



**A System for Objective, Non-Invasive  
Whole-body Human Balance Assessment  
and Improvement**

*including a Web-Integrated, Proprietary  
Clinical Reference Database*



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## **PROBLEM STATEMENT**

The need for an improved method of measurement and quantification of human balance has long existed. Among the growing areas where this need is greatest are:

- ♦ Determination of 'likelihood of a fall' in the growing population of aging Americans, whose injuries or mortality from falls are an increasing national dilemma
- ♦ Assessment and treatment of equilibrium dysfunction associated with concussion or other traumatic brain injury (TBI) from contact sports or battlefield incidents
- ♦ Tracking therapeutic progress during rehabilitation following injury or surgery
- ♦ Prevention of balance-related injuries in various at-risk groups such as obese, developmentally delayed, or those undergoing injury rehabilitation or disease treatment
- ♦ Establishment of a normalized convention of balance measurement, for comparison of equilibrium function across multiple databases, demographics, and subject groups

Despite impressive efforts, attempts to meet the need for a complete and objective method of balance assessment have been particularly challenging and are still insufficient, primarily due to the difficulties in quantitative measurement of the complex integrated physiological systems that determine human equilibrium and balance. These include the vestibulo-ocular, musculoskeletal, neural processing, and multiple afferent and efferent systems (to name only a few). *They encompass the body, literally, from head to toe.*

While current attempts to assess balance utilize individual tools such as force plates, video, spring loaded tilt plates, and simulated or real motion to induce dizziness, there is no device that gathers the necessary objective measurements of the entire body in a manner which relates the modalities of motor, sensory, and biomechanical, and integrates them into a cohesive set of objective scores sensitive enough to track the subtle alterations in human balance and the energy required to maintain it.

Technical experts and clinical thought-leaders at Balance Engineering LLC have decided to solve this clinical and scientific dilemma by designing an effective and affordable system for objective whole-body assessment of balance that is quick, non-invasive, and easy to use. Further, the system is adaptable over a full range of possible subject groups, including injured, aging, developmentally delayed or limited, obese, and those undergoing rehabilitation or disease treatment, to name a few. The system is capable of tracking changes in balance, alignment, sway, and posture over time, providing a powerful tool for a wide variety of real-world instances, including: (a) monitoring the rehabilitation progress following injury or surgery, (b) tracking age-related changes in balance function to determine the likelihood of a fall, and (c) identifying particularly successful courses of individual therapy from larger subject databases.

The system – developed, manufactured, and distributed by Balance Engineering LLC – is known as: **EQUILIBRATE**.

## WHO CAN BENEFIT

**AN AGING POPULATION** – More than one-third of all adults 65 years or older suffer a physical fall, resulting in medical costs topping \$20 billion per year (US) and the leading cause of injury death. Due to the growing population of aging citizens, costs from falls are expected to *exceed \$50 billion by 2020*. Major healthcare research centers such as the National Institute of Aging at the National Institutes of Health have indicated a dramatic need for *“improved methods for determining balance function and tracking age-related changes in balance, posture, and alignment”* in older Americans. Due to the desire to promote the general welfare of an aging population, as well as efforts to reduce national costs, there is a particular emphasis on improving and prolonging independent living.



The Equilibrate System is an optimal solution to the national goals of improved, affordable, and accessible systems of both balance assessment *and* improvement for aging people. Further, Equilibrate is designed for accurate and objective measurement of balance without the need to induce dizziness, physical instability, or other invasive perturbations that risk additional injury in older subjects.

**MILITARY/COMBAT PERSONNEL** – Currently, 19.5% of theatre personnel deployed to Iraq or Afghanistan suffer concussion or other minor traumatic brain injury (mTBI). In acute cases, 90% exhibit balance dysfunction (*i.e.* about one out of every six total deployed). *Recently the Office of Secretary of Defense has specified a severe need for more sensitive vestibular tests for non-invasive detection, diagnosis, and treatment of balance pathologies.* Current methodologies are insufficient to detect the subtle vestibular pathologies responsible for various physiological effects – such as headache, susceptibility to visual or motion-induced sickness, and Benign Postural Positional Vertigo – that result from battlefield blasts, blunt head strikes, or other combat injuries.

The Equilibrate System rapidly measures minute changes in both upper and lower body position, and maps displacement fields over time that yield comprehensive scores for dynamic alignment and sway. Integrative scoring from this quantitative output is able to detect subtle differences in vestibular function based on specific pathologies of the mTBI victim.



**SPORTS-RELATED CONCUSSION VICTIMS** – A key drawback to the improvements in athletic strength training and conditioning (across all ages) has been the resultant increase in kinetic energy of player-player collisions in contact sports. Despite advances in helmets and other energy absorbent protection, concussion injury is dramatically on the rise. Currently, vital instantaneous diagnosis of concussion is conducted on the playing field or in the training room using balance assessment protocols that can be subjective and variable. *Misdiagnosis of such injuries – especially a false negative – has the potential for serious, perhaps fatal, repercussions for the long-term mental and physical health of the athlete.*

The Equilibrate System is a portable, easily set-up device for the rapid diagnosis of vestibular effects of concussion. Deployable in the training room or, potentially, on the field, the system's footprint takes up minimal space (Figure 1A). *Testing can occur in a matter of two to three minutes and can serve:*



1. *As the primary assessment for possible balance dysfunction from concussion,*
2. *To confirm (and document) a trainer's professional diagnosis, or*
3. *To indicate the need for additional professional assessment or observation*

The system is especially authoritative when previous baseline scores have been established for the individual athlete. Current balance scores as well as the subject's equilibrium history are available instantaneously on Equilibrate's screen.

**CLIENTS WITHIN PHYSICAL THERAPY CLINICS** – Physical Therapists play a key role in the diagnosis and treatment of conditions related to balance function. Because of the growing knowledge of the complex physiological systems involved in human balance, the role of the PT is expanding broadly. Seeking to treat greater numbers of patients with increasingly differentiated conditions, clinicians are urgently seeking new tools to deliver improved and efficient care to a growing client base, many of whom are inflicted with balance dysfunction. *The Equilibrate System is a state-of-the-art clinical solution to the pressing need for objective balance assessment, diagnosis, and treatment that addresses many of the oncoming concerns of the 21<sup>st</sup>-century physical therapist as well as many of the established problems of the clinical PT professional.*

As an example, Equilibrate's customizable therapy modules allow the PT to tailor client-specific exercises based on the patient's individual balance aptitude, which can be established through either (1) instantaneous baseline assessment or (2) analysis of the patient's history. *Recorded exercise output and continuous feedback ensure that appropriate therapy is being delivered to the patient, even if the healthcare professional must leave the client autonomous for a few moments.* This type of autonomous and quality-assured therapy is especially beneficial to professionals seeking to cope with the



issues of client-base and incremental revenue growth within the PT industry, as well as the uncertainties surrounding future healthcare mandates.

The Equilibrate System's quantitative output also documents the *type* and *time of exercise* (for potential billing/insurance purposes), and allows both patient and care professional to *confidentially track progress over courses of therapy*. Furthermore, actionable output is sufficiently intricate for the PT professional to analyze subtle changes in balance during qualified analysis, but also comprehensible to the client for tracking progress and actively responding to system feedback in an increasingly patient-interactive world.

'Take-away' material such as graphical charts of personal progress or at-home exercises (from Equilibrate's vast library) are particularly helpful for motivating results-driven individuals such as athletes, military personnel, and a progressively more information-oriented public. Importantly, increased knowledge about an individual's balance aptitude (such as Equilibrate's 'likelihood for a fall' score) initiates healthy attitudes of proactive behavior and 'thinking ahead' that go a long way in the prevention of balance-related injury, or improved rehabilitation following an incident.



**RESEARCHERS** – Due to our increased understanding of human balance as a critical function of feedback from, and input to, broad physiological systems (sensory, neural, musculoskeletal etc.), *balance assessment is finding greater importance as an analytical tool for research in both the clinic and the laboratory*. From trials examining the far-reaching effects of disease-treatment drugs, to individual case studies of the vestibular effects of concussion, *researchers in industry, healthcare, and academia are seeking more quantitative and data-integrative tools for objective assessment of human balance*.

The Equilibrate System offers an instrument-based solution that is: (1) objective, (2) quantitative, and (3) data-driven. Moreover, Equilibrate offers a solution *beyond currently available foot-plate-only devices*, to integrate upper- and lower-body output from a combination of imaging and force sensors. The result is a powerful research tool that provides quantitative scores for sway, dynamic alignment, overall balance, as well as contributions from individual components across the whole body.

**OTHER GROUPS FOR WHOM OBJECTIVE BALANCE ASSESSMENT IS IMPORTANT** – The list is almost all-inclusive; however, a few key populations are identified here:

- ◆ Bariatric/Obese groups (Adults and Children)
- ◆ Amputees
- ◆ Chemically affected groups – e.g. disease treatment (cancer, psychiatric, other)
- ◆ Alcohol or drug users/abusers
- ◆ Individuals undergoing rehabilitative therapy following injury or surgery

## TECHNOLOGY DESCRIPTION

As part of the Equilibrate System, the human subject stands on multi-directional footpads while wearing a lightweight vest with imaging targets placed at specific anatomical landmarks (Figure 1A). Receiving input from *footpads and cameras*, Equilibrate senses minute shifts in forces, positions, directions, and frequencies of motion from individual areas of the body and provides quantitative scores of *dynamic alignment* and *sway*, as well as the integration of their combined effects across the whole body in an *overall score for total balance* (Figure 1B).



**Figure 1A:** *Configuration of the Equilibrate System* – The subject simply dons a lightweight vest decorated with specifically placed targets for image capture, and stands on separate right and left foot pads. Images from two cameras and multi-directional force telemetry from the footpads are integrated and analyzed by proprietary algorithms to generate objective, quantitative, and actionable output regarding comprehensive balance of the subject. Individual readings take very little time (~15 seconds) and range from stationary standing, to single leg exercises, to customizable therapy ‘modules.’

**Figure 1B:** *Equilibrate Interface* – The computer screen through which the operator (physical therapist, doctor, clinician, field medic/trainer, etc.) interfaces, is comprehensive, clear, and easily navigable. Operators are given on-screen prompts as to the stage of the test and a clear indication as to procedure (minimal training is required for operation of Equilibrate). Actionable outputs for the subject include scores for alignment, sway, and overall balance; as well as detailed and more subtle metrics of equilibrium for the healthcare professional. Output data is instantly stored and can be examined immediately at the time of measurement, or later for more complete interpretation of test results.

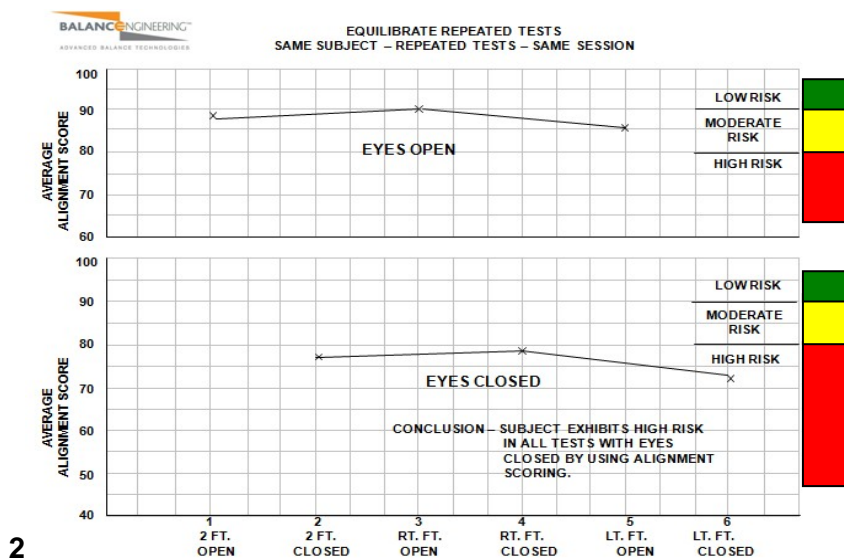
In developing Equilibrate, the innovative approach of Balance Engineering was the *avoidance* of balance measurement techniques that are (A) subjective, or (B) not amenable to the mathematical integration of outputs from and across various parts of the body. Since even balanced standing is a state of dynamic change (involving sensory input and neuromuscular response), the power of the Equilibrate System stems from analysis of energy and motion over time. Metrics from the upper and lower body

are measured, analyzed, and combined for comprehensive scores of sway, dynamic alignment, and overall balance.

Balance Engineering also identified inferior aspects of currently available products in the market, particularly in the area of *reliability* and *operational friendliness* (for both patient and operator). Keeping these deficiencies in mind, during the design and development of Equilibrate an increased emphasis was placed on ease-of-use and durability. The results of these important considerations are reflected in the subject's simple and straightforward interaction with Equilibrate (Figure 1A), and an easily navigable, step-by-step interface for the operator (Figure 1B). Web-integrated design not only provides up-to-the minute software and therapy library updates, but data from Equilibrate users (with patient identity protection) contribute to a database that aid in the identification of superior modes of diagnosis and rehabilitation.

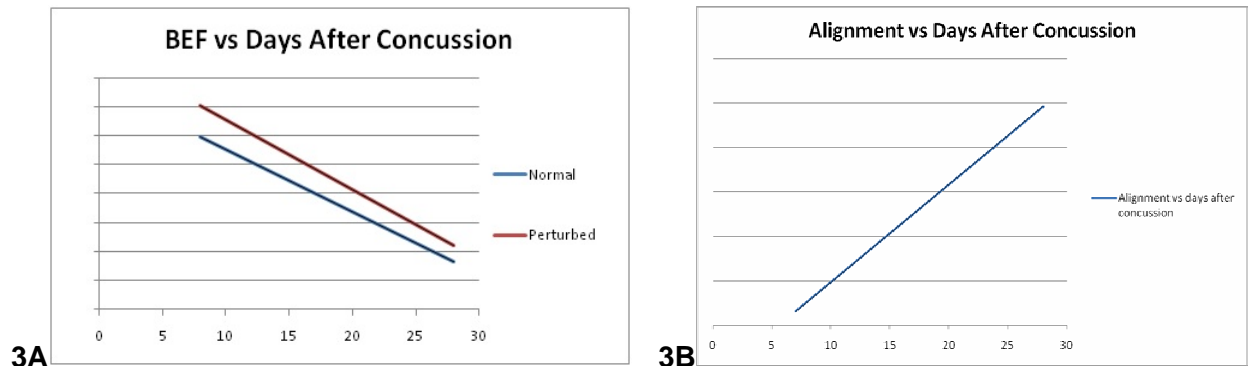
## VALIDATION

**IDENTIFYING FALL RISK IN AN AGING POPULATION** – Of particular use for the population of aging Americans is Equilibrate's quantitative score for *likelihood (or risk) of a fall*. Data presented in Figure 2 are real output from a 70-year old subject prior to knee surgery, whose weakness was evident (especially with eyes closed), and who indeed suffered a fall before surgery.



**Figure 2:** Sample Patient Diagnosis Output from the Equilibrate System – The 'Alignment Score' integrates upper and lower body output and assesses a 'Risk of Fall.' Presented are actual data from a 70-year old subject, prior to knee surgery, whose weakness was evident – especially with eyes closed – and who did indeed fall before treatment. Moreover, following surgery, the subject's progress was able to be tracked during rehabilitative therapy (data not shown). The data represent objective, typical, and actionable output easily obtained during a 10-minute session of simple and non-demanding 15-second tests (e.g. standing with eyes open, standing with eyes closed, standing with feet offset simulating gait, etc.). System repeatability was 99.6%.

**DIAGNOSING CONCUSSION AND TRACKING RECOVERY** – Equilibrate’s ability to measure the energy required to maintain balance allows the system to effectively detect balance dysfunction from concussion or other minor Traumatic Brain Injury (mTBI). Moreover, the system’s sensitivity allows progress/recovery to be tracked over time, as seen in Figure 3, which reflects improvement in balance function of a 19-year-old concussion victim over a period of four weeks following mTBI.



**Figure 3A:** *Improvement of Balance in an Actual Concussion Victim* – One of many output metrics that is measured, scored, and tracked by the Equilibrate System is *Balance Energy Factor* (BEF), a derivative of power. BEF indicates the energy exerted to maintain balance. As the 19-year old female subject’s brain healed from concussive injury, less energy was required to maintain balance. This was especially evident in the perturbed tests (upper red line) versus normal or natural state of the subject (for simplification, units of ‘BEF’ in 3A and ‘Alignment’ in 3B are excluded).

**Figure 3B:** *Improvement of Dynamic Alignment in the Concussion Victim* – The graph illustrates the capability of the Equilibrate System for complete-body measurement (reflected in the *Alignment* score). As the brain recovered from concussion, upper body dynamic alignment of the subject improved, as did the balance capability, leading to a reduced risk for a fall.

**These data provide direct evidence for the potential of the Equilibrate System to serve as a powerful tool for the objective and non-invasive assessment of balance in subject groups of various vital balance dysfunctions. Moreover the therapy modules within the Equilibrate System provide direct modes of rehabilitation and progress for these subjects.**

**CURRENT STATE OF DEVELOPMENT**

Currently available and in distribution, Balance Engineering’s *Equilibrate System* represents a state-of-the-art solution to the pressing need for objective balance assessment, diagnosis, and treatment over a wide range of subjects and applications. Only recently – through advances in system integration merging hardware, software, video and image processing, continuity of web interface, and data processing – is a system like Equilibrate available for reliable wide-spread use.

Equilibrate’s *instant web-integration* makes the platform an adaptable and powerful tool for the delivery of superior diagnosis and therapy in the dynamic healthcare



environment. As an example, *frequent library and software updates give Equilibrate users and their clients access to the most recent therapy exercises for advanced rehabilitation*, as well as the most cutting-edge analysis tools for balance assessment. Archived and protected patient output allows PT professionals to more efficiently and confidently deal with emerging *documentation requirements and increased demands on their limited resources* in the new era of healthcare. Moreover, detailed analysis of broad Equilibrate data from healthcare centers and satellite clinics allows superior modes of therapy to be identified, validated, and distributed to all members of the global Equilibrate System network.

## **ABOUT THE COMPANY**

Balance Engineering LLC was formed in 2008 and spawned from a group of healthcare, business, academic, and technical professionals who sought solutions to the need for improved methods of objective balance assessment in humans. Working closely with researchers at the Rensselaer Polytechnic Institute and care-providers in various New York State therapy clinics and hospitals, experts at Balance Engineering have developed the first ever tool for the quantitative assessment of balance that takes into account movement and displacement metrics from both the upper and lower body, and incorporates them into entirely objective scores for dynamic alignment, sway, and overall balance. The scores are actionable to both healthcare professional and patient, and can be tracked over time.

Technical input and design of the Equilibrate System comes from a wide range of experts in the area of human balance, including: physical therapists, engineers, scientific researchers in biophysics and biomechanics, and dance professionals – who contribute a unique perspective of the complex interaction between the function and form of human balance.

Balance Engineering LLC has partnered with Hydroacoustics Inc. (HAI), an established supplier of integrated systems of hardware, software, control, and sensing to government and private customers across a wide range of applications and markets. Through this marriage, Balance Engineering is able to tap the engineering expertise and fabrication/manufacturing resources of its 40-year-old partner, which specializes in applying multi-disciplined technologies to underwater systems, remote operated vehicles, enhanced oil recovery, and video and software design.



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