THE CAPS®

IN THE CLINICAL PRACTICE

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I PURPOSE

The purpose of this document is to offer to our personnel, clinicians and customers an overview of the issues regarding human balance, vestibular and balance testing, basic clinical management of balance patients, and to illustrate some of the applications and benefits of the CAPS® system in different clinical settings.

This is by no means a complete and exhaustive list, and each medical professional should use this or any other equipment as it will best suit his/her and the patient's needs within the confines of the device intended use and approved purposes.

II SCOPE

This white paper applies to both the CAPS® Lite and the CAPS® Professional systems manufactured and sold by Vestibular Technologies, LLC.

III HUMAN (POSTURAL) BALANCE

In biomechanics, the study of human movement, “balance” is the ability to maintain the projection of the center of gravity (vertical line from center of gravity to the ground) of a body within the base of support with minimal postural sway. Functionally speaking, “balance” is the ability to maintain the desired posture of the body against gravity when subjected to internal and external perturbations. Sway is the horizontal movement of the center of gravity that occurs even when a person is apparently standing still. A certain amount of sway is essential and inevitable due to small perturbations within the body (e.g. breathing, cardiac activity, bowel movement, shifting body weight for one foot to the other or from heels to toes) or from external sources (e.g. air currents, floor vibration, contact with other persons).

Balancing on two feet which are relatively small compared to the entire body is one of the most complicated activities a human routinely performs. The act is so complex that even healthy humans still fall , i.e. lose balance, in their early teenage years, albeit less and less frequently the more their balancing mechanisms improve. Because it requires a lot of practice, research has shown that healthy humans reach their best balance performance only in their 4th decade of life [1]. It has also shown that a healthy individual can still have extremely good balance at an advanced age [1].

Balance involves four different aspects: knowing where we are in space (both our head and each part of our body); sensing the perturbations to our stance; deciding on the appropriate corrective actions to compensate for those perturbations; and finally executing the appropriate corrective actions.

The “sensing” of where we are in space and of the perturbations to our stance is accomplished by three systems:

1. the **vestibular system**: it is part of the inner ear and senses linear and angular accelerations of the head. The linear and angular accelerations signals from the vestibular system are integrated by the vestibular nuclei in the brain, providing the brain the linear and angular velocities and the position of the head. The brain uses this information not only to maintain balance but also to stabilize the images on the retina of the eyes to compensate for the motion of the head via the Vestibulo-Ocular Reflex (VOR). Since

slight head movements are present all the time, the VOR is very important for stabilizing vision: patients whose VOR is impaired find it difficult to read, because they cannot stabilize the eyes during small head tremors and movements, e.g. when walking;

2. the **somatosensory system** in general and **proprioception** in particular: these are aspects of the peripheral nervous system that provide information on the position of each articular joint, the contraction status of the skeletal muscles, and the presence of internal (e.g. cardiovascular, pulmonary and digestive activities), as well as external perturbing forces;

3. the **visual system**: it provides similar and complementary information to the previous two systems (it allows us not only to "see" where the head and each body segment are in reference to the environment, but also allows us to estimate visible external perturbations that are either perturbing or are about to perturb our stance).

The information coming from the vestibular, proprioceptive/somatosensory and visual systems is largely redundant, i.e. these systems provide the brain with similar information. Standing and spending our lives in the very unstable upright position is so important for our species that we have several redundant systems to allow us to maintain balance even if a pathology affects negatively one, or sometimes even two, of those systems. This redundancy is also used in the learning and the "tuning" of the mechanisms. However, redundancy has its drawbacks: it can cause the brain to receive conflicting information leading to confusion (for instance motion sickness is often caused by conflicting sensory inputs to the brain). More importantly, it can mask the presence of dysfunctions in some of the systems. In other words, it can allow a person to balance and function in an apparent normal way most of the time when the the information from a dysfunctional system can be substituted with that obtained from other systems, thus hiding the existence of a problem. Unfortunately, it is not always possible to substitute the information from one system with that from another because the vestibular, proprioceptive/somatosensory and visual systems use different sensing modalities. In certain conditions (e.g. poor lighting, unstable or soft support surfaces, motion of the environment as a bus or an airplane) the redundancy can fail, making the dysfunction become apparent and compromising the ability to balance to the point of falling.

Deciding on the appropriate actions to compensate for the perturbations of the stance occurs mostly in the **central nervous system**, both in the brain, and to a lesser extent in the spinal cord. A major role in maintaining balance is played, as in any muscular action, by the cerebellum. However, to some extent the entire central nervous system is involved, and the role of each part changes depending on the stance as well as the perturbation.

Actuating the appropriate actions to maintain balance is of course, the responsibility of the **muscular system**, mainly the skeletal muscles although all muscles might be used in some way in particularly difficult situations.

It should therefore be clear that **good balance requires the good functioning of the entire body**. In other words, not just of the parts mentioned above but also of all the "supporting" systems and organs of the body like the cardiovascular, respiratory, digestive systems, etc., since changes in any of them will eventually affect some or all of the systems used directly in the act of balancing. For instance, it appears quite obvious that a vestibular pathology will affect balance, and so will muscular weakness. But poor circulation or respiration will also cause poor balance as they impair both the central nervous system and the musculature.

It is also important to remember that **the balance abilities of an individual can change rapidly, even without the insurgence of pathologies**. For instance a person's alertness, blood pressure and cardiac output can change even in a matter of seconds, mostly as a reaction to external conditions and the presence or absence of the need for physical action. Changes that can occur in a matter of minutes to hours include changes in tiredness, the amount of sugar and other nutrients in the blood, changes associated to digestion, the assumption of substances such as medications, alcohol, caffeine, nicotine, and others. Some changes might take days or weeks, like changes in weight and weight distribution, or changes of fitness level in the muscular but also cardiovascular and respiratory systems. These and other changes will almost always modify a person's ability to maintain balance.

IV DIZZINESS, VERTIGO AND BALANCE DYSFUNCTIONS

Unfortunately because balance was not very well understood, over the years a lot of confusing terminology has been created and is still in use. First of all, a lot of confusion is created by the fact that **when most persons, including clinicians, think of balance dysfunctions they think of acute and often debilitating manifestations, mostly dizziness and, more specifically, vertigo or presyncope**. The onset of dizziness usually occurs quite rapidly and violently and the affected persons clearly and quickly realize the difficulty in maintaining balance and the existence of a medical problem.

According the National Library of Medicine - Medical Subject Headings (MeSH) dizziness is "*an imprecise term which may refer to a sense of spatial disorientation, motion of the environment, or lightheadedness*" and is classified as a "*sensation disorder*" which is part of the "*neurologic manifestations*" of "*nervous system diseases*". The term dizziness can be used to mean vertigo, presyncope, disequilibrium, [2, 3] or a non-specific feeling such as giddiness or foolishness [3].

Dizziness is quite common, with an incidence of about 16% in middle aged adults [4] and about 36% in elderly adults 70 years and older [5]. Dizziness is the primary complaint in 2.5% of all primary care visits [6]. Many conditions are associated with dizziness. However, the most common can be broken down as follows: 40% peripheral vestibular dysfunction, 10% central nervous system lesion, 25% presyncope/dysequilibrium, 15% psychiatric disorder, and 10% nonspecific dizziness [3, 7].

Vertigo is a type of dizziness where there is a feeling of motion when one is stationary [11], and it is often associated with nausea and vomiting as well as difficulties standing or walking. According to MeSH, the definition of vertigo is "*an illusion of movement, either of the external world revolving around the individual or of the individual revolving in space. Vertigo may be associated with disorders of the inner ear, vestibular nerve, brainstem, or cerebellar cortex. Lesions in the temporal lobe and parietal lobe may be associated with focal seizure that may feature vertigo as an ictal manifestation. (From Adams et al., Principles of Neurology, 6th ed, pp. 300-1)*".Vertigo, like dizziness, is classified by MeSH as a "*sensation disorder*" which is part of the "*neurologic manifestations*" of "*nervous system diseases*" but, unlike dizziness in general, it is also classified as "*vestibular disease*", a sub category of "*otorhinolaryngologic diseases*".

Vertigo is classified into either peripheral or central depending on the location of the dysfunction. Vertigo caused by problems within the inner ear or vestibular system is called "peripheral", "otologic" or "vestibular". The most common cause is benign paroxysmal positional vertigo (BPPV), but other causes include Ménière's disease, superior canal dehiscence syndrome, labyrinthitis and visual vertigo [12]. Any cause of inflammation such as common cold, influenza, and bacterial infections may cause transient vertigo if they involve the inner ear. Chemical insults (e.g. aminoglycosides and other ototoxic substances) or physical trauma (e.g. skull fractures) can also cause transient vertigo and permanent loss of vestibular function. Motion sickness is sometimes classified as a cause of peripheral vertigo. Vertigo caused by problems within the brain is called “central”, and is usually milder and has accompanying neurologic deficits such as slurred speech, double vision, or pathologic nystagmus. In general, the most common causes of vertigo are benign paroxysmal positional vertigo, concussions and vestibular migraine whereas less common causes include Ménière's disease and vestibular neuritis [11].

Presyncope is a state consisting of lightheadedness, muscular weakness, and feeling faint that is often the cause of dizziness. It does not result from primary central nervous system pathology, nor does it originate in the inner ear, but it is most often cardiovascular in etiology. According to MeSH, a syncope is “a *transient loss of consciousness and postural tone caused by diminished blood flow to the brain (i.e. brain ischemia)*” and “*presyncope refers to the sensation of lightheadedness and loss of strength that precedes a syncopal event or accompanies an incomplete syncope. (From Adams et al., Principles of Neurology, 6th ed, pp. 367-9)”*.

But **dizziness does not encompass all balance dysfunctions and all cases where a balance deficit exist!** Because of phenomena such as habituation and compensation, many persons with pathologies or conditions that reduce balance below physiologic levels do not report dizziness except in acute conditions. For instance diabetes, poor blood circulation, decreased blood oxigen saturation, mild hypovolemia and hypotension, muscular weakness and many other conditions cause a decrease in balance with no manifestations commonly related to balance such as dizziness or vertigo. Similarly, permanent vestibular damage caused by trauma or ototoxicity often manifest with dizziness only in the acute phase and after few hours or days the subjects do not report any dizziness. The fact that dizziness (including vertigo, imbalance and faintness) is associated only with a small number of balance problems is proven by the fact that according to the U.S. Centers for Disease Control and Prevention (CDC) over 75% of Americans aged 70 years or older have a balance deficit [13] whereas about 36% of the elderly adults aged 70 years or older report some type of dizziness [5]. In ours and our customers' experience, approximately 2 out of 3 (66%) adults aged 65 years or older and 1 out of 3 (33%) adults under 65 years old suffer from a balance problem, whereas studies have shown 16% of middle aged adults report some type of dizziness [4]. So it seems **dizziness in its various forms (vertigo, presyncope, disequilibrium, etc.) is present only in about half of the persons with a balance dysfunction!**

Another source of confusion originates from the fact that **too many people confuse “balance” with “vestibular”**. This comes from the fact that the majority of dizziness cases (about 40% [3, 7]) are caused by peripheral vestibular dysfunction. Furthermore, as we have just seen, many people think balance disorder is equivalent of dizziness. So it should not come as a surprise that so many think of balance dysfunctions as vestibular dysfunctions, while in fact vestibular pathologies with associated dizziness account for maybe 20% of all balance impairments (40% of dizziness patients who represent about 50% of the population with balance deficits).

To successfully diagnose and treat persons with balance dysfunctions, it is necessary to stop thinking solely in terms of dizziness and vestibular system. It is a gross simplification that many clinicians have adopted for several reasons, including the fact that, if true, it would make their life much simpler by allowing them to focus their attention to only one area of the body when dealing with balance problems. Unfortunately, it is not that simple. As mentioned previously, **good balance requires the good functioning of the entire body, and almost all pathologies of any part of the body cause a decrease in balance**. This makes diagnosing and treating balance dysfunctions extremely complicated, time consuming, and difficult.

Finally, it is worth mentioning another common terminology issue when talking about balance and balance dysfunctions. Often the terminology "normal" is used. This can be confusing because "normal" in statistical terms means "most frequent or common", it does not mean "healthy" or "physiologic". As more than half of the population aged 65 and older has a balance deficit, "normal balance" in a statistical sense for that population actually means having a balance dysfunction, whereas "normal balance" commonly means "physiologic", i.e. "non-pathologic" balance. So, to avoid confusion, it would be more appropriate to use the terminology "**physiologic balance**" and "**pathologic balance**" instead of "normal balance" or "abnormal balance". This is important, because some companies offering balance testing equipment use, as reference values, data obtained not from healthy subjects but from testing subjects randomly selected from the general population without any consideration as to their actual health status. This is done for different reasons. One is the fact that it is actually difficult to find healthy subjects over 70 years old with no pathologies, and it is even more difficult and expensive to establish if they are actually healthy. The other is that it allows them to advertise that their reference values were obtained from a very large population sample. But these reference values represent "statistically normal", but not "physiologic". When the reference values for the CAPS® were established [1] all subjects had to undergo a complete medical history evaluation as well as a complete physical, neurological and otorhinolaryngologic visit to be considered healthy, and in many instances when there were doubts other testing like blood panels, MRI, CT and VNG were performed. This allowed to obtain reference values based on the health status, so that when the CAPS® equipment produces results that fall within the reference value range we can say a subject is healthy (and in fact at least one other company we know of uses in their products the reference values established for our devices). Whose using reference values obtained without considering the health status of the subjects can only say a subject is "normal" in the statistical sense, i.e. that the subject is like the majority of the population, nothing else. The correctness of our approach is validated albeit in a non-scientific way by the fact that when screening large numbers of individuals with our CAPS® equipment the incidence of balance dysfunctions is found to be in almost perfect agreement with the results of other studies such as those conducted by the CDC.

V BALANCE AND VESTIBULAR TESTING

Because of the aforementioned confusion between "balance" and "vestibular", all too many clinicians identify balance testing with vestibular testing. However, **balance testing and vestibular testing are not the same, they are only related by the fact that the vestibular system is one of the parts of the body used for maintaining balance and postural control**. Whereas when performing "balance testing" one also tests the vestibular system together with some or all the other parts of the body used to maintain balance, when performing "vestibular testing" one only tests the vestibular system (and parts of the related central nervous system because, as it will be explained later, we can't really test the vestibular system alone). In other words, the terminology "balance testing" more appropriately indicates all testing that investigate balance in its entirety or use balance as the observed quantity, whereas "vestibular testing" should be used to indicate tests that investigate specifically the integrity and functionality of the vestibular system. This distinction, although it might seem as a simple matter of semantics, has very important practical consequences. **Vestibular testing** use eye movements rather than balance as the observed quantity, and therefore **will show abnormalities only if there are vestibular or central nervous system dysfunctions. But, as mentioned earlier, these are present in only about 25% of all persons with a balance dysfunction**. On the other hand, **"balance testing"**, since it uses balance as the observed quantity, **will show abnormalities in all persons with a balance dysfunction.** That is a big difference!

If clinicians limit themselves to vestibular testing and do not also embrace balance testing, about 50% of dizzy patients will go undiagnosed and untreated because they have no central or vestibular dysfunction; and most of the 75% of all persons with balance dysfunctions will go undiagnosed and untreated because they have no dizziness (so nobody knows they have a problem) or, if they do, they have no central or vestibular dysfunction. It is also very important to make another point: **the 50% of all persons with balance dysfunctions that have acute symptoms like dizziness** are in some ways the lucky ones, because even if undiagnosed and untreated, they **know they have a balance problem** and so they are careful in their movements and try to avoid falls. **The other 50%** (which means about 35% of the population 70 years old and older) most likely **will not even realize they have a balance deficit until they fall**, and even then they might not think there is anything clinically wrong with them and keep falling a few times before realizing there is a problem. Unfortunately, by the time they realize something is wrong with their balance, most of them will have already suffered the severe consequences of falls, including fractures and other severe injuries.

V.I VESTIBULAR TESTING

First of all, let's start with another common misconception/confusion (yes, another one; unfortunately there are so many when dealing with the topic of balance). It is at this time impossible to test the vestibular system alone because there is no way to measure the actual signals transmitted from the vestibular system to the brain. It is only possible to test the vestibular system in conjunction with the brain. Unfortunately, it is currently also impossible to test the brain directly and it can only be investigated by observing its "outputs", i.e. the external manifestations like speech, muscular tone, movements and such. Fortunately, the signals from the vestibular system are processed by the brain and used by the brain to move the eyes by what is referred to as the Vestibulo-Ocular Reflex (VOR). **All vestibular testing** (meaning all testing specific to the vestibular function and not non-specific balance testing), **relies on the observation or measurement of eye movements**, either fast (saccadic), slow (pursuit) or combined (nystagmus). So the terminology "vestibular testing" is also somewhat misleading, and the more correctly it should be called "vestibulo-neuro-oculomotor testing". In fact, some tests used in "vestibular testing" (for instance the oculomotor tests, i.e. saccadic tracking, smooth pursuit tracking, and optokinetic tracking) are actually neurologic tests that have little to do with the vestibular system, but are necessary to rule out the possibility that the eye movements seen when actually testing the vestibular system might actually be generated by some brain lesion and not a consequence of the signals coming from the vestibular system.

It should also be noted that of the six accelerations sensed by the vestibular system (the three angular accelerations sensed by the semicircular canals and the three linear accelerations sensed by the otholitic organs) only some elicit a VOR response (for instance pure anterior-posterior and medio-lateral linear accelerations do not cause the eyes to move because no movement is required to stabilize the image on the retina). So conventional **"vestibular testing" can not test the entire the vestibular system and its functionality,** albeit it is rare for only parts of the vestibular system and not the entire system (at least isolaterally) to be dysfunctional.

The main purpose of vestibular testing is to find if there is a vestibular (peripheral) or a central nervous system (central) dysfunction, and if it is unilateral or bilateral. Together with an in-depth neurological assessment a highly trained clinician can even determine the localization of a central dysfunction.

Vestibular tests include Elecro-NystagmoGraphy (ENG) (and its modern version Video-NystagmoGraphy (VNG)) testing battery, the Dix-Hallpike Maneuver, Pneumatic Otoscopy, Head Shake Nystagmus test, Head Thrust Test, Positional and positioning tests, caloric tests and rotational chair tests. To be performed in a measured and quantifying manner at laboratory level, they requires expensive equipment (rotational chair, and to a lesser extent ENG and VNG equipment can cost tens of thousand or even hundreds of thousands of U.S. Dollars), time, and sometimes cause severe discomfort to patients (for instance rotational chair tests and caloric tests can induce severe vertigo, nausea and sometimes vomiting). However, with proper training and observational skill, several tests can be performed quickly (albeit subjectively and observationally without recording, measurement or quantification) as part of a field examination outside a laboratory without much patient discomfort, by just observing the patient's eyes without the use of any equipment or using inexpensive tools like Frenzel lenses.

Because of the time, cost and sometimes discomfort of many of the instrumented vestibular tests, before ordering them a clinician should perform a complete evaluation of the patient's medical history and a detailed physical examination that includes basic neurological and vestibular evaluations. Because peripheral vestibular dysfunctions are often associated with hearing loss, an hearing screening should also be performed.

As mentioned earlier, in subjects with any form of dizziness (including vertigo, presyncope, disequilibrium) **vestibular testing will indicate the presence of central lesions in about 10% of the cases, and the presence of vestibular lesions in about 40% of the subjects examined**. The incidence of central lesion and vestibular lesions in the roughly 50% of the population affected by balance dysfunctions that does not present with dizziness is unclear because of the lack of studies. However, it is possible that because of habituation and compensatory mechanisms their incidence could be as high as in the population that presents with dizziness.

V.II BALANCE TESTING

As described earlier, **"balance testing"** indicates all testing that investigate balance in its entirety and **uses balance as the observed quantity**. **Most balance deficits exist without the subject or the physician being able to notice them** because in every day conditions they are masked by compensatory effects. Balance is so essential to a human that several compensatory mechanisms exist to allow a person to maintain good balance at least in the most common situations (good visibility, hard and non slippery surface, without external perturbations). **Balance testing is therefore essential to identify subjects with balance dysfunctions**.

Balance testing has an history dating back almost 200 years. One of the first tests was the Romberg's test commonly performed during the neurological examination to evaluate the integrity of dorsal columns of the spinal cord. Moritz Heinrich von Romberg first described it in

1840. Since then, many other balance tests have been developed. Several are based on observing the subject (e.g., Modified Romberg's, the Berg Balance Scale, the Tinetti Balance Test of the Performance-Oriented Assessment of Mobility Problems, the Balance Error Scoring System or BESS, the Y Balance Test Protocol), whereas others are based on measurements of body movements that nowadays are almost always automated and computerized (mainly posturography).

Observation based balance tests (including those called "objective" because they use scales and scores and should therefore be more appropriately called "quantitative" rather than "objective") appear at first very attractive to general practitioners as they requires minimal investment in equipment. However, they have significant drawbacks exactly because are based on observation and not on automatic measurements. First of all, these tests require a highly trained person to be administered and observed/scored correctly. Secondly, they require several minutes to complete, usually in the order of 10 to 15 minutes. Thirdly, they are more or less subjective as a person has to observe and evaluate the subject's movement, and as much as the test methodology tries to minimize the subjectivity, it is still inherent and unavoidable as several studies have shown [14-17]. Lastly and most importantly, they can not detect small abnormalities or changes in balance, and the minimum amount of change detectable again depends on the person observing the test. An example might be useful to further explain the limitation of observation based balance testing. Consider a person walking on a tight rope or any narrow support: such a person usually appears to "sway" a lot, but in fact considering the proper and scientific definition of sway as "*the movement of the center of mass of the body in the horizontal plane*", he or she is swaying very little (the weight has to stay on the very narrow support to avoid falling) and the balance is extremely good. Conversely, a person suffering from bradykinesia or even akinesia, such as that caused by Parkinson's disease, looks steady and immobile as a rock, but in fact sways a lot and has very poor balance because of the inability to control the movements of the center of mass of the body, with small perturbation typically resulting in a fall.

Balance tests based on measurements of body movements are generally, and again somewhat incorrectly, referred to as posturography (it is incorrect because the term posturography actually refers to the study of posture, not balance, although the two are related). Ideally, these tests would measure the actual sway of the body. Unfortunately, this is practically impossible as to do so requires the measurement of the mass distribution and movement of each and every tissue and fluid in the body. Some systems have been developed that use accelerometers and similar motion sensors attached to the skin or strapped onto the body to measure the movement of the trunk, pelvis, head, and other body segments. These systems require careful and time consuming setup, only measure the movement of the location of the body they are attached or strapped to, cannot measure internal movements of body masses (for instance those caused by respiratory, cardiovascular and peristaltic activity), and suffer from motion artifacts of the skin relative to the body, making them inaccurate. All these issues make them ill-suited for clinical practice. But even if sway cannot be practically measured, it is possible to measure the movements of the instantaneous Center of Pressure (CoP) of the ground reaction force, i.e. the point on the support surface where the resultant ground reaction force is applied. Research has shown that CoP movements track and correlate well with sway [18]. So computerized posturography systems like the CAPS® utilize force platforms to measure the movements of the CoP (some systems utilize insoles or pressure sensitive mats, but whereas these can provide a map of the pressures under the feet, they are not sufficiently accurate to determine the movements of the CoP with the necessary resolution and accuracy).

Several types of tests can be performed using these computerized posturography systems, but by far the most common ones are variations of the static balance test in which the person being tested tries to minimize the sway of the body. The most commonly used variations of static tests comprise the *modified Clinical Test of Sensor Integration in Balance* (mCTSIB) protocol. It consists of four tests: Eyes Open on Firm Surface (NSEO), Eyes Closed on Firm Surface (NSEC), Eyes Open on Unstable Surface/Foam (PSEO), and Eyes Closed on Unstable Surface/Foam (PSEC). These tests are commonly used in clinical practice to identify persons whose balance is pathologic, to provide some initial indication as to the localization of the problem (vestibular, visual, proprioceptive, or central) and to monitor the effects of interventions. They are also used to research the effects of various pathologies or conditions on balance and postural stability.

To obtain meaningful results from any clinical test, it is necessary to understand the factors that might cause a change in the results. This of course holds true also for posturography and balance testing. Particularly, since balance involves the entire body, it can be affected by almost anything that affects the subject being tested. Postural control, the act of maintaining, achieving or restoring a state of balance during any posture or activity, may be affected by strategies that are either predictive or reactive [19]. Such strategies can be affected by several factors, one of which can be the instructions given to the subject [20]. Other factors include the time of day, possibly because of combined effects of fatigue and varying levels of nutrients [21-23]. Postural sway is increased in individuals who have been sleep deprived [24-26]. In fact, stability and sway intensity with eyes closed can show a circadian pattern with a peak at early morning hours and a recovery at 10:00 AM the following day [26]. Stretching of the calf muscles has the effect of increasing postural sway [27]. Sounds at low and middle frequencies result in a significant increase of body sway on the lateral plane and in the closed-eyes condition, suggesting that sound activates the vestibular system [28]. The response to different sound stimuli even affects the posture (lying or sitting) of 6 week old infants [29] and is innately linked to the motor responses of humans. Unexpected sounds can elicit a startle response that produces muscle contractions throughout the body and may produce excessive and inappropriately directed contractions that may change posturographic readings [30]. The influence of sound image motion on postural reactions induces body displacement in the direction opposite to that of sound image [31] and the center of gravity deviates during exposure to a sound stimulus towards the side opposite the direction of movement of the sound source [32]. The integration between visual and vestibular input during quiet standing suggests a dual role for vestibular information. Vestibular information in quiet standing has a role in maintaining whole body postural stability, and may be differentially attenuated by visual stimulation [33]. Sound can also activate a short latency vestibulocollic reflex which appears to arise from the saccule, and affects otolith function [34]. Even spoken words of an examiner or assistant can change postural control in subjects who are undergoing posturographic testing, with changes dependent upon what is being said. While a non-meaningful auditory stimulation does not lead to postural control modification, a meaningful auditory task allows a reduction in postural parameter values, and therefore a better stabilization of posture [35]. Mechanical vibration noise can be used to improve motor control in humans such that the postural sway of both young and elderly individuals during quiet standing can be significantly reduced by a sub-sensory mechanical noise to the feet [36]. Changes in human postural stability may be observed if a loss of vision or any vision impairment appears [37] and conversely improvements in stability might be obtained if some component of visual stimulation is allowed to occur during a posturographic test. The inter-relationship between eye position and neck muscle activity does affect the control of neck posture and movement [38]. A light stimulus from a peripheral source can affect human stability so that having the patient close his/her eyes may not be adequate. Peripheral rather than central vision contributes to maintaining a stable standing posture, with postural sway being influenced more in the direction of stimulus observation, or head/gaze direction, than in the direction of trunk orientation [39]. Even ocular dominance affects postural stability with the non-dominant eye being more concerned with postural control than the dominant eye [40].

Given all of the above, it should be clear that proper balance testing requires controlling the test conditions, as these can affect the results. In other words, balance testing offers an instantaneous insight as to the conditions of the subject and how the subject is affected by the surrounding environment. This must be kept in mind during testing, and can actually be used to the clinician's advantage by eliciting in the subject small temporary changes that can provide insight about the areas that are more problematic for that subject. It should also be noted that this is not at all different from other types of medical tests: arterial blood pressure measures can be greatly affected by the "instantaneous" condition of the subject; sugar blood levels can change rapidly because of eating, exercise and other metabolic events; the same can be said for many more tests.

In terms of repeatability of the balance measures, in particular of the static tests comprising the mCTSIB, research has shown that with an instrument like the CAPS® the variability in the test results is all due to changes in the subjects [41], and that a change in the stability score of more than 1.1 points for the stable surface tests and of more than 2.1 points for the tests on unstable surface is statistically significant to a 95% confidence level.

Balance testing and in particular posturography can measure, if the instrument is sensitive and accurate enough, extremely minute balancing movements of a person. **Unlike vestibular testing, balance testing and in particular posturography will indicate the presence of a balance dysfunction in the vast majority of subjects that, at the time of testing, have one, even if they do not complain of dizziness or balance impairment.** This is about 1 out of 3 (33%) adults below 65 years of age, 2 out of 3 (66%) adults 65 years old and older, and 3 out of 4 (75%) adults over 70 years of age and older.

Since balance testing and posturography investigate balance, which as explained earlier involves the entire body, it should be apparent what has taken years for research to show: **balance testing and posturography have high sensitivity to the general health status of a subject, but very low specificity**. In other words, all the research has shown non physiologic balance testing results when a pathology is present, but from the results it is often very difficult to arrive at a specific diagnosis. We can think of balance testing and posturography as a generalized version of other non specific but indicative clinical tests, e.g. arterial blood pressure, cholesterol, white blood cell count: **non physiologic results suggest a pathology, but do not (and cannot) provide a specific diagnosis**. For instance, a person might have abnormally high blood pressure, but alone this finding does not tell the cause of it and therefore does not provide a specific diagnosis, rather it points to a series of possibilities that should be investigated further using other diagnostic procedures and tests.

Furthermore, **as with any clinical test, the results reflect the status of the subject at that specific point in time which in the case of balance can change quite rapidly for a variety of reasons.**

These characteristics do not make balance testing or posturography any less useful in the clinical practice, but, as it is the case with any diagnostic test, it is important to know the limitations to maximize the effectiveness and usefulness of the test.

VI BALANCE TESTING IN CLINICAL PRACTICE

What should be the role of balance testing and posturography in the clinical practice? In other words, how can they be used effectively from a clinical and economic perspective to improve the health and function of humankind? We believe there are very different schools of thought in this matter.

Several of those involved in balance, be they researchers, clinicians or engineers developing medical devices, apparently believe that balance testing can and should be used for diagnostic purposes, i.e. to find out where a balance dysfunction originates. This has lead to the creation of long and complicated observation-based test protocols that are expensive to use in terms of time (and time is money), as well as to the development of **costly, large and sophisticated posturography equipment** with moving platforms, moving visual environments and other ways of perturbing or confusing the subject's balance. And as a consequence, **it usually takes a long time to test a person**. Years and years of research and hundreds of scientific studies have been performed in an attempt to validate their diagnostic capabilities, unfortunately without much success. In fact, after decades of research, posturography (the only balance testing that is not based on observation and provides documented, automated measures and therefore has a specific procedural and reimbursement codes) is still considered experimental by many health organizations. In our opinion, using posturography as a diagnostic tool is faulted because, as previously discussed, balance depends on the functioning of the entire body, and therefore balance testing is intrinsically non-specific. Although attempts can be made to isolate the effect of the different body systems, so many parts of the body are still involved that there is no way to make the test results specific enough for a diagnosis except in very few cases.

Some of those involved in balance studies understand that **balance testing is non-specific and therefore of limited diagnostic value**. But they also realize that **balance testing can be useful in the screening and identification of persons affected by balance dysfunctions** which relate to the health status of a person and to falls (a major health issue in the elderly population). Again, this has lead to the creation of long and complicated observation-based test protocols (e.g. the Berg Balance Scale, the Tinetti Balance Test of the Performance-Oriented Assessment of Mobility Problems). These suffer from all the limitations discussed earlier on. But the real problem with this approach is, in our opinion, the fact that it neglects the simple fact that **balance can change very quickly**. We believe that the usefulness of these balance testing protocols is very limited simply because they take too much time, and therefore they can not be repeated as often as the changes in a persons' balance would require. The assumption behind these test protocols is that an assessment performed at a specific point in time can be representative of the person's balance for a long time, i.e. that the balance will not change significantly for some time. Some researchers go as far as trying to correlate, either retrospectively or prospectively, the results of a single balance assessment with balance issues and falls 3, 6 o even 12 months away.

We believe that **balance testing is non-specific and therefore of limited diagnostic value**, but that is **a superior tool** and is **essential for the screening and identification** of persons affected by balance dysfunctions. We also believe that **balance can change in a short time** and that **a person should be tested very often** to detect any changes in balance with the goal of catching dysfunctions as soon as they appear, ideally before they result in falls and injuries. All of this made us realize that **to be really useful clinically any balance testing has to be extremely fast, sensitive and accurate enough to detect any change in balance, not require highly trained personnel to perform or interpret, and have very low direct and indirect cost per test** (i.e. not only the initial costs to purchase the necessary tools, but also the material and personnel costs necessary for the training and those to perform the testing, including the costs associated with the space required if dedicated to the balance testing). We believe that **this is possible by using a computerized force platform and a dynamic posturography version of a subset of the tests of the old Modified Romberg's balance test**, i.e. using one or more of the tests that constitute the mCTSIB. **This solution allows to combine the proven characteristics of the Romberg's with the objectivity, sensitivity, accuracy and automated analysis of posturography, eliminating the need of highly trained personnel and allowing to test a person in a very short time**. **This is the basic philosophy behind our CAPS® products**. This seems obvious, but in fact it is far from being so, and in fact we were awarded a patent by the U.S. Patent office on the ability to assess a person's balance, weight and BMI in 60s or less.

VII DIFFERENT CLINICAL APPROACHES TO BALANCE TESTING

Generally speaking there are two quite different approaches to clinically managing persons with balance dysfunctions: **a traditional approach** that up to now has been able to help only a relatively modest number of the many men and women with a balance deficit and that has been able to only marginally reduce the number of falls in the elderly; and **a new approach**, unfortunately still embraced by a very small number of clinicians and medical personnel, that has the potential to help the vast majority of persons with balance dysfunctions and to hopefully decrease the incidence of falls and fall related injuries in the aging population.

These approaches differ in the screening of the general population, in the management in primary care settings and in the management of residents of institutional facilities (e.g. hospitals, rehabilitation facilities, nursing homes, assisted living facilities).

VII.I TRADITIONAL APPROACH

Whereas screenings for many other conditions (e.g. weight and Body Mass Index, vision deficits, high cholesterol and hypertension) are offered at pharmacies, health fairs and other community settings, there is currently no screening of **the general population** for balance dysfunction.

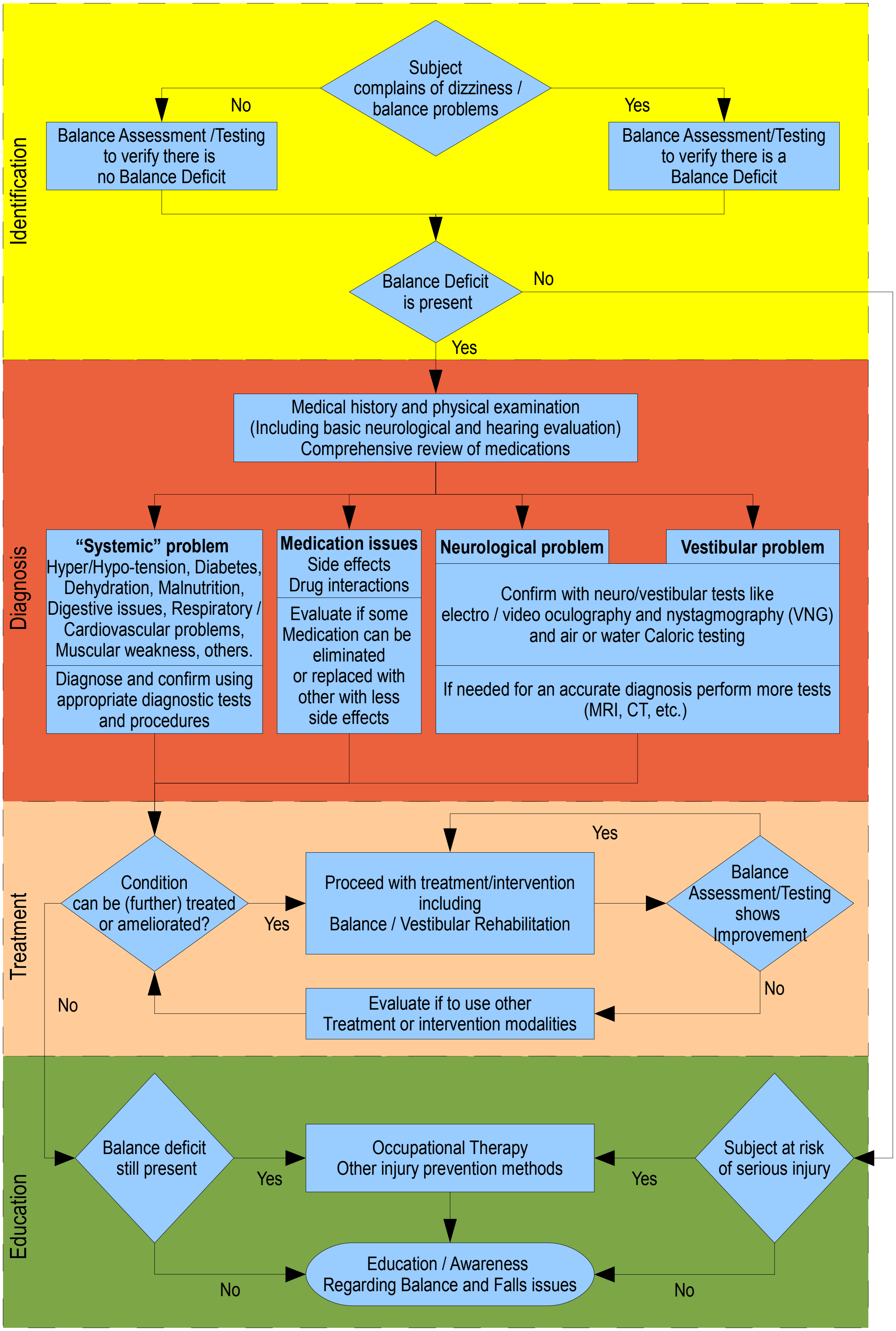
In primary care settings, balance is seldom evaluated. Unfortunately, many primary care clinicians are infrequently educated and trained in managing balance patients. If the patient reports dizziness and/or repeated falls, a basic evaluation using some observational based balance tests might be performed. In case of persistent dizziness and sometimes when a vestibular dysfunction is suspected, the patient might be referred to a specialist (usually an otolaryngologists or sometimes an audiologist or a neurologist). In case of transient dizziness and vertigo (e.g. BBPV), rather than diagnosing the actual cause, the patient is often prescribed antivertigo/antiemetic medications (e.g. Meclizine) and told to take it when an vertigo occurs to help waiting it pass. In case of apparent neuromuscular issues, the patient is prescribed general physical therapy non specific for balance issue. When medication is prescribed for any reason, only in rare instances the effect of the medication regimen on the patient's balance is considered or evaluated. Even in case of primary care clinician trained in balance issues, balance is seldom evaluated, unless the patient reports dizziness or falls. However, at least when presenting these symptoms, the patient is usually further tested and evaluated and is often referred for vestibular testing and/or other diagnostic procedures that relate mostly to the vestibular system or its central nervous system pathways. But even when the primary care clinician is somewhat trained to deal with balance pathologies, unless the subject is symptomatic, balance deficits are often not assessed, nor the possible effects of medications and pathologies on balance are evaluated and explained to the patient.

In institutional settings, because of the pressure by accrediting institutions like The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) to prevent falls, patients are usually evaluated for balance dysfunctions and fall risk. This is usually done using observational based balance tests, questionnaires and other tools developed to evaluate the risk of falls. In presence of acute or severely debilitating pathologies and in non-ambulatory patients, sometimes the only thing that can realistically be done is to take preventive measures rather than addressing the underlying balance deficit. Unfortunately, in less severe situations when a patient is ambulatory, balance dysfunctions, even if identified, are often undiagnosed and untreated, or at most only general rehabilitative measures are taken. This is frequently the case in assisted living settings. The major issue regarding the current approach to the management of balance impairments in institutional settings is the fact that balance testing is not performed often enough. The main reasons are that observational based balance tests take too long, and the speed at which changes in balance can occur is underestimated.

The reasons why balance impairments are conventionally managed this way are several. Among them are: an insufficient knowledge of the issues regarding balance; insufficient sensibility to the consequences of balance dysfunctions; the almost complete absence of specific training of medical personnel; the fact that balance issues are seen as the domain and responsibility of specialists; the fact that balance testing as it usually done, be it using observation based tests or posturography, is too expensive in terms of time and training. This last is in our opinion possibly the main reason. In other words, **the lack of fast, objective and automated ways to test balance is one of the main causes of why balance dysfunctions are currently managed the way they are.**

This approach is leaving unidentified, and therefore untreated, almost all persons with balance dysfunctions that do not present with obvious manifestations (as indicated earlier about 50% of those with balance problems and **approximately 16% of the adult population younger than 65 years and 33% of the population aged 65 and older**). It also leaves many of those with an identified balance deficit without diagnosis and therefore without a real and effective treatment.

This approach also wastes the opportunity offered by balance testing to provide a general and quite comprehensive assessment of a person's general health and therefore to be used as a screening tool for providing an early indication of the insurgence of pathologies. Finally, the difficulties of frequently assessing balance severely hinders efforts to reduce falls.


Identification
Subject complains of dizziness / balance problems
No
Yes
Balance Assessment /Testing to verify there is no Balance Deficit
Balance Assessment/Testing to verify there is a Balance Deficit
Balance Deficit is present
No
Yes
Diagnosis
Medical history and physical examination
(Including basic neurological and hearing evaluation)
Comprehensive review of medications
"Systemic" problem
Hyper/Hypo-tension, Diabetes, Dehydration, Malnutrition, Digestive issues, Respiratory / Cardiovascular problems, Muscular weakness, others.
Diagnose and confirm using appropriate diagnostic tests and procedures
Medication issues
Side effects
Drug interactions
Evaluate if some Medication can be eliminated or replaced with other with less side effects
Neurological problem
Vestibular problem
Confirm with neuro/vestibular tests like electro / video oculography and nystagmography (VNG) and air or water Caloric testing
If needed for an accurate diagnosis perform more tests (MRI, CT, etc.)
Treatment
Condition can be (further) treated or ameliorated?
Yes
No
Proceed with treatment/intervention including Balance / Vestibular Rehabilitation
Yes
Balance Assessment/Testing shows Improvement
No
Evaluate if to use other Treatment or intervention modalities
Education
Balance deficit still present
Yes
No
Occupational Therapy
Other injury prevention methods
Subject at risk of serious injury
Yes
No
Education / Awareness
Regarding Balance and Falls issues

VII.II NEW APPROACH

In the new approach to clinically managing persons with balance dysfunctions, **the general population** is offered balance screening in conjunction with other health screening in many community settings and the general population is educated and aware of balance dysfunctions, fall and the possible consequences.

In primary care settings, balance is tested and evaluated as regularly as blood pressure and weight or even more often, ideally as part of the intake procedures of every visit. Balance is used as an indicator of the insurgence and progress of pathologies. Those persons with balance dysfunction are further evaluated or referred to specialists for vestibular and other diagnostic testing until the etiology of the balance dysfunctions are identified. Unlike in the traditional approach, balance is not synonymous of vestibular, therefore the evaluation includes a review of the medications as well as nutrition, physical condition, lifestyle, neurological conditions and in general an evaluation of the entire well being of the patient. If possible, the underlying cause of the dysfunction is treated and changes in balance are monitored throughout the entire treatment. Patients are referred for specialized balance rehabilitation and their treatment does not end until their balancing ability is maximized given their general health conditions. The possible effects that pathologies, medications and treatments might have on balance are explained to the patient and are actually evaluated and quantified for every patient by following up with repeated balance testings. Patients and their families are then educated as to the possible future consequences of balance dysfunctions, including the increased risk of falls later in life. Patients whose balance cannot be restored to the levels of a healthy person or that are at an increased risk of injuries from falls are educated using an occupational therapy approach (e.g., they are instructed to wear proper shoes, to recognize and avoid situations where their balance might be challenged to its limits, to remove as much as possible from their homes and workplaces things that might cause them to fall).

In institutional settings, the balance of ambulatory persons is regularly evaluated, possibly as often as their blood pressure or other health condition indicators are evaluated (even multiple times a day) to notice changes in their health status and their risk of falls. Changes in balance are quickly noticed and their cause ascertained (just like for blood pressure or body temperature), and patients are informed of the status of their balance and warned of the associated fall risks. The etiology of the balance dysfunctions is identified, if necessary, by further clinical evaluations (including a review of the medications as well as nutrition, physical condition, lifestyle, neurological conditions and in general an evaluation of the entire well being of the patient) or referral to specialists for vestibular, neurologic and other diagnostic testing. If possible, the underlying cause of the dysfunction are treated and changes in balance are monitored throughout the entire treatment. Patients are referred for specialized balance and vestibular rehabilitation and their treatment does not end until their balancing ability is maximized given their general health conditions. Persons whose balance cannot be restored to the levels of a healthy person or that are at an increased risk of injuries from falls are educated as to what to do and what to avoid in their daily routines (e.g. do not shuffle their feet, place their walking aids appropriately so not to trip over them, use rails whenever they are available, do not move around in the dark), active interventions on their environment are performed to remove as much as possible any external, potentially fall causing obstacles (rugs, small tables, power cords), and close monitoring of their daily activities is performed to assess the effectiveness of these preventive measures and avoid as much as possible the devastating consequences of falls.

This approach requires great educational efforts to increase the general awareness of balance dysfunctions and the associated increased risks of falls in an advanced age, and especially to train clinical personnel to identify and manage balance issues. But what **this approach really depends upon is the availability of ways to assess and quantify balance that are similar to the technology available to quantify blood pressure, body temperature or blood oxygen saturation level. In other words, devices that are easy to use, fast, accurate, sensitive to minimal changes, do not require particular skills to be used and to interpret the results thus do not require to be used only by highly trained personnel, and have a negligible cost per use.**

A simplified graphical flowchart of the management of a subject is illustrated in the figure. This is not meant to be a comprehensive and definitive document, rather its purpose is to graphically illustrate some of that has been written in this section as well as throughout this document.

VIII THE CAPS® AND ITS UNIQUE CHARACTERISTICS

The CAPS® was developed specifically to address the needs of the new approach to the clinical management of balance dysfunctions. Several unique characteristics make the CAPS® different and better than other posturography devices for this purpose.

The CAPS® force platform was **designed to be highly portable**. It was the first posturographic device and one of the first medical devices in general capable of being run from a battery powered portable computer without even requiring a power line; and it was the first and still is one of the few balance assessing tools that does not require any special setup such as leveling of the platform on the floor. The extreme portability and power considerations allows it to be used wherever the need for a balance test or screening might arise, and when used in a fixed location it takes up as little room as possible (similarly to a clinician's scale), without occupying too much of the space that in a clinical environment is often at a premium.

The CAPS® force platform was also designed to be **extremely sensitive and accurate**, allowing t**o detect even minute changes in balance** that might provide an early indication of changes in a person's body before these become important and difficult to revert.

Most importantly, the CAPS® **was designed for usability and speed**. Whereas all other balance testing equipments were designed mostly for diagnostic purposes, requiring relatively long set-up and testing times, the CAPS® force platform and software were developed **to objectively and quantitatively assess a subject's balance, weight and BMI in less than 60s without requiring any special training** and to automatically compare the results with reference values established for healthy subjects. This does not mean that the CAPS® can not be used as all other balance testing equipment to conduct advanced balance, neuromotor, and physical performance testing for more in depth evaluations when these are needed. Several of the characteristics of the CAPS® are in fact unique enough that **several patents were granted to protect some of its design features and technology**.

The portability, usability and speed are consequences of having realized that posturography is much more useful for non-specific balance testing assessments than for diagnostic purposes. Unlike our competitors that created devices with sliding and/or tilting platforms and moving visual environments to see how the different sensory inputs affect balance, we concentrated on marrying the traditional Modified Romberg tests with modern posturographic technology replacing the role of the trained observer and creating a sort of instrumented Modified Romberg that is much more sensitive, accurate and objective than the original observational tests and can be performed faster.

However, for all its unique features, the CAPS® is nothing but a very sophisticated and user friendly posturography device that measures a subject's Center of Pressure (CoP) movements during standing. Hundreds of scientific and clinical publications have been written on the applications of these type of measurements in clinical practice. Most, if not all, of that literature applies to the CAPS® as well as to any other posturography devices that measure the subject's sway by means of Center of Pressure movement detection, with the only caveat that few of the instruments used in the past had the resolution of the CAPS®. Therefore, if any earlier research concluded that certain applications of posturography were not successful, it might have been because the instruments were not good enough in terms of sensitivity, resolution and noise. This is a crucial point, so it warrants expressing the concept in another way. Think of MRI or CT machines: any application and study done on a model of MRI or CT machine is applicable to any equal or better model of MRI or CT machine (i.e. a machine having similar or more resolution and/or faster acquisition times), but not vice-versa, since something that can be see and appreciated on a high resolution imaging scanner might not be visible in lower resolution models. The same holds true for posturography and the CAPS® (and any other type of medical instrument, from EKG to microscopes): research performed on one machine is applicable to any machine that is equal or better than the one used in the original research.

It is also important to realize that almost all the research on posturography tried to use the instruments for diagnostic purposes to see if the results could be used to differentiate between pathologies. As stated before, this is almost impossible because balance is an all-encompassing measure that is non-specific. Furthermore, in many studies, the conditions (e.g. subject population and their characteristics, presence of multiple pathologies, when and how the testing was conducted during the progress of the pathology) appear to have been poorly controlled, making the results somewhat questionable.

IX THE CAPS® AND ITS CLINICAL APPLICATIONS

So how can a fast, low cost, sensitive, objective and quantitative balance testing like that provided by the CAPS® be used in clinical practice?

1. **As a fast general assessment/screening tool** to provide a comprehensive evaluation of balance and the health status of a person and to identify those with an asymptomatic balance dysfunction by comparing the result of the subject's tests with the reference values obtained for healthy subjects.
2. **As a verification that a dizzy patient has in fact a balance dysfunction** as in about 15% of the cases dizziness has a psychiatric origin.
3. **As a non-specific diagnostic tool** to determine, by changing the sensory input to the patient and together with a complete medical history and physical evaluation, which of the mayor systems involved in balance might be affected and to aid in the planning of the treatment.
4. **As a fast follow-up to assess and document changes** induced in a patient by treatments (medical surgical, physiotherapic, orthotic, etc.) or by the advancing of a pathology

through the comparison of the test results with baseline values obtained for the same person at the beginning of the monitoring period.

5. **As a fall risk assessment tool** that instead of trying to predict falls far in advance based on a single evaluation allows the frequent testing necessary to use short term instead of long term predictions in the management of fall risk (it is easier and much more accurate to make short therm predictions than long therm ones, just think of weather forecasts).
6. **As an educational tool** to show persons if they have a balance issue and how lifestyle or treatments might be affecting them.

IX.I USING THE CAPS® FOR FAST GENERAL ASSESSMENT/SCREENING

To perform a general assessment/screening, it is necessary to perform a test in the same conditions for which the reference values have been collected. This means a static balance test (the one where the subject stands upright trying to sway the least amount possible) with the subject standing feet shoulder width, looking straight ahead (even with the eyes closed the subject should be instructed to look forward), relaxed and breathing normally. It is possible to perform the testing either with the subject standing on the plate surface, or standing on the perturbing foam cushion positioned on top of the platform. The subject can be tested with eyes open or eyes closed. However, as standing on the hard surface with eyes open is obviously an easy task that does not put much stress on balance, it is recommended that for screening purposes the subject be tested with eyes closed standing on the foam cushion (the most difficult situation).

At the end of the test, the software will automatically compare the subject's test results with the age based reference values and provide a classification of the subject's balance into one of five categories: *Healthy Balance*, *Mildly Reduced*, *Moderately Reduced*, *Severely Reduced*, *Profoundly Reduced*. A subject whose balance is classified as *Healthy Balance* has a 25% probability of a false negative (i.e. the subject has a pathology but the test does not indicate so). A subject whose balance is classified as *Mildly Reduced* has a probability of a false positive (i.e. the probability that the test shows a balance pathology but in fact there is none) between 10% (at the upper limit) and 0.5% (at the lower limit): subjects scoring in this range typically do not suffer from a pathology but only from a temporary condition reducing their balance (like lack of sleep, congestion, or allergies). A subject whose balance is classified as *Moderately Reduced*, *Severely Reduced*, or *Profoundly Reduced* has at most less than a 0.5% probability of a false positive and should definitely be assessed further. The assessment would usually include a complete medical history and physical examination. Most often, especially in elderly subjects, a vestibular problem is one of the causes of the balance impairment, although it might not be the only one. As the vestibular system has a lot in common with auditory systems, usually there is a co-morbidity between vestibular and auditory deficits. It is therefore advisable, if a vestibular deficit is suspected, to proceed with some hearing testing, even if only at a screening level, before any other test is ordered.

Screening for balance problems, especially at the primary care level, is extremely important. According to the CDC over 3 out of 4 (75%) adults over 70 years old suffer from a balance dysfunction (it is the most common disability in the US elderly population), and in ours and our customers' experience about 2 out of 3 (66%) adults over 65 years old and 1 out of 3 (33%) adults below 65 years old suffer from a balance problem. For the clinician, the sometimes minimal decrease in balance and postural stability that a machine like the CAPS® can detect (and that most often is undetectable by observation alone, even with trained eyes) can be the first sign that something is wrong with a patient. For the patients, knowing and treating their balance issues might prevent falls and the serious consequences and costs usually associated with such events.

IX.II USING THE CAPS® TO AID IN THE DIAGNOSIS AND IN TREATMENT PLANNING

One of the main advantages of the CAPS® is the ability to perform objective and very sensitive balance testing in very little time. This can be used to the clinician's advantage to aid in the diagnosis and in treatment planning. The main idea is to provoke temporary changes in a patient and to evaluate the consequences on his/her balance.

For instance, by altering the presence or absence of visual inputs, easily done by testing a subject first with eyes open and then closed, it is possible to evaluate how much the subject relies on vision to maintain balance. A subject that relies a lot on vision (i.e. one for which the tests with eyes closed show a much lower ability to maintain balance than with eyes open with all other conditions being the same) might do so because the vestibular and/or proprioceptive information are deficient. Similarly, altering the proprioceptive inputs, either using the CAPS® perturbing foam cushion or vibratory stimuli to the muscles or to the spinal receptors by applying a vibrating tuning fork, can identify a situation where the subject relies too much on proprioceptive or somatosensory signals for balance. The theoretical basis of the mCTSIB test is exactly this, to see how the subject performs when the combination of vestibular, visual, and proprioceptive/somatosensory information is changed in a controlled manner.

Similarly, lower extremities muscular weakness can be investigated and evaluated by having the subject stand on the platform, with or without foam cushion, for a few minutes and repeating the test every so often to see how quickly the ability to maintain balance deteriorates.

In case of a subject suspected of having Parkinson's Disease without motor symptoms such as tremor or bradykinesia, it is possible to administer a low dose of levodopa and see if and how much balance improves.

If a cerebellar lesion or weakness is suspected, stimulating the identified side of cerebellar dysfunction using hand or upper and/or lower extremity dexterity exercises and then immediately testing the subject typically results in an immediate improvement of the subject's ability to maintain balance.

Various aspects of the vestibular function can also be tested by having the subject position the head appropriately in space so that only specific organs of the vestibular system are active. For instance flexing or extending the head, or tilting or rotating the head, so that specific semicircular canals lay in the horizontal plane, can be used to evaluate if there is problem in one of the canals.

The possibilities are so many, it is impossible to list them all, but the concept should be clear: try to alter even slightly the system or part of the body suspected of having a problem and see if there is a change in the ability to maintain balance, being advised that sometimes the change might actually be for the worst, indicating that such intervention is not the way to make the subject's ability to maintain balance better.

One very often overlooked issue in the treatment is the effect that medications have on balance. Although sometimes this is an unavoidable side effect, it is important to adjust the dosage of the drugs to minimize the effect on balance and to warn and educate the patients on the possible consequences. All too often, for instance, blood pressure lowering medication is prescribed without verifying the functional consequences, with the result that the pressure is lowered to the point of impairing the patient's ability to function and to maintain balance.

It is also essential that any treatment ends with as much a restoration of the patient's abilities as possible. All too often, little attention is paid to the issue of balance, and treatments are considered concluded without taking into consideration if a person's balance has been restored. Balance testing is therefore indicated for verifying if at the end of any treatment the patient might benefit from balance rehabilitation therapy and then to monitor its progress.

IX.III USING THE CAPS® TO MONITOR AND DOCUMENT CHANGES

As maintaining balance and postural stability involve the proper functioning of practically the entire body, it is possible to make the bold statement that **any improvement in a person's health conditions should be accompanied by an improvement in balance and postural stability**.

Accordingly, no matter what the intervention or treatment or progress of a pathology is, balance testing can be used to monitor and document changes. As the CAPS® is a very sensitive instrument and using it to perform balance tests takes very little time, this can and should be done not only pre- and post-, but also during treatment. For instance, during rehabilitative sessions like physiotherapy, the CAPS® can be used to test if the subject is actually fatiguing to the point where it would be better to interrupt the session. Or it can show that the benefits of repeating a certain exercise have reached their maximum, thereby signaling the clinician that it might be time to change exercise type or regimen rather than continuing and getting only diminishing returns.

Although rehabilitative therapies are the most obvious candidate for this type of application, they are not the only ones. For instance, balance testing can be used to monitor the progress of patients who suffered from traumatic brain injuries or mild traumatic brain injuries, especially athletes, to see when they have recuperated enough to resume their normal activities (balance testing is currently used a lot in the management of concussions, especially sports related ones). Or a neurologist might use the CAPS® to decide on the specific amount of levodopa to administer during the day to a patient affected by Parkinson's Disease, to maximize the benefits of the reduction of symptoms with the minimum dosage.

Again, the possibilities are so many, it is impossible to list them all. Nevertheless, the concept here is that if a patient's neurological picture or health status is improving, there should be an associated improvement in the balance and postural stability, at least as a trend (time localized factors could make the results fluctuate because a person never recovers in a straight and linear way, but rather with ups and downs).

IX.IV USING THE CAPS® TO PREVENT FALLS

Because balance can change very rapidly, it is important, for preventing falls, to monitor a person's balance as frequently as possible, sometimes even several times a day. It is unrealistic to expect that a balance test or any other fall risk assessment will predict the occurrence of falls weeks or months in advance. Sometimes the loss of balance that leads to a fall is a temporary event that quickly disappears. For instance, blood pressure can change significantly during the day for various reasons, leading to periods of time when the pressure is low enough that the person is actually experiencing a presyncope. Similarly, the effects of medications or changes in the blood sugar level can lead to periods of critically reduced ability to maintain balance. Therefore, it is necessary to test balance often to see if these temporary events occur.

The health status of a person can also change, for instance because of the onset of a cold or influenza. An elderly person might also suffer transient ischemic attacks. So their balance might be sufficient to avoid a fall one day and worsen the next, and the only way to detect this is by frequent testing.

IX.V USING THE CAPS® TO EDUCATE ABOUT BALANCE

Ultimately, to use balance as an indicator of general heath, to prevent injuries caused by the loss of balance, and to maintain good balancing abilities all life long, it is necessary that the public be educated and aware of the issues related to balance. Being able to show the changes that occur in the ability to maintain balance can be a more effective way to educate the general population about these issues than simply talking about them, because it allows to provide concrete examples.

X ECONOMIC BENEFITS OF THE CAPS®

In the end, although health is priceless, we need to be realistic and deal with the economic realities. This includes considering the direct and indirect costs and benefits of devices like the CAPS®.

For considering the direct costs, we compare the expenses of evaluating a person's balance using traditional observation based assessments, with the expenses of using the CAPS®. Typically, traditional observation based assessments (such as the Berg Balance Scale, the Tinetti Balance Test of the Performance-Oriented Assessment of Mobility Problems, or the Balance Error Scoring System) take about 15 minutes. With the CAPS®, an evaluation can be performed in less than 1 minute and a full mCTSIB testing battery takes less than 3 minutes. Furthermore, traditional observation based assessments must be administered by a highly trained person, whereas the CAPS® can be administered by almost any person with minimal training. Assuming a labor cost of $40/hour for trained personnel and $20/hour for general personnel, a traditional observation based assessment costs about $10 versus less than $1 for the CAPS®. This means that using the CAPS® saves more than $9000 for every 1000 evaluations. A thousand balance evaluations might seem a large number, but considering that a primary care clinician performs more than 2000 visits a year, the CAPS® pays itself very quickly. Furthermore, this does not take into account the fact that for every traditional observation based assessment, at least 5 CAPS® evaluations can be performed, thus multiplying by 5 the number of patients that can be assessed in the same time, or if treating the same number of patients, being able to spend only 3 minutes assessing the patient and 12 minutes diagnosing him/her, instead of 15 minutes assessing the patient with no time left for diagnosis.

Indirect costs and benefits are much harder to quantify. How much is it worth to detect more balance dysfunctions and being able to prevent falls and improve the health and function of many subjects? It can mean higher patient's satisfaction, better outcomes, or reduced costs for unnecessary tests. It also mean having objective documentation of a patient's progress and justification for vestibular testing and rehabilitation. All of these are difficult to quantify, but it is apparent they will be mostly beneficial from an economic point of view.

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