Validating BTrackS™
To Measure Balance

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BTrackS is a force plate that was introduced to the market in 2014. BTrackS is a FDA Class 1 Medical Device (Registration #3010668481) and is licensed for development and manufacture by the California Food and Drug Branch (License # 73881). BTrackS is made in the USA.

For decades, force plates have been used as the “gold standard” for measuring the amount of postural sway an individual has – which is a well-accepted indicator of balance ability. While force plates have traditionally cost thousands of dollars, BTrackS is available at a price less than $900.00. At this price – objective, accurate and reliable balance measurement is now accessible for the widespread use in many domains including concussion management, fall risk assessment and rehabilitation/training.
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**What is a force plate?**

A force plate, such as BTrackS, is a platform used to measure the forces exerted on the ground by a body. These forces, called the ground reaction forces (GRF), are measured by a series of sensors integrated with the plate. The measurement data is typically transmitted to a computer for analysis and presentation.

The first force plate was designed and built by a French scientist Etienne-Jules Marey in the late 1800’s. Over the past 50 years, force plates have become one of the most commonly used measurement tools in biomechanics.

The most common test implemented on a force plate like BTrackS is one that measures static balance by calculating the center of pressure (COP) postural sway of an individual. This test requires an individual to stand on the force plate for a designated period of time while the sensors in the force plate determine the amount of the body sway.

The design of a force plate includes a platform, load cells for calculating the ground reaction forces and electronics for data collection and interpretation. Force plates, such as BTrackS, have a multitude of different capabilities and are used as the “gold standard” for balance assessment in a wide range of medical fields.

**The US Food & Drug Administration (FDA) regulates force plates as medical devices**

The FDA regulates force plates such as BTrackS. They are Class 1 Medical Devices under the product classification: Platform, Force-Measuring. The Product code is KHX.

The FDA works closely with state regulators to make sure that medical devices meet certain standards before they can be introduced into the market. In California, where BTrackS is developed and manufactured, the regulatory branch that works with the FDA is the California Food and Drug Branch (CFDB).

Based on these FDA regulations, there are specific requirements that must be met by companies who develop and manufacture force plates. The FDA and the CFDB work closely together to make sure these requirements are implemented. In California, companies must be inspected before receiving a license to develop and manufacture. While the requirements are too lengthy for this document – here is a simple summary:

The force plate developer must operate under the FDA Quality System Regulation 21 CFR 820. The most important element of this QSR is that the developer must operate a Quality Management System (QSM) that adheres to specific FDA guidelines. The QSM mandates that the developer follow a specific process for developing products and manufacturing products. These processes require the developer to document every phase of product design and production and verify that the product meets the design objectives. The QMS is sometimes referred to as an ISO-9000 System which is an international standard for quality systems. **BTrackS was developed in this environment and an agent from the California Food and Drug Branch inspected the BTrackS development facility to ensure this process was in place.**
How accurately does BTrackS measure center of pressure?

BTrackS has been shown to be extremely accurate in its measurement of center of pressure (i.e. postural sway). This has been accomplished using a scientific validation procedure that compares known points of pressure placed on the BTrackS acquisition plate and the measured location of those points by the BTrackS software. For example – if pressure is placed on the plate at four centimeters from the plate’s central location, the software should accurately report that location as being four centimeters from the center.

Shown below is a sample 11 x 11 cm grid of points that have been tested to demonstrate the accuracy of the central region of the BTrackS acquisition plate. Using a computerized numerical control (CNC) machine, pressure was precisely placed on each of these points and the accuracy of BTrackS software readout was determined.

The following page illustrates two summary figures of the relationship between the actual center of pressure for each point tested and the location measured by the BTrackS software.
In the top graph the accuracy of BTrackS in the left/right (COPx) direction is shown, while the accuracy of BTrackS in the front to back (COPy) direction is shown in the bottom graph. Each point on the graph represents a single test point (121 in all – points overlap that are equidistant from the center of the board). A line of best fit has been applied to this data to show that there is a strong linear relationship between the actual COP of the CNC pressure point and the BTrackS measured COP. The fit of the line, established using a Pearson correlation coefficient (r), is greater than r=0.99 on a scale from 0 (no relationship) to 1 (perfect relationship). This value suggests that COP determined using BTrackS is accurate at a very high degree. Specifically, when the average difference between actual and measured location is calculated, BTrackS measures center of pressure with better than one millimeter accuracy. This is less than the diameter of a pinhead.
How reliably does BTrackS measure center of pressure?

BTrackS has also been shown to be an extremely reliable measure of center of pressure (i.e. postural sway). To scientifically validate this, another procedure has been employed using pressure points placed precisely on the acquisition plate using a CNC machine. In this case, each of 21 individual points tested (shown on the board below) was pressed on 5 consecutive times and measured by the BTrackS software. The variability of the results obtained by the software was then calculated and shown to differ by less than $1/10^{th}$ of a millimeter for any given point tested. This is less than the width of a standard grain of table salt.

What is the BTrackS Balance Test and where does it come from?

The BTrackS Balance Test is designed to detect disrupted balance in a quiet, eyes-closed, feet shoulder width apart standing position. The BBT consists of four 20-second trials. The first trial is a familiarization trial. The following three trials are used to actually measure the number of centimeters of postural sway. The BBT then averages the outcomes from the three trials and provides a final BBT result. BTrackS uses four-sensor, center of pressure measurement technology as the basis for all four trials.

The BBT is a derivative of the Romberg balance test, an important element of neurologic examinations for over 150 years. The test, named after German neurologist Moritz Heinrich Romberg (1795-1873), determines the body sway of an individual while they are standing with their feet together and their eyes closed for up to 60 seconds. By eliminating vision, the Romberg
test challenges the individual to maintain balance based on proprioception and vestibular senses that are known to be key contributors to balance ability. Romberg testing has been shown to be an effective clinical diagnosis tool for balance problems associated with many neurological clinical conditions such as Parkinson’s disease, stroke, and traumatic brain injury.

**Is the BBT a reliable measure of balance over time?**

A key feature of any balance test is test-retest reliability. This is how consistently the test provides statistically similar results from a person when nothing has changed in their health status. Reliability is important because the more reliable the test is, the easier it is to see a true change in balance due to injury, such as concussion, or training/rehabilitation.

Test-retest reliability of a balance test can be determined using a statistic called the intra-class correlation coefficient (ICC). A group test is considered to be reliable if data has an ICC greater than 0.7 on a scale from 0-1. Group data from several research studies have shown that the BTrackS Balance Test (BBT) protocol of three, 20-second balance trials with eyes closed and both feet on the ground is reliable. These research studies have determined that the BBT has an ICC value that is 0.7 or greater. Our own group studies at Balance Tracking Systems have also confirmed these reliability results. When we tested 100 people twice, separated by a week, the BBT had an ICC value of 0.8.

**Can balance be measured in 3 trials of 20 seconds each?**

When using a force plate – like BTrackS – the answer is yes. A recent study by Golriz et al (2012) was performed to determine how many trials a balance test needs to be reliable. Using a test protocol similar to the BBT it was found that acceptable reliability (i.e. ICC>0.7) was achieved with only two balance trials for a measure of center of pressure called mean velocity. This measure is equivalent to the measure used by Balance Tracking Systems in the BBT (i.e. postural sway - total path length).

While two trials was acceptable, Golriz et al (2012) showed that adding a third trial improved the reliability of balance testing further, with an ICC of 0.95 reported. There was no statistically significant improvement by adding a fourth or fifth trial of balance data, suggesting a three trial test was both reliable and practical.

**Can the BBT detect balance deficits in a concussed athlete?**

Testing with BTrackS is ongoing with the assistance of San Diego State University’s athletic training program and other schools in the San Diego area. Since testing began in early 2014, BTrackS has been utilized to baseline over 1000 athletes at these schools. As would be expected, there have also been a number of concussions that have occurred.

Two examples of concussion data are shown below. In each case, the black dashed line represents the baseline BBT. Data from a women’s water polo athlete is shown on the left. This athlete had
more postural sway (i.e. higher BBT) than baseline following her concussion, which improved for the first 48 hours. At 72 hours, the athlete had a relapse of concussion symptoms that was also reflected in her postural sway. The athlete returned to play on day 11 and balance was back to baseline at this point. Data from a men’s rugby player is shown on the right. This athlete’s postural sway increased following his injury and then returned to baseline within a week.

**Sample of organizations utilizing BTrackS**

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<td>United States Air Force Academy</td>
<td>BStrong4Life – Heun Chiropractic</td>
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<td>University of New Hampshire</td>
<td>SDSU &amp; County of San Diego Aging Services</td>
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<td>Georgia Southern University</td>
<td>Saks Wellness Center</td>
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<tr>
<td>Mesa College</td>
<td>OsteoStrong Albuquerque</td>
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<tr>
<td>San Diego City College</td>
<td>Kingen Chiropractic Wellness Center</td>
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