

This software operating manual is available as a pdf file at:

<http://www.b2i.info/download/SwayStarUK.pdf>

Help for SwayStar™

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1. Help - SHORT DESCRIPTION

The SwayStar™ program has been designed to take maximum advantage of modern program techniques, for example, hint bars to guide you through the use of the various available options. This *Help* section provides in-depth information. However many aspects of SwayStar™ software are easily discovered as one uses the software.

This *Help* is a software operating manual that provides efficient user-support for the different SwayStar™ hardware models and feedback components. The most recently added feedback component is the BalanceFreedom™ feedback unit. *Help* also consists of a valuable summary of program commands and capabilities. It is not assumed that the reader has a working knowledge of gait analysis and posturography.

The most effective use of SwayStar™ software is achieved by familiarizing yourself with its user-friendly navigation.

2. SwayStar™ MEASUREMENT AND ANALYSIS TECHNIQUES

2.1 CONCEPT OF BALANCE CONTROL ANALYSIS

The SwayStar™ program records and analyses a test person's balance control capabilities for a set of several stance and gait tasks. For this purpose trunk-sway measurements are used. SwayStar™ answers the need for a simple series of tests from which calculations are derived to indicate the degree or absence of a balance and/or gait disorder. It takes into consideration the fact that individuals with balance instabilities tend to fall in a variety of directions that include both roll (side-to-side) and pitch (front-to-back) directions. Although separate tests exist for both stance and gait analysis, these have no single battery of tests and measurements like those of SwayStar™ which cover the entire range of stance and gait responses. SwayStar™ focuses on those trunk-sway measures that are most sensitive for indicating a balance or gait disorder, and performs these measures simply and rapidly.

Tasks that involve reducing or disturbing sensory inputs (eye closure or standing on a foam support surface) produce larger sway magnitudes than when standing eyes open or on a normal surface. Removing visual input increases sway, as does using a foam surface on which to stand or walk. The SwayStar™ test battery includes evaluation procedures like those of computerized posturography in order to document how visual and somatosensory inputs are used in these environments.

The SwayStar™ summary reports indicate for a set of clinical stance and gait tests whether there is a need for further evaluations that require the use of more elaborate equipment and different expertise. It does this based on quantitative measurements. Thus, SwayStar™ is both cost and time effective. Individuals with balance deficits show instability either during stance and gait tasks or both, particularly following acute onset of a deficit. Repeating the SwayStar™ tests after a treatment regime will permit the clinician to quantify any improvement in the patients' stance and gait instabil-

ity. Although the sway demonstrated by such subjects is often mainly side to side (roll plane), falling in the direction of the deficit, instability in other directions such as the front-to-back (pitch plane) also occurs. SwayStar™ is the only system that includes both measurement possibilities in a single test battery using a single device.

2.2 SwayStar™ LITERATURE ON TRUNK SWAY DURING STANCE AND GAIT

The goal of the SwayStar™ measurements is to make direct comparisons between the amplitudes of trunk instabilities in different groups of subjects for both stance and gait tasks. Including task duration as a measurement makes it possible to weight the information content of duration relative to trunk-sway variables. Clinicians will want to compare a test subject's values to normal reference values and then decide, based on the pattern of the deviations from the reference values, whether the subjects' values are likely to be similar to those of a specific patient group. Examples of this procedure for different patient groups are provided in the following list of clinical-scientific literature. The reviews provide up-to-date summaries.

Reviews:

Allum JHJ, Carpenter MG, Adkin AL. Balance Control Analysis as a method for screening and identifying balance deficits. In: Vestibular Labyrinth in Health and Disease. Eds J Goebel and S.M. Highstein Ann NY Acad Sciences 2001, Vol. 942:413-427.

Allum JHJ, Carpenter MG. A speedy solution for balance and gait analysis: angular velocity measured at the centre of mass. *Current Opinions in Neurology* 2005, 18: 15-21.

Allum JHJ, Carpenter MG. Erkennung und Rehabilitation von Sturztendenzen und Gleichgewichts-Funktionsstörungen mittels Posturographie. *Vestibularfunktion* (ed M Westhofen) Springer Verlag, Vienna 2006, pp 141-156.

Allum JHJ Gleichgewichtskontrolle - Klinische Bedeutung und praktische Relevanz. *HNO Praxis heute Band 27: Schwindel* Eds E Biesinger and H Iro, Springer Verlag, Heidelberg 2007, p 47-58.

Clinical Scientific (Sway Star™):

Adkin AL, Allum JHJ, Bloem BR. Trunk sway measurements during stance and gait tasks in Parkinson's disease. *Gait and Posture* 2005, 22: 240-249

Allum JHJ, Held-Ziolkowska M, Adkin AL, Carpenter MG, Honegger F. Trunk sway measures of postural stability during clinical balance tests: effects of a unilateral vestibular deficit. *Gait and Posture* 2001, 14:227-237

Allum JHJ, Zamani F, Adkin AL, Ernst A. Differences between trunk sway characteristics on a foam support surface and on the Equitest® ankle-sway-referenced support surface. *Gait and Posture* 2002, 16:264-270

Allum JHJ, Adkin AL. Improvements in Trunk sway for stance and gait tasks during recovery from an acute unilateral peripheral vestibular deficit. *Audiology and Neurootology* 2003, 8: 286-302

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- Hegeman J, Shapkova E, Honegger F, Allum JHJ. Effect of age and height on trunk sway during stance and gait. *J Vest Res* 2007,17:75-87.
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- Horlings GC, Kueng UM, Honegger F, Bloem BR, Van Alfen N, Van Engelen BGM, Allum JHJ. Identifying vestibular and proprioceptive loss using posturographic analysis of stance tasks. *Clinical Neurophysiology* 2008, 119:2338-2346.
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- Horlings CGC, Küng UM, Bloem BR, Honegger F, Van Engelen BGM, Allum JHJ. Vestibular and proprioceptive influences on trunk movement strategies during quiet standing. *Neuroscience* 2009, 161:904-914
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- Sjöström H, Allum JHJ, Carpenter MG, Adkin AL, Honegger F, Ettlin T. Trunk sway measures of postural stability during clinical balance tests in patients with chronic whiplash symptoms. *Spine* 2003, 28: 1725-1734
- Van de Warrenburg BPC, Bakker M, Kremer HPH, Bloem BR, Allum JHJ. Trunk sway in patients with cerebellar ataxia. *Movement Disorders* 2005, 20: 1006-1013
- Visser JE, Voermans NC, Oude Nijhuis LB, van der Eijk M, Nijk R, Munneke M, Bloem BR. Quantification of trunk rotations during turning and walking in Parkinson's disease. *Clin Neurophysiol*. 2007, 118: 1602-6

Vonk J, Horlings CGC, Allum JHJ. Differentiating malingering balance disorder patients from healthy controls, compensated unilateral vestibular loss and whiplash patients using stance and gait posturography. *Audiology and Neurootology*, 2009 15:261-272

Vrancken AMPM, Allum JHJ, Siebner HR, Peller M, Visser J, Bloem BR. Effect of bilateral subthalamic nucleus stimulation on balance and finger control in Parkinson's disease. *J Neurology* 2005, 252:1487-1494

Clinical Scientific (Balance Freedom™)

Allum JHJ, Davis JR, Carpenter MG, Tschanz R, Meyes S, Debrunner D, Burger J. Neue Ansätze zur Sturzprävention mittels einer multi-modalen Gleichgewichtsprothese. In *Neues aus Forschung und Klinik 6. Hennig Symposium: Der Gleichgewichtssinn*. (ed H Scherer) Springer Verlag 2008 p 211-221

Allum JHJ, Horlings CGC, Honegger F, Tang KS and Kessler P. Movement strategies after vestibular loss: aiding these with prosthetic feedback. In *Hören und Gleichgewicht im Blick des gesellschaftlichen Wandels* ed PK Plinkert, Springer Verlag 2009, p174-182.

Basta D, Singbartl F, Todt I, Clarke A, Ernst A. Vestibular rehabilitation by auditory feedback in otolith disorders. *Gait and Posture*, 2008, 28:397-404

Burger J, Meyes S, Tschanz R, Davis JR, Carpenter MG, Debrunner D, Allum JHJ. Multi-modales Biofeedback-System zur Vorbeugung von Stürzen. *at-automatisierungstechnik* 2008, 56:467-475

Davis JR, Carpenter MG, Tschanz R, Meyes S, Debrunner D, Burger J, Allum JHJ. Trunk sway reductions in young and older adults using multi-modal biofeedback. *Gait and Posture* 2010, 31(4):465-72.

Hegeman J, Honegger F, Kupper M, Allum JHJ. The balance control of bilateral peripheral vestibular loss subjects and its improvement with auditory prosthetic feedback. *J. Vest Res* 2005, 15:109-117.

Horlings CGC, Honegger F, Allum JHJ, Carpenter MG. Vestibular and proprioceptive contributions to human balance corrections: aiding those with prosthetic feedback. *Proc NYAS* 2009, 1164:1-12. In *Basic and Clinical Aspects of Vertigo and Dizziness* eds M Strupp, C Biettner and B Cohen

Huffman J, Norton LE, Adkin AL, Allum JHJ. Directional effects of biofeedback on trunk sway during stance tasks in healthy young adults. *Gait and Posture* (in press)

Janssen LJF, Verhoeff LL, Horlings CGC, Allum JH. Directional effects of biofeedback on trunk sway during gait tasks in healthy young subjects. *Gait and Posture* 2009, 29:575-581.

Kessler P, Horlings CGC, Küng UM, Tang K-S, Allum JHJ. Multimodales Feedback bei vestibulären Gleichgewichtsstörungen - erste Ergebnisse. *Schweiz Med Forum* (in press)

Verhoeff LL, Janssen LJF, Horlings CGC, Allum JHJ. Effects of biofeedback on trunk sway during dual tasking in healthy young and elderly. *Gait and Posture* 2009, 30:76-81

2.2.1 Advantages of SwayStar™ compared to other types of equipment

- Direct measures of trunk sway
- Mobile
- Quantifies falling tendency
- Bluetooth communication allows large operating range up to 60m
- Extremely low operating costs
- Highly accurate large measurement range
- Accurate sensory analysis of stance tasks
- Large age range of normal reference values for many stance and gait tasks

SwayStar™ directly measures the angular deviations of the trunk near the centre of mass (around L3-L5). Other systems such as static platforms rely on indirect calculations to obtain angular deviations of the centre of mass (CoM) obtained from measuring forces imposed on strain gauges embedded within the support surface. Motion analysis systems use body marker information which must be converted to angle information. Finally linear accelerometer systems use the deviation of the CoM with respect to gravity to obtain angles, but these measurements are corrupted by other linear accelerations of the body. Thus measurement system is the most direct measurement of angle of the body. The SwayStar™ system is mounted on a belt and fits in the small of the back. This makes the system portable, quick and easy to use, allowing registration of how the trunk is moving during different real-time tasks without significantly limiting the subject's movements.

Measuring trunk angular motion near the centre of gravity is probably the most effective way to quantify a falling tendency. It is independent of the linear motion of the body, that is, how fast one is walking. Measuring at another body segment might not quantify balance instability. For example, motion of the head alone would not, because head movements are often independent from those of the trunk.

With the Bluetooth communication system SwayStar™ employs, the test subject can be up to 60 m away from the base recording system software at the PC. Other systems using camera, ultra-sonic or magnetic based sensor systems lack this huge field of operation.

Current camera-based, linear-displacement, motion analysis systems have limitations for analyzing body sway. They lack the sensitivity to accurately monitor small angular movements, they operate within frequency bandwidths that are too low (less than 50 Hz) to quantify a range of angular velocities accurately and the subject is often confined to a pre-defined test area making it difficult to perform and record gait tasks. Such motion analysis systems require repeated calibration to ensure that angles calculated from marker movements on the body are accurate. SwayStar™ avoids the limited accuracy, narrow bandwidth of such systems, and intensive operating costs. One of the prime disadvantages of motion analysis system is the need for dedicated technical personnel to operate the system and to produce the angular measurements that SwayStar™ produces automatically.

One of the main advantages of SwayStar™ is that it can be used to measure the small movements of body sway during stance tasks. For example during standing with eyes open on a firm surface roll sway velocities have a peak to peak range of +/-0.4 deg/sec. SwayStar sensors have a mean drift of 0.002 deg/sec (specification 4 deg/hr, but production values are about 1 deg/hr) with a standard deviation of 0.02 deg/sec. The best micro-mechanical angular velocity sensors on the market provide mean drifts of angular velocity of 0.4 deg/sec with standard deviations of 0.4 deg/sec. The accuracy of implies that Swaystar can define accurately pathological sway movements during stance with eyes open, other systems do not have this functionality. Any drift measured with the SwayStar™

system is that of the earth's rotation (0.01 deg/sec). Furthermore sway measured with different SwayStar units on the same subject is highly reproducible. SwayStar™ also has a large operating range +/- 256 deg/sec. Thus it can be used to measure large sway movements of gait tasks, for example the getting up off a stool phase as part of the get-up-and-go task.

Stance tests can be performed in many forms with SwayStar™. One of the most common is on two legs, with and without vision, and like with computerised dynamic posturography (CDP) with an unstable surface. A foam pad is used as the unstable surface with SwayStar™. By comparing the values of sway under different visual and support surface conditions it is possible to assess the visual, somatosensory and vestibular contributions to stance control just as with CDP, however, not just in the pitch direction. The assessment can be made for the roll direction too which standard CDP equipment cannot perform. The sway-referencing mode of CDP also has a delay which tends to induce 1 Hz oscillations in the pitch direction. (These 2 points are documented in Allum JHJ, Zamani F, et. al. *Gait and Posture* 2002, 16:264-270 - see references below.) SwayStar also performs sensory analysis on stance tests using formulas with proven lower variance than ratio formulas of CDP. Furthermore the difference formulas of SwayStar are sensitive to both vestibular and lower-leg proprioceptive loss. (These 2 points are documented in Horlings GC et. al. *Clinical Neurophysiology* 2008, 119:2338-2346.)

For all 14 tests in the standard balance screening test sequence SwayStar provides normal reference values from the ages of 6 years to 82 years. Reference values are also available for several other tests not part of this screening battery (such as Get-up-Go, walking 8m, standing in tandem stance). Documented in Hegeman J, et. al... *J Vest Res* 2007,17:75-87. These values will be supplied to users on request for statistical analysis purposes.

2.2.2 Advantages of Balance Freedom™

A new addition to SwayStar™ is the combined vibro-tactile and auditory feedback system - Balance Freedom™. Signal transducers mounted on a head-band are driven by the sensors of SwayStar™. Thereby acoustic and vibratory feedback is provided to the patient on the status of his balance control, that is, the leaning motion of his trunk. Thresholds for the activation of vibro-tactile and auditory feedback are set at low and medium angles of trunk sway. A visual warning signal is also activated when the patient leans more than a higher set threshold. Balance Freedom™ is the only rehabilitation device on the market using combined or separate vibro-tactile and auditory feedback.

The use of vibro-tactile feedback at head reduces the transmission time of these signals to the CNS. Furthermore this system used bone-conducting acoustic transducers to provide auditory feedback thereby opening up the air conduction pathway for normal hearing instead of blocking it with loudspeakers or in-ear speakers. Finally combined bone-conducting acoustic transducers and vibro-tactile devices mounted on the head may also excite otolith pathways and provide a means of artificial feedback.

The Balance Freedom™ system replaces the Auditory Feedback System Model 1. This system used 4 loudspeakers to provide auditory feedback (see Hegeman et al 2005 in reference list section 2.2.) produced by BII and now obsolete. The Auditory Model 1 system is still software supported.

2.3 ANGULAR VELOCITY SENSORS MEASURING TRUNK SWAY

2.3.1 Trunk pitch

Trunk pitch is the direction the body sways in forward and backward directions. In order to measure this activity one SwayStar™ transducer is oriented to measure angular velocity deviations in the pitch plane.

2.3.2 Trunk roll

Trunk roll is an effect of the body swaying from side-to-side. In order to measure this activity another SwayStar™ transducer is oriented to measure angular velocity deviations in the roll plane.

2.4 MEASUREMENT-TASK PRINCIPLES FOR DIFFERENT PROTOCOLS

The underlying principle for all balance testing is to measure the functional ability of a subject to integrate different aspects of sensory inputs into a unitary balance command during stance and gait, especially when this ability is challenged. To judge whether the stance or gait is normal or not, SwayStar™ provides reference data of normal subjects over the age range 6-82 years.

WARNING!

All tasks should be performed with the aid of one or two assistants as “spotters“ if the instability of the subject is great enough for there to be a danger of falling during testing or if the subject has a fear of falling. If the test person has to receive help from a spotter, or opens his eyes during a test with eyes closed, or touches the ground with the non-stance foot during 1-legged stance tests then the trial is ended, the recording should be stopped and on saving the “Yes but .. the patient lost control of balance” or Retry buttons should be pressed (See section 3.2.7 Recording - Saving).

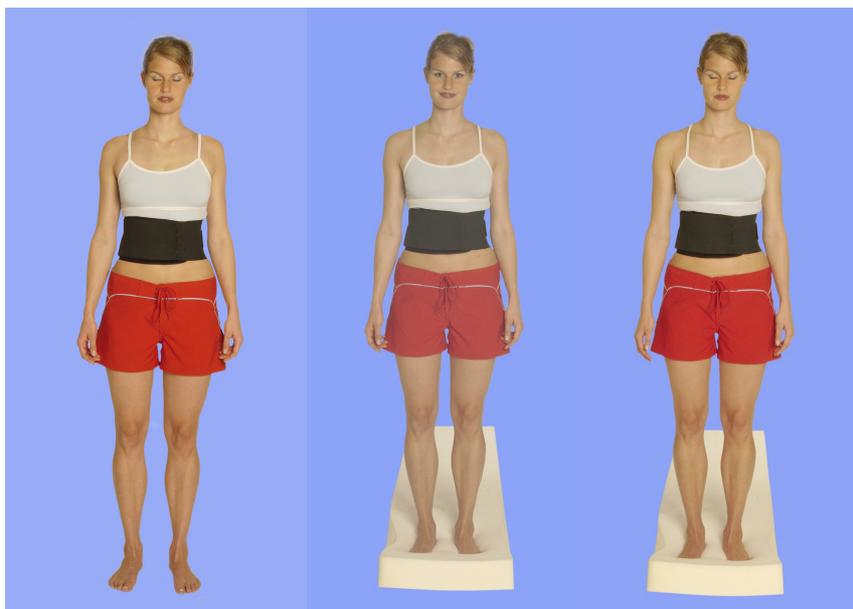
2.4.1 Stance Protocols

Standing tasks are the easiest to perform but can be challenged by modifying the efficacy of visual (eyes closed) and proprioceptive (foam support surface) feedback. There are four two-legged and three one-legged pre-defined stance protocols available in SwayStar™ on first installation. These comprise the stance test part of the “standard balance deficit screening” sequence. Tasks are performed for 20 secs or until the subject losses control of balance.

Two legged stance tasks, 4 tasks, 3 of which are illustrated below

The subject is asked to stand naturally with the feet hip width apart (see photos below).

- standing with eyes open on a normal surface
- standing with eyes open on a foam support surface
- standing with eyes closed on a normal surface
- standing with eyes closed on a foam support surface



One legged (3 tasks). Two of the tasks are illustrated below.

The subject is asked to stand on one leg of his choice. It may be necessary to have the subject try one leg or the other first before starting recording. The test should be started only when the subject is standing on 1 leg

- standing with eyes open on a normal surface
- standing with eyes open on a foam support surface
- standing with eyes closed on a normal surface



Note: With eyes closed, most people cannot maintain balance while standing on one leg on a foam support. Hence this test is not included.

Other stance protocols have been developed to accommodate special needs. For example, a series of protocols exist for testing subjects with Parkinson's disease. These are known as shoulder pull or retro-pulsion tests with the subject pulled from behind (left backwards, right backwards and backwards with the subject warned, (expected) or not (unexpected)).

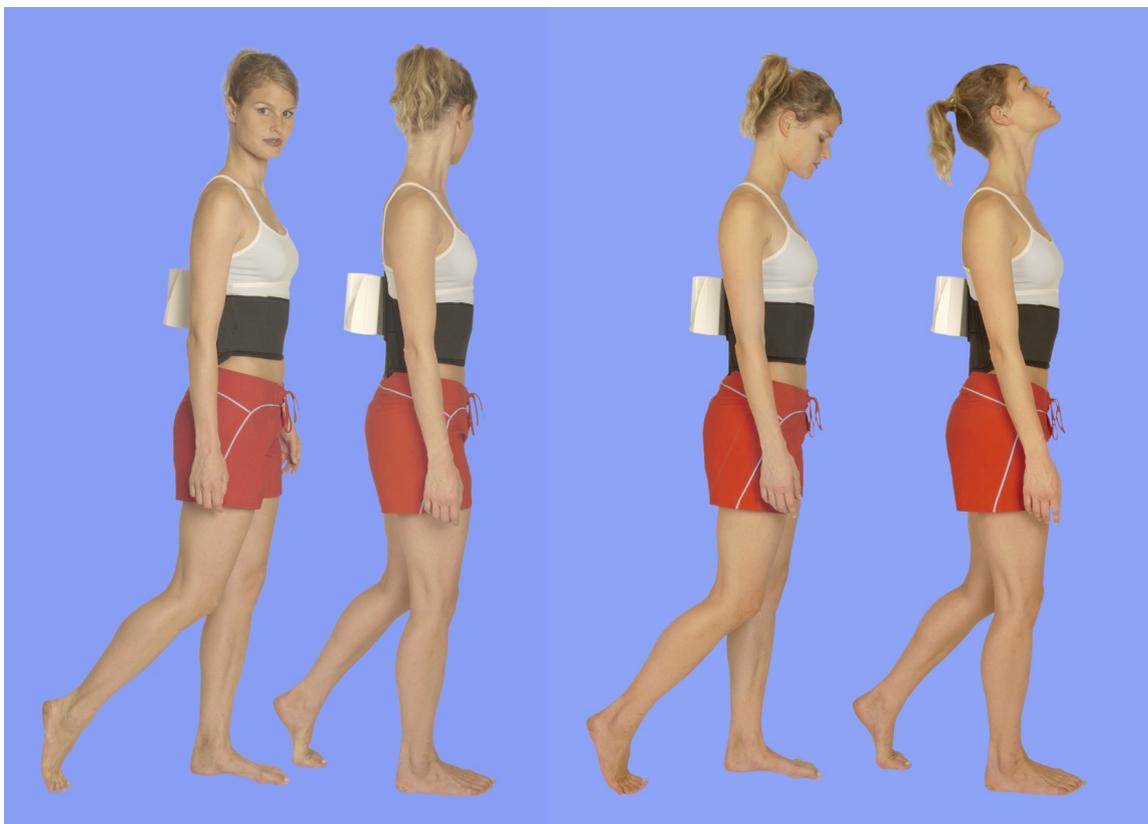
Another task, cone of stability, involves the subject leaning as far as possible in 8 directions, moving solely like a stiff pendulum about the ankle joints.

2.4.2 Gait Protocols

Walking tasks involve more complex uses of sensory inputs and varied motor control. These tasks naturally lead to an increase in trunk sway in subjects who have a balance deficit when compared to normal subjects. There are four gait (one with barriers) and two tandem walking protocols available in the SwayStar™ “standard balance deficit screening” sequence. The subject should start the test in the normal stance position. The recording is ended when the task is complete.

Gait (4 tasks). Two of these tasks are illustrated below.

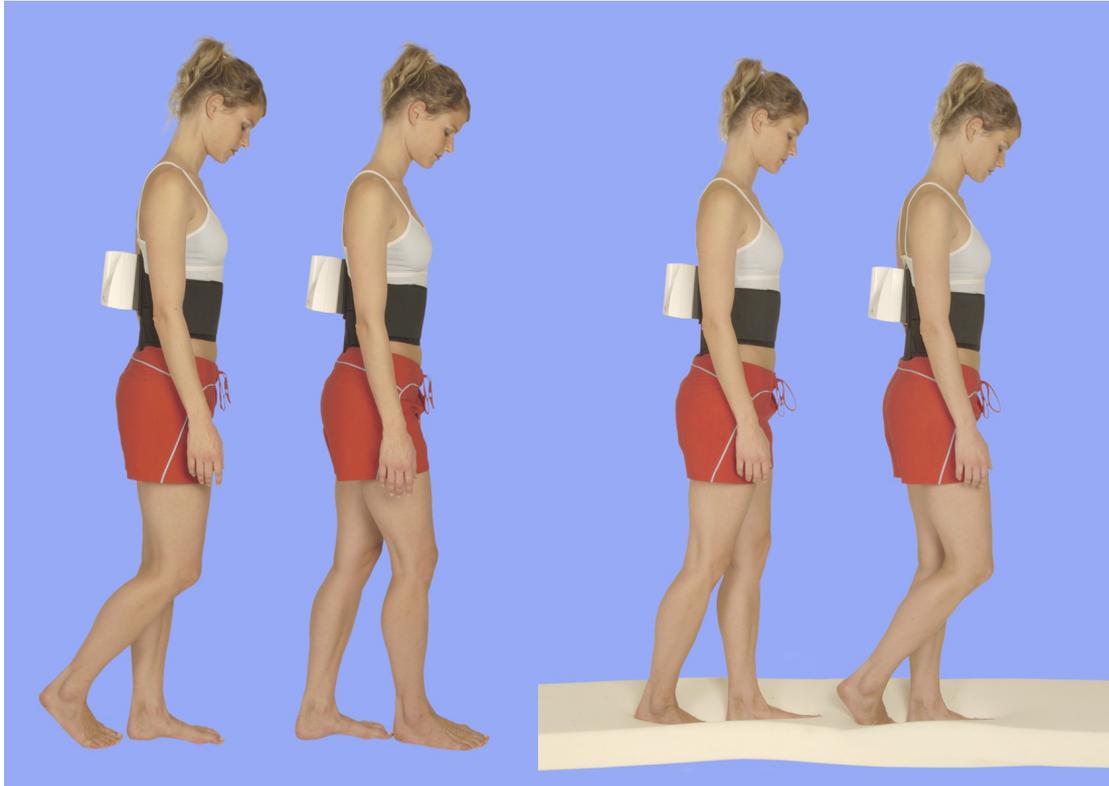
- walking normally 3 meters five (approximately 5 steps) with the eyes closed
- walking 3 m while horizontally rotating the head, left to right, in rhythm with the steps
- walking 3 m while pitching the head, up and down, in rhythm with the steps
- walking over a set of four low (24 cm high) barriers placed 1 m apart



Tandem steps (2 tasks), both illustrated below

The subject places one foot directly in front of the other (heel to toe) for 8 steps, eyes open, with and without foam. The subject is requested to watch his foot placement and avoid treading on his socks. If the subjects wears trousers that might impede the task, the trouser legs should be rolled up

- walk 8 tandem steps on a normal surface
- walk 8 tandem steps on a foam surface



2.4.3 Stairs / Slopes

Walking up and down a set of stairs or a slope requires shifting from one foot to the other at a changed height combined with forward movement and fixation on step edges or slopes.

Stairs (1 tasks)

Walking up a set of stairs with two upward and two downward steps

Note: If there are handrails for the stairs, the subject should be instructed not to touch the handrails. If the handrails are touched during the protocol, it is to be interpreted as a fall and the protocol should be terminated.

2.4.4 Sit to Stand

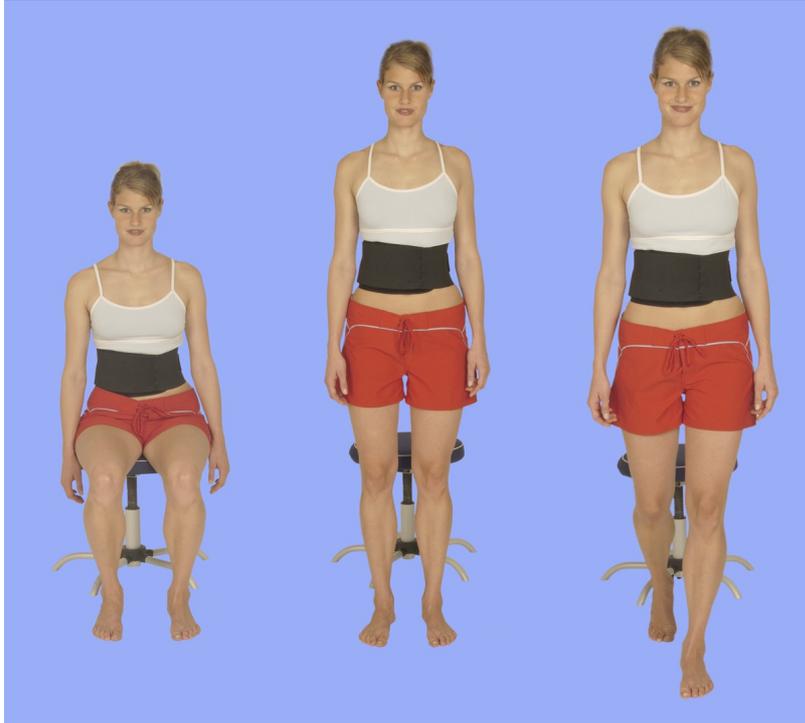
The subject changes from a sitting position with arms hanging by the sides to a standing position (the stool should have no armrests). Three protocols are possible.

Rising from a stool (3 tasks)

get up and go (walking 3 m) - illustrated below

get up twice, sitting down in-between

get up twice FAST, sitting down in-between



2.4.5 Reaching

The subject is asked to stand upright, as straight as possible, with feet normally apart. The goal is to reach, or bend as far as possible, toward an object or mark located in front or to the side of the subject. There are three reaching protocols.

Lateral reaching (2 tasks)

The subject attempts to pick up an object placed laterally at the level of the fingertips (hand hanging at the subject's side). The object is placed at a distance from the subject, relative to his/her height, at 25 cm for each meter tall (4 inches per 12 inches height). The task should be performed without bending the knees, simply bending the trunk laterally. To avoid knee bending, the subject is instructed to lift the opposite leg, i.e., if the object is on the left, the right leg is lifted; if the object is on the right, the left leg is lifted. The arm may also be raised.

Reach laterally with object on the right

Reach laterally with object on the left

- Trunk flexion (1 task)

The subject is asked to flex as far forward as possible without bending the knees, then to straighten up as rapidly as possible.

2.4.6 Other

Currently there are no default protocols listed under “other”. The user may define a protocol as such.

2.5 AUXILIARY TEST EQUIPMENT

2.5.1 Normal surface

A normal surface is any surface that is hard, smooth, flat, not carpeted and not slippery.

2.5.2 Foam surface

The foam should have a height of 10 cm, length 250 cm, width 44 cm and a density of 25 kg/m³ (40% DIN 53577). The length is necessary to accommodate tandem walking tasks.

2.5.3 Stool

A simple armless stool without rollers and adjustable in height should be used. The height of the stool should be adjusted so that the test person’s knees form a right angle. The starting position for the arms should be hanging down, not resting on the knees.

2.5.4 Stairs



As shown on the left the set of stairs needs two upward and two downward steps with a step height of 23 cm, step depth 32 cm, step width 40 cm and preferably no handrails, but with non-slip plastic covering.

2.5.5 Barriers



Construction bricks (about 21 cm high) and wooden slats (3 x 3 x 120 cm) can be used as shown here. When the wooden slats are laid across the bricks, they act as a barrier 24 cm high. Four such barriers should be used spaced 1 m apart.

2.6 TEST PROTOCOLS AND SEQUENCES

2.6.1 Protocols

The complete list of protocols is easily accessed from the software under Options/Protocols (see below). The parameters for user-defined protocols can be altered but those provided as pre-defined protocols by BII cannot be changed. A pre-defined protocol can be modified once it has been given a new name (save as). The reasons to alter the parameters of protocols are to change the amplitude

limits of the on-line display, the recording duration, and any feedback parameters. Off-line analysis amplitude results are auto-scaled but can be re-scaled by the user, if desired. Protocols can be defined with no feedback, auditory feedback Model 1 or BalanceFreedom™ feedback.

Pre-defined factory protocols

These are a series of pre-defined protocols where the test parameters and the name of the test cannot be changed. These are routinely administered tests. When viewing the list of available protocols and the list of sequences, the pre-defined protocols and sequences are **highlighted in green**.

These protocols were developed for several research projects for which SwayStar™ was the principle measuring device, see Literature references in section 2.2.

User-defined protocols

User-defined protocols are easily added within the SwayStar™ program either by creating a new protocol or by modifying a pre-defined factory protocol and giving the modified protocol a new name.

Two aspects that need to be considered when defining a new protocol:

The velocity limit of the sensors is 327 deg/s and recording sessions of 100 seconds or more may have noticeable angular drift.

The mean drift is 0.01 deg/sec, as is the earth's rotation, both acting to create a drift that cannot be compensated without using a GPS (a geographic positioning system) device.

Note: Please be aware that if you choose to delete a user-defined protocol that it is permanently deleted. To reinstate, it will be necessary to add and redefine the parameters. You cannot edit or delete a pre-defined factory protocol unless it is saved (copied) with a new defined name.

2.6.2 Sequences without BalanceFreedom feedback

Sequences represent any defined series of protocols.

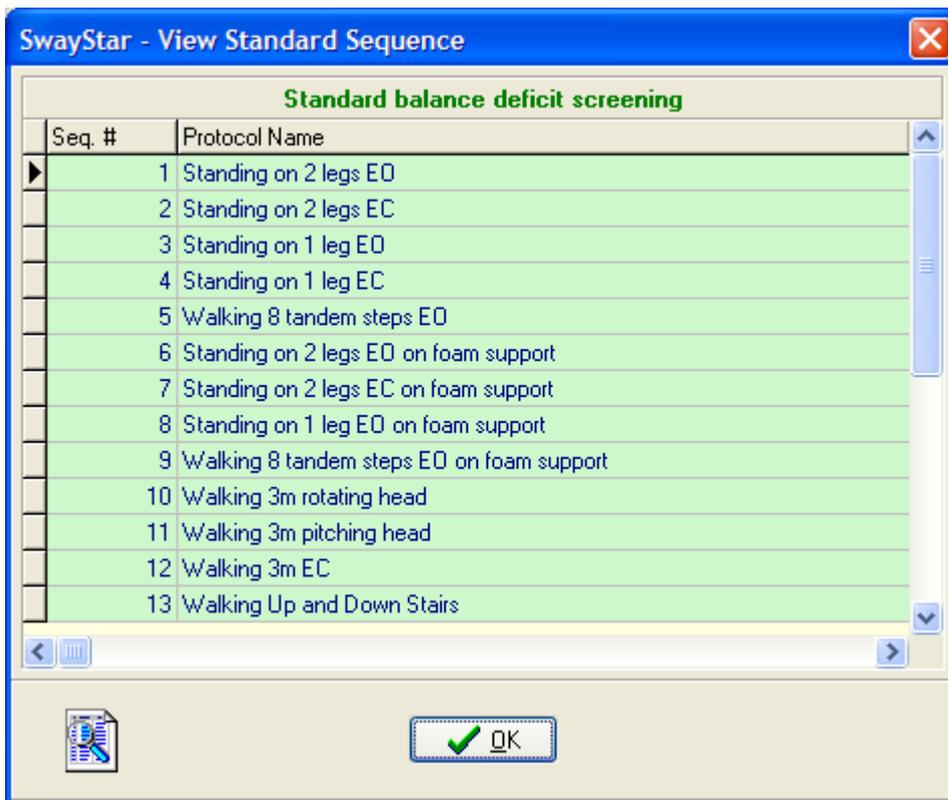
Pre-defined factory default sequences

The current pre-defined factory sequences are for screening subjects are *Standard balance deficit screening*, *PD Balance (Parkinson's disease) screening* and *Spinal column stabilization*. Default sequences are **highlighted in green**.



To review the list of protocols within the pre-defined sequences listed above, navigate the software as follows: left-click on Options/Sequences and the desired pre-defined sequence and double click on the desired protocol. If you attempt to edit, a message will appear explaining that edit is not possible.

Click OK and all of the protocols in the sequence will be displayed.



User-defined sequences

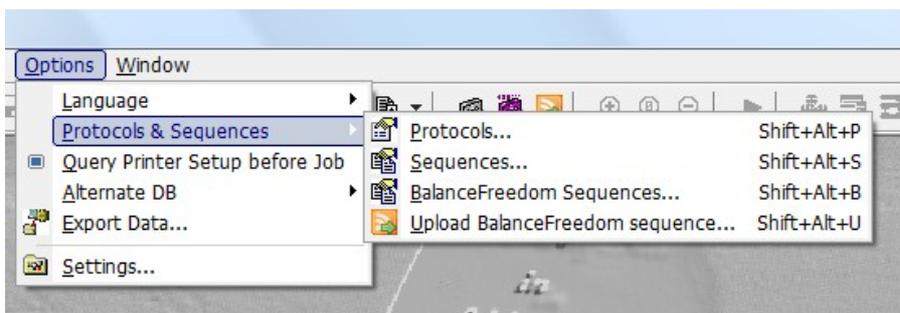
Any of the protocols can be chosen to enter into a sequence (once) and the order of test administration can be varied. Once a sequence is named, the order of administration can be changed without renaming the sequence; however, the change will be saved for subsequent administrations. If a new protocol is added, the sequence must receive a new name.

Note: It is not possible to change the order of protocol administration once a sequence has begun. It is only possible to skip a particular protocol within a sequence.

The sequences of the pre-defined factory protocols have been identified as best characterizing different types of gait and balance deficits. These protocols can be used to generate a Balance Control Summary and Index (BCI) as described in [Section 2.8](#). For a BCI to be derived all its component protocols must be administered using the same sequence, before it and a BCI summary report can be generated.

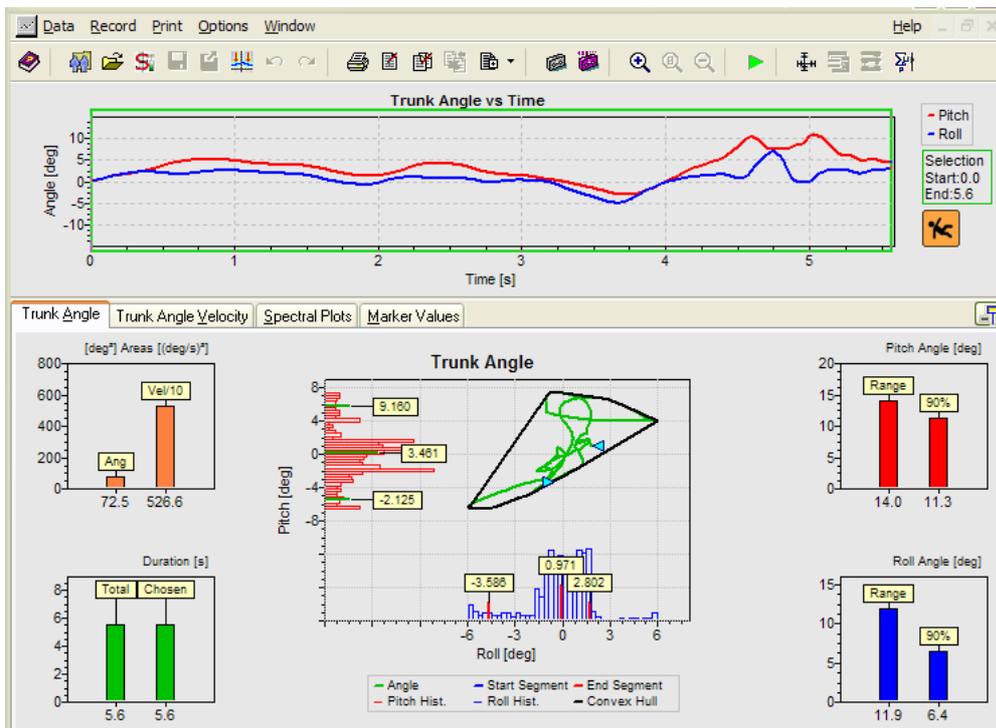
2.6.3 Sequences with BalanceFreedom feedback

It is possible to create and upload up to 63 protocols into the separate BalanceFreedom processor. Retrieving the sequence that has been loaded into the BalanceFreedom processor is not possible.



2.7 DATA ANALYSIS

Angular deviations are calculated on-line using trapezoid integration of angular velocities recordings from the sensors, and are immediately available on re-analysis (for example, by changing the analysis time period of interest). The original recorded data can be retrieved at any time. The original sampled data can also be pasted into the Windows "Clipboard" for retrieval in Excel or Notepad. There are six analysis windows per recording: The original recordings as time plots, x-y plots of Trunk Angle and Trunk Angle Velocity, Spectral Plots of trunk angular velocity, Marker Values and finally analogue to digital (A/D) sampled values if simultaneous acquisition of analogue signals was performed (see [section 2.10](#)). In the case of a fall, if the subject lost balance the primary observation is the shortened task duration of the time plots and the loss of balance indicator, as well as large roll angle deviations as shown here:

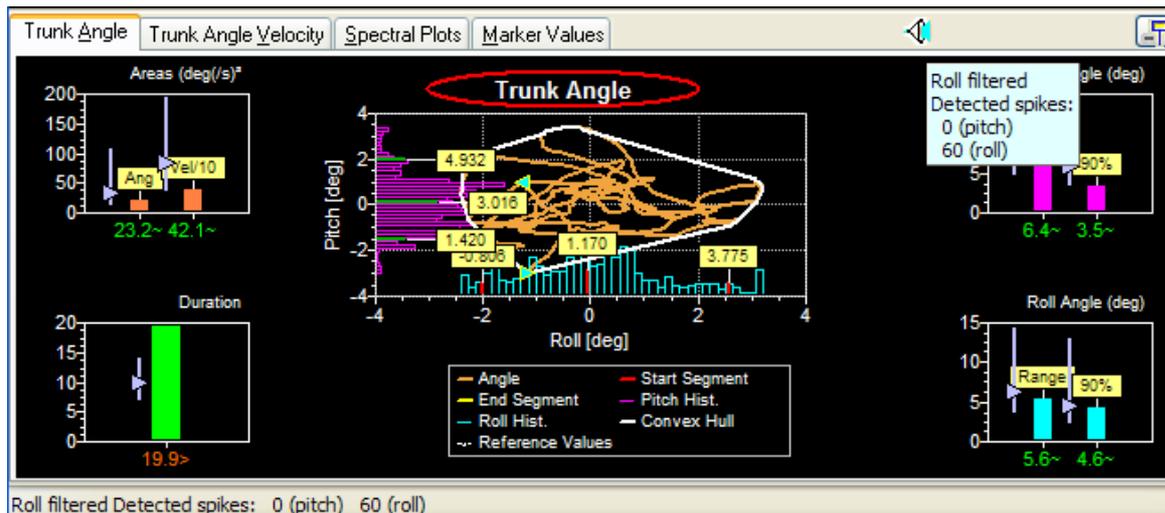


Note: This patient starts (head of arrow pointing right in the trunk angle x-y plot) within the base of support (the orange octagonal shape shows the limits) and then falls to the right and forward after 5.6s (arrow pointing left). The fact that she lost balance is indicated by the orange fall indicator at the end of the recording.

If the subject did not lose balance then the fall indicator is green and the figure in the pictogram is standing. If data was recorded with earlier versions of SwayStar, the fall symbol contains a question mark.

All of the numerical values shown in the analysis windows plus a flag indicating loss of balance may be stored in an Excel (CSV) file.

2.7.1 Trunk Angle Displacement



PITCH

Range of peak-to-peak excursions: The extent of trunk pitch angular displacement over the complete trial.

90% range of pitch excursions: To define this range the peak-to-peak range of the subjects' excursions is divided into 40 bins. Each sample of pitch angle taken every 10 ms is then assigned to one of these bins depending on its amplitude. With all samples binned, a histogram can be drawn shown in red to the left of the x-y amplitude plot in the above example. The 5% and 95% limits can be defined for the recording from this histogram. The amplitude between these limits is the 90% range.

Note: The 5%, 95% and median values of the subjects' excursions, with respect to angular position at the start of the recording, are labelled on the histogram. The x-y (pitch-roll angle) plot is corrected to the median values (bias removed).

ROLL

Peak-to-peak roll excursions: The extent of trunk roll angular displacement over the complete trial.

90% range of roll excursions: The range is defined the same as for pitch, but in this case for roll (see blue histogram under the x-y amplitude plot).

Note: If more than 1 "spike artefact" occurs in the recording every 2 seconds on average, these spikes will have been removed and the data is then filtered. A filter symbol added is in the bar above the recording to indicate the presence of the correction for roll only. For this reason in the above display only the blue roll filter symbol is shown.

Sway area for angle and velocity

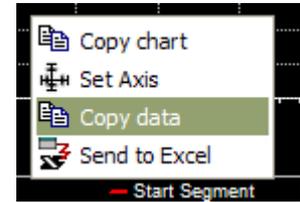
Sway angle area is the area defined by the envelope (the convex hull) of the pitch and roll excursions when these variables are plotted as an x-y plot. As a reminder, the **green arrows** on the trunk angle and velocity x-y plots represent the start and stop positions of a subject. Sway area for velocity is area-defined by the envelope (the convex hull) of the pitch and roll velocity excursions when these are plotted as an x-y plot. Its value is listed in the angle window with values divided by 10.

Stability cone

This is shown by an orange line around the x-y angle plot. It indicates the maximum amount of sway young normals can achieve when leaning and maintaining a straight posture.

SAMPLED DATA

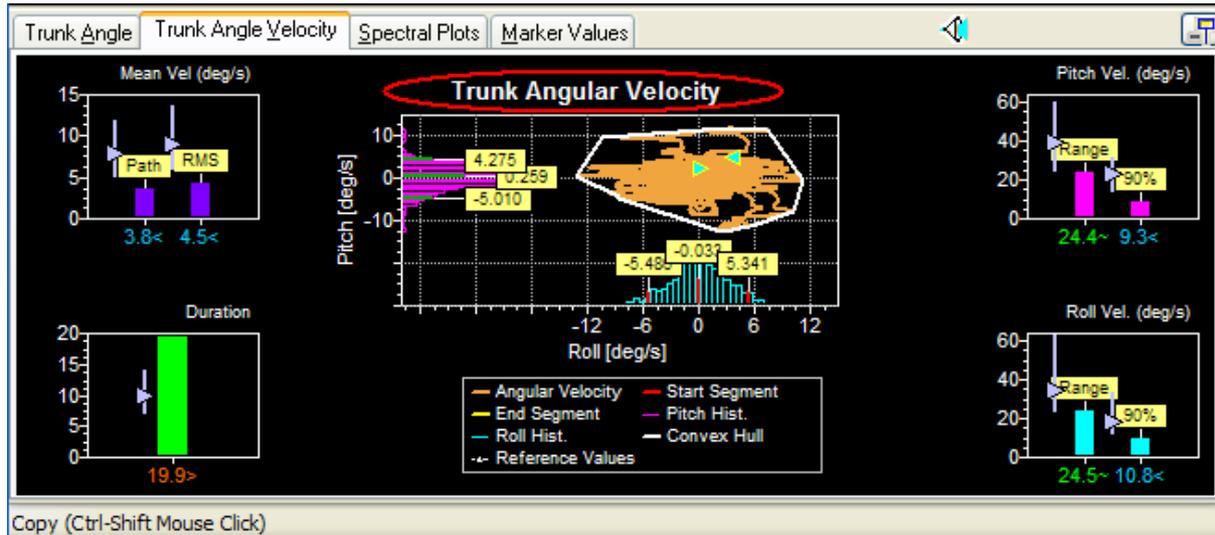
To paste the pre-processed sampled streams of data into the Windows “Clipboard” place the mouse over the trunk angle x-y plot (or angular velocity x-y plot) and simply choose this option when the context dependent command box appears or right “click” while holding down the “control” and “Shift” keys simultaneously. The data is in tab-delimited form and has the following format:



A F, m, 08.07.1957 - Standing on 2 legs EO (1/1 05.08.1999)					
Time (s)	RollAng (°)	PitchAng(°)	Time (s)	RollAngVel(°/s)	PitchAngVel(°/s)
0.00E+00	-9.96E-02	2.19E-01	0.00E+00	1.00E-02	1.00E-02
9.77E-03	-9.88E-02	2.20E-01	9.77E-03	8.00E-02	8.00E-02
1.95E-02	-9.70E-02	2.23E-01	1.95E-02	1.80E-01	1.80E-01
2.93E-02	-9.44E-02	2.27E-01	2.93E-02	2.70E-01	2.70E-01
3.91E-02	-9.34E-02	2.28E-01	3.91E-02	1.00E-01	1.00E-01
4.88E-02	-9.20E-02	2.30E-01	4.88E-02	1.40E-01	1.40E-01
5.86E-02	-9.11E-02	2.30E-01	5.86E-02	1.00E-01	1.00E-01
6.84E-02	-9.05E-02	2.30E-01	6.84E-02	1.40E-01	1.40E-01

The list is headed by a line identifying the examination by the subjects name, first name, birth date and the name and date of the examination, followed by a header row identifying the data columns. Note that the sample interval is 10 ms.

2.7.2 Trunk Angular Velocity



PITCH

Range of peak-to-peak velocity excursions: The extent of trunk pitch angular velocity over the complete trial.

90% range of pitch velocity excursions: To define this range the peak-to-peak velocity range is divided into 40 bins. Each sample of pitch angular velocity is then assigned to one of these bins depending on its amplitude. With all samples binned a histogram can be drawn as shown in red to the left the x-y velocity plot in the above example. The 5% and 95% limits can be defined for the recording from this histogram. The velocity amplitude between these limits is the 90% range.

Note: The 5%, 95% and median values are labelled on the histogram. The x-y (pitch-roll angular velocity) plot is not corrected to the median values (no bias removal).

ROLL

Peak-to-peak velocity excursions: The extent of trunk roll angular velocity over the complete trial.

90% range of roll velocity excursions: This is defined in the same way as for pitch velocity but, in this case, for roll.

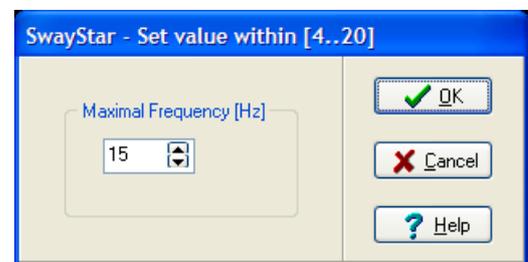
Mean path and rms velocity

Mean path velocity (plotted in the velocity analysis window) is the mean velocity of the vector movement of roll and pitch angular displacements, sample to sample, over the recording interval. The root mean square (rms) velocity - plotted in the velocity analysis window is the square root of the squared mean velocity of the vector movement of roll and pitch angular displacements, sample to sample, with the mean velocity removed.

2.7.3 Spectral Plots of Trunk Sway Angular Velocity Frequency Spectra



Spectral densities of pitch and roll angular velocities
 This is shown by the continuous curve in the diagram. The spectrum is computed using a moving box-car window of time period 2.56s with a shift of 0.64s from window to window. The spectra for all windows of the recording are averaged across the analysis period (green frame on time plots). The extent of the frequency axis can be changed in integer frequencies between 4 and 20 Hz using a right mouse button click.



Spectral weights

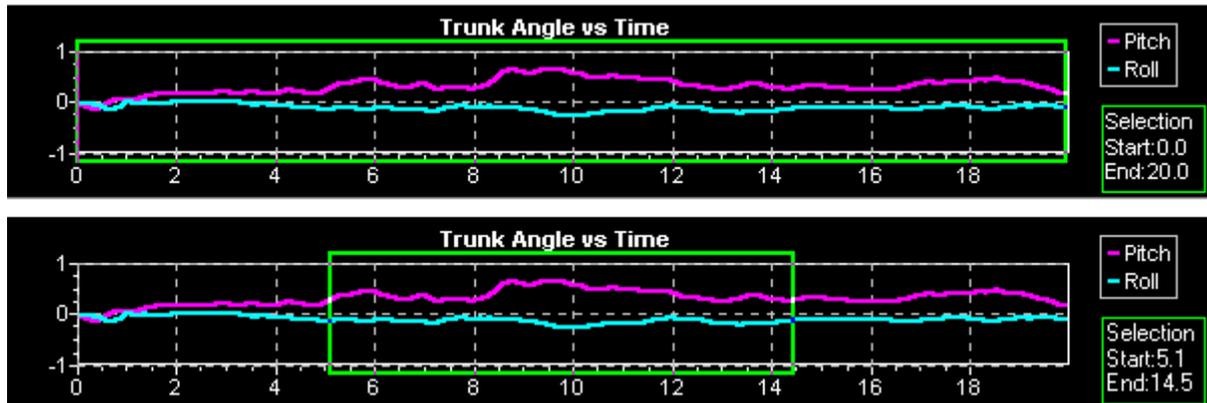
The columns in the diagram show these weights. They are computed by taking the spectral densities every 0.4 Hz computing the square root to get an estimate of the velocity amplitude at frequencies separated by 0.4 Hz and then averaged together at 3 values. That is, at 1.2 Hz the value is the average of 0.8, 1.2 and 1.6 Hz and so on for 2.4, 3.6, 4.8 Hz, etc.

Note: Spectral density values greater than 1 will lead to lower weights and, thus, values less than 1 higher weights.

Note: The copy function will copy either the Pitch Spectra or the Roll Spectra, depending on where the mouse pointer is resting.

2.7.4. Data analysis window

The time period used for analysis can be reduced to less than the total recording time by altering the analysis time-frame. This is the green frame shown in the example below. The minimum analysis time is 1.26 s.



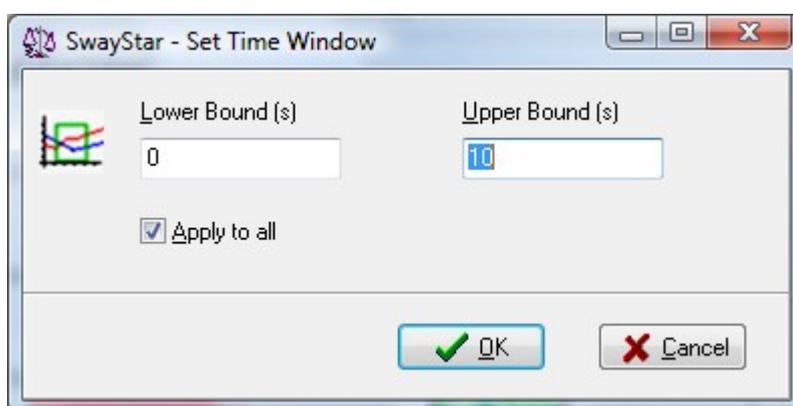
To change the analysis time (the frame size), click within the graph, where you would like your selection to begin and drag to the end of the selection. The green box will appear as you drag it to the desired size. While changing the frame size, notice that on the lower-left hand of the screen, the start and end time of the frame and the percentage of the frame time is compared to the total time of the recording. These are displayed numerically. The figures change dynamically as the green box is sized. For instance, in the example above, the final result was displayed as:

$(5.14s : 14.24s) = 45.4\%$

. The starting point was at 5.14 sec, the end point at 14.24 sec, thus measurement criteria are applied to 45.4% of the recording. *If the start point for the measurement begins at a later time and the green frame is dragged to an earlier time, the percent will be shown*

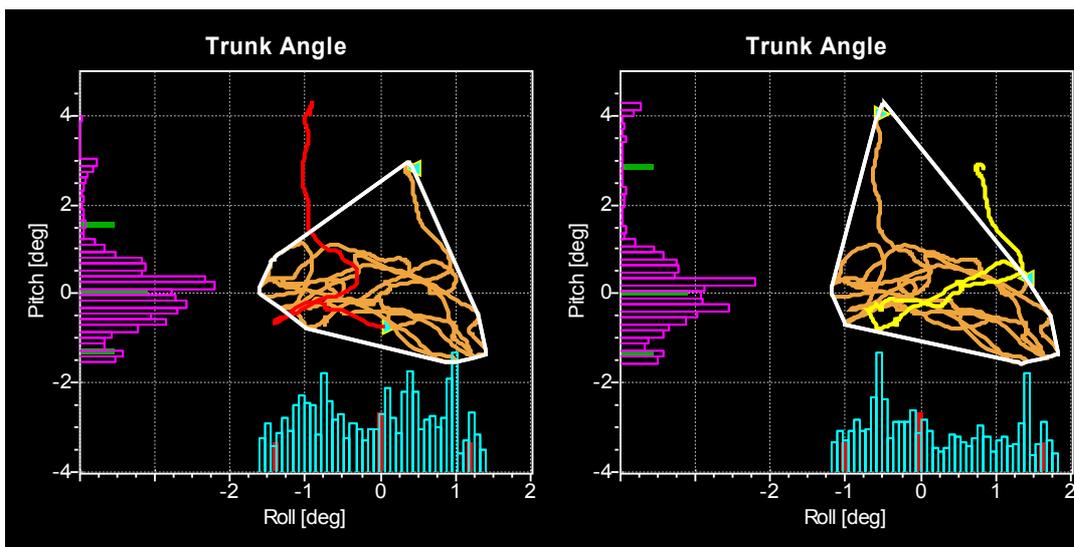
as a negative value: $(14.24s : 5.14s) = -45.4\%$

The alternative way to change the time window is to set the start and end points using the “change time window” icon in the tool bar. With this option all open data windows can be set to the same analysis times.



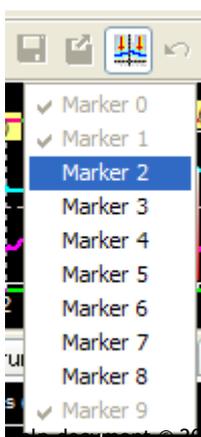
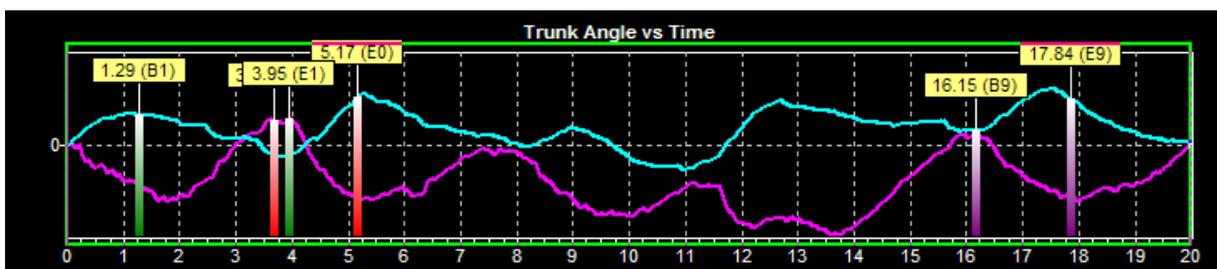
A third way to change the time window is to set it to triggered markers events- see section 5.4.6 [Settings, Trigger](#).

When the green frame surrounding the data analysis window is set so part of the beginning of the recording is not within the green frame (excluded from the analysis), that part of the x-y plot is shown in red and the rightward pointing green arrowhead on x-y plot moves to the point on the x-y plot where the analysis window begins. Likewise when the analysis window is set so part of the end of the recording is excluded this is marked in the x-y plot as yellow and the leftward pointing green arrow moves in the x-y plot to the new beginning of the data. This effect is illustrated below.



2.7.5 Markers on time plots

Up to 10 pairs of markers (Marker pairs 0 to 9) may be set on the time plots of roll and pitch. The beginning marker and end marker of each pair, as well as a label of the marker times are displayed.



To select a marker pair first click on the marker icon to obtain a pull down list of marker pair possibilities. Once a pair is selected the beginning marker of the pair can be placed at a location with a left mouse click, likewise the end marker. When moving the vertical marker bar along the recording time window, the time, roll and pitch angle and angular velocities at the marker position are displayed in the lower status bar.

To remove a marker or all markers place the mouse on the marker so that marker symbol appears, click on the right mouse button and make an appropriate selection from delete marker pair or all markers.

Numerical values at the marker locations are listed under the tab “Marker Values” as shown below

Trunk Angle Trunk Angle Velocity Spectral Plots Marker Values									
Marker Pair	Begin	Int.	Begin Ang.	End Ang.	Ang. Diff.	Begin Vel.	End Vel.	Mean Vel.	Vel. Diff.
()	(s)	(s)	(°)	(°)	(°)	(°/s)	(°/s)	(°/s)	(°/s)
0 Pitch	3.69	1.47	0.13	-0.288	-0.418	-0.25	-0.24	-0.284	0.01
0 Roll	3.69	1.47	-0.0553	0.259	0.314	-0.13	0.4	0.213	0.53
1 Pitch	1.29	2.66	-0.222	0.142	0.364	-0.46	0.25	0.137	0.71
1 Roll	1.29	2.66	0.163	-0.0563	-0.219	-0.07	-0.03	-0.0826	0.04
2 Pitch									

For each marker pair the following information appears as marker values.

Marker begin and interval between markers

Roll and pitch angle amplitude and velocity at Begin and End Marker of the marker pair.

Difference in angle amplitude and velocity, as well as mean angular velocity between begin and end marker.

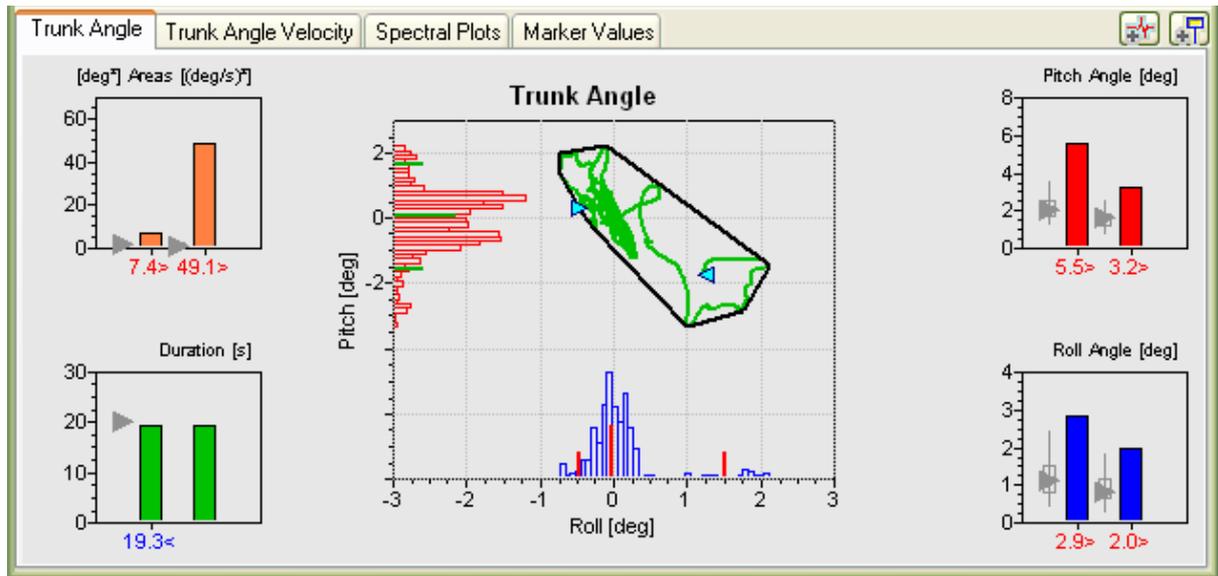
This information is also stored in the log csv file once the marker data has been stored.

2.7.6 Durations

The total recording duration is the time from the start to the end of the recording. It is not affected by changing the analysis time (green frame around the time histories) in the analysis window. The chosen duration is analysis time set by the green frame. It can be entered in the log file depending on the operation log file settings (see section 5.4.6).

2.7.7 Reference Values

Normal reference values are shown in the Data Analysis Window as triangles, thin vertical bars, and vertical rectangles next to the test subject's values. The symbols are violet if the user assigned the reference value set to the recording. The triangles represent median values and the top and bottom of the vertical bars are equal to the 95 and 5 percentile limits, respectively and the top and bottom of the vertical rectangles are equal to the 75 and 25% percentile limits, respectively. These data are available for all the analysis variables listed above, except spectral densities and weights. Reference value sets are available for all pre-defined protocols in the standard balance deficit screening sequence.



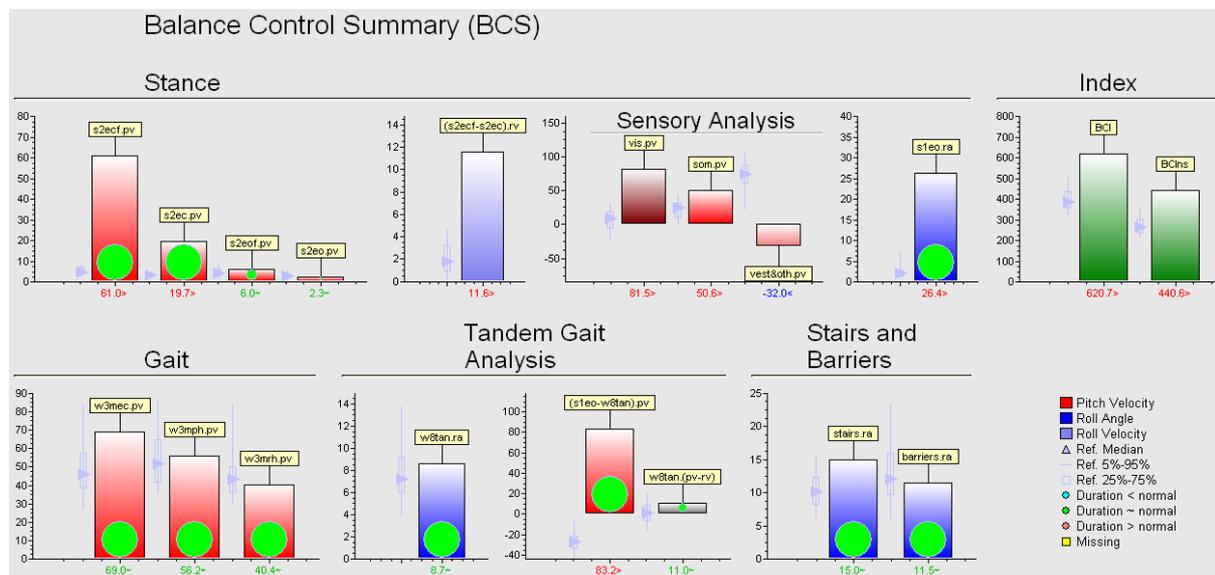
In the diagram above the pitch angle values of the patient standing eyes closed on foam are clearly above the 95 percentile limit but the roll values are on the edge of the 95 percentile. Consequently, the area values are also above the 95% limit. The duration is just shorter than normal (19.3 s) because the subject was not able to stand without falling for the maximum duration of the trial.

Displayed reference values are calculated for an age group ± 5 years either side of the test subject's age (see diagonal yellow arrow above). There are at least 10 subjects in such age groups. If the subject's values are greater than normal reference values, they are marked in red and followed by a >. If they are less, then they are marked in blue and followed by a <, otherwise in green and followed by a -. Reference values are available for the ages 6 to 80 years. When no reference values are assigned, analysis values appear in white (black in printed versions) with no symbols following the value.

Note: Recordings should be long enough for reference values to be valid. Thus, reference values are considered applicable only if the duration of the recording is longer than 75% of the reference recording time.

2.8 BALANCE CONTROL SUMMARY and INDEX (BCI), SENSORY ANALYSIS.

Founded on investigations of several patient groups (see [references in section 2.2](#)) BII has developed a balance control summary of those stance and gait tests and associated sway variables which can be consistently used to discriminate between patients with balance deficits and age-matched normal subjects. In addition to values of the test person's measurements displayed in the summary, the summary provides a **Sensory Analysis Graph** for two-legged stance tests (see [section 2.8.5](#)), a comparison between stance and gait tests (see [section 2.8.6](#)) and a combined cumulative value of all test results in the summary. This latter cumulative value is called the **Balance Control Index, or BCI**. An example of the summary for a patient with bilateral vestibular loss is shown below (15 SSB and 7.2 Case Studies). Detailed explanations of the summary and how to obtain it may be found in [section 2.9 Examples of Balance Control Summary...](#) and [section 4.1.4 Main Menu, Balance Control Summary](#), respectively.



The derived BCI value is a single summary value of several stance and gait test results, with and without (ns) the stairs test result included. The BCI is a cumulative value which may indicate a tendency for a particular test subject to have similar results to patients with balance problems or to have normal balance control. Thus both the summary and the BCI can be used as a screening value to infer a balance deficit. These help to build a diagnostic picture and serve as indicators of the potential need for further evaluations. The SwayStar™ software permits one type of screening BCI to be calculated from a sequence of records. The main use of this BCI is to screen for a balance deficit due to an organic deficit (such as peripheral vestibular loss) or a non-organic balance disorder (simulator). The user is made aware herewith that other, more disease specific BCIs could be used to screen in detail patients suspected of having Parkinson's disease, or a whiplash-associated balance deficit or cerebellar ataxia. ([see refs. 2, 3, 6, 7, 8 and 9 in section 2.2](#)).

2.8.1 Background Information on the BCI

The principle underlying the BCI provided by BII is based on a stepwise discriminant analysis of patient data collected with SwayStar™ ([see references 2,3,6 and 7 in Section 2.2](#)). Once data was collected it was possible to ask the questions:

1. For which stance and gait tasks is the trunk sway of patients (for example those with a balance deficit due to unilateral peripheral vestibular loss) different from that of normal subjects?

2. What is the minimum number of tasks and associated trunk and task duration variables required to optimally identify patients within a specific group (e.g. those with vestibular loss) as different from healthy normals.

The first question can be answered by using standard post-hoc Bonferroni t-tests to examine differences in patient and normal subject means across all the tests comprising the factory pre-defined sequence standard-balance-deficit screening ([see Section 2.6.2](#) and [see reference 6 in section 2.2](#)). Once a list of significant variables was obtained, the list could be ranked in order of significance in its capacity to differentiate patients with balance deficits from normals.

To rank the measurement variables in the order of importance in classifying the severity of the balance deficit, a stepwise linear discriminant analysis is performed using the measurement variables that are significantly different between populations. Stepwise linear discriminant analysis, as a first step, performs an ANOVA analysis on the individual variables and then selects the variable with the highest F value (greatest statistical significance) to enter the discriminating function (which is a linear combination of the measurement variables that is, the BCI). Before the next ANOVA is repeated on the remaining variables, the covariation of the entered variable explaining the variation between populations in the remaining variables is removed from the remaining variables. This procedure is repeated until the F values of the remaining variables are no longer significant and thus no new variables can be entered in the BCI. Finally, ANOVAs are repeated on the entered variables to ensure that only variables with a significance greater than $p < 0.05$ remain in the BCI. A variable among the entered variables is removed if it failed to satisfy this criterion.

The variables entering the discriminant function or BCI are weighted to obtain the best separation with the function between the populations. The weighting is dependent on the significance and the size of the variables in the BCI. That is variables which are most significant and have a small range will be weighted most and vice versa. The BCI can then be used to assign a new test subject to one of the two populations. Essentially the larger the BCI value, the more pathologic is the patient's balance problem, and vice versa. For the BCI of SwayStar™, the higher the value of the cumulative BCI, the more likely the test subject is to have a balance deficit, and the closer the BCI is to that of the normal reference median value, the more likely the patient has normal balance control.

2.8.2 Balance Control Index (BCI) for screening a balance deficit due to an organic or a non-organic disorder.

The combination of protocols and SwayStar™ variables used for the standard BCI of SwayStar™ are listed below, in order of significance (most to least).

TASK	SURFACE	MEASUREMENT	WEIGHT
Stand on 2 legs, eyes closed	Foam	Trunk pitch velocity	2
Walk 3 m, while pitching head	Normal	Trunk pitch velocity	1.5
Stairs	Normal	Trunk roll angle	12
Walk 3 m, eyes closed	Normal	Trunk pitch velocity	1.5
Walk 8 tandem steps	Normal	Trunk roll angle	1.0
Walk 3 m, eyes closed	Normal	Duration	20

The above combination of tasks and variables can be associated with the standard Balance Control Index (BCI). The Index considers the significance of the variables in the classification procedure and the magnitude of the measured variables. The BCI, with its various variables, results in a measure that can be used in a classification procedure to determine whether a test person should be assigned to a group with a balance deficit or not. BII has also developed the Sensory Analysis in conjunction as a means of determining the relative use the patient makes of sensory inputs during stance and if a patient is simulating a balance disorder or not ([see example in section 2.9.2](#)).

2.8.3 Balance Control Index for screening a balance deficit due to Parkinson's disease

The combination of protocols and SwayStar™ variables that could be used to screen for a balance deficit due to Parkinson's disease are listed below, in order of significance (most to least). Note that this Index is not yet available within the SwayStar™ software.

TASK	SURFACE	MEASUREMENT
Stand on 2 legs, eyes closed	Foam	Trunk pitch velocity
Expected retro-pulsion pull	Normal	Trunk roll angle
Stand on 2 legs eyes open	Foam	Pitch 5 Hz
Walk 3 m, eyes closed	Normal	Duration

Notice how using these variables to screen for a balance deficit due to Parkinson's disease would create a BCI which differs slightly from the standard BCI listed above in section 2.8.2.

2.8.4 Balance Control Index for screening a balance deficit due to a Whiplash Associated Disorder (not available)

The combination of protocols and SwayStar™ variables that could be used for this type of screening BCI are listed below in order of significance. These patients sway less than normal for simple gait tasks such as walking while rotating the head, but more than normal for stance tasks and for complex gait task such as walking up and down stairs.

TASK	SURFACE	MEASUREMENT
Stand on eyes closed	Foam	Trunk pitch velocity
Walk 3 m, while rotating head	Normal	Trunk pitch angle
Stairs	Normal	Trunk roll angle
Stairs	Normal	Trunk pitch velocity

2.8.5 Sensory Analysis for 2-legged stance

Ratios of the sway recorded in the pitch and roll directions are computed by SwayStar™ software for a sensory analysis graph in the Balance Control Summary. These ratios are based on the “pitch angular velocity range”, \mathcal{V} , as this variable is most affected during stance by a balance deficit. The user shall be aware that sensory analysis can only be used to identify vestibular loss and how other sensory inputs are used for patients with vestibular loss (see Literature references, section 2.2.).

The indices used in the formulas below have the following meaning:

s2:	standing on 2 legs	eo:	eyes open
		ec:	eyes closed
f:	Foam		
w:	Walking	3m:	3 meters
8tan:	8 tandem steps		

2.8.5.1 Visual Sensory Control Ratio (CR_{VS})

The Visual Control Ratio is expressed with pitch velocity values as:

$$CR_{VS} = \left(\frac{(v_{s2ecf} - v_{s2eof}) + (v_{s2ec} - v_{s2eo})}{(v_{s2eo} + v_{s2ec} + v_{s2eof} + v_{s2ecf})} \right) * 100$$

This ratio expresses the dependence of the test subject on visual inputs. The higher the ratio, the more the subject sways when visual inputs are removed, relative to the total sway under all test conditions.

2.8.5.2 Somatosensory Control Ratio (CR_{SS})

Lower-Leg Somatosensory Control Ratio is expressed with pitch velocity values as:

$$CR_{SS} = \left(\frac{(v_{s2ecf} - v_{s2ec}) + (v_{s2eof} - v_{s2eo})}{(v_{s2eo} + v_{s2ec} + v_{s2eof} + v_{s2ecf})} \right) * 100$$

The ratio expresses the dependence of the test subject on lower-leg somatosensory inputs. The higher the ratio, the more the subject sways when lower-leg somatosensory inputs are no longer helpful in controlling sway as the subject is standing on a foam support surface.

Vestibular and “Other” Control Ratio (CR_O)

This ratio expresses the dependence on other types of control of stance such as vestibular, upper body somatosensory, predictive etc. under the assumption that these remaining inputs can be derived as the simple difference with respect to the other sensory ratios defined above. That is

$$CR_O = 100 - CR_{VS} - CR_{SS}.$$

Notice that this can lead to negative values.

2.8.6 Gait to Stance Ratios

Ratios of the amount of sway recorded during gait compared to stance. Basis for the stance is the sway recorded during standing eyes closed on foam as this is the most demanding stance task.

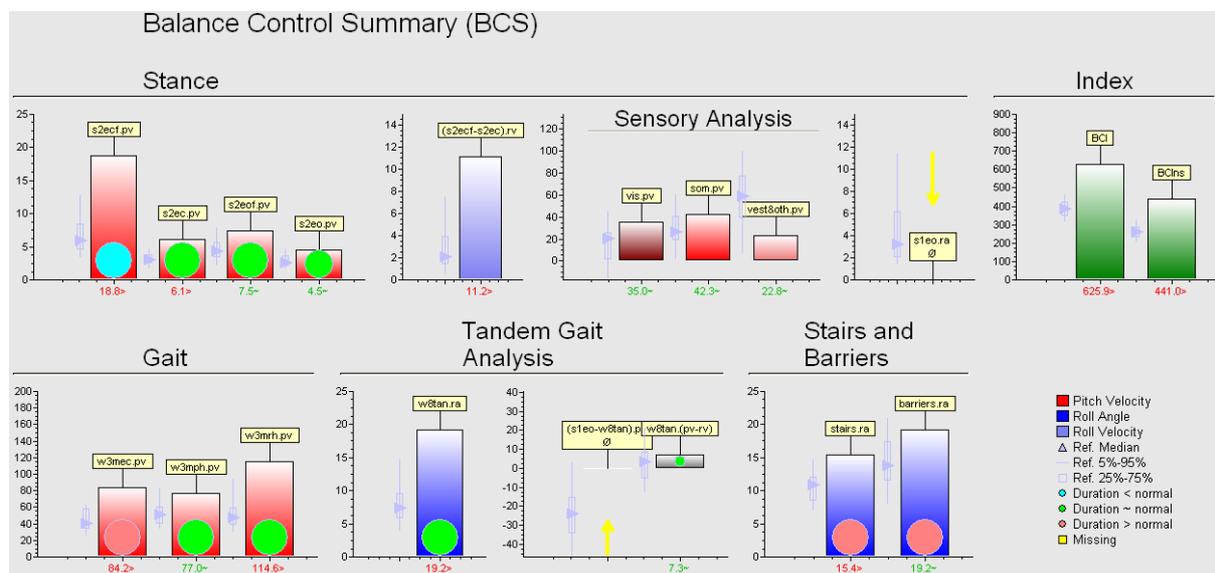
The ratio is defined for pitch velocity as $\left(\frac{v_{w3mph}}{v_{s2ecf}} \right)$ and for roll angle as $\left(\frac{a_{w8tan}}{a_{s2ecf}} \right)$, where a stands for the “roll angle range”.

2.9 Examples of Balance Control Summary and Index with Sensory Analysis

Two examples of the Balance Control Summary and Index, one for a patient with an acute unilateral peripheral vestibular deficit and the other of a patient suspected of simulating a balance disorder are shown below. These patients' recordings were collected using the standard balance deficit screening sequence. More details of these patients' case histories and examples of Summaries and Indexes for other types of patients with balance deficits are provided in section 7. How the patient's recordings and Balance Control Summary should be interpreted as described in [reference 9 in section 2.2](#).

2.9.1 Example of Balance Control Summary for a vestibular loss patient

The patient is suffering from an acute unilateral vestibular loss (7.1 Case Studies). The patient's symptoms include spontaneous nystagmus in the eye movements and a unilateral canal paresis for one ear ([see section 7.1.1](#) for more details).



Explanation of summary symbols:

There are two types of results displayed - results of specific recordings, and composite scores such as the Sensory Analysis, Balance Control Index (BCI), and Tandem Gait Analysis.

Three types of measurements are presented, red columns for pitch velocity, and blue columns for roll angle. Green columns are used for the BCI and grey columns for the Tandem Gait Analysis, as these use a linear combination of both types of measurements. A coloured circle appears at the base of the column for a specific test. The colour of this circle is a coding for the test recording duration. Green is within the reference duration range, blue is less than normal (that is for stance or other tests a "fall" occurred) red is for greater than the reference duration, often seen when a patient needs more time to complete a gait test. Other columns show the Sensory Analysis (which is based on pitch velocity measure during four 2-legged stance tests), Balance Control Index, and Tandem Gait Analysis. On all columns the median reference value and 5 to 95 percentile limits for the variable are displayed as a triangle and a thin vertical bar. The box on the vertical bars shows the 25 to 75 percentile limits. The reference values are for an age range 5 years either side of the test person's age. If the recording duration is less than 75% of the normal reference duration, reference values are not displayed. Furthermore, the BCI composite score can not be computed without these variables (except for the stairs test) because variables with reference values are needed for the score. Below the columns the actual numerical values of the columns are listed. These values are

also colour coded: green is within the reference value range, blue is less than normal, red is for a value greater than the reference value normal.

If the subject could not perform the test a downward pointing yellow arrow replaces the column and a label indicates a zero value. In the example above, the column for s1eo (standing on one leg, eyes open) is not displayed because the subject could not complete this test. Instead an arrow is displayed. Likewise part of the Tandem Gait Analysis can not be displayed. Such arrows and labels with a zero (Ø) are also used to indicate composite scores (e.g. BCI) that could not be computed. Above each column a flag indicates the type of test and the measurement variable. For example, the top left hand column is marked s2ecf.pv (standing on 2 legs, eyes closed, foam support surface for pitch velocity).

As the stairs test often can not be completed the BCI is also computed without this test result included.

The following abbreviations are used:

s = stand (2 = 2 legs, 1 = 1 leg), ec = eyes closed, eo = eyes open, f = foam, w = walk, 3 m = 3 meters, ph = pitching head, rh = rotating head, 8tan = 8 tandem steps, pv = pitch velocity, rv = roll velocity, ra = roll angle.

Description of the Balance Control Summary of the patient in the above example:

This summary contains all the elements typical for a patient with a unilateral peripheral vestibular deficit.

An inability to stand on one leg eyes open.

Ability to stand eyes closed on a normal surface but not for a normal duration on foam.

Standing eyes closed on foam or on a normal surface leads to excessive pitch velocities.

Sensory analysis for stance shows increased use of visual and somatosensory inputs.

Walking eyes closed or walking eyes open with simultaneous head rotating movements leads to excessive pitch velocities and the walking eyes closed task takes longer to complete.

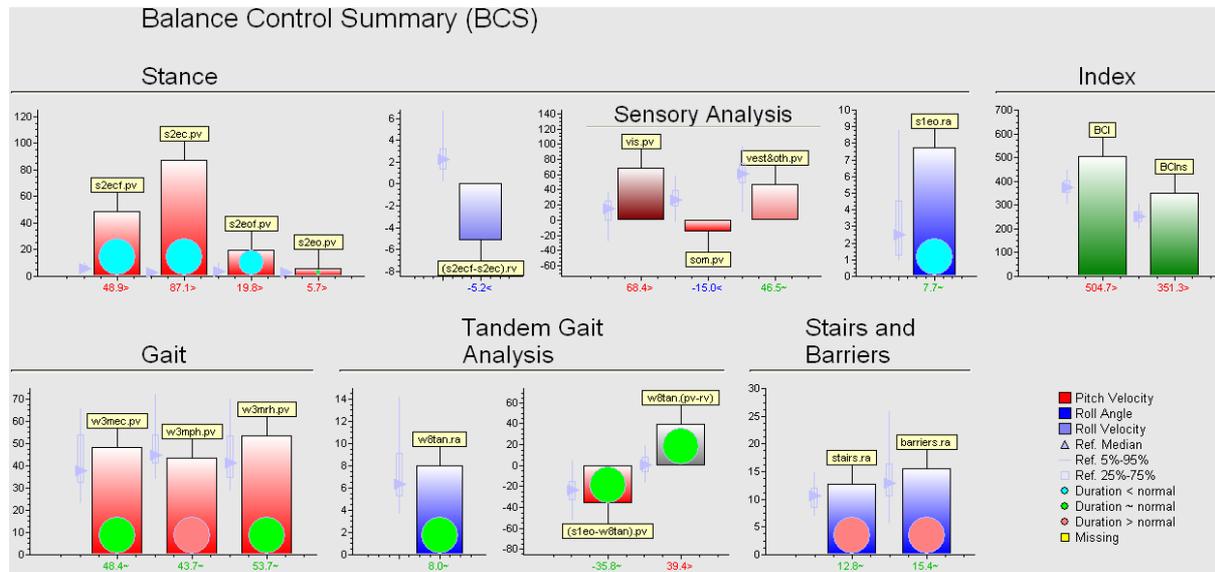
Walking 8 tandem steps leads to excessive roll angles.

Walking up and down stairs and over low barriers produces large roll angles.

The BCI is greater than normal.

2.9.2 Example of a patient with a non-organic balance disorder

The results of this patient (see 7.4 Case studies) are typical of patients often called “simulators” or “malingerers”



Description of patient’s Balance Control Summary

The summary shows a number of inconsistencies often observed with these patients.

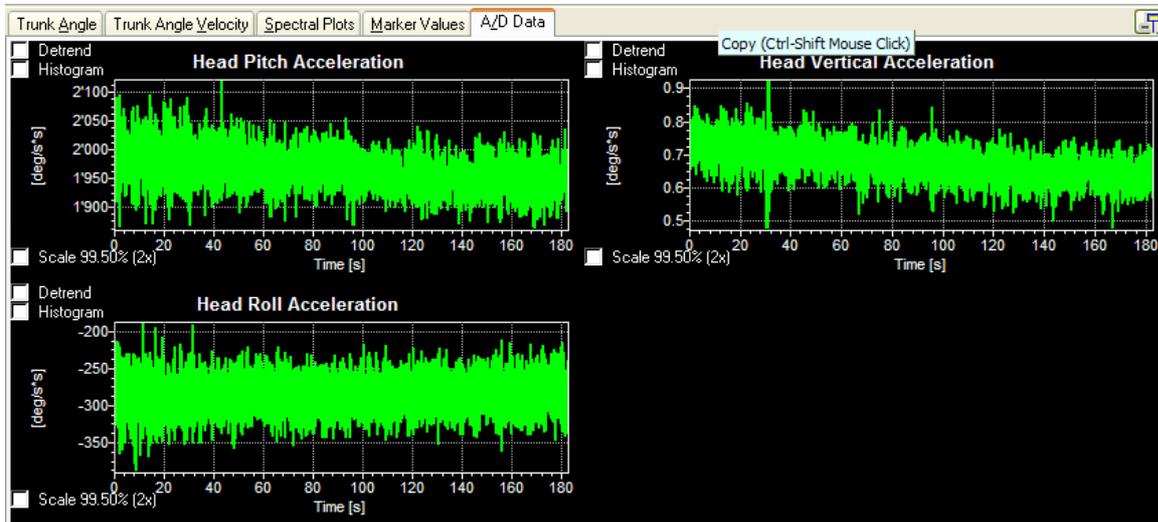
Pitch velocity sway values for stance on foam are less than on a firm surface, leading to a negative somatosensory component in the Sensory Analysis Graph. Sway for stance eyes closed is excessively greater than with eyes open leading to an apparently greater than normal use of visual inputs in the Sensory Analysis Graph. Roll velocity were as large eyes closed on foam as on firm support surface.

Standing on one leg without loss of balance was not possible but tandem walking could be performed within a normal time. However pitch was greater than roll velocity.

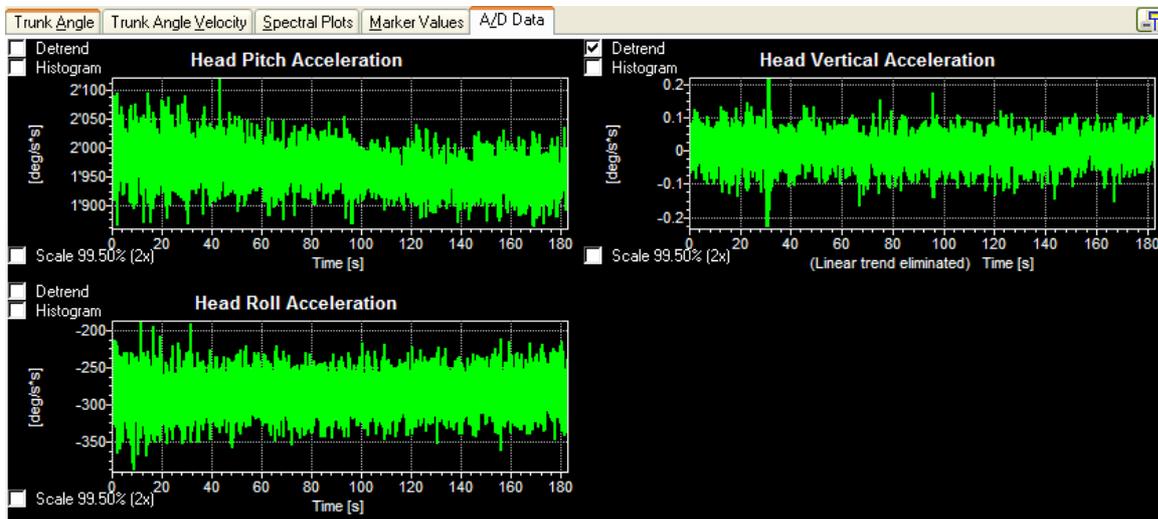
Stairs and barriers tasks were performed slowly.

2.10 Analogue to digital sampled data

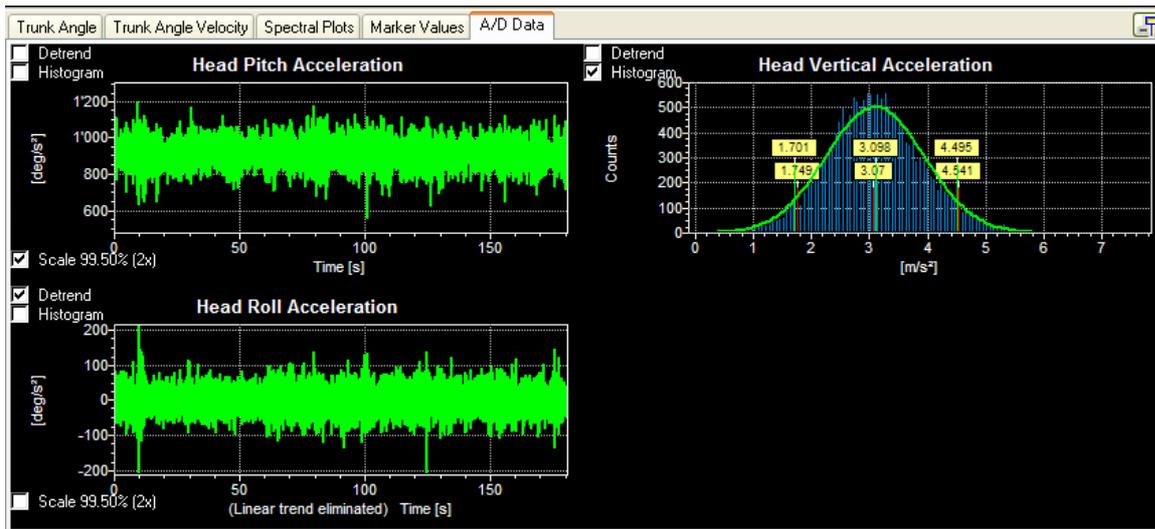
When a Data Translation A/D system is used to sample analogue signals simultaneously with Sway-Star™ signals, the data is available as a tab in the data analysis window as shown below:



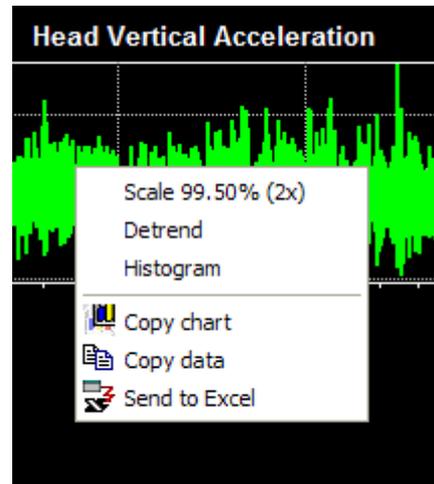
The data is automatically auto-scaled on display (the peak-to-peak values of the recording define the ordinates' maximum and minimum values). However, the linear trend can be removed as shown:



Furthermore the ordinate scaling can be changed to be a range of 2 times the 99.5% extent of the data (approximately ± 5 sd). A histogram of the data can also be plotted which marks the median and 90% range of the data (see red vertical bars in the plot below) and the mean and ± 1.645 sd (green bars on histogram). The green envelope trace on the histogram represents the best Gaussian probability density fit (pdf) to the sampled data. If the green and red bars overlap then the data is likely to be described by a Gaussian (or normal) pdf.



To paste streams of A/D sampled data onto the windows “Clipboard” or into an Excel file simply place the mouse on the display of the channel to be transferred and choose the option desired when the context dependent command box appears.



3. GETTING STARTED

3.1 EQUIPMENT

3.1.1 The SwayStar™ System

- The SwayStar™ hardware consists of four to five elements depending on whether the system was a prototype system (Model 1 Software key number less than 1000) or a Model 2 system (Model 2 Software key number greater than 1000) with power cable or a Model 2B system which can be operated in a wireless mode (Bluetooth communication) or with a connecting cable (Versions 1 & 2). A system which operates in a wireless only mode, Model 2B Ver 3, it is a unit for which CE approval has been obtained. A model 0 system is for demonstration purposes only (without hardware) emulates the sensors using a random “walk” generator and movements of the mouse.
- Belt with sensors integrated and a connecting cable to a power supply/computer interface. The belt is similar to a motorcycle belt that is shaped to provide lower-back support. There is a hard, reinforced portion at the back that is tapered, a soft elasticized portion on the sides and elasticized flaps that, like the belt, have Velcro® closures. The sensors are mounted on the reinforced portion. The belt design makes it possible to measure trunk-angular deviations at the level of the lower back (lumbar 2-3) near to the body’s centre of mass without restricting movement of the hips and pelvis with respect to the trunk. The long connecting cable used for Model 1 and 2 systems still allows the subject to move freely during all tasks.

For Model 2B Ver 3 systems (systems with serial number 1200 and greater)

- Bluetooth communication module or “Dongle” for USB port.
- Combined Power supply for charging sensor batteries.
- If a cable communication (COM) port connector is provided as a separate delivery then CE Approval is no longer valid.

For Model 2B Ver 2 systems (systems with serial number 1100 or greater)

- Bluetooth communication module or “Dongle” for USB port.
- Combined Power supply for charging sensor batteries and communication (COM) port connector (see Hardware manual for plug connections) - same as used for Model 2 system, see below.

For Model 2 (produced prior to 2005) and Model 3 systems

- Combined power supply and communication (COM) port connector (see Hardware manual for plug connections)
- COM port adapter (Qatech SSP-100 Single Channel RS-232 PCMCIA Card recommended see http://www.qatech.com/catalog/rs232_pcmcia.php for systems) where no COM port is available.

For Model 1 systems

- Power supply (110 to 240 Volts)
- Interface cables between the power supply and computer interface card
- PCI or PCMCIA National Instruments® 485 dual-part serial interface card unless a SwayStar™ auditory feedback controller is present, in which case a COM port connection is provided.

3.1.2 The Analog to Digital Converter

The analogue to digital converter which can be used with SwayStar™ to sample up to 16 A/D channels (single ended mode) is a DT980X (X=1-6) unit from DataTranslation™. It is connected to the PC via the USB port. Further details on this unit are available at www.datx.com.

3.1.3 Hardware Configuration

It is recommended that a IBM-compatible desktop or laptop computer be used that equals or exceeds the capabilities of a Pentium III 850 MHz having a graphic chip with at least 16MB dedicated memory for optimal performance. Notebooks with an UMA (Unified Memory Architecture) - shared video memory - are not recommended. The program, itself, requires a minimum of 30 MB hard disk space to install and should have at least 500 MB hard disk space available for data storage. RAM space varies: 128 MB RAM is required for a stand-alone computer but 256 MB if used in conjunction with a networked system (and at least 1 GB hard disk drive) and another 128 MB is needed for Windows XP. A graphics capable printer (colour or monochrome) is required for generating hard copy of recordings and analysis.

3.1.4 Software Operating Environment

The software operates under all MS Window versions higher than or equal to Windows 95. For model 2 SwayStar™ with Bluetooth, the Bluetooth software restricts Windows Versions to Windows 98 SE, Windows ME, Windows 2000, Windows XP or Windows Vista. We strongly recommend Windows XP or Vista. General features of the software are compatible with standard Windows operations, such as maximize, minimize, restore, etc. In order to use a log file (data analysis values), MS Excel or another spreadsheet program (e.g. Quattro Pro) should be available. The software assumes that MS Internet Explorer version 4.01 SP2 or higher is installed. SwayStar™ also operates with OpenOffice.

3.1.5 Software Installation

To install the software either download the current release version from internet www.b2i.info or by inserting the CD provided. Then insert the software key details when requested, and perform an update via internet.

For the **Model 2 SwayStar™** with Bluetooth the Bluetooth® software must be installed first.

Do **not** plug in the dongle into the USB port before the software is installed. First install the system and driver software for the Bluetooth® Dongle. The installation may request you to reboot the system. Once the system and driver software is installed completely, plug the dongle into the USB port. Wait until the system signals that the hardware is recognized and ready to be used.

For detailed instructions on how to install the Bluetooth® dongle and software refer to the documentation provided with the installation CD delivered with the dongle.

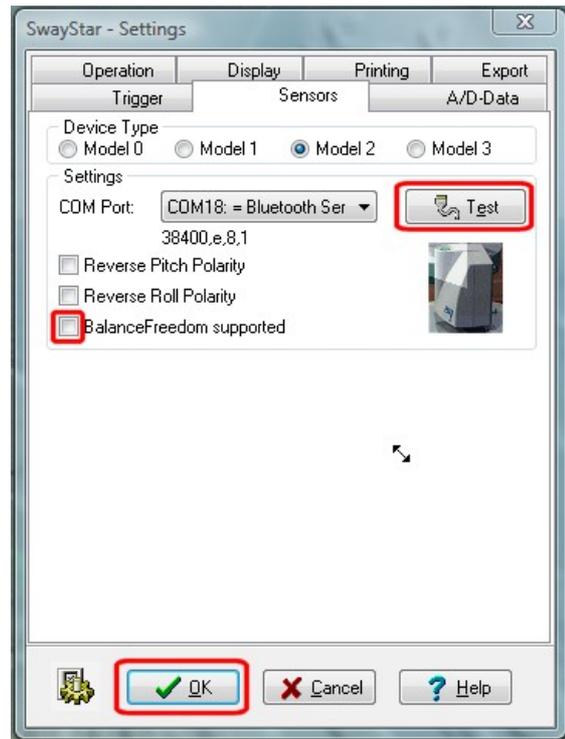
For systems delivered in 2006 and later, the Bluetooth® software BlueSoleil from IVT corporation, which SwayStar uses, is supplied with the Bluetooth dongle. Then setting up the communication is simple. There are two possible ways to accomplish this task. The first way works with [drag and drop](#) and is available for SwayStar™ software version 4.3.7.264 (to which this document refers) provided the BlueSoleil being used is version 5.0.5.178 or later if running on Windows 2000 or XP, or is version 6.0.226.0 if running on Windows Vista. The second way to set up communication is menu oriented and works for all BlueSoleil versions newer or equal then 2.3.0.0 (refer to sections "[5.5.3 Bluetooth Places](#)" and "[5.5.6 About SwayStar](#)" to check the version if drag and drop seems not to work).

The drag and drop method:

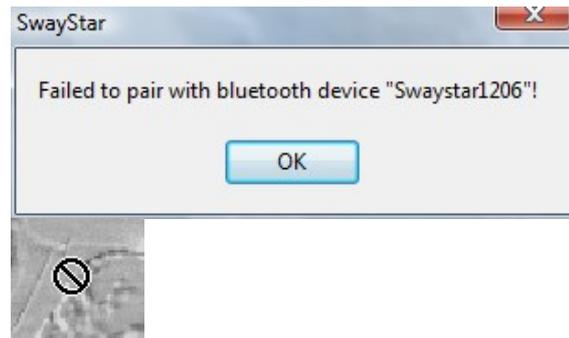
- Make sure that the sensor box is turned off and its battery is charged.
- Activate the PC and check that the software driver for Bluetooth Dongle has been installed.
- Plug the Bluetooth™ Dongle into the same USB port of the PC used for installation. Wait until the system has recognized the Dongle (the BT symbol in the task bar will change its background colour from grey to blue).
- Turn on the sensor box and be sure the connecting communication cable is NOT plugged in, if one exists (serial numbers 10xx and 11xx). The power and sensor LEDs on the sensor box will light up orange for 1 second. After this only the Power LED should light up green indicating status OK. Wait 3 seconds before continuing.
- Double click on the Bluetooth™ symbol in the task bar or on the icon 'My Bluetooth Places' on the Windowsdesktop if available, or use the menu item "Bluetooth Places" of the SwayStar Help menu.
- Double click on "Search devices". Bluetooth starts searching wireless devices within range of the PC. In a first step new devices show up having set their figure caption to the device [MAC address](#). In a second step the caption will reveal a device name, provided the device delivers a name in time. If the device name is not revealed one can right click on the corresponding icon and select "Get Device Name" in the menu that pops up, or double click "Search devices" a second time. The identification name of the SwayStar sensor box follows the pattern "SwayStar<serialnumber>" or "SwayStar-Box SN<serial number>".
- Once the device has shown up you click on it and drag the symbol over the SwayStar window and drop it by releasing the mouse button. At this moment the cursor changes to an hourglass and the SwayStar software tries to pair and connect to the SwayStar sensor box. Watching "Bluetooth Places" you can observe the following: after a while a chain link sign  is attached to the symbol to signal paired status, next, parts of the symbol change their colour to green to show this device is connected.



- At this stage if connection to the device, that is, the SwayStar sensor box, was successful the SwayStar software displays the “Sensor” tab of the “Settings Dialog”. Here you can test the device operation by clicking on the test button and marking the BalanceFreedom option if necessary. Exit this dialog by clicking on [Ok]. The device is ready to use.

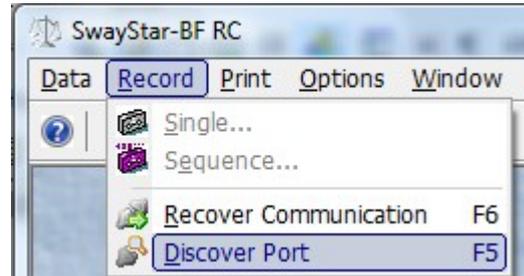


- Otherwise, if connecting fails, an alerting message box pops up.
- Once a device is in use a further drag and drop operation will be rejected. This is indicated by the cursor displayed as a stop symbol.

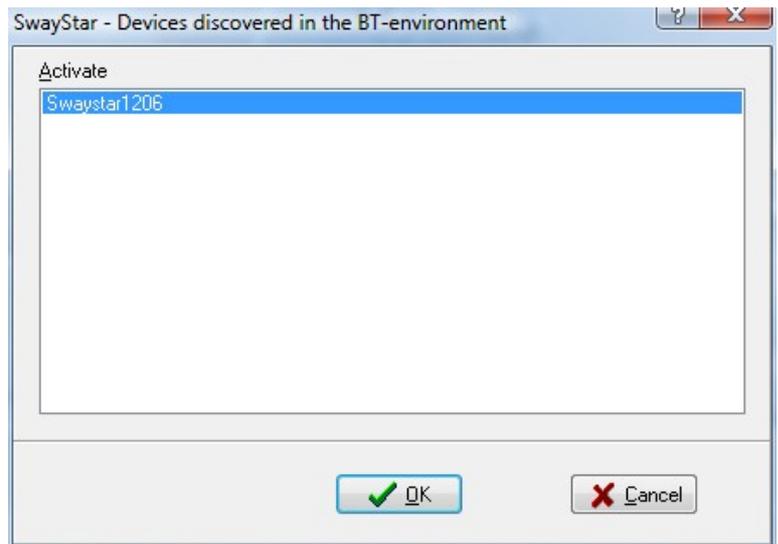


The menu oriented procedure:

First under the main menu “Record”, click on “Discover Port” or simply press F5.



The software then searches first for all Bluetooth® devices and subsequently for all connected serial communication (COM) ports. The user then simply has to choose the device to record from out of the list. An alternative is to look up the COM ports under the Device manager - see [Help section 5.5.2](#) .



For systems delivered prior to 2006 using the Bluetooth® Dongle with Microsoft Windows XP Service Pack (SP)2 needs several additional steps to set up the communication. In the case the dongle is recognized by XPSP2 native Bluetooth® support the native driver takes over the dongle. To correct the assignments the following steps are necessary.



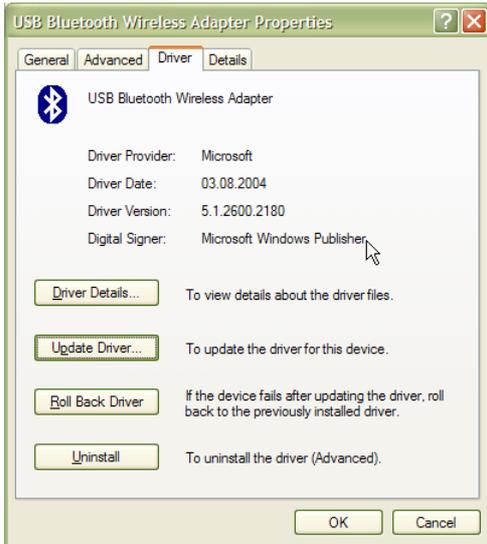
First go to the device manager. The fastest way to do this is to press the Windows Key [] together with the Pause key. This opens the “System Properties” dialog. Here you can select the hardware tab and then you can click the “Device Manager” button.

In the device manager tree expand the “Bluetooth Radios” branch.



Right click on “USB Bluetooth Wireless Adapter and select “Properties” in the context menu.

Right click on “USB Bluetooth Wireless Adapter and select “Properties” in the context menu.



In the new dialog box select the “Driver” tab.

Here click on the button “Update Driver” and the “Hardware Driver Wizard” dialog will be shown.

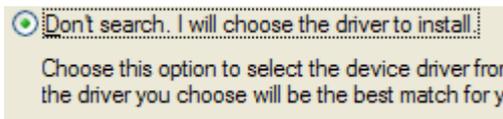
Select on the radio button “No, not this time”

- Yes, this time only
- Yes, now and every time I connect a device
- No, not this time

followed by a click on the “Next” button.

- Install the software automatically (Recommended)
- Install from a list or specific location (Advanced)

In the next dialog select “Install from a list or specific location and proceed by clicking the “Next” button.



In the next dialog page select “Don’t search. I will choose the driver to install” and again click on the “Next” button.



In the new dialog presented verify that “Show compatible hardware is checked”. In the list field you should see two drivers. The windows standard driver “USB Bluetooth Adapter” is checked ()

Select the unchecked driver and ignore the fact that the driver is not digitally signed. Proceed by clicking the “Next” button to install the driver

Once the driver is installed it is wise to reboot the system leaving the dongle in place.

If you already had a **Model 2 SwayStar™** system without Bluetooth, The SwayStar™ Software has to be updated in order to use the Bluetooth™ function. Start SwayStar™ application. Click 'Help' → 'Internet Update'.

To download the update manually via internet use following URL: <http://www.b2i.info/download>. (Version number 4.0.7.186 or higher must be installed for SwayStar™ to operate with Bluetooth)

For **Model 1 SwayStar™** versions the National Instruments (NI) software should be installed before the SwayStar™ software. Once the NI software is installed, the NI 485 card should be inserted into the computer and the NI card tested with the NI diagnostics program. The diagnostic software from NI should indicate that both parts of the card are operating "PASS". If the NI card is not detected; that is, a "FAIL" occurs in the diagnostic program, check under system manager COM ports to insure that the ports are assigned to the NI card. If not assigned properly, delete incorrect assignments and refresh.

If a **Model 1** user has acquired the **SwayStar™ Auditory Feedback (AF)**, this updates data communication to that of a Model 2 system and the NI hardware is no longer needed, unless the AF hardware is disconnected.

Downloading and Installing the SwayStar™ Software

The SwayStar™ software operates on a Windows 95 or NT or 2000 or XP platform (Windows 98 can be used but it is not recommended for Model 1 users due to variations in sampling times caused by the internal clock timer). The software is available only to authorized purchasers who have obtained an access key code. The software can be downloaded via the Internet at:

<http://www.b2i.info/download>.

Once the download is complete, simply follow the installation instructions and insert the access key code, name and number when requested. Then in the SwayStar™ program go to Help-menu and select  internet update to get the latest software modifications. Finally check the sensor function as indicated in [section 3.2.3](#). A dummy database with sample patients will have been loaded on first installation. To create a new database follow the instructions in [section 5.4.4: Alternate database \(DB\)](#).

3.1.6 Setting up SwayStar™ Equipment

- Connect the belt containing the sensors to the power supply with the connecting cable.
- Connect the power supply and COM port connector to the computer's COM port or USB COM port adaptor (Model 2 and Model 1 with AF)
- Connect the power supply to the NI 485 interface or PCMCIA card using the two interface cables. (Model 1 without AF)
- Open the SwayStar™ program by clicking the Desktop icon. It can also be opened from the Start Menu/Programs/SwayStar™
- Activate the sensors by connecting the power supply to the mains and switching on the power supply (Model 1 or power at the sensor box Model 2). In both cases a red power on-light is illuminated.

3.2 EASY START

3.2.1 Placing SwayStar™ Equipment on Test subject

Test subjects may have varying degrees of stability when standing. It is advisable to have an assistant or two, if necessary, on hand to help during the test procedures. The belt is put on first, with the sensor cable hanging down, and then the flaps are tightened. With the test subject standing and with arms slightly extended away from the sides of the body, wrap the belt around the torso of the test subject with the flap closures at, or near, the diaphragm. Do not secure the belt too tightly but insure that it is firmly held in place, then tighten the belt using the flaps. Allow the test subject to take a couple of steps so that he/she feels comfortable with the equipment.

Note: tasks are performed without shoes, preferably barefooted.

3.2.2 Turning on the Equipment

- Turn on SwayStar™. The switch is located on the sensor box of Model 2 or at the back of the power supply box for Model 1.
- The two icons on the upper left-hand edge of the screen will initially show **grey**. Once the communication handshake has occurred between the hardware and software, one of the icons will appear in colour (**magenta**). This usually takes between 5-10 seconds. If this does not happen it is important to check the sensor function in Options (see 3.2.3, below).

3.2.3 Establishing the Bluetooth connection and Checking Sensor Function

Model 2B users **MUST** establish the Bluetooth connection for the first time before the sensors can be tested via the wireless communication. The connection with cable (no CE Mark) is tested as described below - 3.2.4 Checking Sensor Function . Before establishing the Bluetooth the software driver for the dongle must be installed and the SwayStar™ software undated (see 3.1.5 Software Installation).

To establish the Bluetooth connection.

- Be sure that the sensor box is turned off and the battery is charged.
- Your PC has to be activated and the software driver for Bluetooth Dongle has to be installed.
- Plug Bluetooth™ Dongle into the same USB port of your PC you used for installation. Wait a moment until the system has recognized the Dongle (BT symbol in task bar changes colour from red to white).

Note: *The Bluetooth™ standard contains several search and authorisation procedures which are recognizable in form of process delays (some 10 seconds). So if your PC seems not to react just wait!*

- Double click on the Bluetooth™ symbol in task bar or on the icon ‘My Bluetooth Places’ on desktop if available.
- Turn on the sensor box and be sure the connecting cable is NOT plugged in. Power LED and Sensor LED on the sensor box will light up orange for 1 second. After this only the Power LED should light up green as status OK. Wait 3 seconds before continuing.
- Click on “View devices in range”. Bluetooth starts searching wireless devices in range.

- The sensor box will be found. Each Bluetooth™ device has its own identification name. The identification number of the sensor box is the “SwayStar-Box” followed by the serial number e.g. ‘SN1004’.
- Double click on the appropriate device to see the available services.
- Only one service is available. Double click on the virtual connection symbol.
- Bluetooth tries to build up a connection to the sensor box.
- If the virtual connection is found the authorisation bubble - a “balloon tip” - appears pointing at the Bluetooth™ symbol in the task bar.
Don’t click on the close cross of the bubble. **Click inside** the bubble. The authorisation dialog appears.
 The Bluetooth™ application wants to know the PIN¹ of the detected Bluetooth™ device. The PIN is identical to the serial number of your sensor box, e.g. “SwayStar-Box SN1004” has the PIN “1004”.
- Enter the PIN. (The bubble may appear again asking for the PIN, just repeat supplying the PIN number.)
- Click OK in the authorisation dialog.
- The Bluetooth™ connection will be completed.
- A dialog box shows the number of the virtual COM port which will be generated for your sensor box device (e.g. COM5). This is the port you have to select in the settings dialog of SwayStar™ application. So it is very important to note this COM port number.

Once you have established the Bluetooth connection, the sensors can be checked.

The procedure above has to be executed only once at first installation. Even if you unplug the Bluetooth Dongle the next time you plug in the dongle again (at the same USB connector) to your PC it will remember the port number.

3.2.4 Checking Sensor Function when operating via the communication cable

From the Main Menu, select Options and left click on Settings. The Settings window displays the option to choose the Model Type of Sensors and test the communication.

Model 0 uses the computer mouse movements plus the output of a pseudo-random generator for demonstrating recordings without sensors. It is the default sensor type if no sensors are connected.

Model 1 is a BII prototype system using 2 COM ports with a NI 485 interface.

Model 2 uses 1 COM port with a custom-built interface.

Model 2B is a standard production unit which uses a virtual Bluetooth COM port and 1 COM port when the communication cable is employed. The cable cannot be used for communication when the unit has a CE mark.

Model 3 is another BII prototype system.

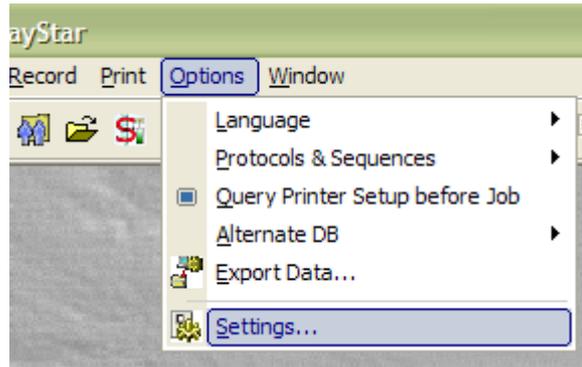
It is possible to reverse the polarity of the recording by ticking in the reverse polarity box. Generally this is not done. The standard polarity is backward pitch and left roll set negative.

Select the model type for which you want to test the sensor function.

If the user has acquired rights to use the BalanceFreedom™ feature of the software, the box under the sensor options should be checked.

¹ PIN: personal identification number

- Make sure a COM port is selected from the available list. It may be necessary to choose another port in the list if one COM port indicates a sensor communication failure. An alternative is to click on the animated SwayStar image to discover the available channels. This discovery function looks first for Bluetooth devices available and allows the user to select one in list.



- For Model 2B users the COM port to use will have been displayed when setting up the Bluetooth communication for the first time. (see section 3.1.5)

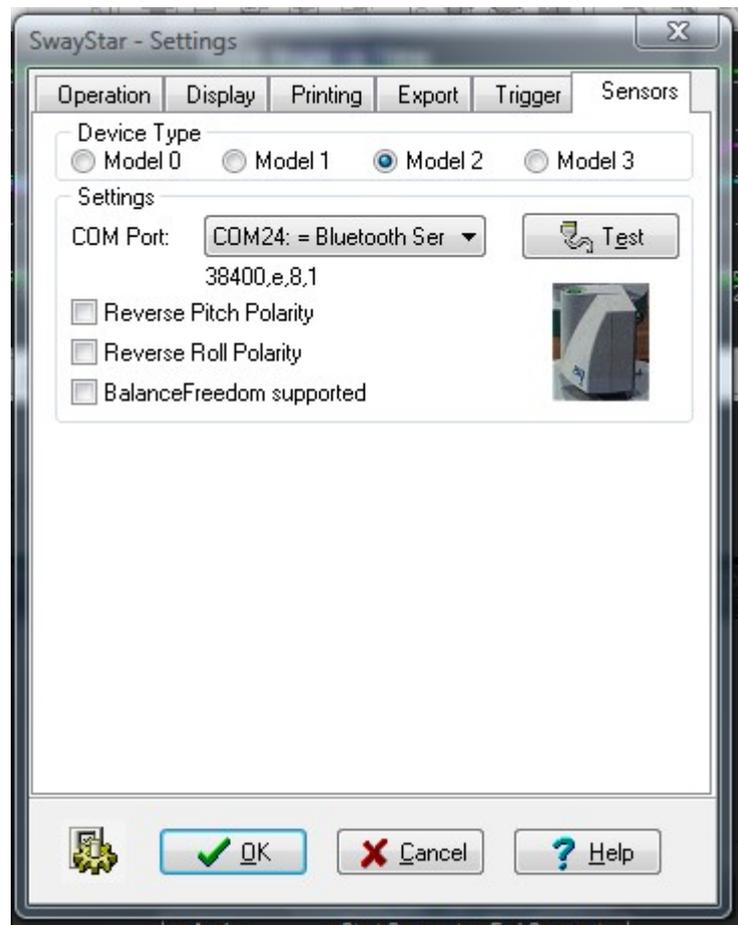
- For Model 1 systems the COM ports to use were displayed when testing the NI 485 card.

- Left click on the Test button (for Model 1 systems separate Pitch and Roll test buttons are used).

- If the sensors are functioning, a message will appear:

- “Communication interface and sensors are working properly!” With Bluetooth systems this test includes a search for the Bluetooth device and may take several seconds.

- If the sensors are not functioning, a message will appear: “The sensor test failed! Check the cables, and power off and on the device!” (You may also wish to review the log report that appears in red under the message.)



Note: If sensor test fails, either no power is available or the correct COM ports from those available in the list have not been selected. If only one sensor works for Model 1 systems either the cables to the failed sensor are not connected properly, the COM port has not been selected correctly or the sensor itself has failed.

Note: SENSORS RARELY FAIL!

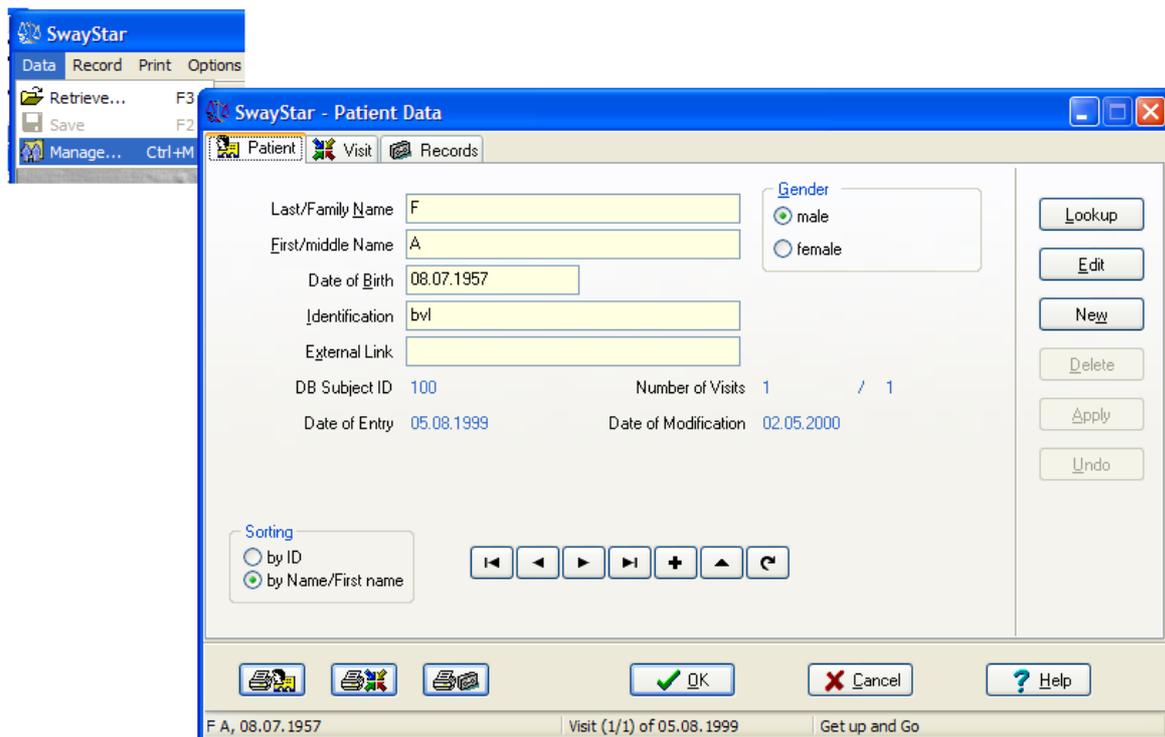
Every time the SwayStar™ Model 2 with Bluetooth is started the sensor box should be switched on first and then the SwayStar™ software started. The Bluetooth authorization bubble will appear and the authorization pin must be entered.

It is usually not necessary to test sensor function each time the program is started. The icons that appear on the upper left-hand side of the Main Screen indicate that the sensors are connected, powered and functioning.

If sensor communication fails during a recording then you will be asked to accept, retry or abort the recording unless the battery sensor was too low for the Model 2B system to operate.

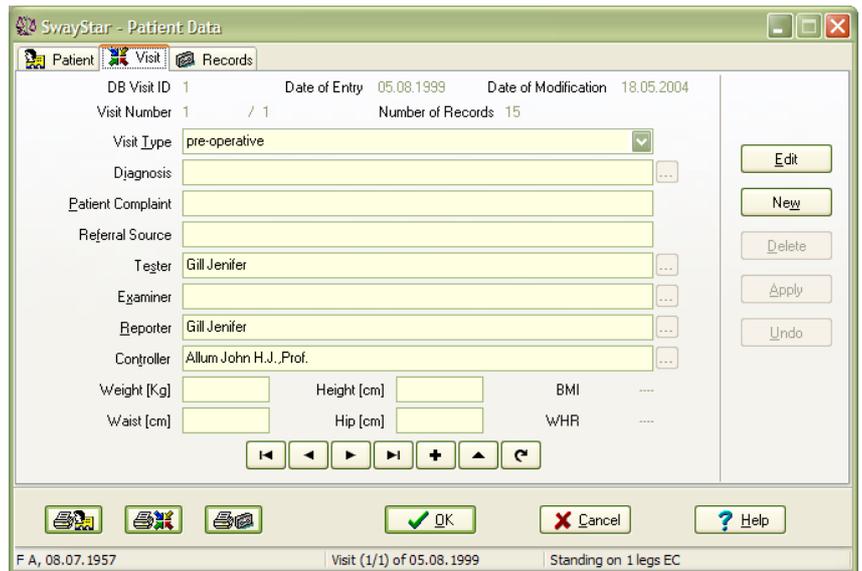
3.2.5 Selecting Data and Managing Data

All relevant fields should be completed when entering a subject for the first time.



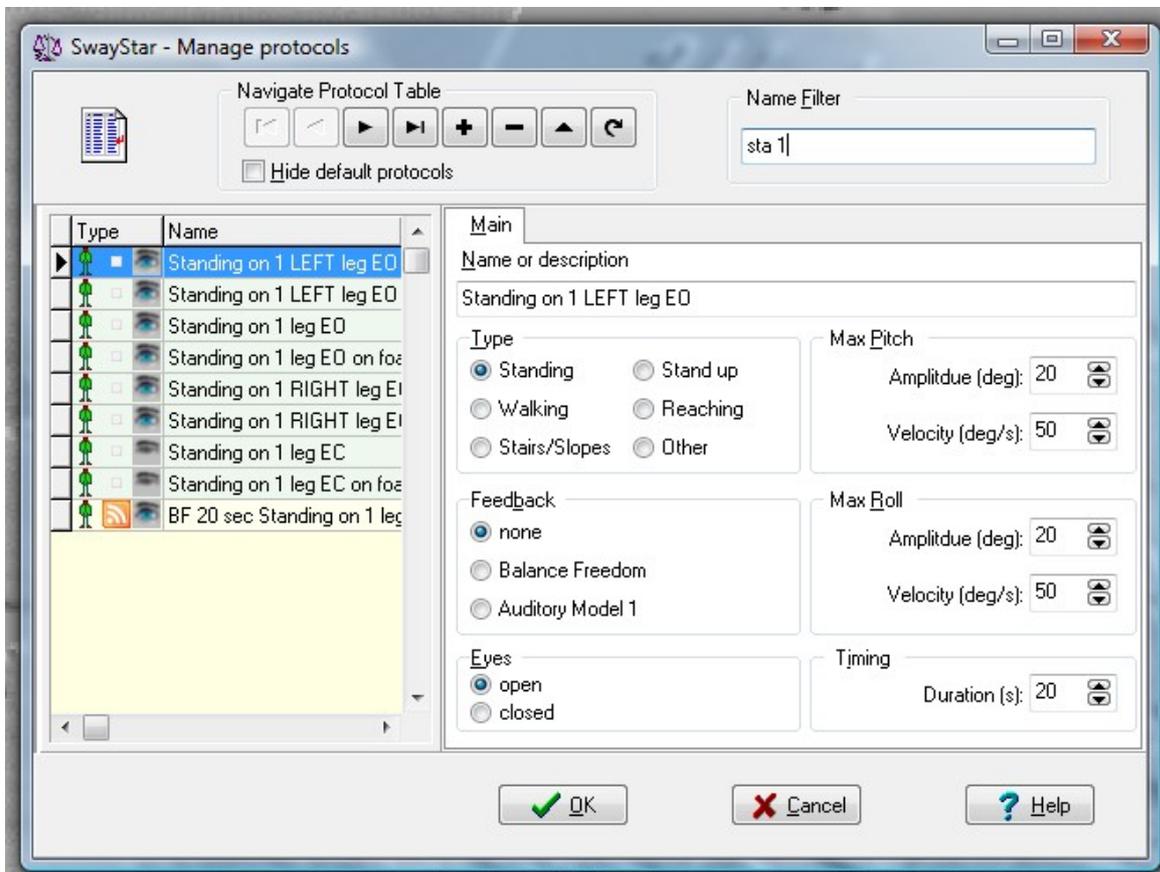
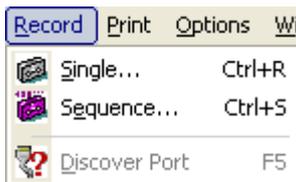
- If you have entered Manage and a subject's (patient) name appears in the field, you may sort by ID or by last name (Name).
- Alternatively, you may look up previous subjects, select edit, see next in list or add a new patient.
- To add a new subject, select New then enter the relevant patient details in the *Patient* window and select OK. This will close the window but maintain the patient record in memory. The minimum data that needs to be defined is Last and First name and Date of Birth.
- When proceeding to record data, the most recently selected subject in the Patient Data window will be the current test subject.

- To complete the entry, select the Visit tab and supply the relevant information. Add the subject's weight, height and waist and hip measurements if you wish to have these stored. First-time subjects will have no records to review.



3.2.6 Selecting a Single Protocol

From the Main Menu, select Record and left click on Single.



- The *Select protocol* window displays the available test protocols and shows the various parameters that have been set. The settings for amplitude, velocity and duration have been chosen to cover most cases of individual variations. It is not necessary to alter these settings as the off-line analysis provides auto-scaling. The pre-defined factory protocols (highlighted in green) do not allow settings to be altered.
- Use the Name Filter field, to enter part of the protocol name in order to search for the desired protocol, and then double left click on the desired test protocol.
- The Record window will open showing the protocol that was selected

Note: The subject is listed in red in the recording window if the visit of the last selected subject is more than 24 hours old.

Note: The word “faked” is automatically added to the record name if the Model 0 sensor type (random generator is used).

Note: Trying to record with an auditory Model 1 feedback or BalanceFreedom™ protocol if either of these feedback controllers are not connected and switched on will cause an error message to appear when the recording is started unless the feedback settings have been suppressed in the protocol.

3.2.7 Recording

To begin recording, click Start (top left) or press [ALT] + [S] and the recording will be started after a short delay. Triggered starts (see section 5.4.6 Trigger) start with no delay.

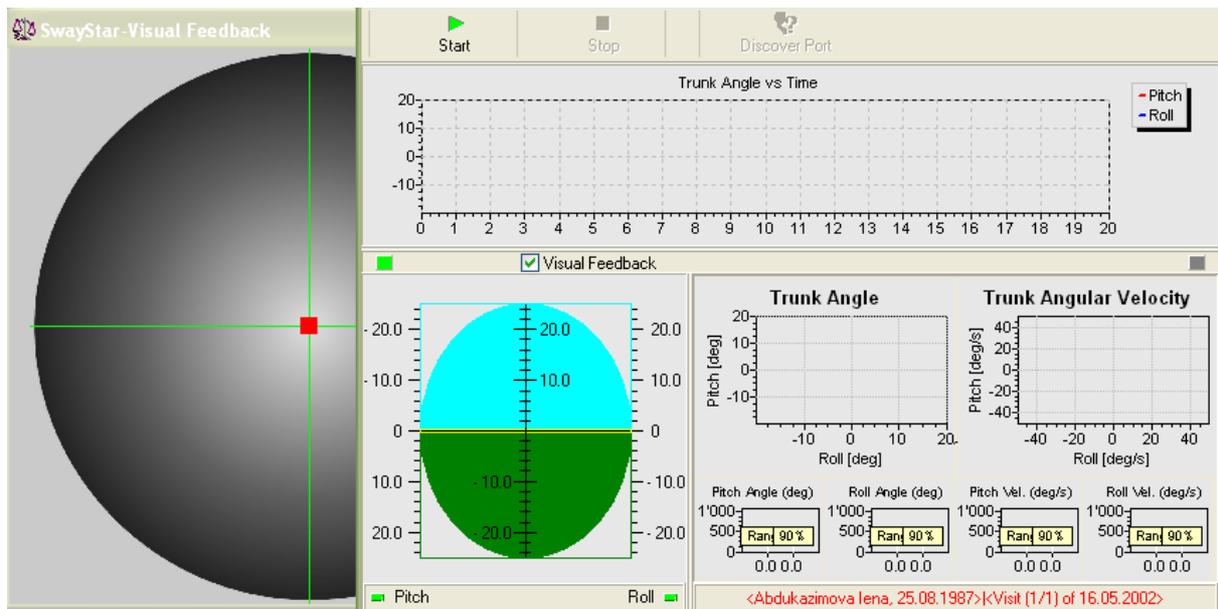
A number of indicators inform the user that the hardware is functioning correctly.

An indicator left and below the time plot indicates system power is sufficient if green. If it is not, a recording can not be started.

Another indicator below the time plot and to the right indicates the rechargeable battery status for Bluetooth function (if it is in use). Green is sufficient power, a flashing yellow critical and when red no recording is possible.

Two further indicators show the sensor status. These are marked Pitch and Roll and are green when the sensors have sufficient power, yellow when power is insufficient, and red when the sensors are not functioning, that is not switched on.

If the user has the Balance View Option, they can click on the “Visual Feedback” box and enable the visual feedback display. This display will fill the whole screen (or the screen of an auxiliary monitor) where the recording starts. It is downsized before recording starts.



- You may stop the recording at any time by clicking the Stop button or pressing ALT and t on the keyboard. If you stop before 1.26 sec, insufficient data will be available for analysis. An error message informs the user that such a recording will not be stored and it must be redone.
- As the recording progresses, a real-time display appears and on-line analysis.
- You may check the correct orientation and recording polarity of the sensors in real time. Pitching backwards (or simply tilting the sensors) should cause the pitch traces to move down, as well as the display of the artificial horizon. Rolling left should cause traces in the x-y plots to move left, the horizon right, and the roll trace in the time plot to move down. If this is not the case, contact the manufacturer before checking the reverse polarity box under Sensor settings.

Note: In order to view the on-line display in real time, the recording window should not be maximized or resized before or during recordings. Also for some Laptop computers recordings should not be run on battery power.

Triggering an external device

Model 2 SwayStar™ users can use the Start and Stop command signal to synchronise recordings with those of another device or the external device can trigger SwayStar™ data collection. Two BNC connectors on a special USB connector box (available from BII) provide or receive appropriate TTL signals for this purpose. In the record mode pressing Start, for example, causes trigger OUT1 TTL signal to go HIGH. When the Stop command is given the OUT1 TTL signal goes LOW. Once the other device is ready to start recording, that is, ready to accept the SwayStar™ trigger signal as its recording “Start” signal, the SwayStar™ start signal can be given. Whether SwayStar™ is triggering (via BNC connector OUT1) or is triggered (via BNC connector IN1) can be set under Options, Settings, Triggering.

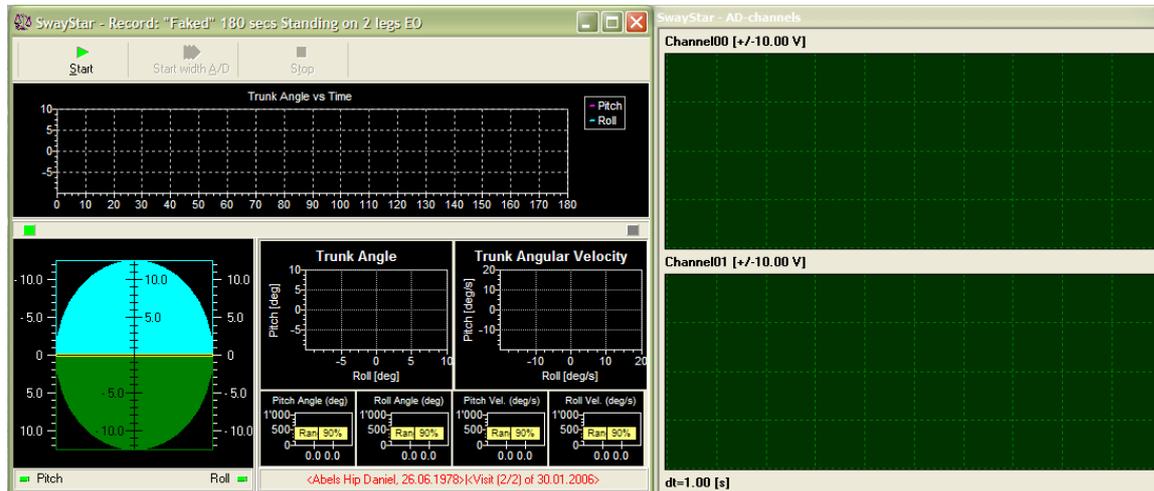
Recording with the Analogue to Digital Converter present

If the A/D board DT9800 is connected via its USB connector, its associated software installed, and its usage is enabled in the SwayStar™ program settings (see section 5.4.6 A/D-Data Settings) a re-

ording window with a display of the sampled channels appears once a recording protocol is chosen. There are 2 options to start recording.

Press start if A/D data acquisition is enabled (in settings). If so, the second option will be greyed out.

Press start with A/D, if A/D data acquisition was set selectable per recording in the settings. Simply pressing start will start a recording of SwayStar™ data without A/D data.



The recording window can be resized as one complete window. However, if a minimum size is reached for the A/D channel display, further reduction of the A/D display is not possible.

The A/D channel displays are of the maximum voltage set in the settings with 1s time graduation along the time axis.

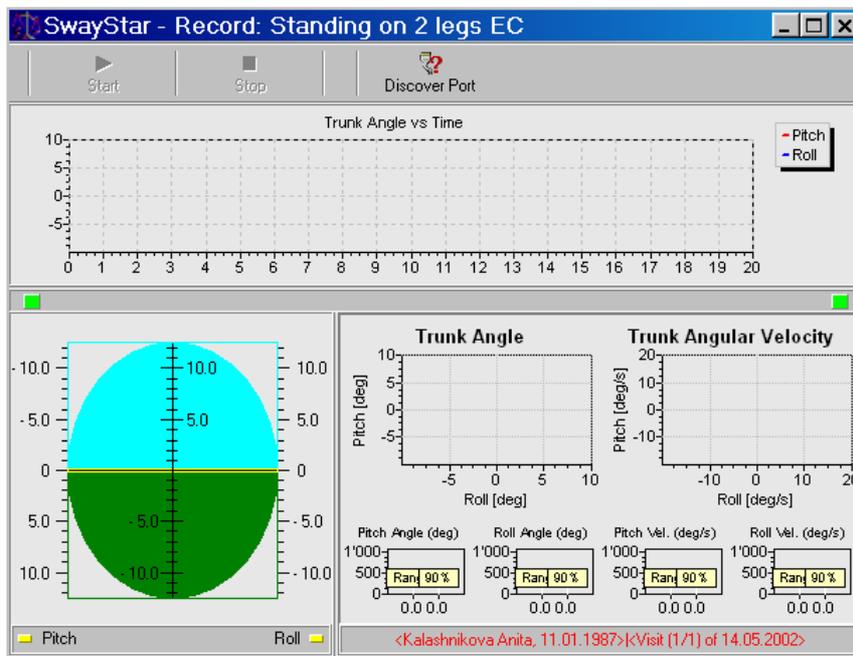
Saving

When the recording is completed, or if the Stop record button has been clicked, a message will appear asking if the recording is ok and choice of buttons is presented (YES; YES, but ... (the subject lost control of balance); ABORT; RETRY).



Click YES or YES but ... for the following screens, which show first the possibility of adding reference values and second the subject under which data will be saved.

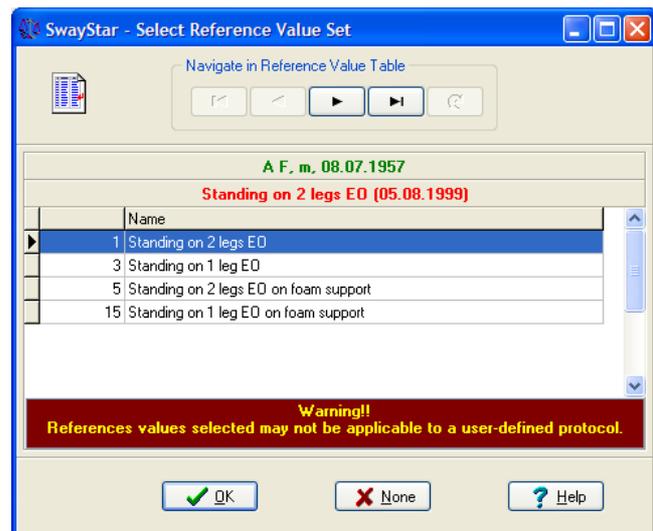
If Bluetooth communication failed during the recording (because the power was at a critical status or the sensor box was too far away from the Bluetooth dongle) a system error message appears. The user can still elect to save the data in this case or use the "Discover Port" function to switch to a serial line COM port and retry the recording.



Adding reference value comparisons

Reference values are plotted with the analysis. If the data was recorded with a pre-defined factory protocol then the set of reference values is assigned automatically. If, however, the recording was done with a user-defined protocol, you are asked to assign the reference value set, unless you have suppressed this function (see [Settings-operation, section 5.4.6](#)).

Based on the *type* of protocol used, the program offers possible reference value sets to assign. For example, when the user-defined protocol is a standing protocol with eyes closed, all similar reference value sets are presented as possible choices. The choice can be changed later (see section 4.5.5: Alter reference set) or the analysis results can be presented without reference value comparisons by selecting None (see below).



If the duration of the recording is less than the lower 5% limit of normal durations for the selected reference set, you are warned that the reference set may not be applicable. Likewise, when if the time window used for analysis is too short, a warning message will appear- see section 5.1.2: New time analysis.

When analysis data are printed, a remark at the bottom, left-hand corner of the printed page indicates whether the reference set was user defined or not and also whether the analysis period was less than 75% of the recording time (for later versions it will be less than the lower 5% limit of the duration for the normal reference). See also section 5.1.2: New time analysis. Median values and 5% and 95% limit bars are printed grey if user-assigned, black otherwise.

Assigning the recording to a subject

When the assignment of the reference value set is completed or skipped, the following message will appear

- The subject is listed in red in the recording window only if the last selected subject and visit is more than 24 hours old (see further description in see [section 5.1.2](#)). Make the selection of your choice.
- If you choose to save, you will be transferred to the Save Recording window, shown above, where you can add (+) or select (...) the subject if this has not been done previously.
- It is not possible to add further description in the Record / Test Protocol field. However, you can rename it once stored, see [section 5.1.3](#).
- If you choose YES but... when saving the recording a pictogram indicating a person falling will be shown at the end of the time plots in the analysis screen.

Controlling recording with the Targus™ Multimedia Remote Presentation Controller

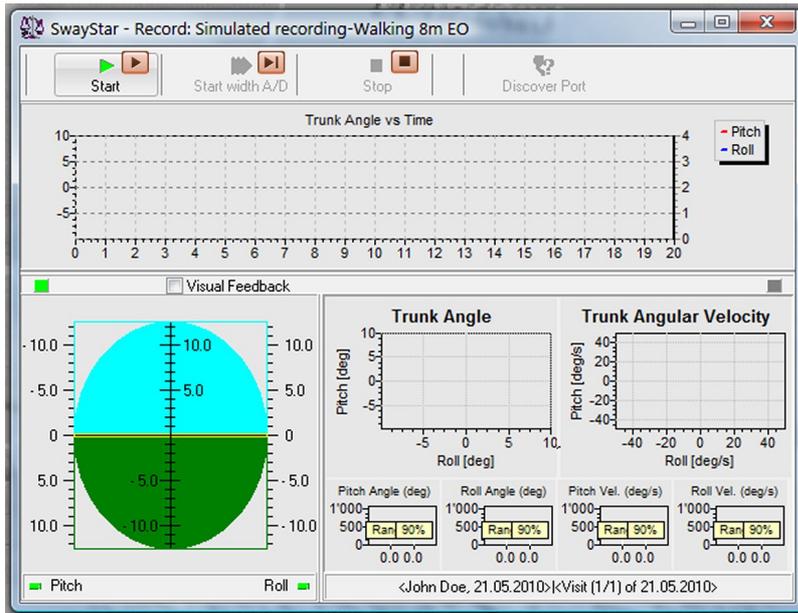
This device delivered with the system may be used to remotely control the recording (start and stop, accept the recording or not, accept the subject assigned to the recording). Other devices that carry out the same function may also be used, for example, media presenter available within Sony Eriksson mobile telephones. This function is particularly useful for recording during sequence.



If the person present to help the patients with the tasks and prevent falling in case of loss of balance, is also operating the remote controller, then that person should be aware that the first priority is to help the patient.

There are 3 stages of commands used for recording and storing. The buttons on the controller to use for each stage are illustrated below. Note that stage 3 commands are only used after the first protocol of a sequence is stored as storing within the same visit occurs automatically for a recording sequence.

Set 1 is as follows:



Set 2 is as follows:



And Set 3 is as follows:

SwayStar - Save Recording

Patient

Last/Family Name: John Gender: male female

First and/or middle Names: Doe Date of Entry: 21.05.2010

Date of Birth: 21.05.2010 Date of Modification:

Identification Number: DB Subject ID: 133

External Link: Number of Visits: 1 / 1

Visit

DB Visit ID #	Date of Visit	Visit Class	Patient Complaint	Diagnosis	Referral
	21.05.2010	other			

Record / Test Protocol

Name: Simulated recording-Walking 8m EO

OK Cancel Help



4. OPTIMAL USE OF THE DATA ANALYSIS WINDOW AND ICON DEFINITIONS

To enter the Data Analysis Window without first making a recording, you must Retrieve data. Once one, or several, recordings have been retrieved, operations can be performed using the various Icon Commands.



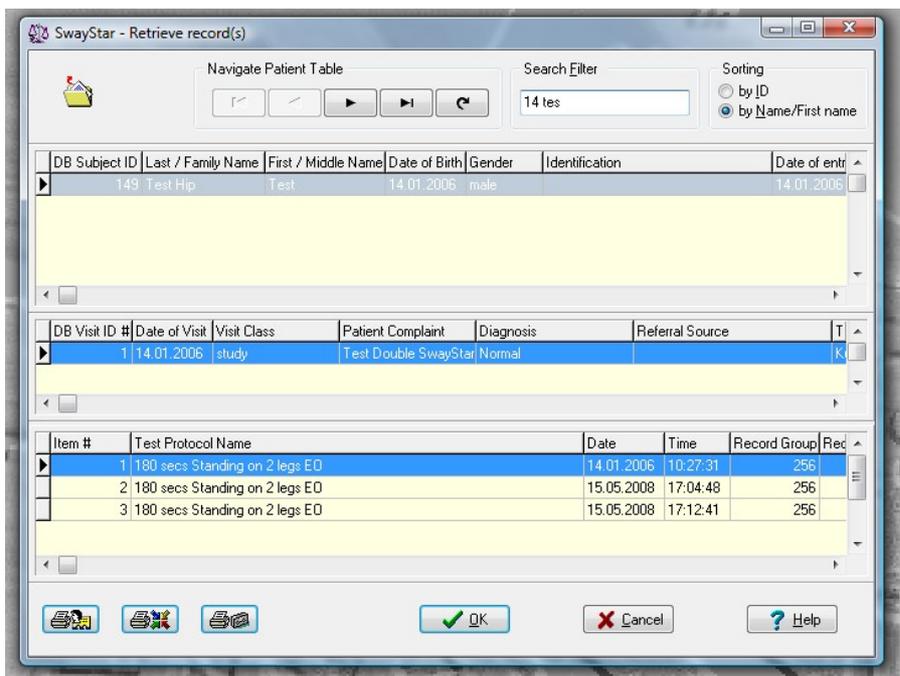
4.1 GENERAL COMMANDS

4.1.1 Manage Patient Database

Although it is possible to enter a new patient from the recording window, in the interest of keeping test time to a minimum it is not recommended. It is best to set up the patient and visit information ahead of time before starting a new recording.

4.1.2 Retrieve and View Records

It is possible to retrieve and view records in two (2) ways *after* clicking on the retrieve icon :



- 1 Double click on the **blue highlighted** bar in the middle area showing Visit information. This will retrieve all recorded protocols for that session (visit).
- 2 Double click on any single protocol (bottom) or highlight with a single click, and click OK.

Note: Under Retrieve, you may also search for a new subject either by ID, or by all or only the first part of a last or first name or date of birth or a combination of all these. The sorting can be by ID or by name. The screen is split under the list of visits. Extend the split downwards to see all the visits of a selected patient.

4.1.3 Save Changes

Any feature of the analysis or assigned normal reference value set which is changed must be saved if you wish these changes to be retrieved after closing. You will, however, be prompted to save each recording before closing it if you changed aspects of the analysis window.

4.1.4 Balance Control Summary

To obtain a Balance Control Summary (BCS), and its associated composite scores, Sensory Analysis and Balance Control Index as described in [section 2.8](#), click on the icon to make all the recordings from the patient's relevant visit available for the BCS. The visit is selected in the same way as all records in a visit are retrieved (see [section 5.1.1 Retrieve](#)). When selecting for the BCS, however, only the visit option is highlighted.

To be accepted for the BCS, the recordings must have been performed with pre-defined factory protocols (those for which reference values are available). If reference must be assigned to the recording (as is the case with older Model 1 records), the user is prompted to make the assignment. If the user wishes to exit this process, the window requesting assignment just needs to be closed. Also if more than one recording exists with the same name in the visit (for example, standing on 1 leg, eyes open), the user is requested to choose the record to use for the BCS.

If only 3 or less of the 10 pre-defined records needed for the BCS are available in the patient's visit, then the BCS information will be displayed temporarily to inform the user. Click on OK to end the action. If the stairs test is missing for computation of the BCI, the BCI is still computed but a warning is issued.



To look at the tests used and a list of numerical values in the display, click on the tab "Values"

  above the display. Clicking on "Graph" focuses on the display again. Both may be printed by pressing the Print icon. The symbols used in the display are described in [section 2.8](#)

Charts and tables displayed for the BCS may be copied to the clipboard or Excel, respectively using a right click of the mouse.

4.1.5 Set marker pairs

Allows up to 10 marker pairs to be set on the time plots of pitch and roll angular displacement. (See [section 2.7.5](#) for more details).

By clicking on this icon you can activate the beginning marker of the first marker pair on the time plots of trunk angle. Once the marker is set, the end marker of the pair appears automatically. To move the mark simply click and drag it to the required position. To activate the next marker pair click again on the marker icon.

To delete any or all markers right click on a marker when mouse symbol is below the zero amplitude line of the time plots and carry out the desired change.

4.1.5 Reset

Resets the analysis status to that of the last user modification after data retrieval.

4.1.6 Undo

Resets the analysis status to what was displayed when last retrieved.

4.1.7 Redo

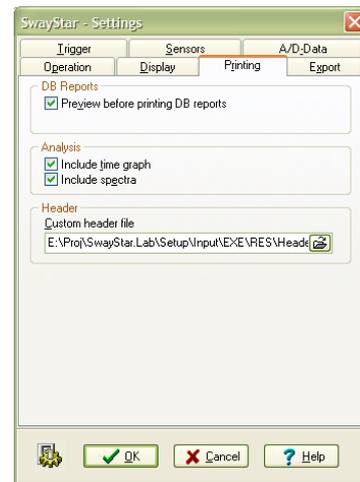
Set the analysis status back to that prior to an undo.

4.2 PRINT DATA

Transfer data to hard copy via any Windows-application default printer or a specifically defined printer. The options are to print the *current window* only, to print *all retrieved data* (click on “Windows” to view a list of retrieved data) or to setup printer variables (i.e., use a printer that is not the default printer).

The analysis may be printed with or without the pitch-time or roll time plots (time graph) or without the spectra depending on the print settings. Select this option following Main Menu/ Options/ Settings/ Printing.

Preview print is available for the database reports.



4.3 LOG AND EXPORT DATA

You may log the numerical data displayed in the analysis window to a csv (comma, separated values) file that can be viewed with MS Excel (or other spread-sheet program). The variables shown in the .csv file are described in [section 2.7](#). If a variable value is greater than the reference set’s 95 percentile limit, it appears in red in the log file; if less than the 5 percentile limit it appears in green, in all other cases, it appears in black (either within the limits or if no reference set was assigned). A list of analysis values is provided in section 6.3.

4.3.1 Logging data into a .csv file

- Check that the desired .csv file has been selected. Do this by passing the mouse arrow over either of the two icons  . A hint will appear (write values to....) listing the last log file used. For normal subjects, set this to Normal subjects.csv, for example. The default file on delivery is called AnalVal.csv).
- To write the numeric values for all the data you have retrieved to a .csv file, use the icon with two pages and a red  tick. Using the icon with only one page and a red tick  will log the data of the currently open and selected window printer icon.
- To export a .csv file to Excel via SwayStar™ in order to view the data click on the icon . SwayStar™ directs Excel to open the exported file.
- To select a new log file, click the icon .

- If you selected a file that already exists as a new log file, you will be asked if you want to reinitialize it. Answer NO if you do not want to initialize the file (as is usually the case); YES, otherwise.)

Once the values are written to the log file the icons are shown in the disabled state  .

If for the current data window there are pending modification indicated by the Save or Reset icons



both “Write values ..” icons will be displayed in their inactive state  . If modification are pending for a different but the current window than the “Write values ..” icons are shown in active state for “the current” respectively inactive state for “the all”  .

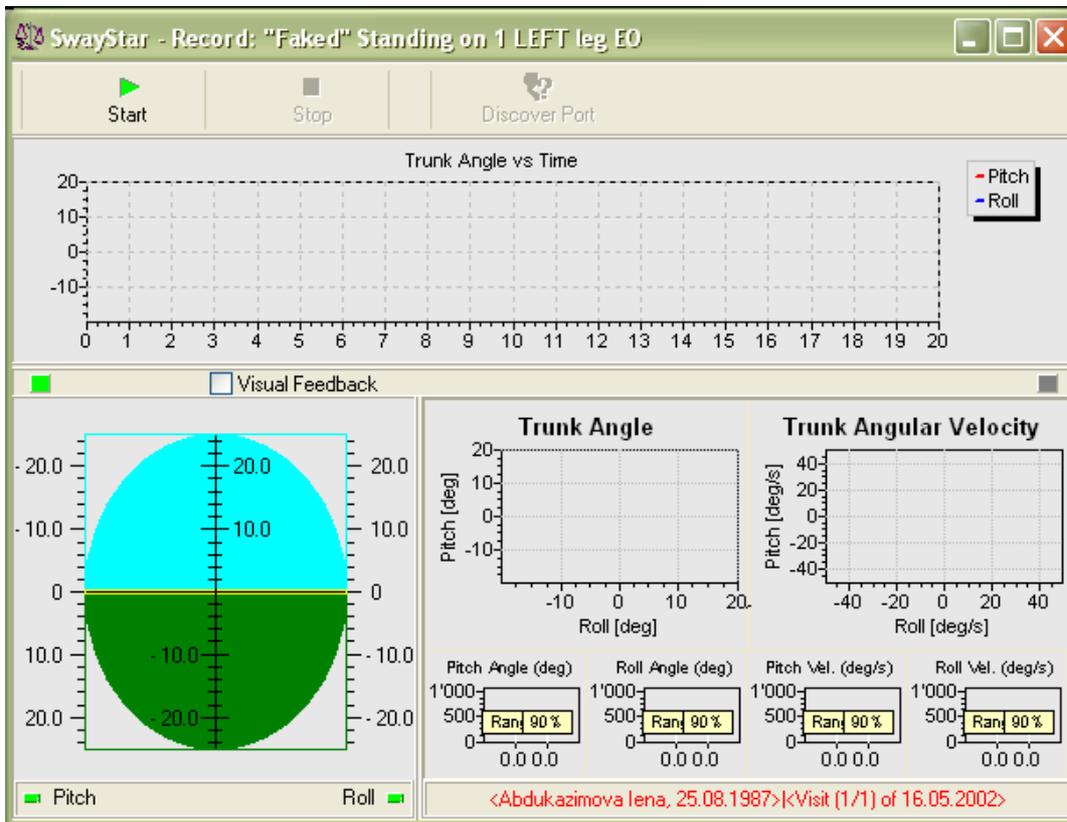
4.3.2 Viewing and Exporting the .csv Log File to a Spreadsheet

To export the current .csv log file to a spreadsheet such as MS Excel, or to view the file, click on the icon  (third to the right of the printer icon). Excel or the desired spreadsheet will automatically be opened. Values in the csv file will be followed by the symbols <,~, and > depending on whether the value is less than, within the range or greater than reference values, respectively (provided a reference value was assigned

Note: To save the file, do NOT select File/Save. You *must* perform the operation SAVE AS and give the file a new or old spreadsheet name. It should not be the same name end path used by SwayStar™ on opening MS Excel because SwayStar™ deletes this file in the working directory on re-opening the program.

4.4 COLLECT DATA

 = Start



 = Stop

4.4.1 Select a Single Protocol to record

(only available if the sensors are turned on and the sensor box power for Bluetooth function is not critical).

For information see [section 3.2.6](#), above

4.4.2 Select a Sequence to record

(only available if the sensors are turned on).

For information see [section 2.6.2](#), above

4.5 VIEW DATA

4.5.1 Copy and paste graphics

A unique innovation is available for those individuals wishing to either make visual presentations using the graphics from the program or wishing to print documents that include graphics from the program.

Wherever the mouse is passed over a graphic image, a message automatically appears for a short time with the message: *Copy (Ctrl-Shift Mouse click)*. Executing the command (with the left mouse click) will automatically make a copy of the graphics being displayed on-screen and hold it in the clipboard. It can easily be transferred to a graphics program (PowerPoint, Harvard Graphics, Photoshop, etc.) or inserted into a document (WORD, WordPerfect) for report writing by using Ctrl-v (paste command).

Note: When the image first appears in the imported window of your graphics program, it will be very small. You will need to enlarge it by clicking on the corners and dragging. To preserve the image proportions, if using MS PowerPoint, hold the Shift key down while dragging.

The interested user will want to explore and experiment with the options for viewing and transferring graphics.

4.5.2 Replay

Once the recording of a protocol has taken place, you may wish to replay it. This is easily accomplished in the analysis window by clicking on the replay arrow . Stop the replay at any time by clicking on the stop replay button . Once stopped, the complete recording will automatically be reinstated in the analysis window.

4.5.3 Zoom in, out and restore display

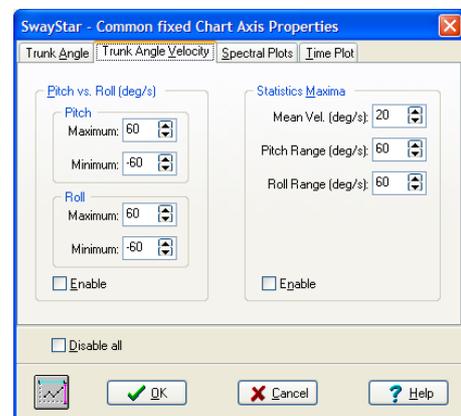
These functions operate only on the upper set of pitch- / roll-time traces. To shift the zoomed display to the centre of the time plot, hold the right mouse down and drag the display to the desired position.

4.5.4 Scaling displays

It is possible to adjust one or more records that are open so that they are scaled similarly according to the exact wishes of user. This is useful when wishing to compare results from different subjects, or results from the same subject over time.

User-defined analysis scaling

The scaling is accomplished by 'selecting the icon  that allows the auto-scaling to be disabled. In this way, two graphs that have different auto-scaled images can be assigned values equal values for more effective visual comparison.



This user defined “Common Fixed Chart Axis Properties” offers several options for viewing the results. The top tabs automatically open according to the current analysis results on the monitor; however, any tab (angle, angular velocity or spectra) may be selected and altered. Simply scroll to, or type in, a new setting. In order to activate new scaling, toggle off (click on) the tick mark in the Disable all box (or press Alt + D) and toggle on (click on) the tick mark in the Enable box (or press Alt + E).

The left side of the “Common Fixed Chart Axis Properties” box selects changes for Trunk Angle (Alt + A) and Trunk Angle Velocity (Alt + V). Select the desired values to adjust and then comparing two records to which the auto-scaling had originally been applied. That is, the two graphs will now have

common maximum and minimum values. The right side (Statistics Maxima) of the box simply sets the scales for the column plots; that is, area, duration, peak-to-peak values etc.

Note: To toggle a function on or off, simply click in the enable box or disable all boxes.

Window-defined current analysis scaling 

Scalings in all other displayed analysis windows can be set to those of the currently selected analysis window by selecting the icon .

The auto-scaling in the currently selected window is not altered. This command permits a quick comparison between displayed records.

The icon  is selected again, to reverse the selection.

User-defined ratio split 

The ratio of the split between the upper and lower analysis windows may be changed by clicking on the adjust display ratios  icon. All of the records that are open will be adjusted to have the same display sizes for the upper and lower windows. Once this option is chosen, it is possible to return to the original display simply by readjusting the window (click on edges and drag to the desired size).

4.5.5 Alter reference set 

A normal set of reference values may be assigned or a current assignment removed by clicking on the icon . To keep this assignment the data must be saved. The window used to select the reference value set is described under section 4.1.2: Retrieve and view records.

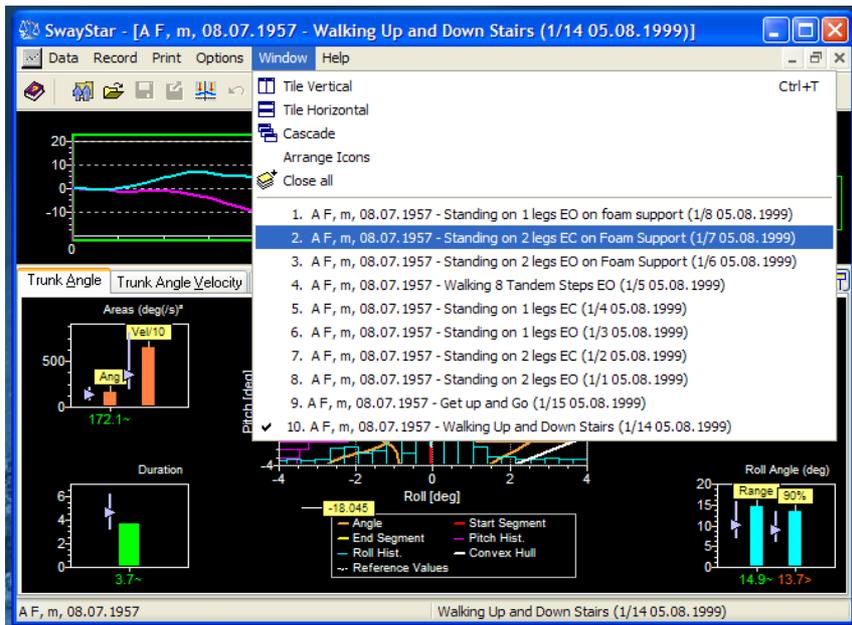
4.5.6 Remove or show labels

Labels appear on the analysis graphs. These may be toggled on or off by clicking on  in the tool bar below the recording time window.

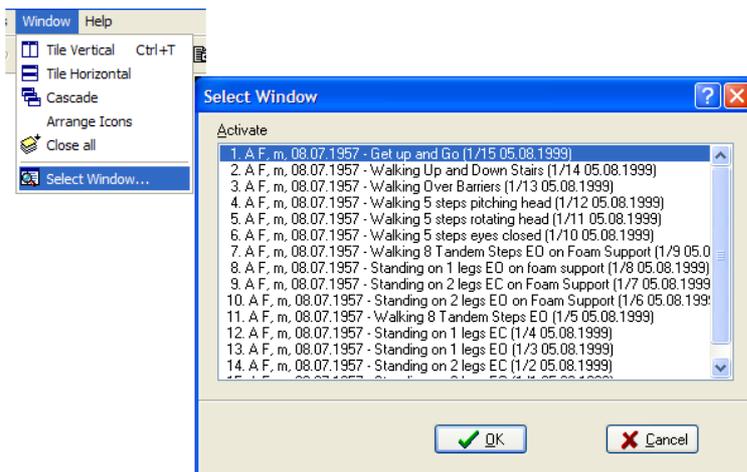
4.5.7 Window (no icon)

Clicking on Window offers the opportunity to view more than one record at a time, either by tiling vertically, horizontally or cascading files. All the records may be closed at one time (Close all) or closed one at a time by clicking on the top, right-hand x of each individual record

The Window option will display 10 files.



If more files are opened at one time, a List Box appears.



Note: It is important to pay attention to resource capacity. Opening too many saved records uses up resources.

4.5.8 Set Time Window

This command allows the user to set the time analysis to precise values for the current data window displayed. This setting can be applied to all data windows recalled.

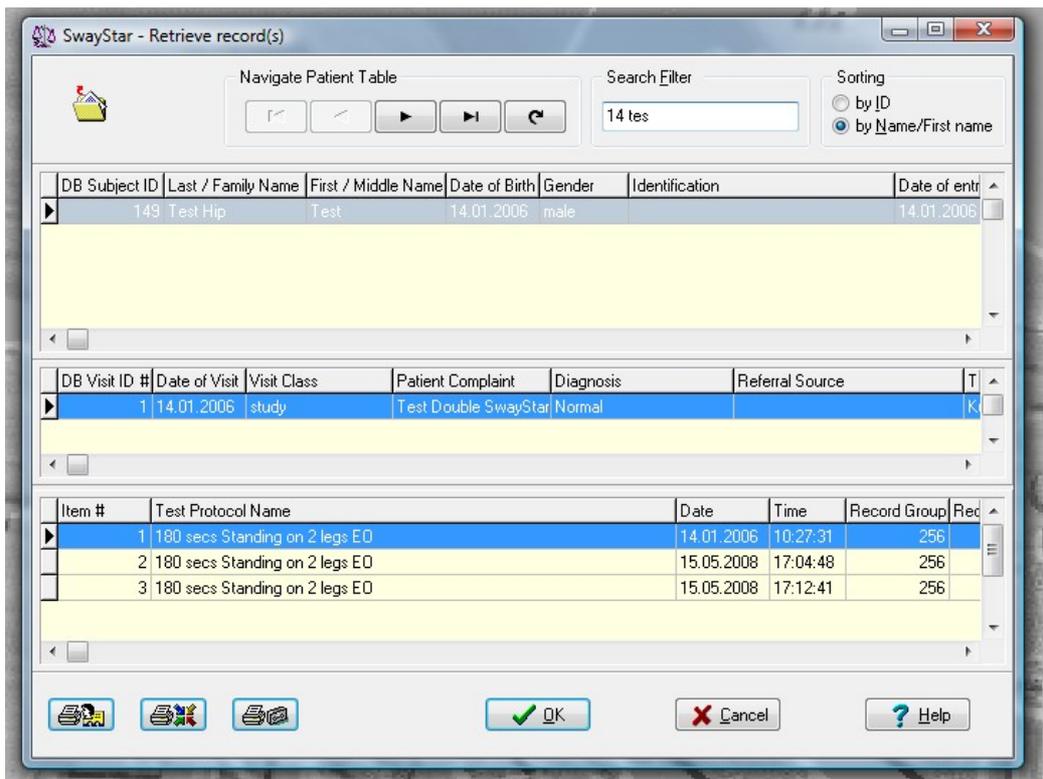
5. MAIN MENU

This section provides additional information to that supplied in [section 3.](#) and [section 4.](#) It is useful to refer back to these sections.

5.1 DATA (Alt + D)

5.1.1 Retrieve (F3)

The retrieve option recalls all data that has been stored during previous sessions. It is accessed in two ways: either Main Menu/Data/Retrieve and left click or simply click on the retrieve icon . All of the patient records are displayed in the upper box. The last name to have appeared in the Retrieve Window is displayed when you first open the program, have retrieved records in the database, or have set up a new patient. Using the scroll bar to the right it is possible to display all patient names. Whenever a patient name is selected (highlighted), the associated files appear in the lower two boxes. To enable quicker searching, choose either the ID number or the Name to arrange the listing order, and then type the appropriate information in the white Search Filter field depending on whether the search should be, by the ID number or by all or only the first part of a last or first name or date of birth or a combination of all these.



The headings for each box relate to the Manage Data windows described in section 5.1.3: Manage data.

Several retrieve options are available. You may select either to retrieve ALL records contained in a particular visit (second box) or individual protocols for the selected patient (third box) relative to a particular visit. Double left-click on the desired visit or protocol and the record(s) will immediately

be displayed in the Data Analysis Screen. It is not necessary to retrieve individual records if you are interested in reviewing an entire session.

The last name that was selected and displayed as the name under which a recording was last saved will always be the name displayed when you first select the retrieve option. This is true whether you have just started the program, retrieved earlier records in the database or have setup a new patient.

5.1.2 Save (F2)

The save function is available in five (5) instances: after entering details for the first time (new patient), after editing and details for an existing patient (edit options), after altering a time analysis window that recalculates the data for display, after markers are placed on the time histories or in the process of adding new recordings.

New patient details

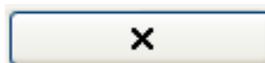
New patient details will be saved to the database by clicking on OK (see description under Easy Start).

Editing

To change any details of an existing entry, it is necessary to edit them. The edit option is available via Manage. You may select edit by clicking on the button (right panel of the screen) or by using a common icon (see 5.1.3, below). When the edit option is active, you may either type in new details or select from a list. Accept or reject the new details by clicking the appropriate symbol:



Accept



Reject

After pressing the Accept button, the revised information is saved to the database.

New time analysis

The data will always remain as originally collected once a recording is been saved. However, it is possible to analyze and then save any part of the recording at a later time. Changing the analysis window does this.

Note: if the scaling values are altered in the Data Analysis Screen (see examples in 4.5.3 and 4.5.4), the new presentation of the data on the screen will not be saved. Such changes are for viewing purposes only.

Add Markers

If markers are added to the time plots, the position of these markers must be saved for later retrieval and before this information can be stored in the log file.

Adding new recordings

When you attempt to store new data into a currently selected visit record, the name of the subject will appear in red

<F A, 08.07.1957><Visit (1/1) of 05.08.1999>

It changes to black once you store the new recording. You will be reminded that the visit that is currently selected contains records older than 24 hours.

When you attempt to store data under a red name, the information relating to the name will be displayed. You have a number of options.

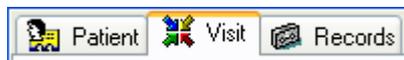
- If you are certain that you want to store data to this subject you can click OK.
- If the visit is older than 24 hours, you will be asked if this is really what you want to do. If your answer is NO, no action is taken and the recording is lost.
- If you answer YES, then the recording is stored under the old visit.
- If you did not want to use this patient name, you can hit the button next to the name information with on it and select another patient, or you can click the button labelled  to add another patient, which allows you to create a new visit or select an old visit by clicking the buttons next to the visit information. Then click OK and the data is stored under the selected name and visit.

It is best is to set up the patient and visit information ahead of time, then it will be in black and will automatically store in the correct place. Even if the name appears in black, it is still possible to change details when the name information is displayed.

5.1.3 Manage Data (Ctrl + M)

Managing patient data accesses general information in the database. It is possible to add, edit and delete details that are not directly related to data analysis.

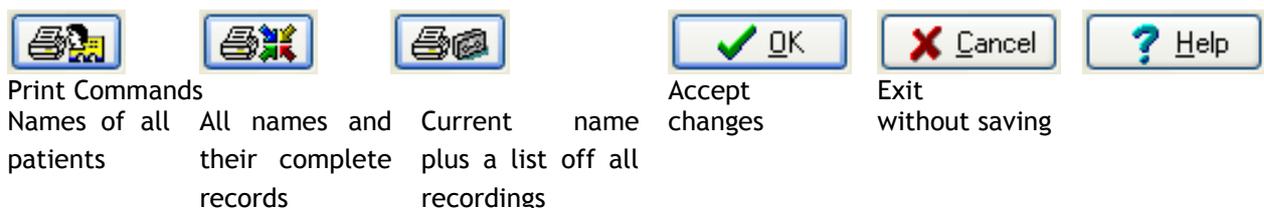
Navigate between the three options using the tabs.



There are a series navigation icons available in all data management windows. A drop-down Hint describes each.



Other common icons are:



The current data that has been selected in the three categories (patient, visit and record) are shown at the bottom of each window under Manage.

F A, 08.07.1957

Visit (1/1) of 05.08.1999

Standing on 2 legs EO

Patient

Patient information contains relevant details to enter (name, age, sex, etc.) and details that are automatically stored by the SwayStar™ program (subject number within the database, date of first visit, date on which details were modified and number of visits).

The meaning of the abbreviations and headings shown in the Patient window (in addition to name, sex and date of birth) are as follows:

Identification:	Description of subject or other text
External link:	A number from an external database that a user can define; for instance, an identification number for a patient from the external database.
DB Subject ID:	Database subject identification number (automatically entered). Entries are numbered chronologically; i.e., the first patient entered into the database will always be DB Subject ID 1.
Number of Visits:	Number of visits entered in the Visit window
Date of entry:	Date subject was first entered into the database
Date of modification:	Date on which the most recent record was modified.

Logged .csv files contain the following Patient information:

Identification, External link (useful for sorting purposes), Last Name, First Name, Gender with suffix as indicator of loss of balance for recording, Age not Date of Birth and DB Subject ID.

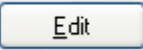
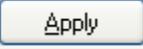
It is possible to use the navigation buttons to display database entries according to name or according to the identification relative to the order in which the subject was added to the database; e.g.

the DB number. This option is available in the Sorting box where you select to sort by ID or by Name/ First name



Select either ID or Name

The right-hand panel shows a set of buttons:

	Lookup allows you to search for a subject from this screen without going to retrieve.
	Edit allows entry details to be changed (for instance, change the spelling of a name or enter an identification number). It is the same as  .
	New sets the details to a new default patient and allows completely new information to be entered. It is the same as  .
	Delete is only available when there are no visits and records (or all deleted) for a particular patient. It is not possible to accidentally delete patient details if there are associated data.
	Apply is only available once Edit or New has been selected. Click to accept new entry data. It is the same as  .
	Undo is only available after Edit has been selected. It is the same as  and cancels changes that have not been saved.

Visit

A visit usually refers to a particular recording session although a visit can be added without completing a protocol or sequence.

 A screenshot of the "SwayStar - Patient Data" application window. The window has three tabs: "Patient", "Visit", and "Records", with "Visit" selected. The main area contains a form with the following fields:

- DB Visit ID: 1
- Date of Entry: 05.08.1999
- Date of Modification: 18.05.2004
- Visit Number: 1 / 1
- Number of Records: 15
- Visit Type: pre-operative (dropdown menu)
- Diagnosis: (empty text field)
- Patient Complaint: (empty text field)
- Referral Source: (empty text field)
- Tester: Gill Jenifer (text field with dropdown arrow)
- Examiner: (empty text field)
- Reporter: Gill Jenifer (text field with dropdown arrow)
- Controller: Allum John H.J.,Prof. (text field with dropdown arrow)
- Weight [Kg]: (empty text field)
- Height [cm]: (empty text field)
- BMI: ----
- Waist [cm]: (empty text field)
- Hip [cm]: (empty text field)
- WHR: ----

 On the right side of the form, there are five buttons: Edit, New, Delete, Apply, and Undo. At the bottom of the form, there are six navigation buttons: back, forward, home, search, refresh, and a circular arrow. The bottom status bar contains icons for Patient, Visit, and Records, followed by "OK", "Cancel", and "Help" buttons. The status bar text reads: "F A, 08.07.1957 | Visit (1/1) of 05.08.1999 | Standing on 1 legs EC".

The user defines a list of optional entries for several fields (diagnosis, examiner, tester, reporter and controller). It is only possible to change the lists after Edit has been selected (either with the edit button or by clicking on the  icon). The list for visit type is accessed by clicking on the  icon. This list cannot be changed.

Clicking on New clears all windows and also allows access to the lists. The rows for these entries are indicated by  . Once edit or new has been selected, the greyed button becomes active and a new window with one of these lists is opened. Using the standard icon commands (top left corner of the screen), the list can be modified. To enter a choice, double click on the appropriate row or click on OK.

There are two additional text fields the user can define: Patient Complaint and Referral source.

Logged.csv files contain the Patient Complaint and DB Visit ID.

The right-hand panel shows a set of buttons:

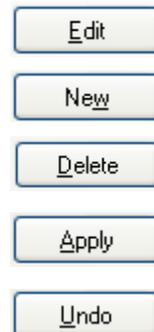
Edit to modify entry.

Choose **New** to add a visit

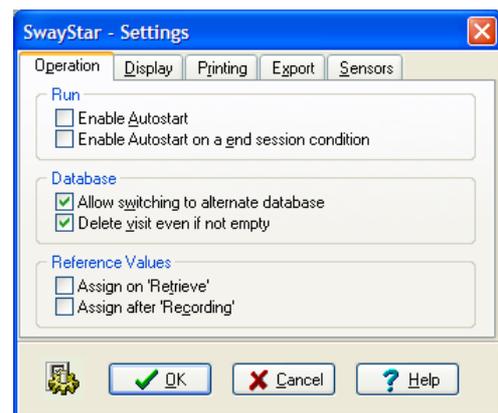
Delete a visit only if there are no records or if the delete visit option has been chosen in setting (see section 5.1.1).

Accept data entry

Clear new details if they have not been saved.

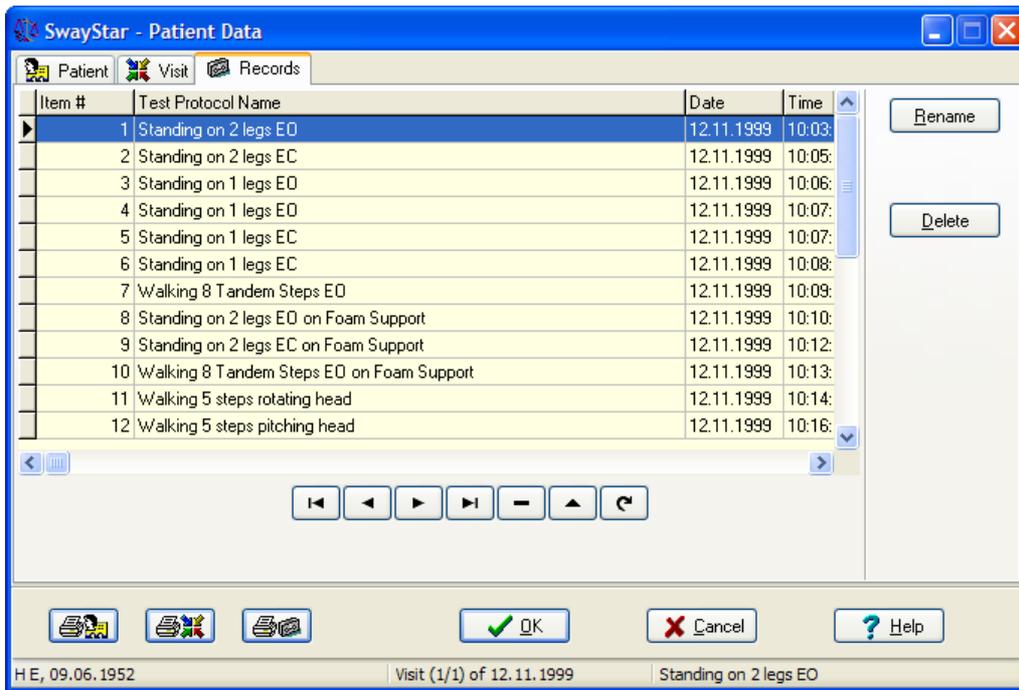


If you wish to delete a name, you must first delete the visits under the name and all recordings under a visit or delete the visit altogether and its records providing the option has been selected under Options/Settings.



Record

A record is any saved protocol that has been completed for a particular patient.



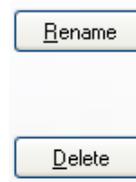
The abbreviations and heading shown in the Record window (and contained in logged .csv files) are as follows: The record screen shows relevant details of protocols for each visit. An explanation of the abbreviations and heading are as follows:

Item#:	the protocol in the order entered for examination and in which the tests were performed
Test Protocol Name:	either a selected item or a user-defined item
Date:	date of test
Time:	time at which protocol data were collected

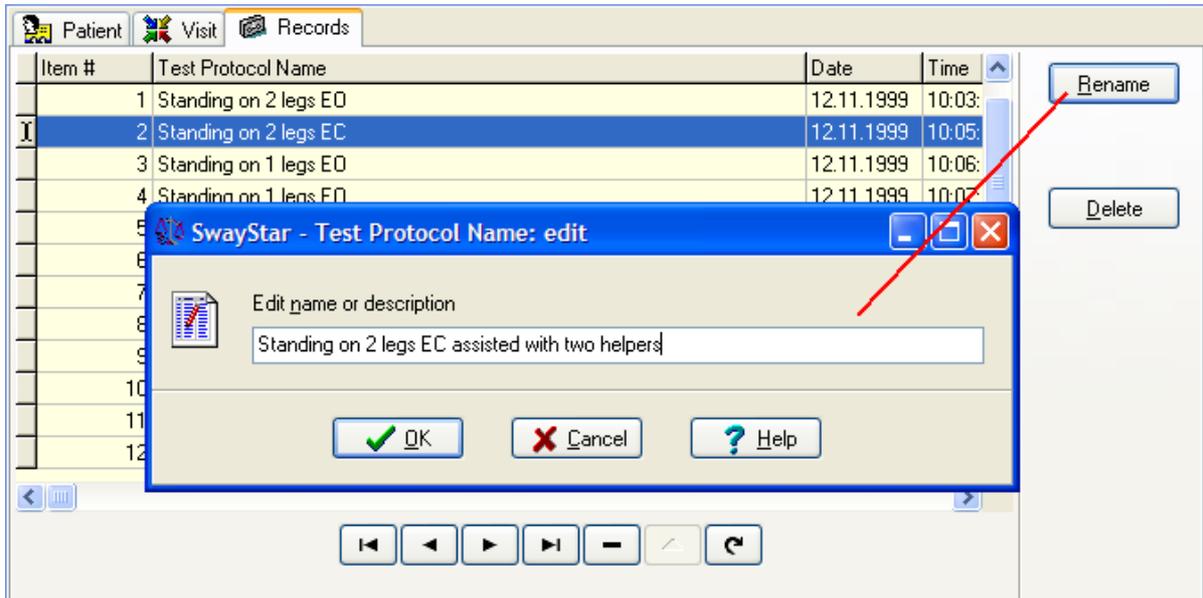
(Note: The following columns and headings are not in the csv file; however, the log time is entered in the csv file.

Record Group:	defines in code the setup type
Record Type:	defines in code the type of record (recording or report)
Date of modification:	date of test
Time:	date on which the most recent record was

The record name may be edited or the record may be deleted.



Renaming a record, changes the name only for the current subject and not for the protocol, in general. You may rename the protocol to any other relevant description, i.e., Standing on 2 legs EC assisted with two helpers (in this example).



Note: it is possible to rename user-defined protocols. Default factory protocols cannot be renamed or deleted.

5.2 RECORD (ALT + R)

In order to use these commands, the sensors must be active or the system is in demo mode (Model 0).

5.2.1 Single (Ctrl + R)

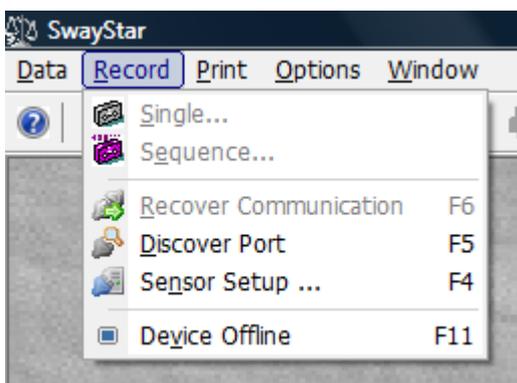
Enables the operator to choose a single protocol for recording. A drop-down window will display the options

5.2.2 Sequence (Ctrl + S)

Enables the operator to choose a sequence of protocols for recording. A drop-down window will display the options.

5.2.3 Recover communication (F6)

This allows the user to recover the COM port SwayStar™ previously used for recording.



The port communication could be lost when, after a period greater than 40s, no communication with the SwayStar™-sensor box could be established. In this case communication with the device is stopped. Switching on the SwayStar™-sensor box off and on again does not bring back the communication.

You have to hit F6 or you can disconnect and reconnect your USB device (BlueTooth Dongle or serial to USB cable).

If the communication is down the following events reawaken the communication:

- Disconnect and reconnect the USB device
- Selecting “Recover Communication” or hitting F6
- Selecting “Discover Port” or hitting F5
- Returning from the “Settings” dialog
- Bringing the device on-line by pressing F11 - see [Device Offline 5.2.6](#)

The advantage to leaving the communication down is that on average the program is more responsive if one works “off line”. In addition executing F6 stops and closes the connection and restarts it. It is like closing the program and running it again.

5.2.4 Discover Port (F5)

This allows the user to let SwayStar™ discover COM ports available for recording, select that required and use it.

5.2.5 Sensor Setup (F4)

This permits direct entry into the command window Options, Settings, Sensors - see [Settings 5.4.6](#)

5.2.6 Device Offline (F11)

Provides an easy means to switch the device off- and on-line, based on last COM port used. It is assumed that the COM port is available and ready for use.

5.3 PRINT (ALT + P)

5.3.1 Current (Ctrl + P)

Print the current record (see [section 4.2](#))

5.3.2 All (Ctrl + Alt + P)

Print all records that have been retrieved

5.3.3 Setup printer (left click)

Standard printer options are available.

5.4 OPTIONS

5.4.1 Language

Choose your language and SwayStar™ will automatically change all text comments to the appropriate language. Currently English, German, Spanish and French are supported.

For interested users who have different languages, you may enter your own translations.

- Enter the root directory for the drive on which SwayStar™ is resident.
- Go to BII CH GmbH\SwayStar\Res\String.DEU (if your reference language is German) or String. ENU (if your reference language is English) in the programs folder.
- Use Notepad to edit and save in a new folder labelled String.xxx, where xxx represents the abbreviation for your language.

- Inform BII about the new language (info@b2i.info) so we can update the language list.

5.4.2 Setup

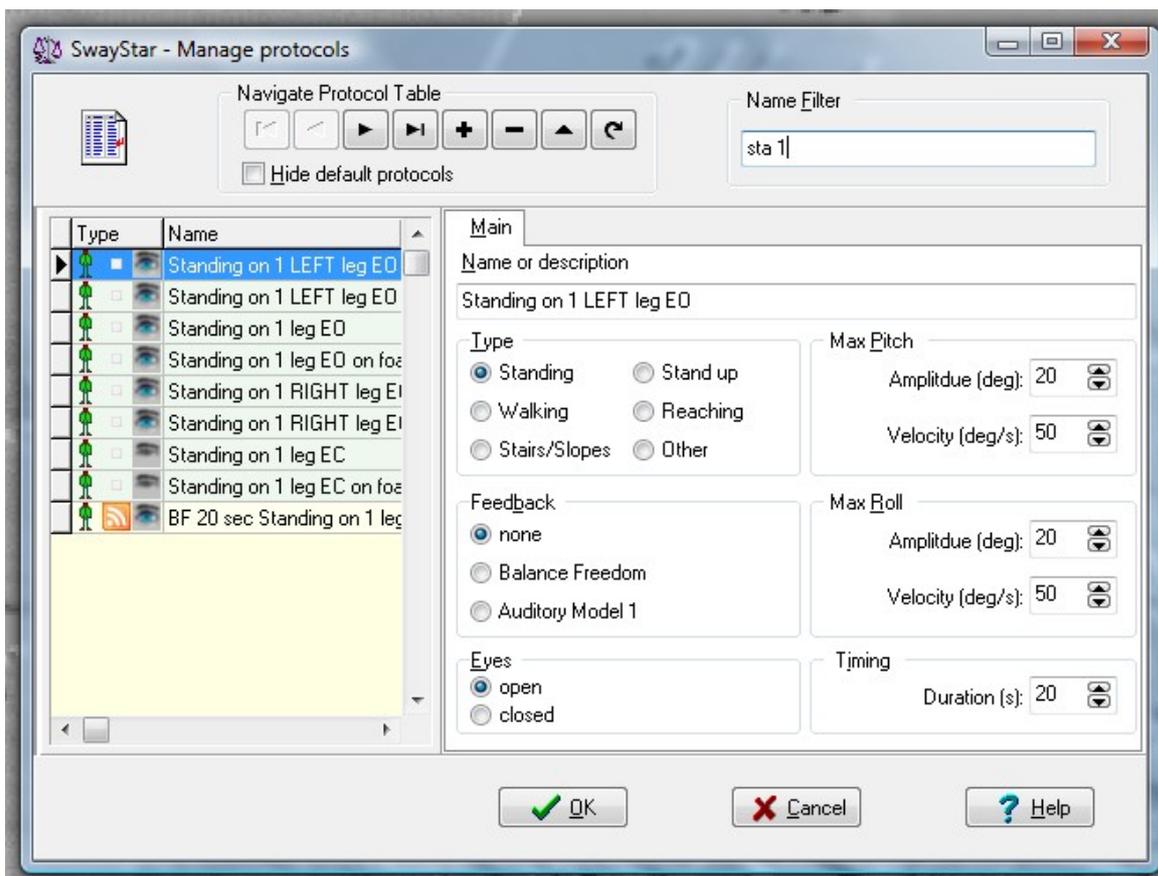
Protocols

To create a new version of a protocol, the edit or add button must be selected. Pre-defined factory protocols can be renamed to become user-defined protocols. To do this, first highlight the pre-defined protocol to use as template. Then click on the add (+) button. The user can give the new protocol the same name or a name different from the original predefined name.

There are up to 2 sets of values to be defined for each protocol: main settings and feedback settings if a feedback type has been selected under the main settings. Currently only auditory feedback is supported.

Main recording settings

Here the extent of the trunk angle and angular velocity and the recording duration displays in the recording window can be set. Usually there is no need to change these values from those suggested in the pre-defined factory protocols as these values are only approximate for recording. Auto-scaling is automatically applied to any analysis display. The type of protocol (Standing, Walking, etc. see section 2.4), and whether the eyes are open or closed for the protocol are also set in the main settings.



The type of feedback: none, BalanceFreedom which permits vibrotactile and/or auditory and/or visual feedback to be set, or Auditory Model 1 feedback which uses only auditory feedback.

Balance Freedom Feedback settings

The BalanceFreedom settings can be changed for every protocol. There are 3 levels that need to be set by the user. The user can also decide to suppress use of the feedback settings.

Velocity or Position feedback.

With velocity feedback the feedback is proportional to the trunk velocity of the test person and units of thresholds are deg/s, with position feedback to the angular displacement and units of thresholds are deg.

Acoustic, Vibrotactile or Visual Feedback.

The user can decide to activate any or all of these options. The settings for the feedback are defined within the respective tabs shown below.

	Front	Back	Left	Right
Threshold*	_1.7	_1.7	_1.9	_1.9
Upper Limit*	_3.1	_3.1	_3.5	_3.5
Min. Volume (%)	50	50	70	70
Max. Volume (%)	99	99	99	99
Frequency (Hz)	_260	1371	_873	_505
Hop Size	_8	_1	_8	_8
Hop Duration (ms)	_110	_60	_50	_50

Type

Velocity

Position

Acoustic

Vibrotactile

Visual

*[deg]

Default

Feedback Suppression Sector.

The user can decide to deactivate a sector for the feedback. If none is set no sector is deactivated. If simple is set, the centre direction for the sector must be set (Note 0 deg is forward, 90 deg is right direction, 180 deg backwards and 270 deg left.) and the sector angle. The sector deactivated is then 0.5 the sector angle either side the direction angle. If double is set, the mirror image sector (point symmetry) is also deactivated.

It is possible to just have a small sector active by defining a large sector angle. For example direction 270 deg, sector angle 270 deg would mean only 90 deg sector 90 deg would be active.

Feedback Suppression Sector

simple Centre direction (deg) Sector Angle (deg)

none

simple

double

OK Cancel Help

BalanceFeedback Auditory Settings.

For the acoustic BalanceFreedom settings, the thresholds and upper limits of sway to which the feedback responds in each direction need to be set. Likewise, the sound volume of maximum that

the two bone-conducting transducers are activated at between these limits must be set. Between threshold and upper limit the sound volume is increased linearly. The feedback works by activating the left bone conductor with one frequency when the subject sways to the left, the right bone conductor with another frequency for sway right, and both conductors for sway forwards or backwards. Thus, the frequency of acoustic stimulation needs to be set for each sway direction. This frequency can be oscillated across nearby frequencies (see Hop size in the settings below). The new frequency is changed at intervals set under the setting Hop duration. The bone conductors are arranged in the headband of the BalanceFreedom system so that these are placed over the mastoid processes above the ears.

The acoustic settings shown below are the default settings and are applicable for young (20-30 years of age) subjects performing the task of standing on 1 leg on a firm surface eyes open. For these settings the threshold ordering is vibrotactile, acoustic and then visual. Generally settings are arranged to be task dependent (see references in section 2.2), but can also be individually set.

	Front	Back	Left	Right
Threshold*	_1.7	_1.7	_1.9	_1.9
Upper Limit*	_3.1	_3.1	_3.5	_3.5
Min. Volume (%)	50	50	70	70
Max. Volume (%)	99	99	99	99
Frequency (Hz)	_260	1371	_873	_505
Hop Size	_8	_1	_8	_8
Hop Duration (ms)	_110	_60	_50	_50

Type

Velocity

Position

Acoustic

Vibrotactile

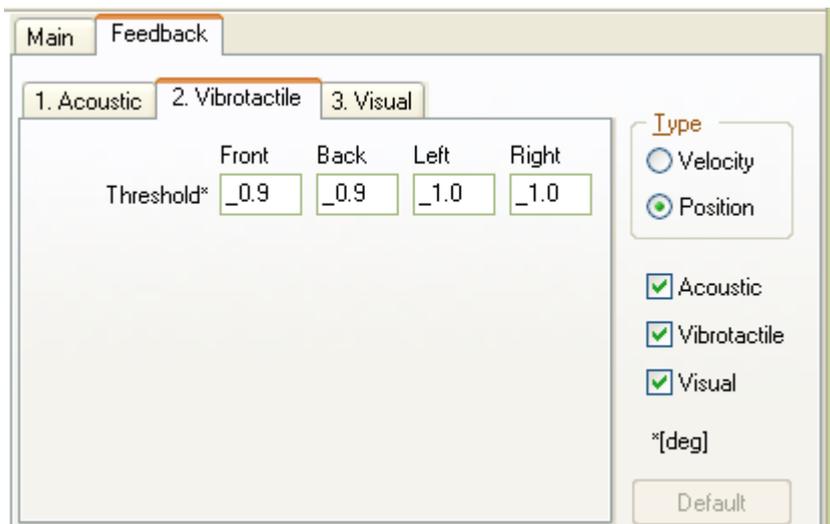
Visual

*[deg]

Default

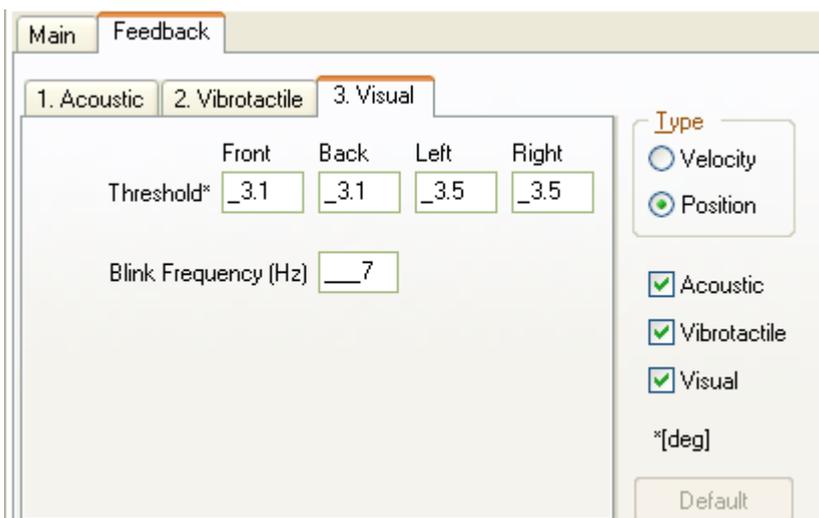
BalanceFeedback Vibrotactile Settings.

Vibrotactile feedback is set on or off dependent on directional specific thresholds as listed below for the default setting. Usually vibrotactile feedback is set on before acoustic and visual feedback. The vibrotactile feedback transducers consist of 8 vibrators arranged in the headband of the BalanceFreedom system, each being activated when sway is in direction of the transducers.



BalanceFeedback Visual Settings.

The visual feedback is considered to be an alarm signal for the BalanceFreedom system. Hence it is set on or off at a greater threshold than the auditory or vibrotactile feedback. The thresholds as listed below are for the default setting. The LEDs on the BalanceFreedom headband are set flashing with a frequency when sway exceeds any of the directional thresholds.



Typical BalanceFreedom assessment and rehabilitation schedule for patients with chronic balance problems due to peripheral vestibular loss.

Initial Balance assessment:

- Participant complete 12 balance tasks (Table 1) without receiving biofeedback. This takes about 15 minutes. From this data the participant specific onset thresholds are calculated for the vibro-tactile, auditory and visual feedback from the recorded 90% ranges of pitch and roll angle and pitch and roll velocity. The factors 40%, 80% and 150% of the recorded values are used to calculate the onset thresholds for the vibro-tactile, auditory and visual feedback, respectively. An Excel table for this purpose is provided on BII's website.

WEEK 1 (3 training sessions of about 30 mins)

Training session 1: Monday

Patients perform the BalanceFreedom training protocol consisting of repeated training with feedback on a subset of the tasks used in the initial assessment (Table 2). Patients are instructed to stand or move during the training so that the feedback signals are not active,

that is trunk sway is reduced as much as possible. The last trial of each protocol is recorded for following patient progress.

Training session 2: Wednesday

Patients perform the BalanceFreedom training protocol consisting of repeated training with feedback on a subset of the tasks used in the initial assessment (Table 2). The last trial of each protocol is recorded for following patient progress.

Training session 3: Friday

Same as session 2.

Second Balance Assessment: Friday

- Patients complete the same 12 balance tasks (Table 1) without receiving BalanceFreedom biofeedback. From this data we will re-calculate the patient specific onset thresholds are recalculated for the vibro-tactile, auditory and visual feedback from the recorded 90% ranges of pitch and roll angle and pitch and roll velocity of this assessment. These values will be used in the following week to make the training task more difficult. If a pitch or roll value is worse than for the initial test, then the threshold for that value and task is left unchanged.

WEEK 2

Training session 4: Monday

Patients perform the BalanceFreedom training protocol consisting of repeated training with feedback on a subset of the tasks used in the initial assessment (Table 2). However, biofeedback onset thresholds will be based on their second balance assessment values. The last trial of each protocol is recorded for following patient progress

Training session 5: Wednesday

Same as session 4.

Training session 6: Friday

Same as session 5.

Third Balance Assessment: Friday

- Patients complete the 12 balance tasks of Table 1 without receiving biofeedback regardless of group assignment. A decision is then taken whether to continue the rehabilitation having recalculated thresholds or to reassess again a week later.

Table 1:

Balance tasks Assessment	30 secs Standing feet together EO
	30 secs Standing feet together EC
	20 secs Standing on 1 leg EO
	30 secs Tandem Stance EO
	30 secs Tandem Stance EC
	30 secs Foam Standing feet together EO
	30 secs Foam Standing feet together EC
	Walk 8m EO
	Walking 3m pitching head
	Walking 3m rotating head
	Walking 8 tandem steps EC
	Walking 8 tandem steps EO

Table 2:

Balance tasks	30 secs Standing feet together EC	6x
Training	20 secs Standing on 1 leg EO	3x

30 secs Tandem Stance EC	2x
30 secs Standing feet together EC Foam	2x
Walk 8m EO	5x
Walking 3m rotating head	5x
Walking 8 tandem steps EC	5x

Auditory Model 1 Feedback settings

The auditory Model 1 feedback (AF) settings can be changed for every protocol. There are 4 levels that need to be set by the user. The user can also decide to suppress use of the feedback settings.

Velocity or Position feedback. With velocity feedback the feedback is proportional to the trunk velocity of the test person, with position feedback to the angular displacement. The threshold, maximum and minimum values, can also be set differently for stance (standing) and gait.

Thresholds which must be exceeded for the AF to produce a sound. These can be set differently for pitch backwards and forwards, and roll. The default values set in the AF hardware are as follows:

	Velocity		Position	
	Stance	Gait	Stance	Gait
Pitch Forwards	3 °/s	10 °/s	0.5°	6°
Pitch Backwards	3 °/s	10 °/s	0.5°	3°
Roll	2 °/s	10 °/s	0.3°	2°

Where Stance thresholds are for standing protocols and Gait for walking, sit-to-stand and other protocols involving locomotion.

Maximum values which when reached the AF system does not increase in its sound volume further. The default values set in the AF hardware are as follows:

	Velocity		Position	
	Stance	Gait	Stance	Gait
Pitch	20 °/s	50 °/s	15°	15°
Roll	20 °/s	50 °/s	15°	15°

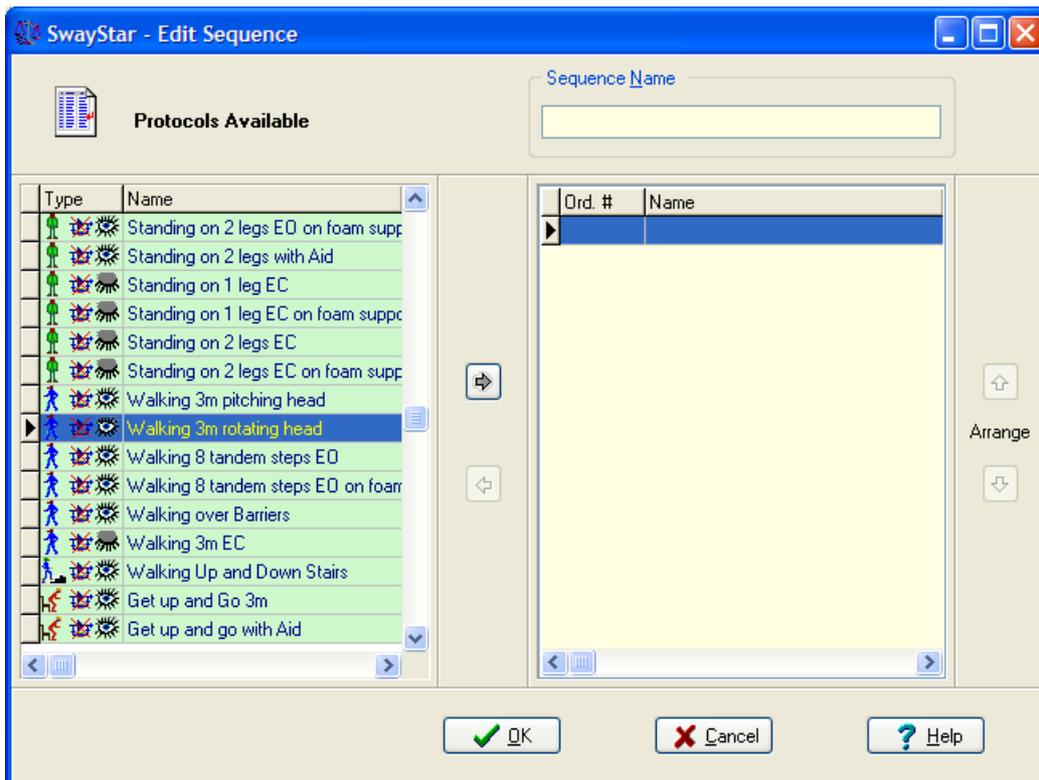
Minimum (Offset) values of sound used where the AF thresholds are exceeded. These are set by default for the 4 loudspeakers as follows:

Front	60 dB	SPL (A)	Rear	75 dB	SPL (A)
Left	60 dB	SPL (A)	Right	60 dB	SPL (A)

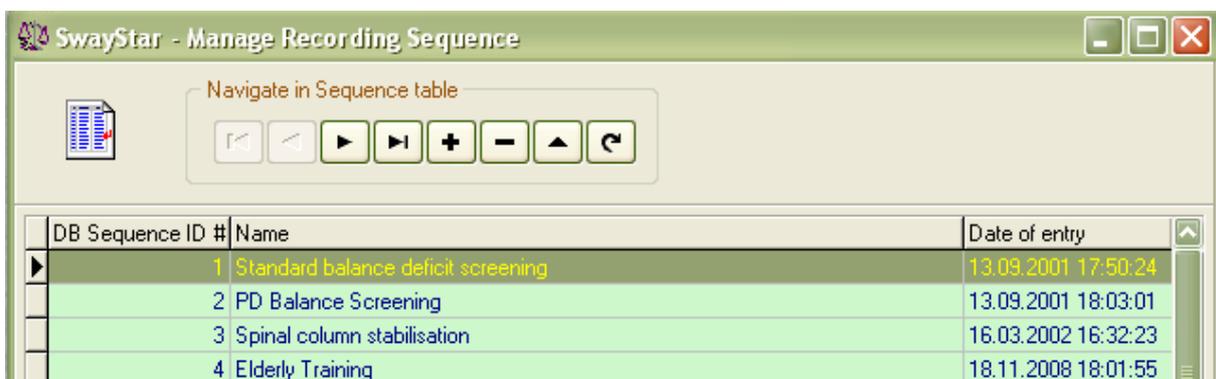
It is recommended that a louder effect be used for the rear loudspeaker because of the shadow effect of the ears. The maximum volume (ca. 90 dB SPL (A)) and the frequency of each loudspeaker tone (left 1000 Hz, right 900 Hz, front 500 Hz, rear 1500 Hz) cannot be changed. **Note:** When these values are set by the protocol during a recording, these become the default hardware values set in the SwayStar™ AF controller box. If the user tries to record with an AF protocol and the feedback controller is not switched on then a warning will appear.

Sequences (Normal and BalanceFreedom)

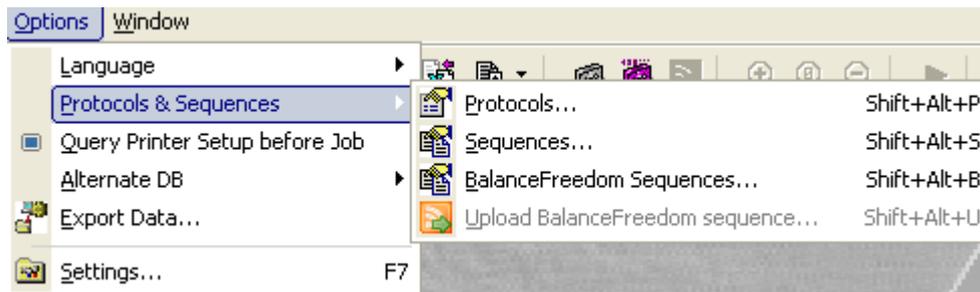
To create a new sequence, click the + navigate button to add a sequence. The following screen will appear.



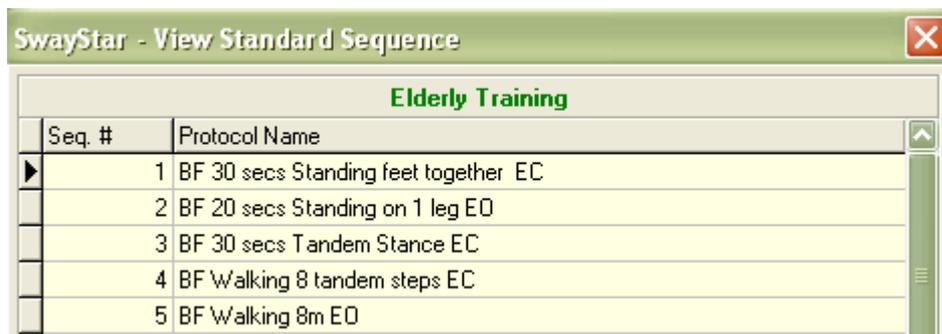
Select the available protocol and move it to the right-hand panel by clicking on the  arrow. Change the order of the selected protocols by using the  or  buttons. Use  arrow to remove a protocol after first clicking on the protocol in the right-panel that you wish to delete from the sequence. A number of default sequences are available:



The same procedure is used to create BalanceFreedom sequences for uploading into the stand-alone BalanceFreedom controller when it is connected to the SwayStar™ sensor unit.



There is one default BalanceFreedom sequence which has protocols for training the elderly.



5.4.3 Query printer setup before job

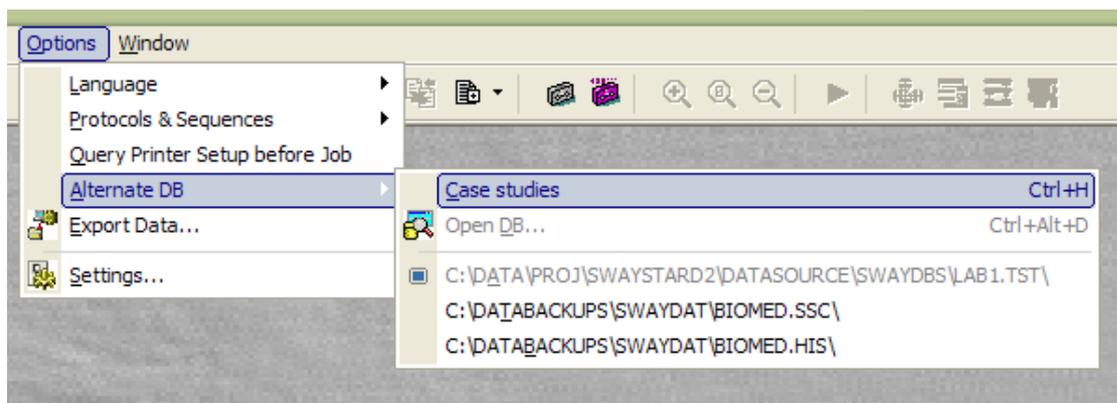
In cases where different printers or difference paper size, or other printer variables change as a result of several printers being available within one clinical facility, this option reminds the user to select and set-up the appropriate printer and its parameters.

5.4.4 Alternate database (DB)

SwayStar™ can work with different databases that all have the name BIOMED.xxx existing on different logical devices, provided the operation setting that switches to “alternative databases” is ticked (see Main Menu/ Options/ Alternative DB). The user can search for an existing database or create and open a new database.

Sample Case Histories

SwayStar™ also has a special database of case histories containing typical patient results (see section 7. Sample Case Histories). The user may select the Case History database, but once selected can not modify the entries or make any recordings.



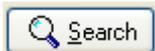
You will then be informed that this data base is active:



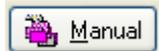
User Databases

The user may choose to open an alternative database of user data. If you wish to open an alternate database, select Open DB (as shown above). This opens a new dialog shown below.

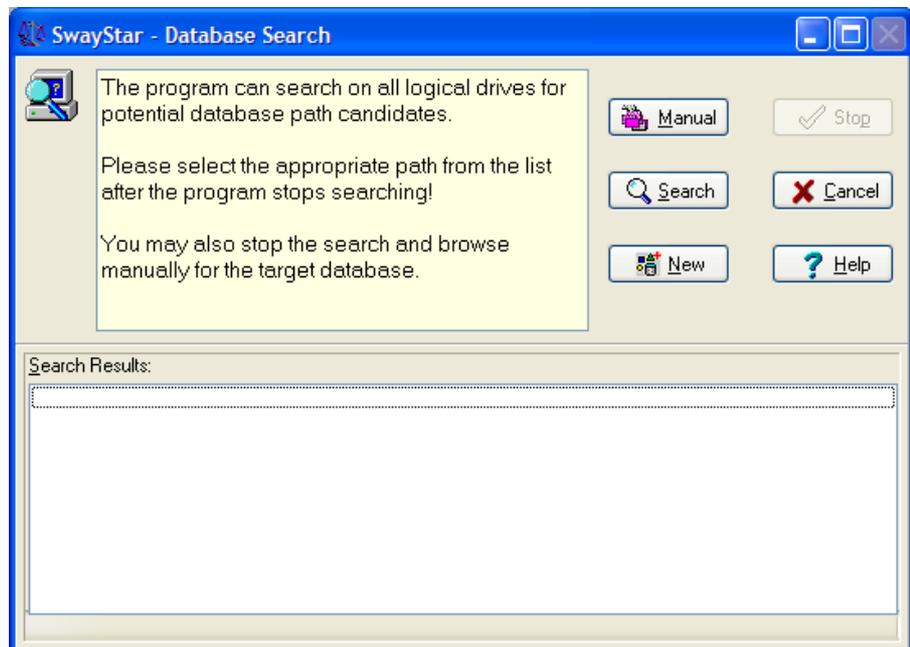
Within this dialog by clicking the corresponding button the user can search automatically



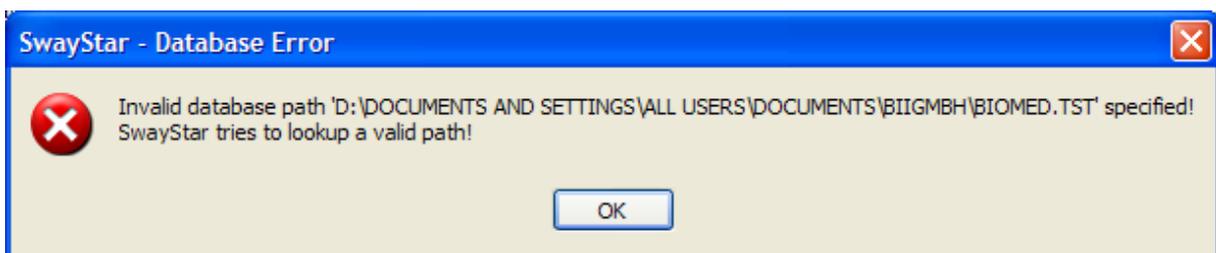
or manually



for all possible SwayStar™ databases on the host computer and its associated network drives. In the case of the automatic search a list of all possible DB candidates is generated from which you may select the DB of choice. Whether the search procedure is stopped or completed, you may still search for a DB manually or generate a new DB clicking the button



If you attempt to start SwayStar™ with a DB selection located on a server to which the user is not connected the following error message appears:



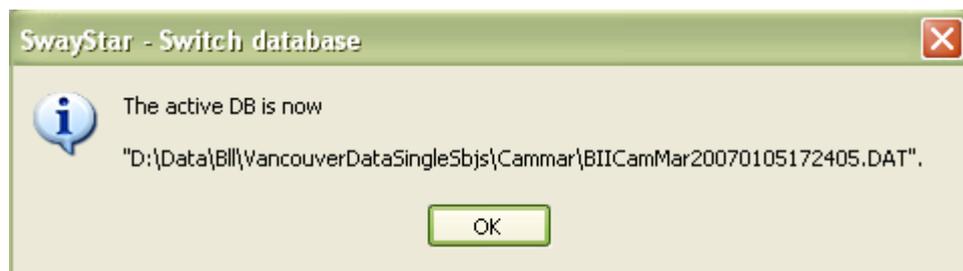
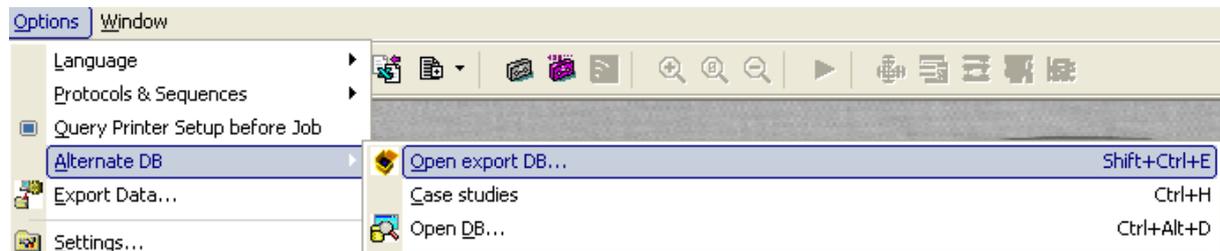
A new DB section must be made or the drive mapping must be restored.

Once the data base has been located and activated the user is informed.



Export Database

The user may receive a by SwayStar™ encrypted exported database from another user. The procedure for opening this data base is the same. First select the command, then the file and finally the selection will be confirmed.



In addition, dragging a DB-Folder or an archive onto SwayStar™ opens the corresponding DB. An archive is extracted in the folder of that archive.

Assume BIIILos20070121154907.7z.001 is the name of the archive the DB Folder is named BIIILos20070121154907.dat. If an archive is dragged from a E-Mail the file is extracted in the %temp% folder. In this case when restarted SwayStar™ opens the previously opened DB as this file dragged from an email was only temporary active.

5.4.5 Export Data

In order to export any data, any logical drive connected to the PC can be used. For security reasons (patient data over internet) the export data base is encrypted. Starting this option automatically requests definition of the device and the path. It is possible to export all recordings from a single visit

or all recordings in all the visits of a subject (in other words a complete subject). For selection purposes, the retrieve data window (see [section 5.1.1](#)) is opened automatically.

Acknowledgement: The encryption procedures is an open source Delphi VCL for 7zip format see <http://www.7-zip.org>)

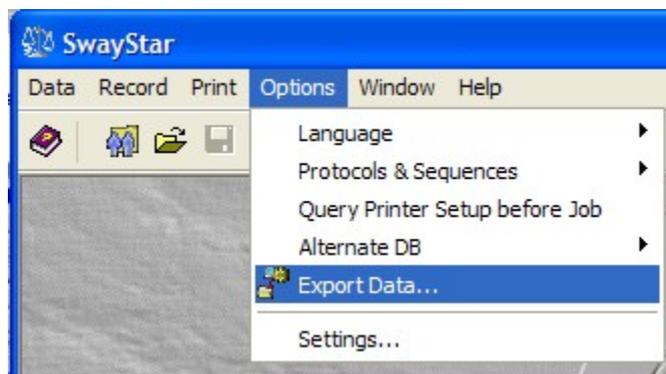
Note: The directory will need to be defined properly in the box provided. The maximum size and type of the file should have been defined - see Settings, section 5.4.6, Export.

After the export process is complete it may be automatically emailed to BII in cases where troubleshooting is requested.

There are four steps to Exporting data.

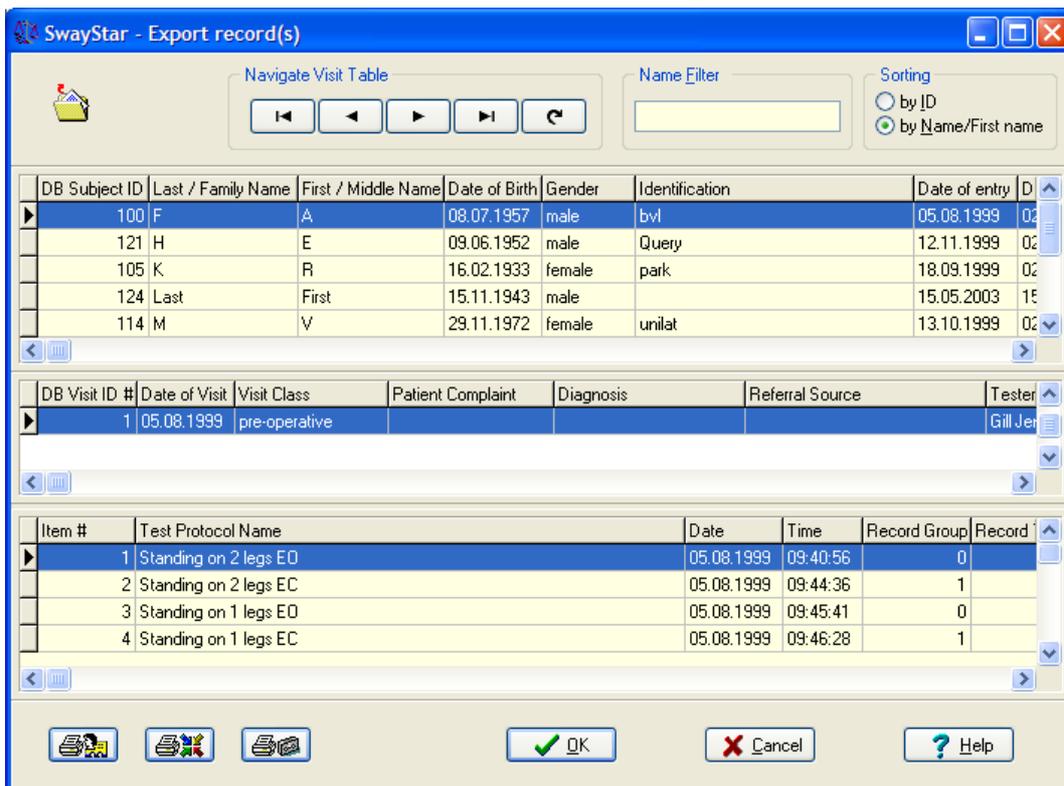
Step 1:

Under Options, select Export Data
This will bring you to the Retrieve Records Window (below)



Step 2:

Select the subject, visit or single trial you wish to export and double click the left mouse button.

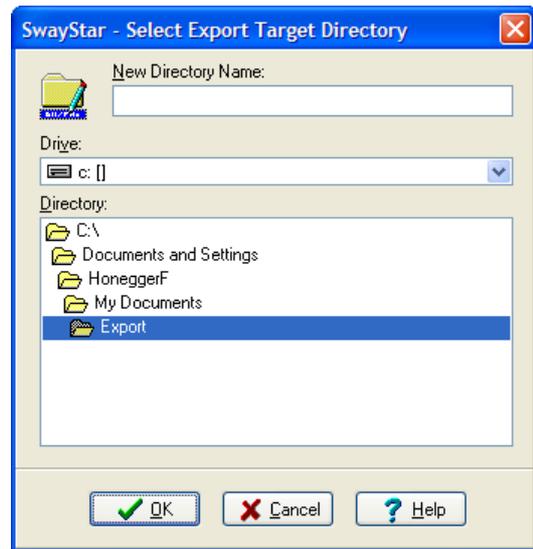


Step 3:

- Specify the directory.
- Select the drive and the directory.

The subdirectory name entered in the field “New Directory Name” is created relative to the directory selected with the navigational controls.

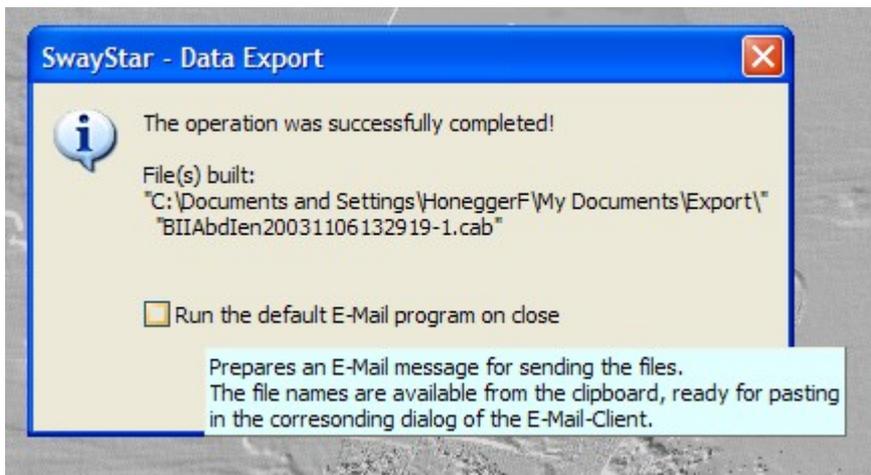
Note: A fully qualified name entered in this field (i.e. C:\DATA\EXPORT) overrides navigation selected in “Drive” and “Directory”.



Step 4:

The Export function is completed by click OK

If you wish to send the data to BII either for the purpose of requesting information or to request troubleshooting, click in the white box and then on OK.



This will automatically open an email window.

Step 5:

To use the export file.

Unpack the cab file to the directory, using the manual search function of SwayStar™ under Options-Alternate DB Open Export DB to locate the export directory, chose the directory and double click on the subject.db file. The data can now be retrieved normally, provided “Allow switching to alternate data bases” has been set under Settings.

Alternatively, when many patients are involved, it may be easier to copy the whole “biomed“ directory on the source computer to another “biomed” directory on the host computer, rather than export individual patients.

5.4.6 Settings

Operation

Run

Enable Autostart (control A): Choose this if you wish for SwayStar™ to open automatically when your computer is first booted.

Enable Autostart on an end-session condition (control E): Choose if you wish SwayStar™ to open again should it still have been open on powering down the computer.

Database

Allow switching (control W) to alternate database

Delete visit even if not empty: all records will be deleted from the visit folder. If this is not chosen, in order to delete a visit folder, the user must first delete each record in the visit separately and then delete the visit folder. (See section 5.1.3, Visit, for further description.)

Reference values

At end of recording no reference set assignment for user defined protocols

On data retrieval no reference set assignment for user defined protocols. This setting is only useful for users who have data recorded with user-defined protocols prior to SwayStar Version 4.0.0.120, that is prior to having reference value assignment.

Log file

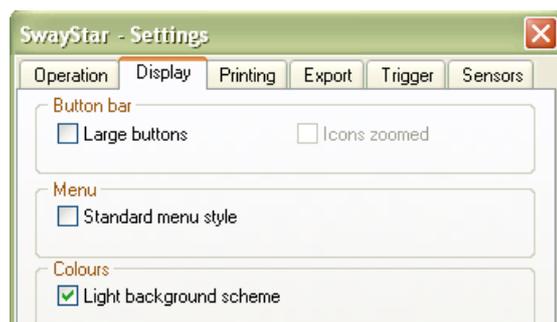
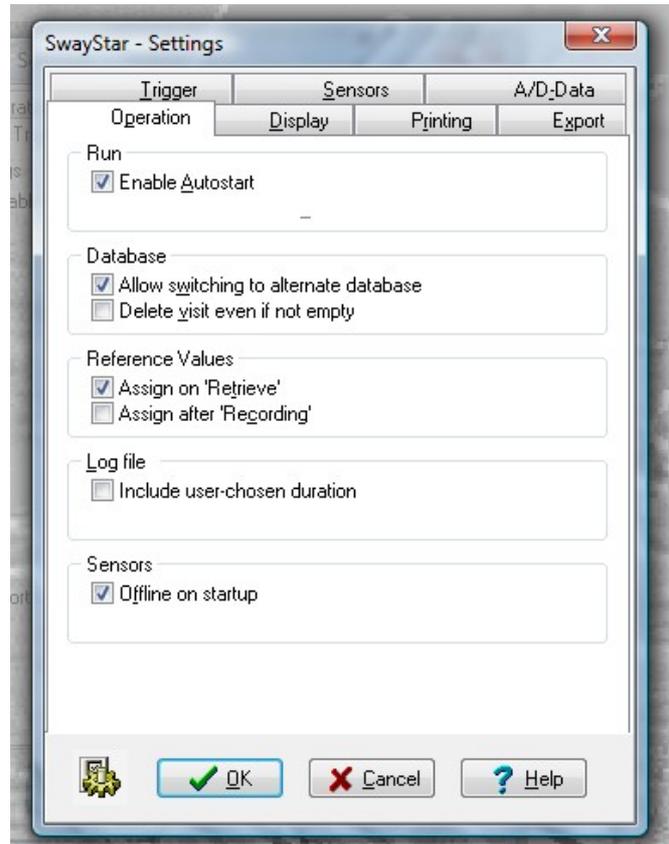
Enable the user selected duration for analysis is to be entered into the log file.

Sensors

Ensures that the sensors are offline, and communication is not attempted when the program is started. The default setting is online after installation.

Display

Choose the size of the icons to be displayed. Larger icons require two rows in the tool bar. Change the background colour of the display to white or leave it black.

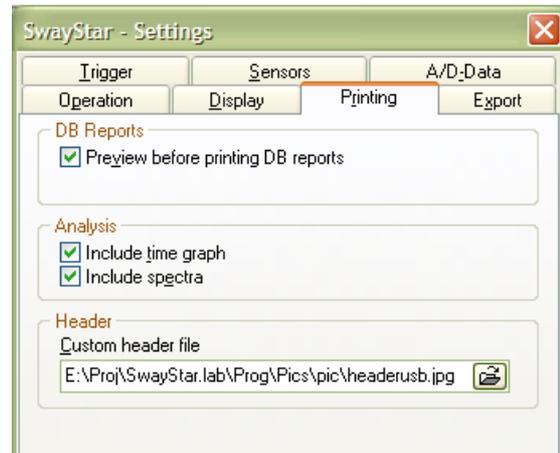


Printing

Some or all of the graphs appearing in the analysis window may be sent to the printer. (See [section 4.2](#) for further explanations)

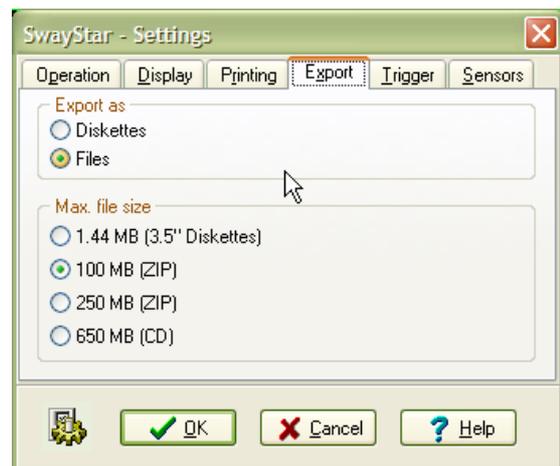
Preview print (control v) before printing DB (data-base) reports.

The Analysis may be printed with or without the pitch time or roll time plots (*time graph*) or without the *spectra* depending on the print settings and printer capacity. A header may be added to the printed sheets. The default header is from BII. An operator may create and select his own header. The width of the header image should be at least 800 pixels and the width to height ratio should be between 9.5 and 9.7



Export

The type of file (floppy or to a logical drive) and its maximum size can be defined.



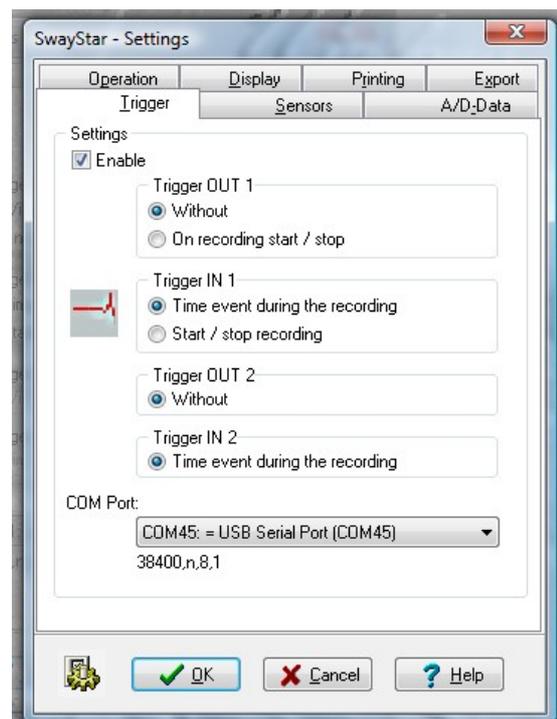
Trigger

On request BII will supply the trigger box for connection to a USB port via a COM port convertor. This trigger box has 2 BNC connectors for an inbound trigger signal and 2 BNC connectors for an outbound connectors. When the trigger function is enable in the software, a COM port for the trigger must be defined, otherwise an error message appears. It is recommended that the USB port of laptop computers is set switched on on battery low.

Outbound triggers OUT 1 and OUT 2

OUT 1 can be programmed so that SwayStar™ provides a triggering signal at the BNC connector setting a TTL pulse high on recording start and low on recording stop, or it can be without output.

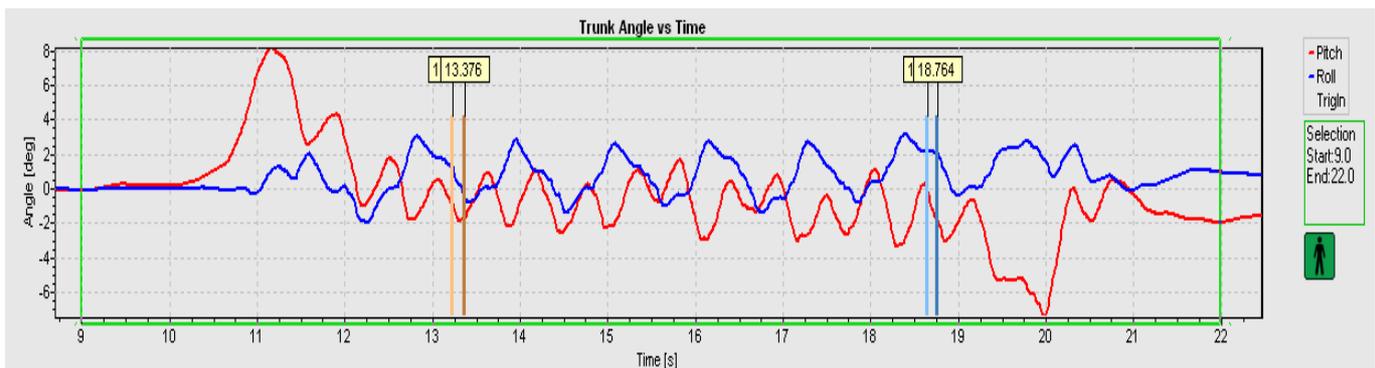
OUT 2 is always without output



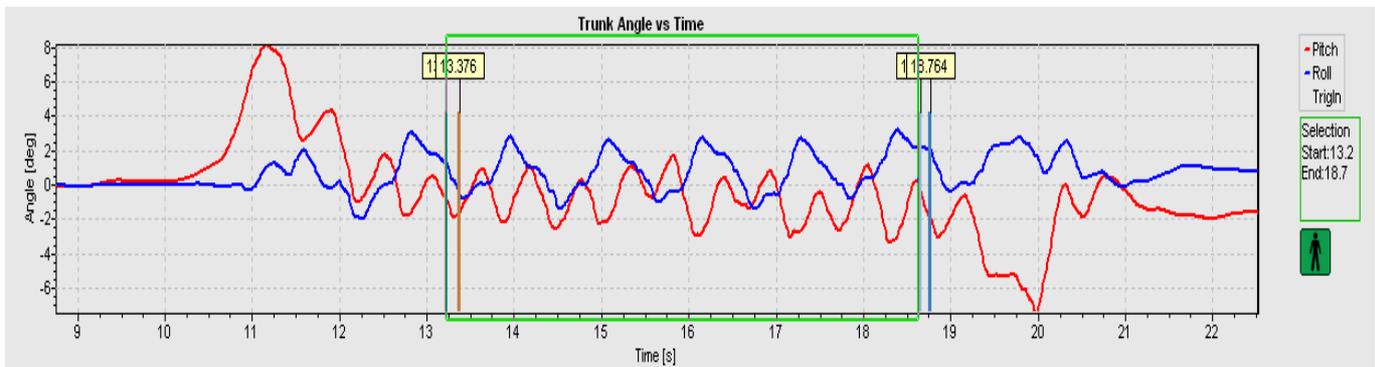
Inbound triggers IN 1 and IN 2

At the IN 1 connector the leading edge of a TTL signal can be used to start SwayStar™ recording and and stop the recording with the falling edge.

At both IN 1 and IN 2, TTL signals can be set to mark events on the time plot of trunk pitch and roll. Two markers are set for each signal, one on the leading and one on the trailing edge as shown by the example below of a young normal walking past to light barriers which sent TTL signals to IN 1 and IN 2. The first marker of the pair is a light colour and the second a dark colour, each marked with the time of the marker event as shown below.



The data analysis window can be set to the triggered markers by placing the cursor on the marker bar. A vertical arrow appears. Press Ctrl plus the Windows button and left mouse click to set the lower time limit of the analysis window, and Alt plus Windows button and left mouse click to set the upper time limit to the analysis window. The result appears so:

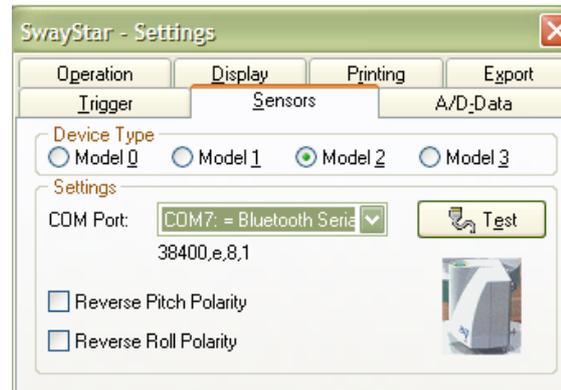


To set the analysis window on the correct marker event it may be necessary to zoom the recording and then to drag the area of interest into the centre of the time plot using the right mouse button.

Sensors

See section 3.2.4 for full description

Note: It is possible to change the polarity of the sensors for both Pitch and Roll. Changing the polarity only affects the way in which signals are depicted on the display monitor.



A/D-Data

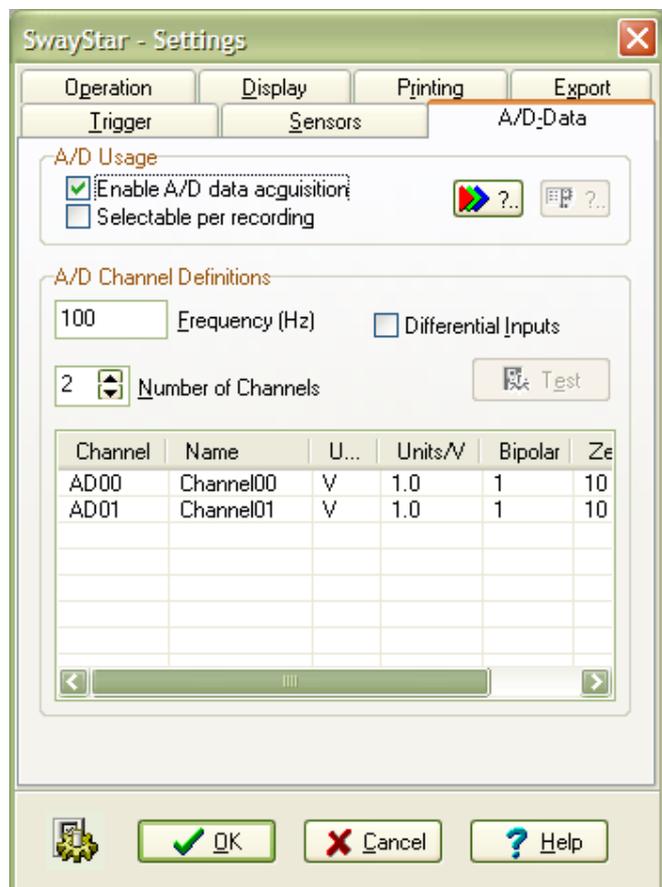
The A/D Data tab is only available after installing the “Data Translation DataAcq Omni CD” that installs the “DT Open Layers for Win32” software.

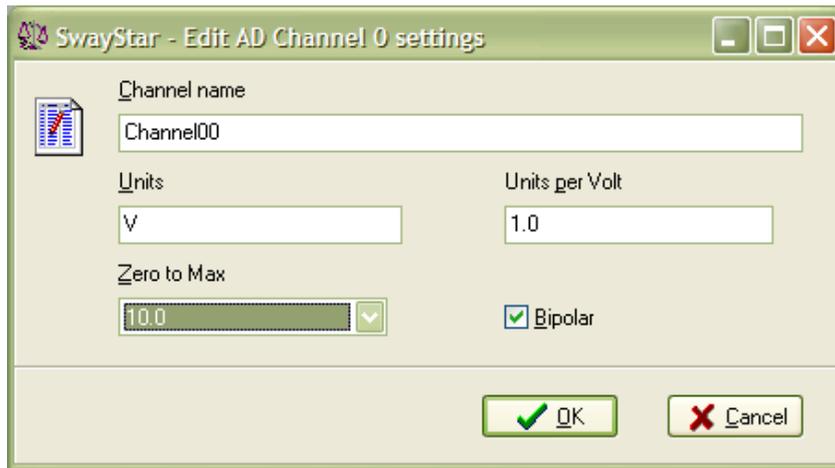
The mode of data collection and the channel definitions for A/D data collection can be defined for the DT9800 - A/D converter used with SwayStar™.

Buttons with ? can be clicked to obtain information about the external A/D connector box and its properties.

Checking the box “enables A/D data acquisition” means that analogue data is always recorded, whereas “selectable” gives the user a choice whether to have A/D data or not when the recording is started.

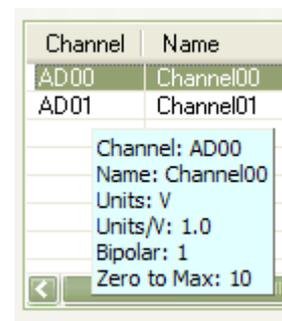
The button “Test” allows settings to be tested with respect to those the A/D board supports.





The A/D channel values, name, units, units per volt and the zero to maximum voltage range can be set by double clicking on the line in the box with the channel listings or highlighting the line in the box and then striking “enter”.

The current values are displayed as a hint when the mouse passes over the line.



5.5 HELP

This help section appears with a search functions and index.

5.5.1 System Information

The details associated with your computer are particularly useful when troubleshooting problems with the operation of SwayStar™. The relevant details should be reported to the service department by simply copying the details and emailing them for reference.

(Note: this is not available for all installations and the format may vary for different iterations of Windows)

Hardware Resources

These are Windows functions and are available in most Window's operating systems.

Conflicts/Sharing, DMA, Forced Hardware, I/O, IRQs, Memory

Components

Multimedia, display, infrared, input, miscellaneous, modem, network, ports, storage, printing, problem devices, USB, history, system

Software Environment

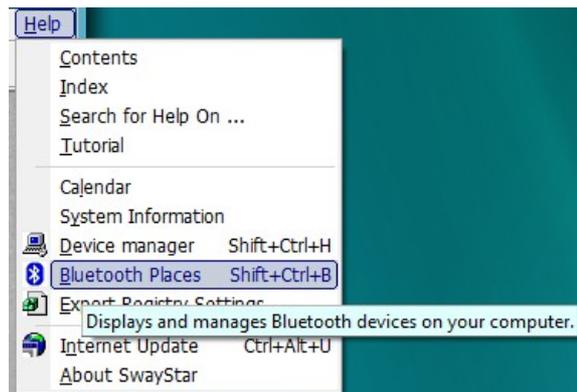
Drivers, 16-bit modules loaded, 32-bit modules loaded, running tasks, startup programs, system hooks, OLE Registration and Software Updates.

5.5.2 Device manager

This command calls up the device manager and permits the user to view the COM ports available.

5.5.3 Bluetooth Places

This menu item was introduced for SwayStar versions 4.3.7.264 and higher. The menu item is only present provided the host operating system is Windows 2000 or Windows XP and the Bluetooth® software BlueSoleil from IVT Corporation is at least version 5.0.5.178, or Windows Vista and the BlueSoleil software is at least of version 6.0.226.0. The presence of this command indicates that device drag and drop from “Bluetooth Places” to SwayStar is supported. The command opens BlueSoleil’s “Bluetooth Places” in a Windows Explorer window. The version of BlueSoleil present on the PC can be determined by opening the corresponding “About BlueSoleil” window in either the classic or Windows Explorer integrated view or in the “[About Swaystar](#)” window (see 5.5.6 About SwayStar).



5.5.4 Export Registry Settings

This command helps to transfer settings (see [Settings-operation, section 5.4.6](#)) and the users license key to another PC. A file is generated which has the name SwayStarSettings-(time stamp).reg. Transfer the file to the new PC. Then, clicking on the file will transfer the settings file automatic-

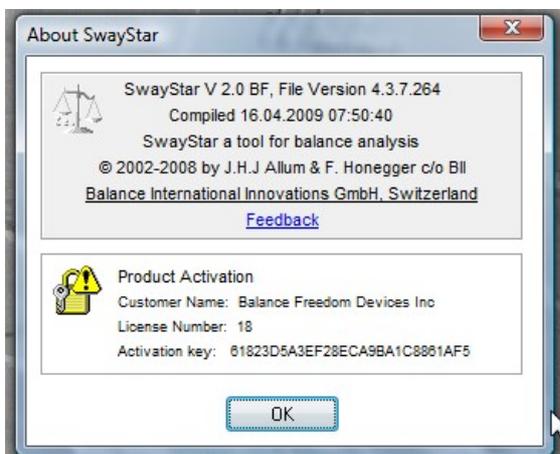
ally to the correct location. Simply follow the instructions. Data bases and CSV files will need to be transferred separately. The files to transfer for all protocols and sequences (see section 5.4.2 Setup) are def+ref under program files. We advise making a copy of the original version of the files created at installation on the new PC, for safety's sake.

5.5.5 Internet Update

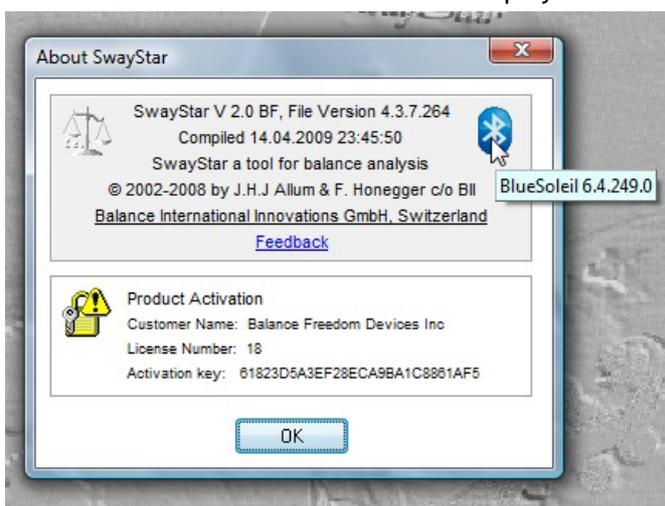
You must have an active connection to the internet (Modem, DSL, Cable, T1, ...) to update your SwayStar™ software. On clicking on update , the update will proceed automatically. Simply follow the instructions. Data bases and CSV files are not affected by an update.

5.5.6 About SwayStar

Entering this section informs the user about the status of the software-version number. Clicking on the lock symbol enables the user to update their software key, for example if it is about to expire or if the user has acquired additional features such as BalanceFreedom™ or BalanceView and wishes to activate these features.



If the Bluetooth® software BlueSoleil from IVT corporation is installed and this is at least version 2.3.0.0, an additional Bluetooth icon  is displayed. When the mouse is passed over the Bluetooth icon the BlueSoleil software version is displayed as a hint.



6. REPORTS AND TABLES OF ANALYSIS DATA

6.1 BALANCE CONTROL INDEX

6.2 REPORT LETTER

6.3 EXCEL TABLES OF ANALYSIS VALUES

A description of the Excel table generated by SwayStar™ is given below. The first five columns of the table are fixed to maintain a reference to the patient name and the protocol (called ExpName). Thus, horizontal scrolling occurs after the first 5 columns. Click and drag the horizontal scroll bar beginning in column 6 to see the rest of the data for the recordings (shown in blue). A fuller description of the variables heading each column with an abbreviated label is presented in [section 2.7](#):

If the reference values have been assigned the following coding is used:

Blue value less than 5% percentile of the reference value

Green value within the 5 and 95% percentile of the reference value

Red value greater than the 95% percentile of the reference value

Analysis Variables Table for log file

Abbreviation	Parameter	Unit	Definition
Identification	Subject type		User defined text field
External Link	Link parameter to statistical program		User defined text field
Complaint	Subject's symptoms		User defined text field
Subject	Last name, first name		
ExpName	Protocol name		
ExpId	Number of protocol	N	
ExpTime	Date and time of recording		
SubjectID	Number of patient	N	Chronological number of entry into database
VisitId	Number of visit	N	Chronological number of entry into patients' visit database
RecId	Number of recording	N	
Sex	Subject's sex, loss balance indicated	m/f+/-	+ for no loss, - loss of balance, ~ unknown
Age	Subject's age	yrs	
RecID	Subject/visit/number of recording	N	
Total Duration	Trial duration	s	Time from the start to the end of actual recording. Not the analysis period!
Chosen Duration	Duration chosen for analysis	s	Time from the start to the end of recording period used for analysis.
MVPath	Mean path velocity	°/s	Mean velocity of the vector movement of roll and pitch angular displacement over the complete trial
MVRms	Mean velocity RMS	°/s	Square root of the squared mean velocity of the vector movement of roll and pitch angular displacement
TotAngArea	Total Angular Area	(deg) ²	Area defined by the envelop of the pitch and roll angular excursions over the complete trial
TotVelArea	Total Velocity Area	(°/s) ²	Area defined by the envelop of the pitch and roll velocity excursions over the complete trial
RoAngMedian	Median value of roll excursion	deg	Median value of roll excursion with respect to first sample
RoAngRange	Peak-to-peak roll excursion	deg	Extent of trunk roll angular displacement over the complete trial
RoAng90%	90% range of roll excursion	deg	90% percentile range of trunk roll angular displacement over the complete trial
RoVelMedian	Median value of roll velocity excursion	°/s	Median value of roll velocity excursion
RoVelRange	Peak-to-peak roll velocity excursion	°/s	The extent of trunk roll angular velocity over the complete trial
RoVel90%	90% range of roll velocity excursion	°/s	90% percentile range of trunk roll angular velocity
PiAngMedian	Median value of pitch excursion	deg	Median value of pitch excursion with respect to first sample
PiAngRange	Peak-to-peak pitch excursion	deg	Extent of trunk pitch angular displacement over the complete trial
PiAng90%	90% range of pitch excursion	deg	90% percentile range of trunk pitch angular displacement over the complete trial
PiVelMedian	Median value of pitch velocity excursion	°/s	Median value of pitch excursion
PiVelRange	Peak-to-peak pitch velocity excursion	°/s	The extent of trunk pitch angular velocity over the complete trial

PiVel90%	90% range of pitch velocity excursion	°/s	90% percentile range of trunk pitch angular velocity
RoFreq 1.2	Spectral density of roll velocity	(°/s) ²	Square root of 3 averaged adjacent spectral density weights at freqs: 0.8, 1.2, 1.6
RoFreq 2.4	Spectral density of roll velocity	(°/s) ²	Square root of 3 averaged adjacent spectral density weights at freqs: 2.0, 2.4, 2.8
RoFreq18.0	etc	(°/s) ²	...
RoFreq19.2	etc	(°/s) ²	...
PiFreq 1.2	Spectral density of pitch velocity	(°/s) ²	Square root of 3 averaged adjacent spectral density weights at freqs: 0.8, 1.2, 1.6
PiFreq 2.4	Spectral density of pitch velocity	(°/s) ²	Square root of 3 averaged adjacent spectral density weights at freqs: 2.0, 2.4, 2.8
PiFreq18.0
PiFreq19.2
MPOBegin	Marker Pair 0, begin	s	Time of the beginning of the Marker Pair 0
MPOInt	Marker Pair 0, interval between markers	s	Interval between the markers of the Pair 0
MPORoBegAng	Marker Pair 0, roll begin angular value	deg	Roll angular value at the time of the beginning of the Marker Pair 0
MPORoEndAng	Marker Pair 0, roll end angular value	deg	Roll angular value at the time of the end of the Marker Pair 0
MPORoAngDif	Marker Pair 0, roll ang. amplitude difference	deg	Roll angular value of the difference amplitude of the Marker Pair 0
MPORoBegVel	Marker Pair 0, roll begin velocity value	°/s	Roll velocity value at the time of the beginning of the Marker Pair 0
MPORoEndVel	Marker Pair 0, roll end velocity value	°/s	Roll velocity value at the time of the end of the Marker Pair 0
MPORoMeanVel	Marker Pair 0, mean roll velocity value	°/s	Roll velocity mean value inside the interval defined with Marker Pair 0
MPORoVelDif	Marker Pair 0, roll vel. amplitude difference	°/s	Roll velocity value of the difference amplitude of the Marker Pair 0
MPOPiBegAng	Marker Pair 0, pitch begin angular value	s	Pitch angular value at the time of the beginning of the Marker Pair 0
MPOPiEndAng	Marker Pair 0, pitch end angular value	s	Pitch angular value at the time of the end of the Marker Pair 0
MPOPiAngDif	Marker Pair 0, pitch ang. amplitude difference	s	Pitch angular value of the difference amplitude of the Marker Pair 0
MPOPiBegVel	Marker Pair 0, pitch begin velocity value	°/s	Pitch velocity value at the time of the beginning of the Marker Pair 0

7. SAMPLE CASE HISTORIES

The sample case histories are available in SwayStar™ as a separate data bank that may be used but not modified see section 5.4.4 Alternate database. The header above the tool bar then changes from



7.1 Peripheral Vestibular Loss

7.1.1 Acute Unilateral Peripheral Vestibular Loss. (208.1 BB)

Age at test: 61

Key Signs:

Shows the features typical of patients with balance problems due to vestibular loss - excessive trunk pitch velocity when tested standing on two legs, eyes closed, on foam. The patient tends to fall backwards and finally has to be caught at 13 seconds, see traces below.

Standing on two legs, eyes closed, on foam. Red is pitch angle and blue is the roll angle. Peak-to-peak (range) and the 90% range for velocity is shown compared to normal values (median, 5% and 95% range are shown by the triangle and vertical bar).

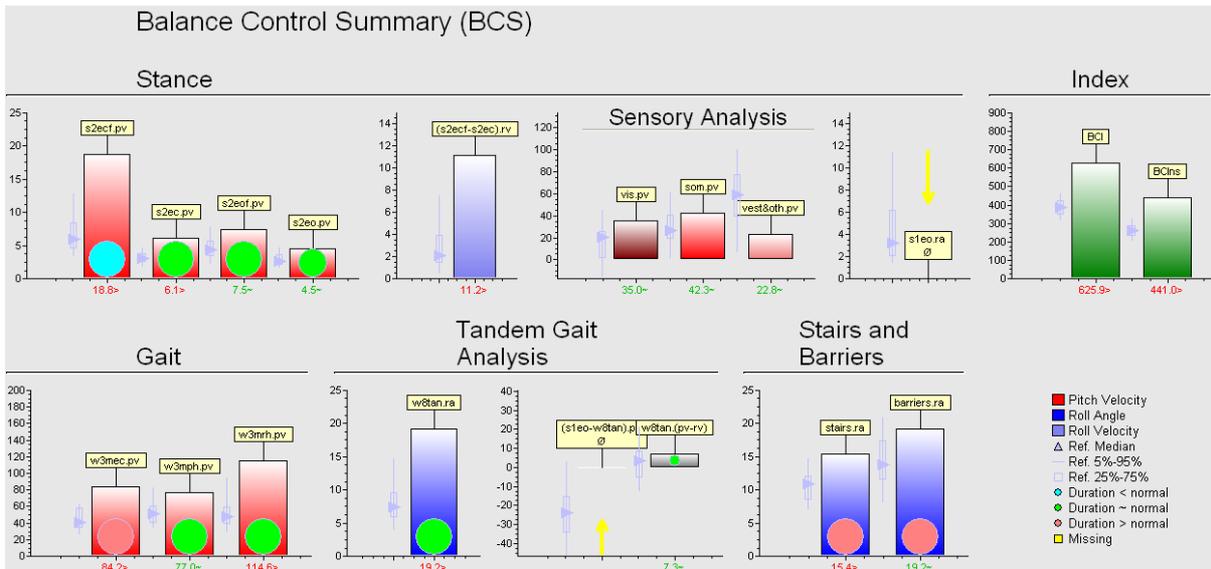


Summary Data:

Shows that for this patient, there are two general situations where poor balance control is most apparent. Tasks requiring exact control of trunk roll or tasks conducted with eyes closed. Thus the patient cannot perform 1-legged stance eyes open, has difficulties controlling trunk roll walking up stairs, and therefore performs this and other tasks (e.g. barriers) slowly. The patient also has excessive trunk sway walking eyes closed. Functionally this will mean that the patient will have difficulty with gait tasks requiring simultaneous fixation or in poor lighting conditions.

Indexes:

Show clearly that the patient has a balance problem.



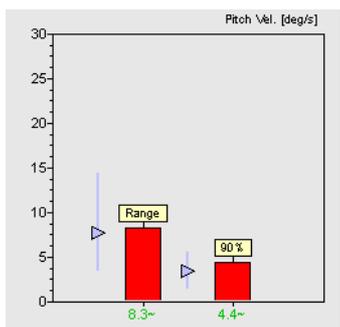
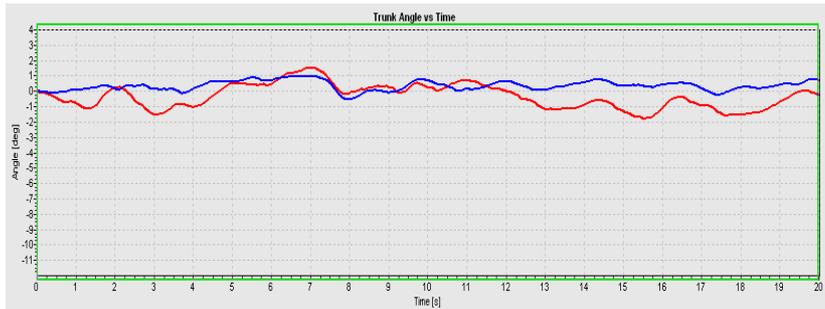
7.1.2 Compensated Unilateral Peripheral Vestibular Loss. (208.3 BB)

Age at test: 62

Key Signs:

When the patient illustrated above is retested 3 months after the onset of the deficit, the question will be if there improvement is sufficient to permit the patient to work normally and if not the focus of continued rehabilitation. A clear improvement for the task of standing eyes closed on foam (see traces below) with reduction of pitch velocity to within the normal range (see columns at end of traces). Remaining deficit is excessive trunk roll when standing on 1 leg and when walking up and down stairs. Also trunk pitch while walking with head movements (pitching of head) has a value on the borderline of normal.

Standing on two legs, eyes closed, on foam.

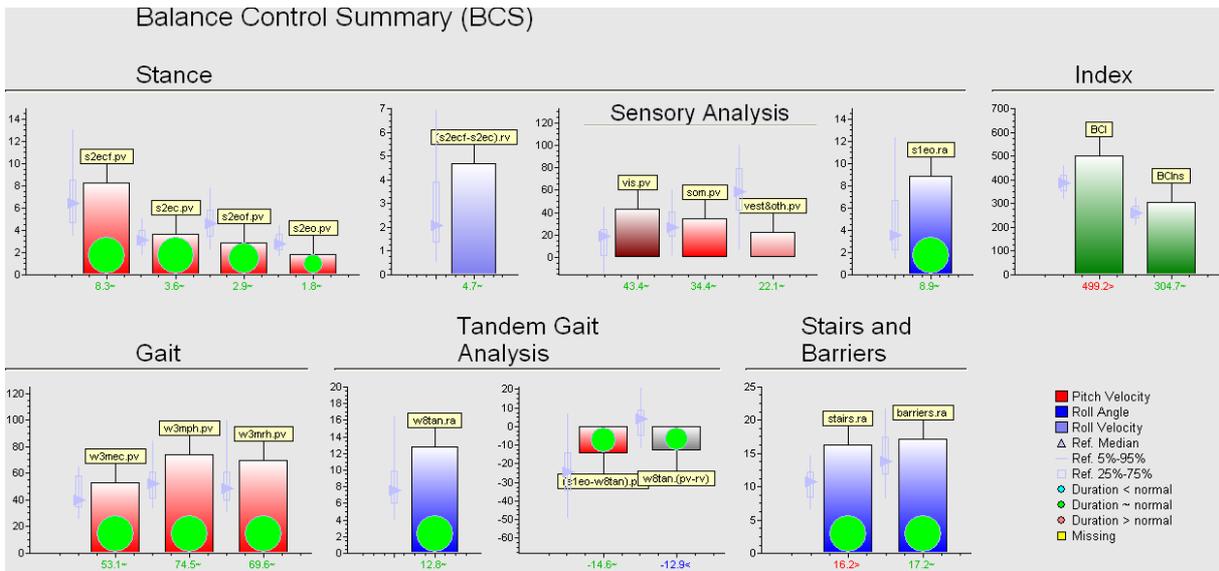


Summary Data:

Shows that stance control has improved considerably compared to the acute situation, however walking up stairs is still abnormal. The sensory analysis indicates the increased use of visual inputs to control trunk sway. The summary also suggests rehabilitation should concentrate on improving balance control during gait tasks with head movements or walking over obstacles, especially if this aspect is crucial during work performance.

Index:

Indicates an improvement in balance control compared to the acute status 3 months earlier.



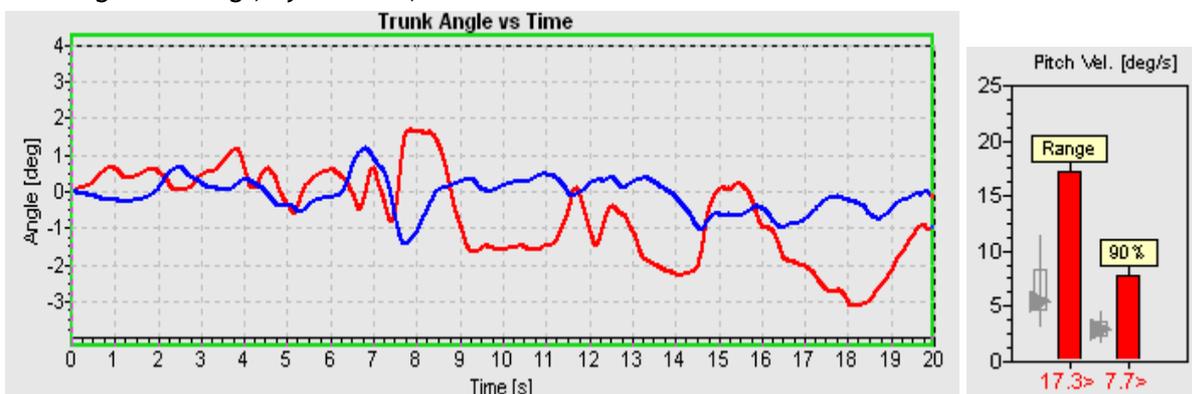
7.1.3 Uncompensated Unilateral Peripheral Vestibular Loss: Postural control improved using *BalanceFreedom™* biofeedback. (348.1&2 SSC)

Age at test: 55

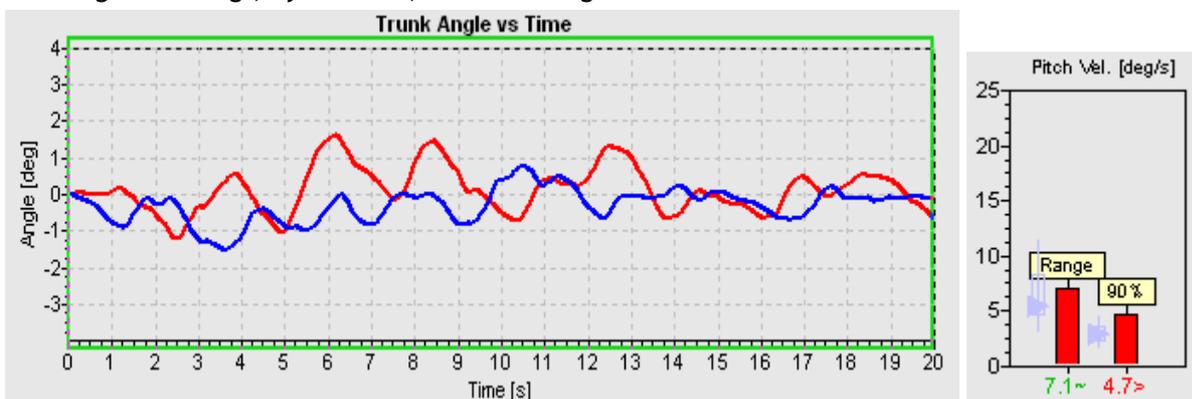
Key Signs:

When the patient was retested 3 months after the onset of the deficit, there was 100% canal paresis in the caloric examination and a 40% remaining asymmetry in the horizontal VOR tests, even though an accompanying facial paresis had completely recovered. Examinations with SwayStar showed continuing instability in a number of tests at this time point: standing eyes closed on foam (see below), walking 3 metres with head pitching, walking 8 tandem steps (see traces below). The BCI was clearly pathological and sensory analysis showed no use of vestibular inputs. The question arose if improved balance control could be obtained with BII's BalanceFreedom system as the focus of treatment. The clear improvement for the task of standing eyes closed on foam (see traces below) with reduction of pitch velocity to within the normal range (see columns at end of traces). An even greater improvement was obtained with the task of walking 8 tandem steps.

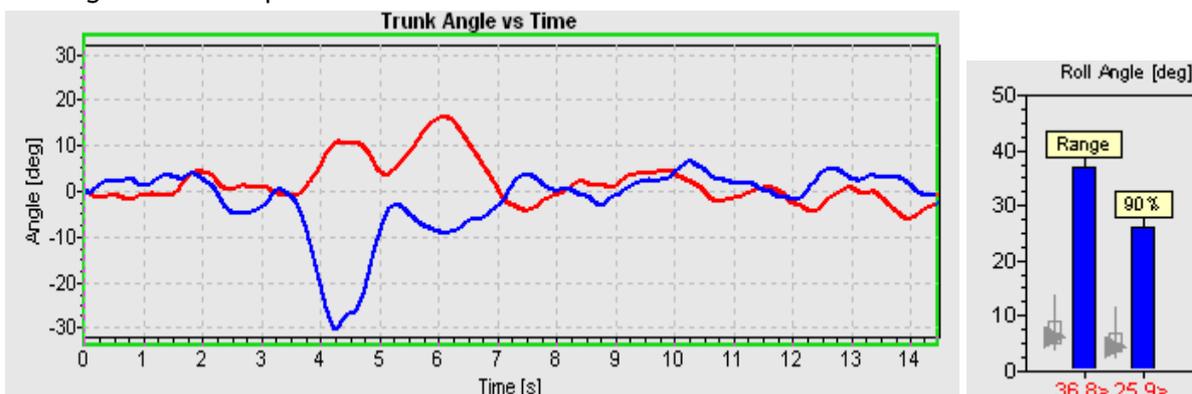
Standing on two legs, eyes closed, on foam.



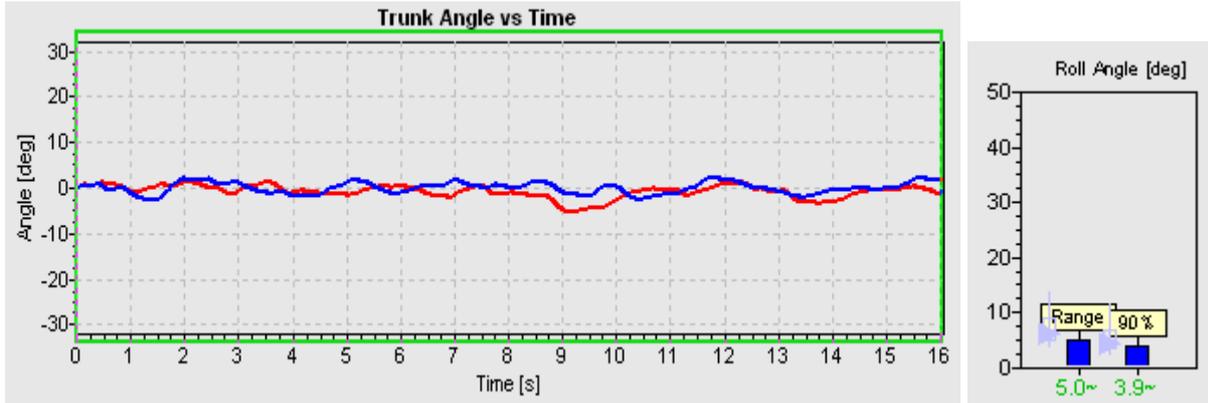
Standing on two legs, eyes closed, on foam using BalanceFreedom biofeedback.



Walking 8 tandem steps.



Walking 8 tandem steps using BalanceFreedom biofeedback.

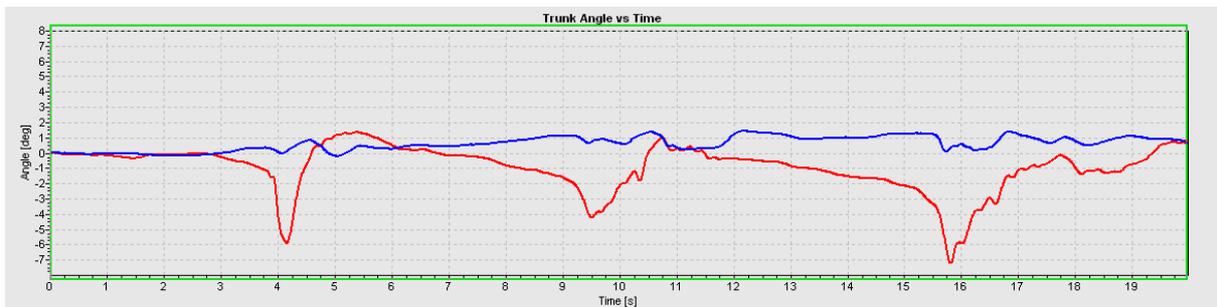


7.2 Bilateral Peripheral Vestibular Loss. (15 SSB)

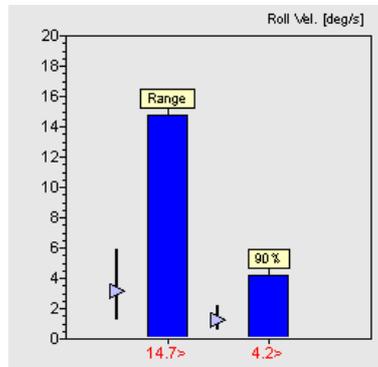
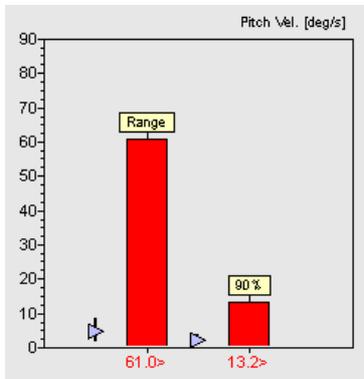
Age at test: 38

Key Signs:

Knowledge of the pattern of balance control for this patient with a long-term loss is important when considering results of patients simulating a balance problem. Clearly this patient has compensated well but still has difficulties with control of trunk pitch standing eyes closed (see traces below). Note how the patient really tries to rapidly correct his backwards falling (pitch trace deflection downwards). Both pitch and roll velocity are abnormal. Contrast this with patient results for a non organic disorder, case 7.4 below. The simulator slowly falls forward in the pitch direction only (see case below). Test results for 1-legged stance in the bilateral loss patient also indicate instability. Trunk pitch velocity when walking, eyes closed, and roll angle when walking up and down stairs are borderline normal.

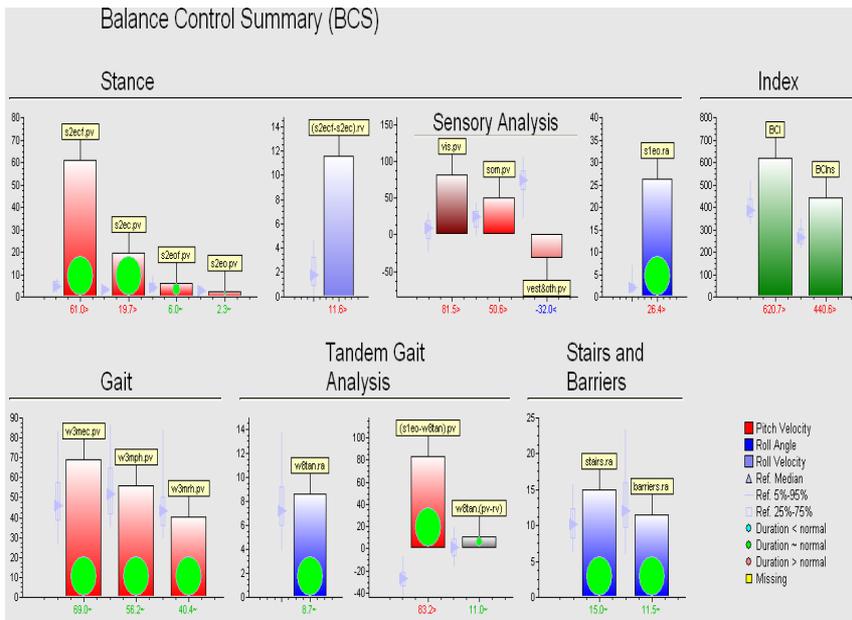


Standing on two legs, eyes closed, on foam.



Analysis Data:

The patients values on the left indicate the instability standing eyes closed on foam. Both pitch and roll values are greater than normal, pitch more so.



Summary Data:

The sensory analysis ratio “vestibular” clearly indicates a deficiency in the use of vestibular balance control signals. Rehabilitation should concentrate on improving balance control during difficult gait tasks.

Indexes:

Confirms this classical type of balance deficit as the patient has a value outside the normal reference range.

7.3 Whiplash Associated Disorder. (60 BB)

Age at test: 30

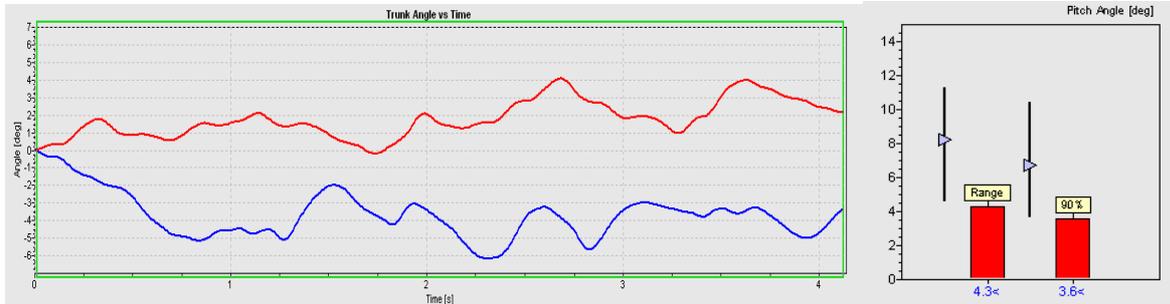
Key Signs:

These patients show a characteristic pattern consisting of three components. First, roll angles are abnormal for several complex gait tasks (for example walking up and down stairs or going over barriers - see first set of traces below). Second, gait tasks with simultaneous large voluntary head movements (walking with head pitching movements - see second set of traces below) show pitch angles and velocities less than normal, and thirdly, stance tasks show sway slightly greater than normal values. This pattern often yields a normal Balance Control Index (even to a less than normal index without the stairs values - see summary below).

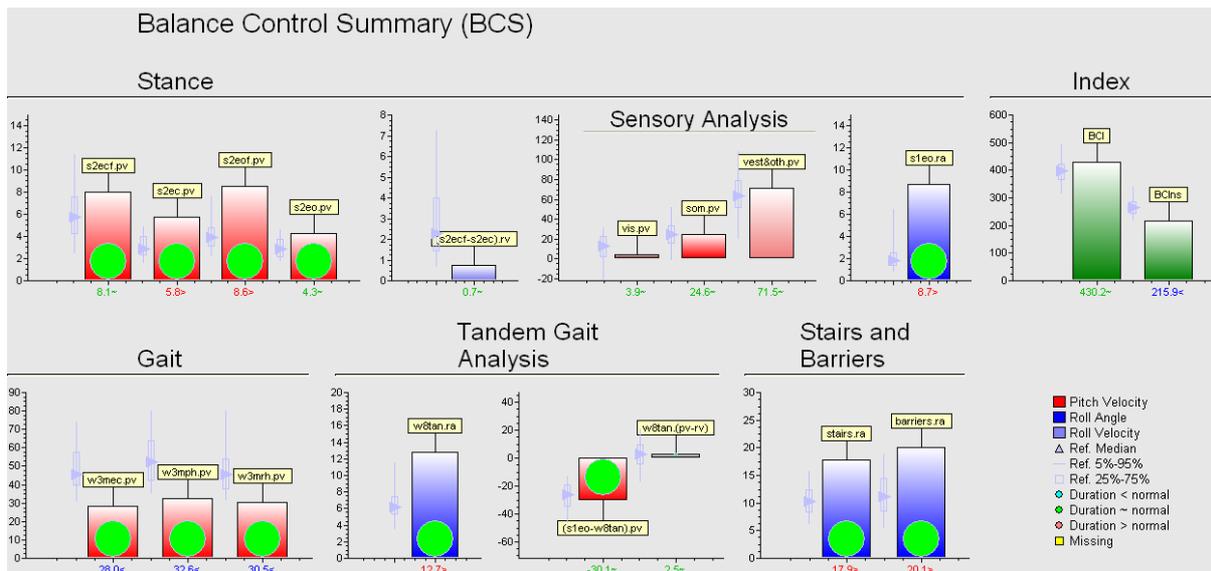
Walking up and down stairs.



Walking 3m with head pitching.



Summary Data:



The summary shows the typical pattern due to these patients stiffening themselves up during gait. Any task which requires head movements to keep gaze fixated, for example walking upstairs or over barriers, leads the excessive roll sway because the trunk is moved instead of the head on the trunk. In contrast, for walking tasks where gaze fixation is not required, the patient hardly moves the head and walks slowly leading to less than normal trunk movement. Thus, rehabilitation should concentrate on improving neck mobility.

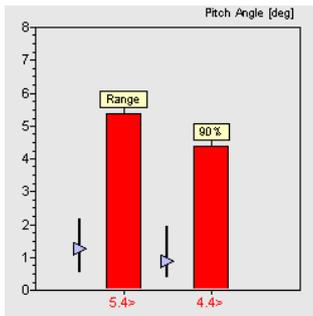
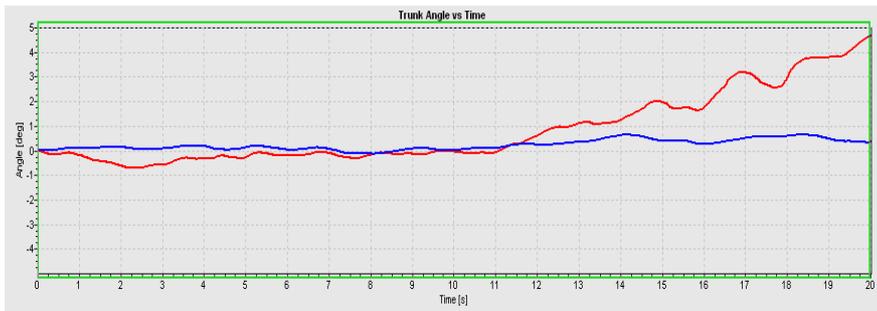
7.4 Simulator (Non-organic balance disorder) (226 BB)

Age at test: 49

Key Signs:

Typically these patients show results inconsistent with a balance disorder. For example, pitch sway velocity for two-legged stance eyes closed on foam is half that for eyes closed on a firm surface (see summary below). Here even for two-legged stance eyes open on a firm surface (see traces below) slow sway movements were observed. Such sway is almost never seen for patients with real balance problems. The patient cannot stand on 1 leg, eyes open, for more than 7 seconds, but again, inconsistently, this patient can perform the task walking with eyes closed and tandem steps with normal times.

Standing on two legs, eyes open, firm surface.



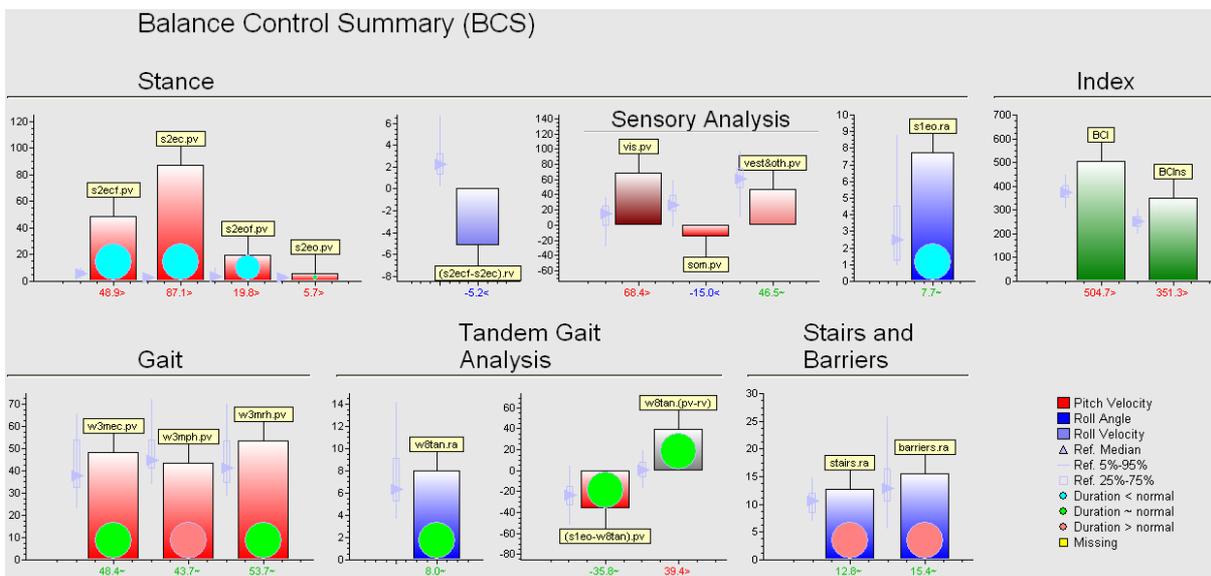
Summary Data:

Pitch velocity sway values for stance on foam are less than on a firm surface, leading to a negative somatosensory component in the Sensory Analysis Graph. Sway for stance eyes closed is excessively greater than with eyes open leading to an apparently greater than normal use of visual inputs in the Sensory Analysis Graph. Roll velocity were as large eyes closed on foam as on firm support surface.

Standing on one leg without loss of balance was not possible but tandem walking could be performed within a normal time. However pitch was greater than roll velocity. Stairs and barriers tasks were performed slowly.

Indexes:

Greater than normal.



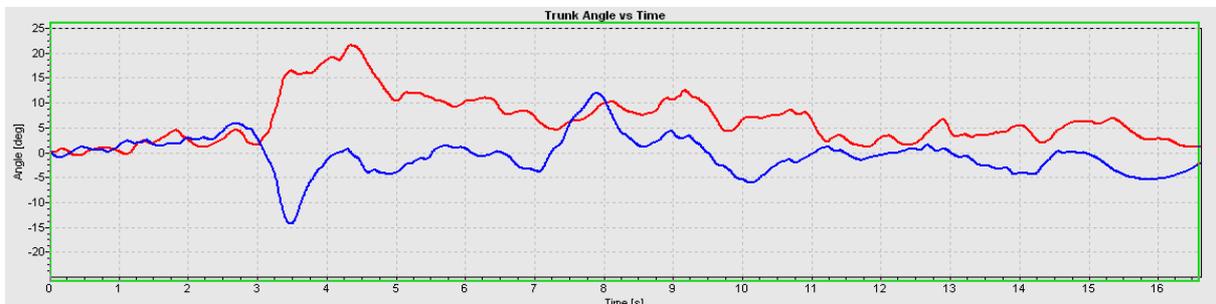
7.5 Spino-Cerebellar Ataxia

7.5.1 Spino-Cerebellar Ataxia (SCA 3) with normal vestibular-ocular reflex. (150 SSC)

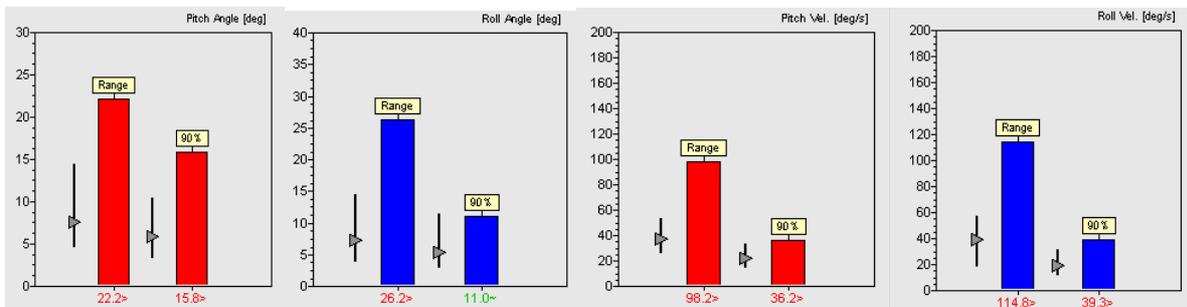
Age at test: 41

Key Signs:

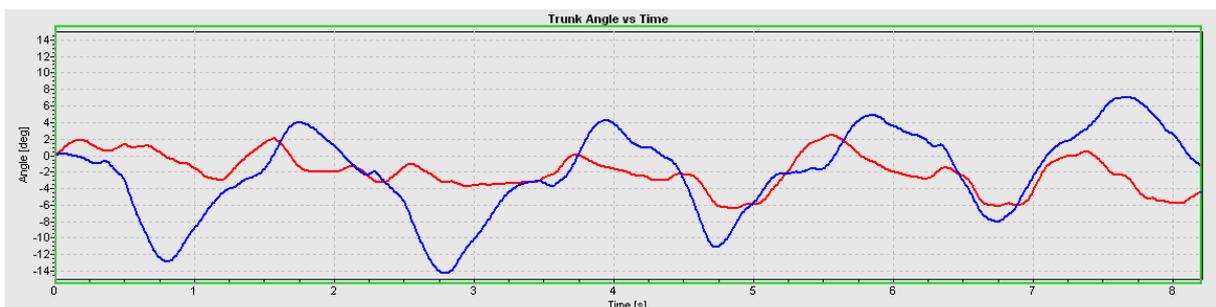
The two cases of SCA shown below indicate how balance and gait tests may be used to screen for early systems of SCA with and without central vestibular problems. Two legged stance is normal in this patient, but as soon as the patient is required to perform tasks with stance on one leg, especially tandem gait, excessive roll angle values are observed (see first set of traces below), and the time takes to complete such tasks is longer. Note that pitch and roll trunk control are equally unstable. For the task of walking over barriers, roll is very unstable (see second set of traces). The patient could not perform the task of walking up and down stairs without assistance, thus the Index in the Summary is only available without stairs.



Walking 8 tandem steps

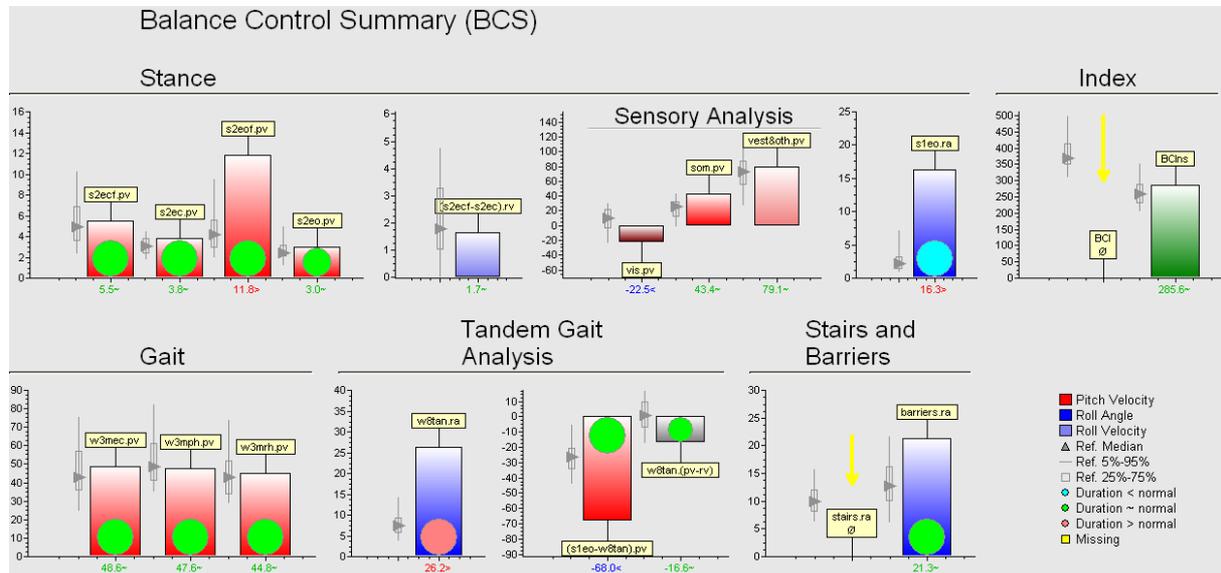


Walking over low barriers spaced 1 m apart.



Summary:

Indicates that patient cannot control trunk roll sway well when required. Thus roll velocities are much greater than pitch for tandem walking and roll angle sway is generally abnormal. Stance tasks are performed within normal bounds.



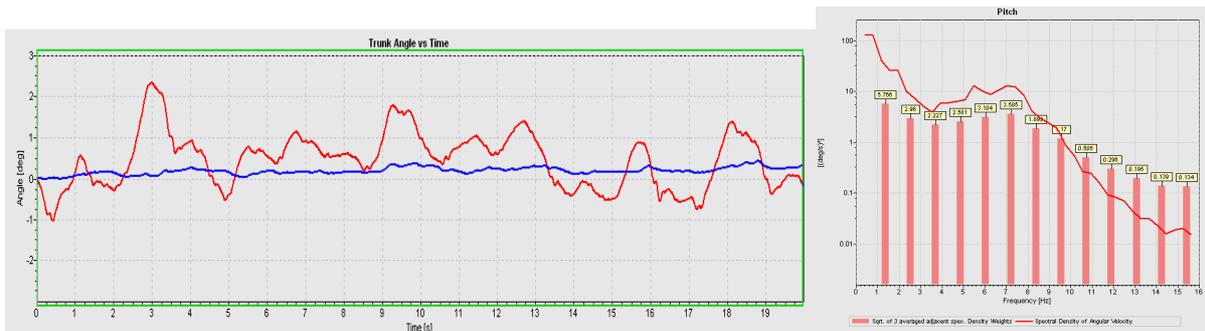
7.5.2 Spino-Cerebellar Ataxia (SCA7) with low vestibular-ocular reflex gain (146 SSC)

Age a test: 44

Key signs:

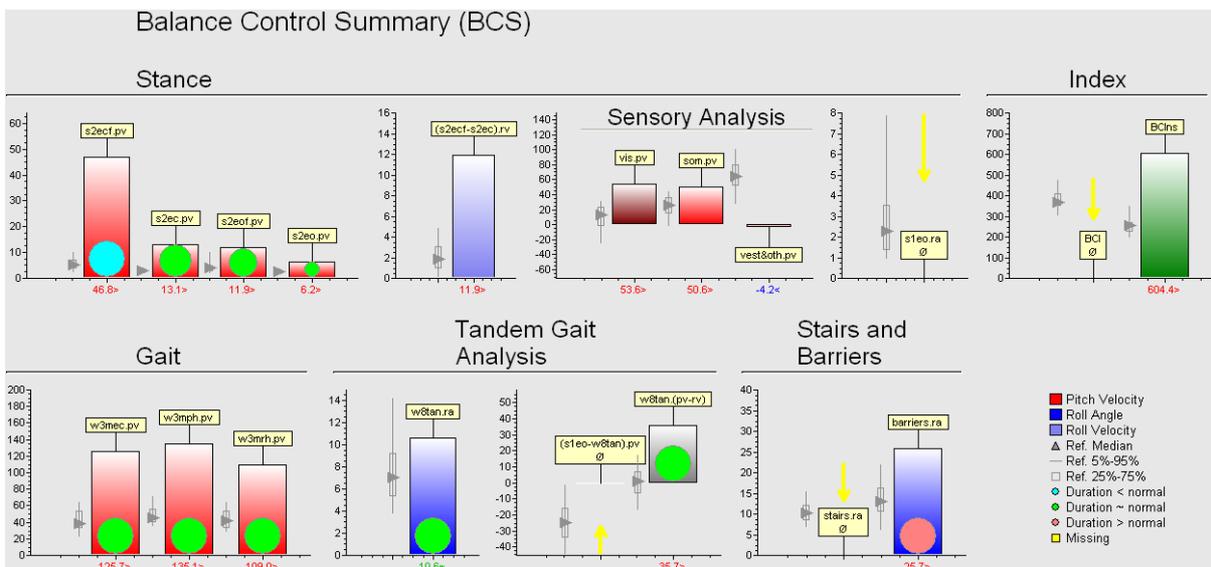
In addition to poor roll control described for the patient above, this patient shows additional abnormalities due to a central vestibular deficit, for example, abnormal sway standing eyes closed with tremor at 6-7 Hz (see below) and inability to stand on one leg eyes open. Walking with voluntary head pitching or head rotation is abnormal (see summary below)

Standing on two legs, eyes closed



Summary:

The sensory analysis of stance indicates that the patient is using visual and somato-sensory inputs to control stance to a high degree, but is unable to use vestibular inputs and therefore has a low value for this sensory input in the sensory analysis. The patient's roll control for tandem walking is borderline normal. However the control of pitch velocity is abnormal across several gait tasks. For the barriers task roll angle sway is abnormal.



7.6 Total Hip Replacement after severe osteoarthritis (316:1&2 FP4)

Age at test: 63

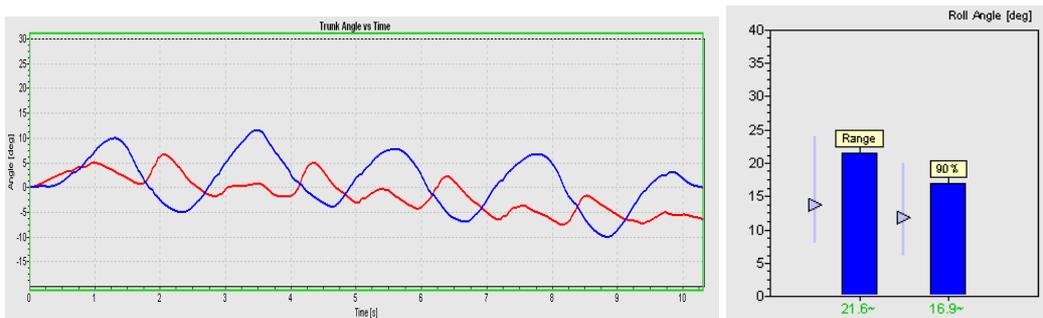
Key signs:

For this patient situation the interest is in documenting post-operative functional improvement. The task results especially those for the barriers test indicate very this well (see traces below with equal scales) as the excessive roll is reduced post-operatively and the time to complete the task is less. Other tasks that can be used to illustrate the functional improvement of the patient are the get-up-and-go task (increased trunk flexion during getting up, decreased trunk roll during walking should be seen post-operatively). Though roll angle deviations are reduced for the barriers and stairs tasks post-operatively, these still remain in upper percentile of normal, suggesting that rehabilitation should pay careful attention to a falling tendency. Stance on 2 legs is very stable in these patients, especially in the roll direction when standing on foam, indicating that these patients may be standing stiffer than normal.

Pre-operative result, walking over low barriers spaced 1 m apart.



Post-operative result, walking over low barriers spaced 1 m apart.



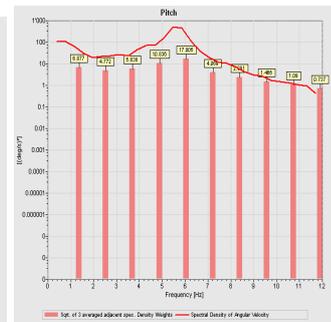
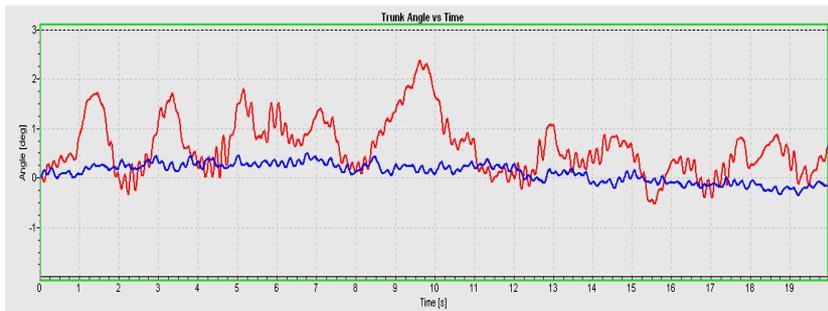
7.7 Parkinsonian Disease with bilateral STN stimulators ON and OFF (4 SSB)

Age at test: 40

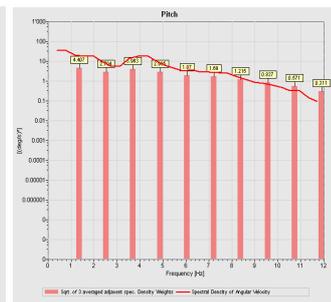
Key signs:

With PD patients with stimulators, the interest is in documenting post-operative improvement with the sub-thalamic nucleus stimulation bilaterally. The clear effect of the STN stimulation is in reducing the tremor during stance as illustrated in first set of traces below for the task of standing eyes closed on foam. Tremor measurements at 5 Hz indicate a considerable improvement with a four-fold reduction in sway velocity amplitudes (see spectra next to time traces). Other tasks such as walking with eyes closed are performed faster but only with a slight improvement in trunk sway. This confirms the general impression that STN stimulation improves tremor but not axial instability in PD patients. The task results illustrated for the STN stimulation on and off stimulation also suggest which measures need careful monitoring when SwayStar is used to screen for the presence of PD.

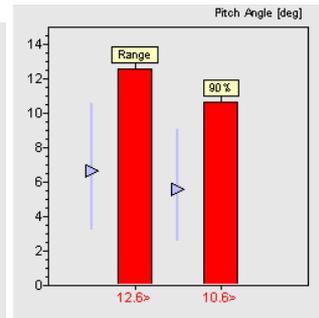
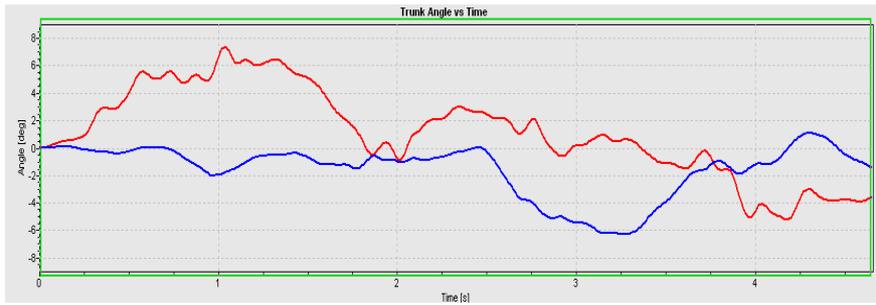
Stimulation off, standing eyes closed on foam



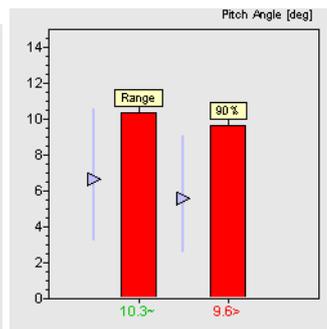
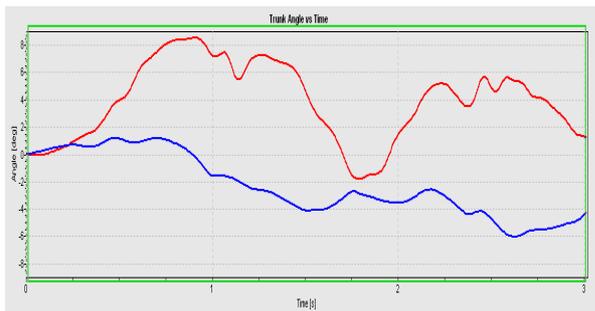
Stimulation on, standing eyes closed on foam



Stimulation off, walking 3 m eyes closed



Stimulation on, walking 3 m eyes closed.



8. HOT-KEYS and ICONS TABLE

Note: When a letter is underlined, it indicates that the Hot-Key is a combination of pressing Alt (or Ctrl) + the underlined letter.

Function	Hot-Key	ICON	
		Active	Display
Main Menu			
<u>D</u> ata	(Alt + D)		
Retrieve	F3		
BCS Report	(Ctrl + Alt + B)		
Save	F2		
Manage Patient Data	(Ctrl + M)		
<u>R</u> ecord	(Alt + R)		
Single	(Ctrl + R)		
Sequence	(Ctrl + S)		
<u>P</u> rint	(Alt + P)		
Current	(Ctrl + P)		
All	(Ctrl + Alt + P)		
Setup the Printer	Left click		
<u>O</u> ptions	(Alt + O)		
Language	None		
Setup for Protocols	None		
Protocols	None		
Sequences	None		
Query printer setup before job	None		
Alternate database (DB)	None		
Open DB	(Ctrl + Alt + D)		
Export Data	None		
Settings	Left click on Toolbar		
Sensors	None		
Operation	None		
Display	None		
<u>W</u> indow	(Alt + W)		
<u>T</u> ile vertical	(Ctrl + T)		
Tile horizontal			
Cascade			
Close all			
<u>H</u> elp	(Alt + H)		
Internet Update	(Ctrl + Alt + U)		
Device manager	(Ctrl + Shift + H)		
Bluetooth Places	(Ctrl + Shift + B)		

Toolbar only			
Save changes	F2		
Reset (changes)	(Ctrl + F3)		
Add a new marker pair	(Ctrl + Alt + M)		
Undo last modification	(Alt + Backspace)		
Redo Last modification	((Shift + Alt + Backspace)		
Write values to the log file	(Ctrl + A)		
Write values from all ... to the log file	(Ctrl + Alt + A)		
Export log file (to Excel)	(Ctrl + X)		
Select a new log file	(Ctrl + N)		
Axis scale dialog	(Ctrl + N)		
Window-defined current analysis scaling	(Ctrl + Alt + S)		
Display ratio	(Ctrl + Alt + F)		
Hotkey Only			
Open temporary folder of analysis window in Windows Explorer*	(Ctrl + Shift + A)		
Open DB folder in Windows Explorer*	(Ctrl + Shift + D)		
Open log file folder in Windows Explorer*	(Ctrl + Shift + L)		
Reload language	(Ctrl + Alt + L)		
Open "My Documents" folder in Windows Explorer	(Ctrl + Shift + M)		
Display loaded module (.dll) list.	(Shift + Alt + M)		
Open SwayStar program folder in Windows Explorer*	(Ctrl + Shift + P)		
Open Registry and jump to the SwayStar registry key	(Ctrl + Shift + R)		
Open SwayStar working folder in Windows Explorer*	(Ctrl + Shift + W)		

* On systems with "Total Commander" installed, the directory is opened in a new tab of "Total Commander". Pressing the left Ctrl and Shift keys opens the tab in the left pane, pressing the right keys opens it in the right.

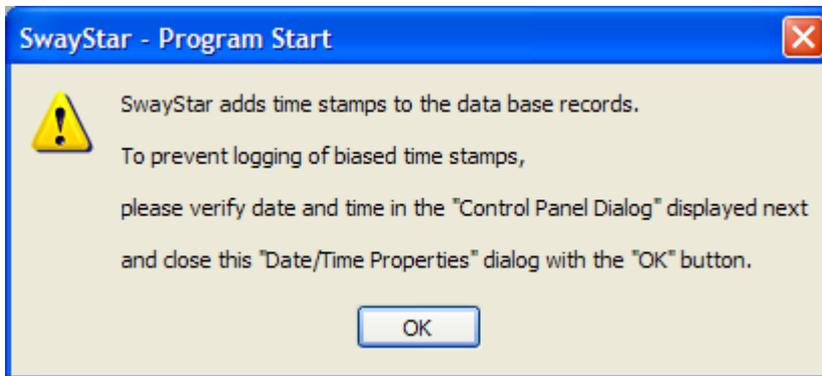
9. TROUBLESHOOTING

9.1 SENSOR FAILURE

If sensor fails, either no power is available or the COM ports have not been selected properly. Check that the cables are connected properly, the COM port is selected correctly or that the sensor rechargeable batteries have enough power.

SOLUTION: A quick check of the sensors can also be done visually once they are functioning. While in the record mode, without a subject attached to SwayStar™, slowly rock the belt to-and-fro and side-to-side and observe the recorded movements.

9.2 TIME STAMP PROBLEM ERROR MESSAGE



If this message appears, it indicates that the time (and date) displayed on your computer are not consistent with saved data in SwayStar™ because the computer date is *earlier* than the saved records. There is a faulty time relationship because the date is earlier than the last time the program was opened. This can occur if there has been a power shortage to your computer (battery goes down). It may also occur with a bios update.

SOLUTION: Follow the instructions in the error message or simply double click on the time stamp (lower right-hand corner of your computer). The Date and Time window opens for your operating system. Set to the current date and time and click OK.

9.3 UNABLE TO INSTALL ON A CORPORATE SYSTEM

Corporate IT environments often prevent installation of software by restricting user rights and applying policies. On an NT based system (NT, W2K, XP, Vista), the user account that is used to install the software must have administrative rights to install the program. On an attempt to install or update the software as a restricted user the installer will prompt with a window asking for login credentials of an administrative user.

SOLUTION: Contact the responsible systems administrator of your IT department.

9.4 SwayStar™ OPERATES SLOWER THAN NORMAL

This indicates that your computer resources are low. When your computer's RAM is fully utilized, resource swapping will occur between the RAM and hard disk. This takes time and slows down the operation of the program.

SOLUTION: Close down the SwayStar™ program and reopen. This will clear the memory.

NOTE: Another symptom of low resources is that the program simply stops operating or images do not appear. This may occur when too many programs are open at once; for instance, if SwayStar™, PowerPoint, WORD, Wordpad, EXCEL are open at the same time. This depends completely on your computer.

SOLUTION: Shut down as many programs as possible. It may be necessary to Shut Down completely and restart your computer. All unsaved data will be lost. It is best to pay attention to resource capacity and to refrain from opening too many programs at one time.

9.5 Bluetooth permanently turned off.

It could happen that Bluetooth service is turned off - a  grey symbol is displayed in the system tray - although the dongle is plugged in. This could happen after returning from the sleep or hibernation modes. If you had "Bluetooth Places" open in Explorer this state can be recognized by the view shown on the right. If double clicking on the system tray icon  or selecting "Turn on Bluetooth" in the context menu (see figure below) does not bring the Bluetooth services to the "on" state, one might need to disconnect and reconnect the Bluetooth dongle or reboot the system.

