Block Diagram” on the right

The developed program uses a digital-analog acquisition card (DAQ USB-6008) for acquiring signals coming from the central-unit to monitor the walking. The NI-DAQ USB-6008 provides connection to eight Analog Input (AI) channels (AI resolution: 12 bits differential, 11 bits single-ended), two Analog Output (AO) channels, 12 Digital Input/Output (DIO) channels, and a 32-bit counter with a full-speed USB interface. The NI-DAQ is used for acquiring the (digital) signals from the two photocells placed in the walkway for marking the start and stop of the patients’ walking. Further, the DAQ board acquires the number of the steps: the digital signal coming from the central-unit. In the control software application, for each walking trial of a patient, when the signal of the “start photocell” becomes high, a timer starts and it is stopped when the signal of the “stop photocell” becomes high: the number of steps is counted and the timer measures the time of the walking. At the end of the walking, the program, considering the length and time of the walkway and the number of steps, computes other parameters described in the following and stores the data in the text file.

3.3.1. Program structure

The interface of the control program is constituted by two Front panels of interface for the user. The first Front Panel (Figure 17), belonging to the main program named “GEMU_pathway.vi”, contains three control buttons:

- NEW SESSION button: to begin a session of measurement
- CLOSE button: to close the main application
- HELP [F5] button: to open a window containing a descriptive help of the application.

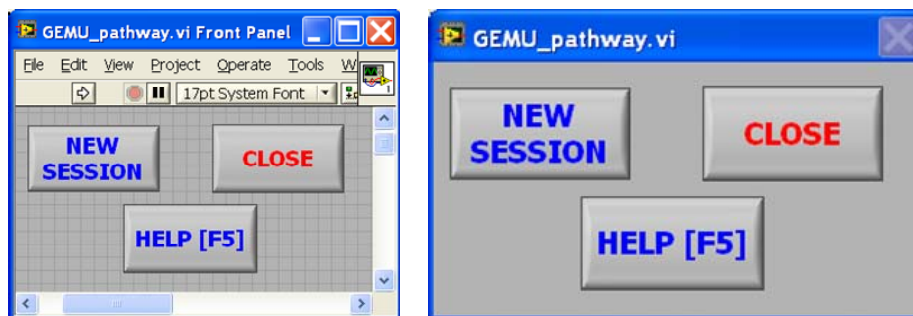


Figure 17. Front panel of the main VI: aspect of the panel in the non-executing program (right) and in the running program (left)

The second Front Panel, belonging to the SUBVI “GEMU-path_session.vi”, is displayed when the control button “NEW SESSION” of the first Front Panel is pressed: a session of measurement is started for computing the parameters of the patients’ walking (a session could be constituted from one or more trials) and the “GEMU-path_session.vi” Front Panel is displayed for the monitoring and controlling the trials of the current session (Figure 18).

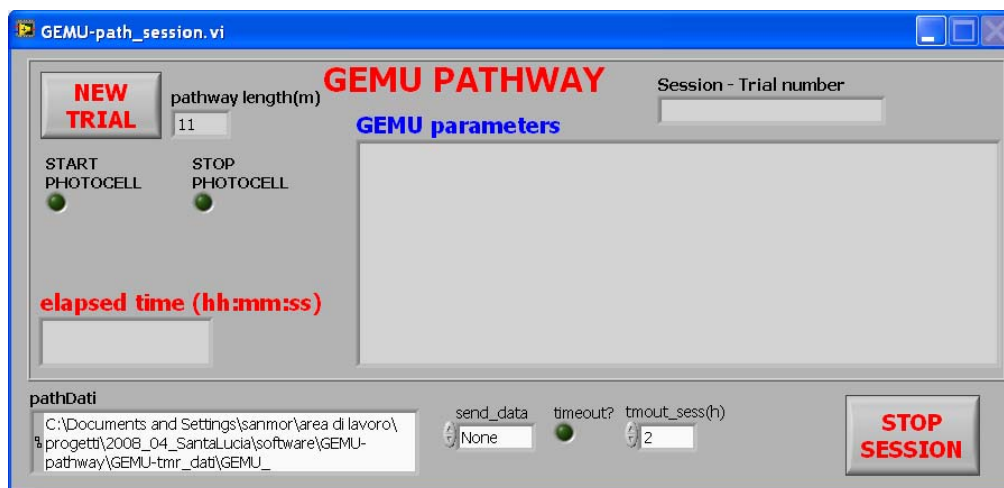


Figure 18. Front Panel of “GEMU-path_session.vi” for monitoring a trial of the patients’ walking

At the beginning of a new session, the user must insert the name of the patient and the walkway length (in meters) and a new text data file shall be opened, containing this information.

If the user does not insert the right inputs, an alert message shall be displayed and the application shall be terminated. For inserting the two inputs, two input windows are displayed.

The Front Panel of “GEMU-path_session.vi” contains:

- NEW TRIAL button: pressing it, the program begins the acquisition of the new trial;
- two LED indicators, “START PHOTOCELL” and “STOP PHOTOCELL”: they indicate respectively the beginning and the end of the walking of the patient along the walkway;
- “elapsed time (hh:mm:ss)” indicator: it displays the elapsed time from the start of the walking;
- “Session – Trial number” indicator: it shows the number of the current trial;
- “GEMU parameters” indicator: it displays the computed walking parameters at the end of the walking;
- STOP SESSION button: pressing it, the current session terminates and all data of the patient are stored.

The two LED indicators become green when the signals of the reference photocells are high. In particular, as soon as a new trial is started, the LED indicator of the start photocell is yellow blinking, until the reference signal remains low, still awaiting the patient starts to walk along the walkway.

While the patient walks along the walkways, a timer, started at the start signal high, shows on the relevant indicator, the elapsed time from the beginning of the walking. When the patient arrives to the end of the walkway, the signal of the stop photocell becomes high, stopping the trial: the program computes the walking parameters, stores the data in the current data file associated to the current session and the data of the current trial are displayed in the relevant “GEMU parameters” indicator (Figure 19).

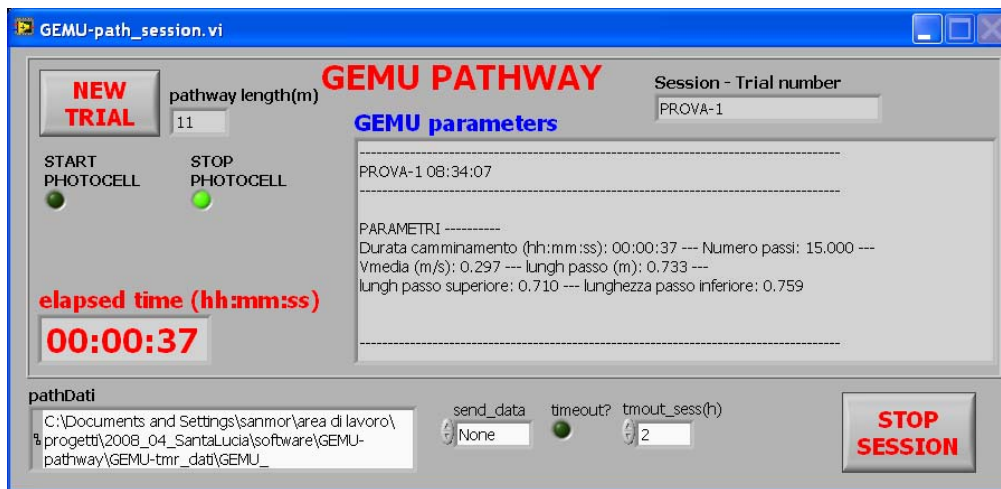


Figure 19. Front panel of the “GEMU-path_session.vi” at the end of a trial

The STOP SESSION button allows to terminate the current session. When this button is pressed, the data file of the current patient is closed, the Front Panel of “GEMU-path_session.vi” is closed and the SUBVI “GEMU-path_session.vi” ends. The Front Panel of “GEMU-pathway.vi” remains opened and a new session can be started or it could be closed the application.

The program computes the parameters of the walking according the above described model reported in Table 1.

Table 1. Parameters of the walking computed by the program

Formula	Definition
L_{pathway} (m)	Length of the pathways (or walkway) along the patient walks; the value in meters is inserted in the program by the user
N_{step}	Number of step; this parameter is computed from the GEMU device and its value is acquired from the program at the end of the walking
$V_m = \frac{L_{\text{pathway}}}{\Delta t}$ (m/s)	Mean velocity; Δt is the walking time in seconds
$l_{\text{step}} = \frac{L_{\text{pathway}}}{N_{\text{step}}}$ (m)	Approximate step-length
$l_{\text{step_sup}} = \frac{L_{\text{pathway}}}{N_{\text{step}} + 0.5}$ (m)	Superior range of the step-length
$l_{\text{step_inf}} = \frac{L_{\text{pathway}}}{N_{\text{step}} - 0.5}$ (m)	Inferior range of the step-length

The $l_{\text{step-sup}}$ and $l_{\text{step-inf}}$ are the superior and inferior range of the step-length obtained in the case of the maximal range of errors at the moment of the end of the exercise.

Figure 20 shows a section of the Block Diagram of the main VI program “GEMU_pathway.vi”.

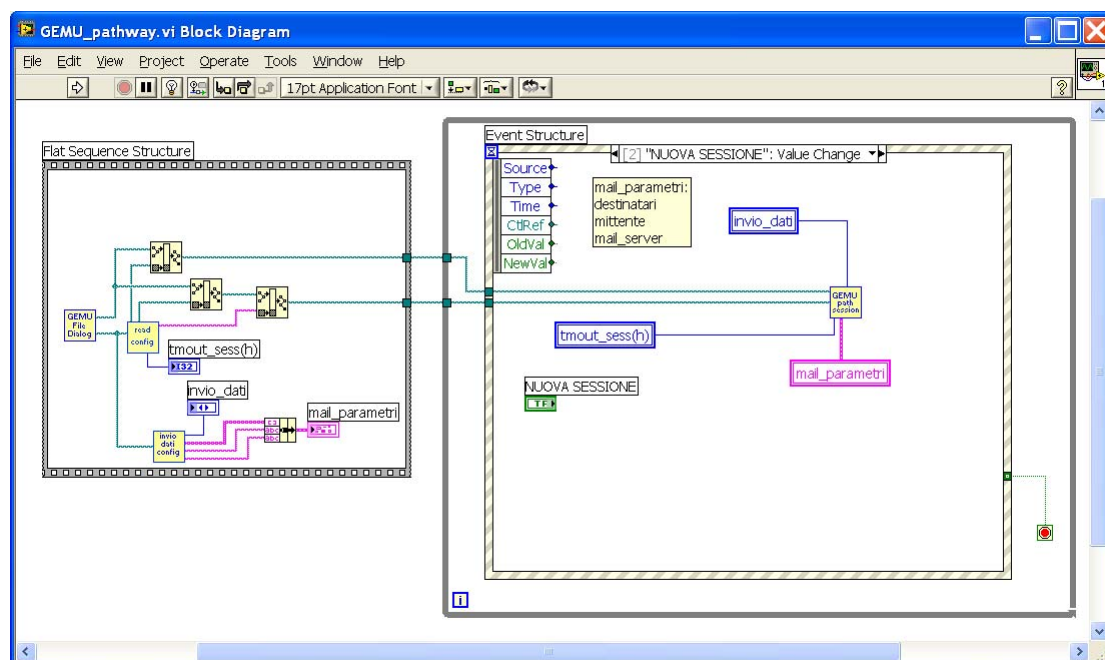


Figure 20. Section of the Block Diagram of the main VI program, the “GEMU_pathway.vi”

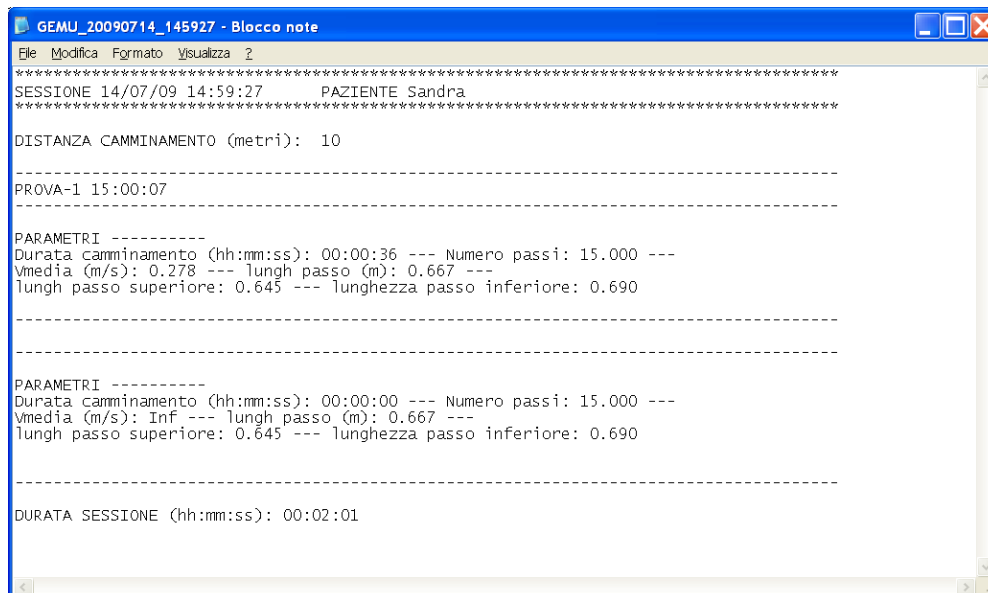
The sub-section on the left is a “Frame Sequence Structure” containing some SubVIs used for the configuration of some parameters of the program. The sub-section instead on the right is an “Event Structure”, indicating the event calling the “GEMU-path_session.vi” SubVI, for the execution of a measurement session.

3.3.2. Data file

A data file is associate to each measurement session. The file name is GEMU_<YYYYMMDD>_<hhmmss>, where the fields <YYYYMMDD> and <hhmmss> are respectively date (Year, Month, Day) and time (hour, minute, second) of the start of the session, when the data file is created. At the start of the session, the program writes in the data file the information relevant to the session start, the patient name and the walkway length. At each trial of the current session, the data file is written in append for adding the walking parameters computed from the current walking trial. At the end of the session, the program writes in the data file the time duration of the session and file is closed. The data file contains the following information:

- date and time of the start of the session;
- patient name;
- walkway length in meters;
- walking parameters relating to each trial:
 - walkway time (hh:mm:ss)
 - step number
 - mean velocity (m/s)
 - step length (m)
 - superior step length (m)
 - inferior step length (m);
- time duration of the overall session (hh:mm:ss).

Figure 21 reports the screen shot of a data file. The set of the data file can be arranged for creating a patients’ database, useful for monitoring the performance and the progress in a rehabilitation program.



```
GEMU_20090714_145927 - Blocco note
File Modifica Formato Visualizza ?
*****
SESSIONE 14/07/09 14:59:27          PAZIENTE Sandra
*****
DISTANZA CAMMINAMENTO (metri): 10
-----
PROVA-1 15:00:07
-----
PARAMETRI -----
Durata cammino (hh:mm:ss): 00:00:36 --- Numero passi: 15.000 ---
Vmedia (m/s): 0.278 --- lungh passo (m): 0.667 ---
lungh passo superiore: 0.645 --- lunghezza passo inferiore: 0.690
-----
PARAMETRI -----
Durata cammino (hh:mm:ss): 00:00:00 --- Numero passi: 15.000 ---
Vmedia (m/s): Inf --- lungh passo (m): 0.667 ---
lungh passo superiore: 0.645 --- lunghezza passo inferiore: 0.690
-----
DURATA SESSIONE (hh:mm:ss): 00:02:01
```

Figure 21. Example of a data file of a measurement session

4. STATUS OF THE PROJECT

The simulated stress analysis of the system (based on the data-sheets of the components) showed a foreseen life of 20 years for the complete equipment. Furthermore all the components used show from data-sheet to allow more than 5000 trials. The step counter used in this first illustrative test (GEMU) has been fully validated in an application with the Parkinson's disease (29).

4.1. A case study with statistics

As an example of application of the methodology to one healthy subject at the 1nd level of the Tinetti test (54) of motion unbalance disability (male; height 1.80 cm; weight 84 kg; age 69 years) we report an output (Table 2) of a single clinical application and the values relevant to 10 repetitions are: $l_{\text{step}} = 0.665$ and Standard Deviation = 0.013. All the trials were performed on a 10 m walkway.

Table 2. Parameters as output of the single application of the portable clinical kit

Item	Value
Time of task	36 s
Number of steps	15
Mean speed	0.278 m/s
l_{step}	0.667 m
$l_{\text{step-inf}}$	0.645 m
$l_{\text{step-sup}}$	0.690 m

Table 3 shows the direct costs in detail.

Table 3. Costs of the clinical portable kit

Description	N.	Price (in euro)
Cost of the production (materials, test and construction)		
Mechanics (cases / boards / general mechanical hardware)	-	25
Microprocessor PIC	2	30
Sensor Force Sensing Resistor (FSR)	1	30
Couple of Foto-emitter / Detectors	2	120
Transmitter / Receiver	1	44
Cost associated to the time of construction and test 30 € / h	-	180*
Other passive electronic components	-	57
Other active / integrated components	-	62
Total		548
Cost of the study of the circuit, master and software		
Study of the circuit 30 € / h		400
Study of the optimization of the masters of the boards 30 € / h	-	105
Study of the development of the software program 30 € / h	-	450
Total		955

The cost of production (montage, materials and test) in the minimum setup has been separated from the cost of the study to allow an estimation of a serial production. The complete cost of the prototype equipment is 548 € for the materials, montage and test and 955 € for the study, i.e. about 20 times lower than the cost of a baropodometric equipment and hundreds of times lower than the optoelectronic equipment. The cost of the software has not been included, since the software LabVIEW 8.2 is currently available in biomedical laboratories and it generates an executable file without cost for the interface.

4.2. Discussion and future perspectives

Today there is a continuous demand of easy, low-cost-and interoperative technology for purposes of rehabilitation to promote and monitor health. One of the most used technologies in the motion monitoring is represented by the step counter or pedometer. The step counting is an important index of motion activity and useful to monitor the response to the rehabilitation care therapy or in the obesity care and diabetes care. Furthermore, when it is accompanied with other kinematic information such as velocity, distance and time, it could give to physician and therapists useful quantitative information to assess the progress of a patient and useful biofeedback information that motivate the patient to continue the therapy. In this report we have proposed a kit that answers to the following need.

The kit comprehends a hardware unit that allows the telemetric acquisition of the row data from the subjects wearing the step counter and the triggering of the task by means of two photocells. The row data from the hardware unit is sent by means of a national instrument acquisition board NI-DAQ USB-6008 to a PC via an USB connection. A software interface, designed by means of LabVIEW 8.2, pre-processes the information in the PC according to a model and arrange it in a text file easy to manage and to send by LAN or WAN connection for the final post-processing and archiving purposes.

From a global point of view the kit allows an easy monitoring of gait parameters and adds the following advantages:

It allows the use of different properly designed step counters. Even if we have used a GEMU for illustrative purposes different step counters can be used in the hardware solutions such as step counters based on accelerometers or on Force Sensing Resistors embedded in a sole of the shoe or a step counter embedded in an AFO. The only requirement to meet is the very simple handshaking protocol.

It can be used with different ground rugosity. This is an important parameter affecting the unbalance and, mostly important, the fall-risk.

The equipment can be used with different rehabilitation mechanical equipments (from staircases to slides).

The customization of complex walkways is also possible for the daily monitoring; properly designed walkways in a form of complex paths (also with obstacles) may be traced for examples at a patient's home to daily assess parameters and encourage to motion activity.

When comparing to the other listed and examined solutions, the kit shows the following advantages:

Very low costs; not also when compared to optoelectronic solutions but also when compared to other portable solutions such as the activity monitoring commercial solutions (such as LifeGait) or the portable gait analysis systems such as GAITRite.

Very high accuracy when using properly designed step counters for subjects with problems of unbalance when compared to commercial step counters or wearable systems with accelerometers and rate-gyroscopes and activity monitoring.

Furthermore the comparison to the portable Gait analysis system GAITRite shows that second one allows a very fine complete Gait Analysis in a limited to a carpet distance with a constant and thus not changeable rugosity; the designed kit allows a simplified Gait Analysis not limited in length, shapes (also labyrinth are possible) and rugosity. The two approaches are thus complementary and complete each other.

From the project side of view this report represents a meeting moment among the project partners in the phase of integration; useful to accept revision proposals or suggestions (for example about the interfaces of the menu, the keys and records of the databases)

At the moment the work route has three directions:

1. The integration of the equipment versus the Hospital LAN and Hospital Information Service (HIS) in collaboration with the partners of the project Fondazione Maugeri, Fondazione Santa Lucia and the TDS Project srl company. Figure 22 shows an example of possible distributed implementation.

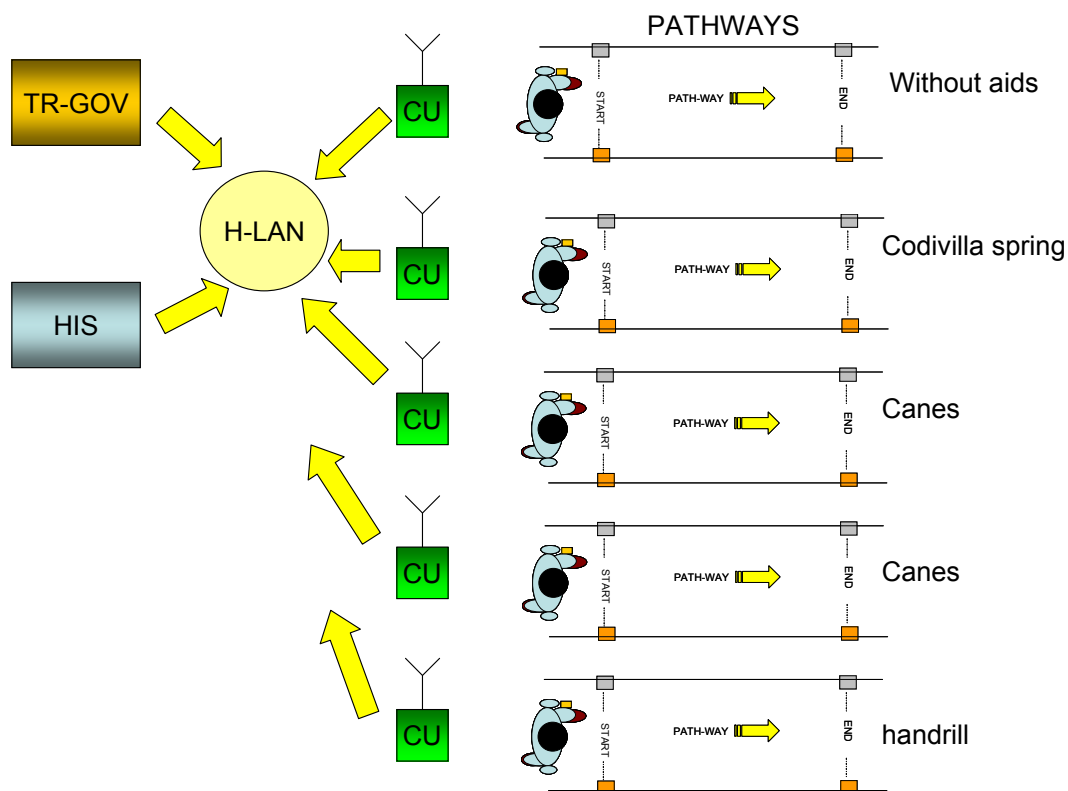


Figure 22. Example of a possible integration of the clinical portable kit

There is a Daily-rehabilitation Government (TR-GOV) that monitors these equipments and other similar ones designed with other Daily-rehabilitation aims. There is the feasibility to access to the virtual-directory of the patients available in the Hospital Information Server (HIS) for the clinical use. The estimated cost of the sensorization of the 5 walkways shown in the example is 548 Euros \times 5 (one without aids, one based on the Codivilla spring a prosthesis fully used in post-stroke rehabilitation (28); two with different canes; one with handrail).

2. The enrichment of the equipment with further functionalities. In fact thank, to the careful discussion between the biomedical engineers and the physicians we are adding to the equipment further potentialities characteristic for different categories of pathology/patient. The equipment thus represents a baseline version which will evolve with the suggestions of the experts in the field and new exigencies of application (Figure 23). As first two non-exhaustive examples of emerged needs of upgrading we can cite
- The need of measuring the distance among the legs
 - The assessing of the temporization of the waking-pattern

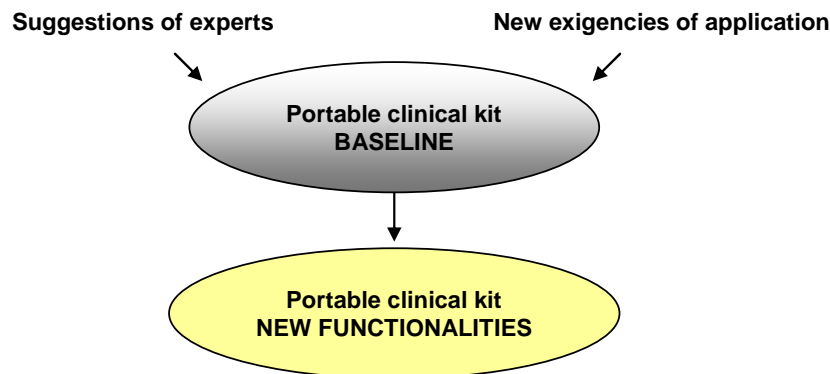


Figure 23. Evolution of the baseline version of the portable clinical kit

3. A further possible evolution of the study will consider the connection in cascade of different walkways to constitute a complex pathway for the assessment of the parameters relevant to the final path as a whole and relevant to each singular element of walkway.

Figure 24 elucidates a final possible scenario, a pathway embedding a cascade with different walkways (handrail, stairs, slide) with different rugosity $\rho = \rho_1, \rho_2, \rho_3$ for rehabilitation purposes in a hospital, while Figure 25 shows a cascade of flat walkways to constitute a complex pathway in a form of labyrinth for rehabilitation purposes at home (linear, curvilinear, linear with obstacles) with different rugosity $\rho = \rho_1, \rho_2$.

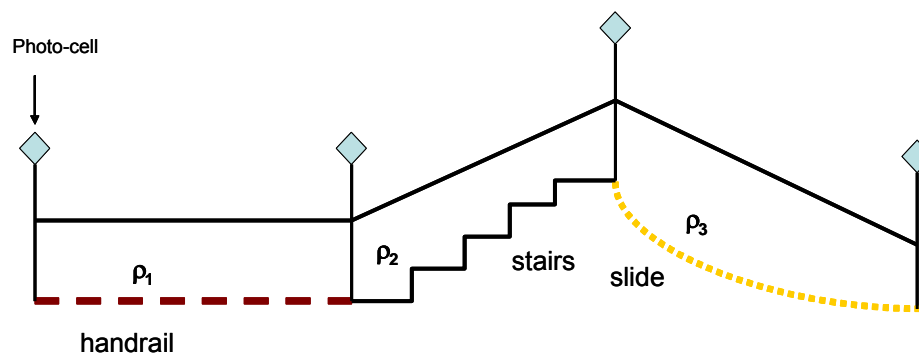


Figure 23. Possible rehabilitation pathway with a cascade of 3 rehabilitation tools: handrail, stairs, slide

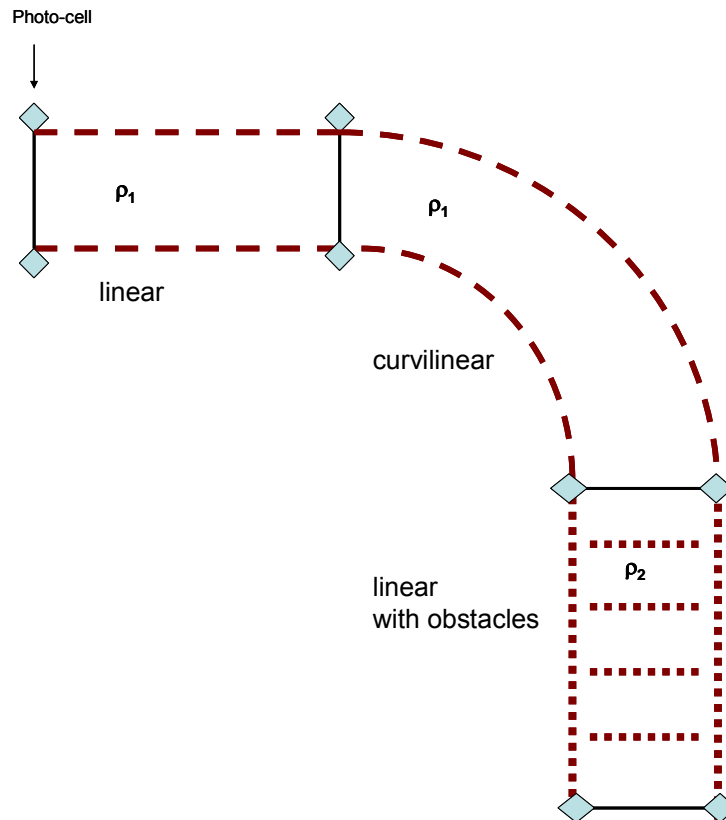


Figure 24. Horizontal view of a rehabilitation pathway at home with a cascade of 3 walkways (linear, curvilinear, and linear with different rugosity and obstacles walkways)

At the moment we are upgrading the software-package to reach this objective, by inserting the appropriate cascade-menus.

REFERENCES

1. Giansanti D, Maccioni G, Macellari V. The development and test of a device for the reconstruction of 3-D position and orientation by means of a kinematic sensor assembly with rate gyroscopes and accelerometers. *IEEE Trans Biomed Eng* 2005;52(7):1271-7.
2. Morris JR. Accelerometry - a technique for the measurement of human body movements. *Journal of Biomechanics* 1973;6(6):729-36.
3. Padgaonkar AJ, Krieger KW, King AI. Measurement of angular acceleration of a rigid body using linear accelerometers. *ASME Journal of Applied Mechanics* 1975;42:552-6.
4. Giansanti D, Macellari V, Maccioni G, Cappozzo A. Is it feasible to reconstruct body segment 3-D position and orientation using accelerometric data? *IEEE Trans Biomedical* 2003;50(4):476-83.
5. Giansanti D, Maccioni G. Comparison of three different kinematic sensors assemblies for the locomotion study. *Physiol. Meas* 2005;26(5):689-705.
6. Miyazaki S. Long term unconstrained measurement of stride length and walking velocity utilizing a piezoelectric gyroscope. *IEEE Trans Biomed. Eng* 1997;44(8):753-9.
7. Kataria P, Abbas JJ. Estimating body segment orientation using a lightweight, inexpensive gyroscope. *Proc Biomed Eng Soc Conf P* 1998;S-133.
8. Williamson R, Andrews BJ. Detecting absolute human knee angle and angular velocity using accelerometers and rate gyroscopes. *Med Biol Eng Comput* 2001;39(3):294-302.
9. Wu G, Ladin Z. The study of kinematic transients in locomotion using the integrated kinematic sensor. *IEEE Trans Rehabil Eng* 1996;4(3):193-200.
10. Giansanti D, Maccioni G, Benvenuti F, Macellari V. Inertial measurement units furnish accurate trunk trajectory reconstruction of the sit-to-stand manoeuvre in healthy subjects. *Med Biol Eng Comput* 2007;45(10):969-76.
11. Tudor-Locke C. Taking steps toward increased physical activity: using pedometers to measure and motivate. *Research Digest* 2002;3(17):1-6.
12. Gibbs-Smith C. *The inventions of Leonardo da Vinci*. London: Phaidon Press; 1978.
13. Wilson DL, Stanton L. *Jefferson abroad*. New York, NY: Modern Library; 1999.
14. Bassett DR. Validity and reliability issues in objective monitoring of physical activity. *Research Quarterly for Exercise and Sport* 2000;71(2):30-6.
15. Kalscheuer LK. *Determining the validity of pedometers*. Arizona State University: Mesa, AZ; 2002.
16. Leenders NYJM, Sherman WM, Nagaraja HN. Comparisons of four methods of estimating physical activity in adult women. *Medicine and Science in Sports and Exercise* 2000;32(7):1320-6.
17. Tudor-Locke CE, Myers AM. Challenges and opportunities for measuring physical activity in sedentary adults. *Sports Medicine* 2001;31(2):91-100.
18. Freedson PS, Miller K. Objective monitoring of physical activity using motion sensors and heart rate. *Research Quarterly for Exercise and Sport* 2000;71(2):21-9.
19. Welk GJ, Corbin CB, Dale D. Measurement issues in the assessment of physical activity in children. *Research Quarterly for Exercise and Sport* 2000;71(Suppl 2):59-73.
20. Welk GJ, Differding JA, Thompson RW, Blair SN, Dziura J, Hart P. The utility of the Digi-walker step counter to assess daily physical activity patterns. *Medicine and Science in Sports and Exercise* 2000;32(9):S481-S488.

21. Eisenmann JC, Laurson KR, Wickel EE, Gentile D, Walsh D. Utility of pedometer step recommendations for predicting overweight in children. *Int J Obes (Lond)* 2007;31(7):1179-82.
22. Dasgupta K, Chan C, Da Costa D, Pilote L, De Civita M, Ross N, Strachan I, Sigal R, Joseph L. Walking behaviour and glycemic control in type 2 diabetes: seasonal and gender differences-study design and methods. *Cardiovasc Diabetol* 2007;15(6):1.
23. Albright C, Thompson DL. The effectiveness of walking in preventing cardiovascular disease in women: a review of the current literature. *J Womens Health (Larchmt)* 2006;15(3):271-80.
24. Schneider PL, Crouter SE, Bassett DR. Pedometer measures of free-living physical activity: comparison of 13 models. *Med Sci Sports Exerc* 2004;36(2):331-5.
25. Keenan DB, Wilhelm FH. Classification of locomotor activity by acceleration measurement: validation in Parkinson disease. *Biomed Sci Instrum* 2005;41:329-34.
26. Tudor-Locke C, Williams JE, Reis JP, Pluto D. Utility of pedometers for assessing physical activity: convergent validity. *Sports Med* 2002;32(12):795-808.
27. Berlin JE, Storti KL, Brach JS. Using Activity Monitors to Measure Physical Activity in Free-Living Conditions. *Phys Ther* 2006;86(8):1137-45.
28. Giansanti D, Tiberi Y, Silvestri G, Maccioni G. New wearable system for step-counting telemonitoring and telerehabilitation based on the Codivilla spring. *Telemed J E Health* 2008;14(10):1096-100.
29. Giansanti D, Macellari V, Maccioni G. Telemonitoring and telerehabilitation of patients with Parkinson's disease: health technology assessment of a novel wearable step counter. *Telemed J E Health* 2008;14(1):76-83.
30. Centre for Disease Control and Prevention; U.S. Dept of Health & Human Services Editorial Staff. *Physical activity and health. A report of the surgeon general*. McLean, VA: International Medical Publishing Inc; 1996. Available from: http://www.internationalmedicalpublishing.com/Product_Disc.cfm?ProductID=34; last visited 04/06/2010.
31. Blumenthal JA, Babyak MA, Moore KA, Craighead WE, Herman S, Khatri P, Waugh R, Napolitano MA, Forman LM, Appelbaum M, Doraiswamy PM, Krishnan KR. Effects of exercise training on older patients with major depression. *Arch Intern Med* 1999;159:2349-56.
32. World Health Organisation. *International classification of impairment, disabilities and handicaps; a manual of classification relating to the consequences of disease*. Geneva: WHO; 1980.
33. Skelton DA, McLaughlin AW. Training functional ability in old age. *Physiotherapy* 1996;82(3):159-67.
34. Skelton DA, Dinan SM. Exercise for falls management: rationale for an exercise program to reduce postural instability. *Physiother Theory Pract* 1999;15:105-20.
35. Morris JRW. Accelerometry – a technique for the measurement of human body movements. *J Biomech* 1973;6:729-36.
36. Veltink PH, Bussmann HBJ, Koelma F, Franken HM, Martens WLJ, van Lummel RC. The feasibility of posture and movement detection by accelerometry. In: *Proceedings of the 15th Annual International Conference of the IEEE, Engineering in Medicine and Biology Society*; October 28-31 1993. San Diego, CA: IEEE; 1993. p. 1230-1.
37. Veltink PH, Bussmann HBJ, et al. Detection of static and dynamic activities using uniaxial accelerometers. *IEEE Trans Rehab Eng* 1996;4:375-85.
38. Aminian K, Robert P, Buscher EE, Rutschmann B, Hayoz D, Depairon M. Physical activity monitoring based on accelerometry: validation and comparison with video observation. *Med Biol Eng Comput* 1999;37(3):304-8.

39. Busser HJ, Ott J, Uiterwaal M, van Lummel RC, Blank R. Ambulatory monitoring of children's activities. *Med Eng Phys* 1997;19:440-5.
40. Bussmann JBJ, Tulen JHM, van Herel ECG, Stam HJ. Quantification of physical activities by means of ambulatory accelerometry: a validation study. *Psychophysiology* 1998;35:488-96.
41. Bussmann JBJ, Veltink PH, Koelma F, van Lummel RC, Stam HJ. Ambulatory monitoring of mobility-related activities: the initial phase of the development of an activity monitor. *Eur J Phys Med Rehabil* 1995;5:2-7.
42. Fahrenberg J, Foerster F, Mueller W, Seja M. Assessment of posture and motion by multi-channel piezoresistive accelerometer recordings. *Psychophysiology* 1997;34:607-12.
43. Fahrenberg J, Muller W, Foerster F, Smeja M. A multi-channel investigation of physical activity. *J Psychophysiol* 1996;10:209-17.
44. Foerster F, Fahrenberg J. Motion pattern and posture: correctly assessed by calibrated accelerometers. *Behav Res Methods Instruments Comput* 2000;32:450-7.
45. Foerster F, Smeja M, Fahrenberg J. Detection of posture and motion by accelerometry: a validation study in ambulatory monitoring. *Comput Hum Behavior* 1999;15(5):571-83.
46. Dunne DM, Lyons GM, Grace PA. The feasibility of posture and physical movement detection using accelerometers. *Ir J Med Sci* 2000;169:22.
47. Kiani K, Snijders CJ, Gelsema ES. Computerised analysis of daily life motor activity for ambulatory monitoring. *Technol Health Care* 1997;5:307-18.
48. Kiani K, Snijders CJ, Gelsema ES. Recognition of daily motor activity classes using an artificial neural network. *Arch Phys Med Rehabil* 1998;79:147-54.
49. Uiterwaal M, Glerum EB, Busser HJ, van Lummel RC. Ambulatory monitoring of physical activity in working situations, a validation study. *J Med Eng Technol* 1998;22:168-72.
50. van den Berg-Emons HJ, Bussmann JB, Balk AH, Stam HJ. Validity of ambulatory accelerometry to quantify physical activity in heart failure. *Scand J Rehabil Med* 2000;32(4):187-92.
51. Bussmann HB, Reuvekamp PJ, Veltink PH, Martens WL, Stam HJ. Validity and reliability of measurements obtained with an "activity monitor" in people with and without a transtibial amputation. *Phys Ther* 1998;78(9):989-98.
52. Bussmann JB, van de Laar YM, Neeleman MP, Stam HJ. Ambulatory accelerometry to quantify motor behaviour in patients after failed back surgery: a validation study. *Pain* 1998;74(2-3):153-61.
53. Lyons GM, Culhane KM, Hilton D, Grace PA, Lyons D. A description of an accelerometer-based mobility monitoring technique. *Med Eng Phys* 2005;27(6):497-504.
54. Kandel ER, Schwart RJ, Jessell TM. *Principi di neuroscienze*. Milano: CEA - Casa Editrice Ambrosiana neuroscienze; 2000.
55. Robinson TK, Robinson S. Using assistive gait devices in rehabilitation. In: Prentice WE, Voight MI (Ed.). *Techniques in musculoskeletal rehabilitation*. New York, NY: McGraw-Hill; 2001. p. 347-61.
56. Moran PT, Harris GF, Acharya K, Hongsheng Zhu, Wertsch JJ. A biofeedback cane system: instrumentation and subject application results. *IEEE Trans Rehabil Eng* 1995;3(1):132-8.
57. Cohi O, Viladot R, Clavell S. *Ortesi e aiuti per la deambulazione*. Roma: Verduci; 1988.

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