The invention relates to a non-invasive device and method for measuring spinal curvature. Apparatus shown in Figure 1 includes a wheeled member rotatably mounted on a handle, which in use is moved along the spine. A camera is used to record the a path of a reflector mounted at the centre of the wheel to provide an indication of the curvature of the spine as the wheel is moved. Software is used to analyse images recorded on the camera.
before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.
Device for Measuring Spinal Curvature

The invention relates to a device for measuring spinal curvature and a system for use in connection therewith.

The human spine is a complex and inherently unstable and mobile structure comprising 14 vertebrae. These vertebrae are inter-connected by inter-vertebral joints that allow movement in all three planes. The pelvis consists of two inominate bones and a sacrum forming a stable ring that is connected to the spine via a relatively stable lumbo-sacral joint. Due to the close vertebral and pelvic inter-connections, movement at one spinal segment influences the movement of other segments within the spine and pelvis. Therefore, evaluation of spinal-pelvic curvature requires a tool that is capable of detecting a change in the whole spine and movement of the spine relative to the pelvis. Due to the three-dimensional freedom of movement, measuring spinal movement at every level has always been a challenge for clinicians as well as researchers.

Nevertheless, the measurement of spinal and pelvic movements is routinely undertaken to evaluate and monitor the progress and response of a patient to treatment in spinal pathologies. Several non-invasive measurement techniques have been developed in clinical and research setting ranging from simple skin distraction techniques to computerised movement analysis systems. Such methods demonstrate varying degrees of reliability as discussed below.
Measurements of spinal and pelvic range of movement can be obtained with number of methods including radiography (1981 onwards), the tape measure (1983 onwards), the goniometer (1983 onwards) or quite complex computerized movement analysis systems such as 3Space Fastrack (2000 onwards), 3Space Isotrack (1989 onwards), electronic inclinometer (1986 onwards) and piezoresistive accelerometer (1999 onwards).

Biplanar radiographs are generally considered to be the gold standard for measuring curvatures and range of movement in the spine (Ordway et al. 1997; Portek et al. 1983). The reliability studies demonstrated however, a wide intra- and inter-observer angular variability ranging from 2.8 to 10 degrees when measuring kyphosis and scoliosis. Such variability in the angular values was suggested to seriously question the use of radiographic spinal measures as a gold standard measure.

Moreover, using radiography for assessment of spinal movement is generally expensive, time consuming and raises an ethical issue with regards to exposing subjects to repeated radiation.

A ruler or a tape measure is used to measure spinal flexion and lateral flexion by recording the distance between the finger tips and the floor (FTF). This is a relatively inexpensive, easy-to-use and a quick method of assessing spinal movement in a clinical setting. However, reliability studies produced mixed
results. In terms of the validity, it is argued that an FTF measurement cannot be solely attributed to spinal motion but also reflects relative hip mobility.

Other tape measure methods include skin distraction tests where bony landmarks are marked and the distance between the marked points is measured during sagittal and frontal plane spinal movements. Modified and classic Schober test, for example, first described by Troup et al (1968), is a method that measures skin distraction between a marked lumbo-sacral junction and a set distance above and below that mark during full flexion. Although, workers have found high intra-observer correlation in flexion ($r=.88$) and side bending ($r=.93$), there were significant inter-observer differences in means. In addition, the Schober test was found not to correlate well with angular movements of lumbar spine. Other workers have evaluated a number of clinical spinal measurement methods, including a battery of skin distraction tests, and found poor inter-tester and test re-test reproducibility for plumb line and skin distraction tests and argued that this is due to relative variations in skin mobility over the bony landmarks. It has also been suggested that due to measuring only small differences in length, relatively small deviations in marker placement could lead to large percentage errors. This argument is supported by workers who investigated the sources of error in spinal measures and demonstrated that problems with identification of the bony landmarks were the number one contributors to poor reproducibility of spinal measurement methods.
Due to the poor reliability and questionable validity of the above methods, researchers began to develop new and quite complex computerized and highly accurate movement analysis systems including 3Space Fastrack, 3Space Isotrack, electronic inclinometer and piezoresistive accelerometer. Such devices express spinal movement in degrees within given sections of the spine using various sensors attached to the skin at positions corresponding to intervertebral spaces, as determined by palpation. The undeniable advantage of such devices is that spinal movement can be monitored and recorded continuously while the curvature of the spine changes during functional tasks.

In brief, 3Space Isotrack and Fastrack systems are non-invasive electromagnetic devices that measures the position and orientation of points in space in three dimensions and have been used to determine re-positioning errors when measuring spinal and pelvic joint position sense. They involve a number of sensors that are attached to the skin over various bony landmarks. Each sensor position is then detected and sagittal plane angles, such as sacral tilt, lower lumbar and upper lumbar angle, are then calculated.

Fastrack correlated well with radiographs in cervical spine, compared to ex motion device.

The reliability of 3-Space fastrack has been specified by a manufacturer to 0.15 degree and is influenced by the operating environment in particular the distance.
of sensors and the source. Further, it has been demonstrated that 3Space Fastrack is highly accurate in measuring inter-vertebral motion to 0.2 a degree.

Swinkels and Dolan (1998) assessed the reproducibility of spinal position sense measurements recorded at T1, T7, L1 and S2 using 3-Space Fastrack on twenty subjects. Absolute error was measured in 3 randomised measurements of upright and flexed positions during movements in coronal and sagittal planes, taken on two separate days, two weeks apart. The subjects were able to reproduce the spinal position with a high accuracy within a day and in day to day measurements. Flexion movements were reproducible to within a mean of 5.27 (3.47) for movements in sagittal plane and 3.70 (2.62) for movements in coronal plane. Volunteers were able to re-position their spine with considerable accuracy during same day measurements.

Weaknesses of the 3Space systems include the varying levels of agreement with other methods of spinal measurement or the validity of the measurements. Although Ordway et al (1997) demonstrated high levels of agreement between 3Space Fastrack and gold-standard radiographic measurement methods when measuring cervical protraction and retraction, there were some significant differences between the two methods when measuring global cervical flexion and extension. Similar discrepancies were also found between 3Space system and bi-planar radiographic measures in lumbar spine (Pearcy and Hindle 1989).
This lack of agreement was associated with the choice of a reference system used by the different instruments. In short, in order to assign an angular value to a moving segment, there needs to be a reference point to which this value relates. The reference point is either bony landmark-based (internally-based reference system) used by Fastrack systems, or environment-based point (externally-based reference system). The important characteristic of the internal reference system is that it isolates movement to specific segments only, whereas the external reference system accounts for movement in the whole spinal-pelvic complex relative to the surroundings. This leads to reduced comparability with the external reference systems such as bi-planar radiographs or inclinometer systems (Ordway et al, 1997).

In addition, although the above devices carry the advantage of accuracy and repeatability, only a fraction of the vertebral movement, often limited to motion between two vertebrae can be examined (Mannion et al. 2004). This could be still very useful when looking at specific spinal pathologies at a given segment. However, the clinical usefulness of such instruments may reduce when investigating disorders such as non-specific low back pain (NSLBP), where a single pathology at a specific level has not been identified.

*Electronic inclinometer* is a device that is secured or held directly over previously palpated vertebrae (most commonly the sacrum and T17) during spinal movements. It measures spinal motion using one or two sensors containing an optical angular scanner. The computer reads the point of reference and point of
post-movement from the sensors, identifying the difference between the two positions. The method of calculating the angular value of lumbar curvature varies depending on the specific type of the device. Unlike the previous two devices, where the sensors are attached to the skin, the inclinometer is held firmly over the bony point during the movement. This method of securing the inclinometer, however, again appears to vary between different types of devices. Workers have used two miniature inclinometers, developed by the ARC Occupational Health Research Unit at Guy's Hospital London. They attached the inclinometers directly to the skin with double-sided adhesive foam. Others have used a single inclinometer (Cybex EDI-320) that was directly held over the sacrum and then over T12.

The validity of such apparatus has been debated in literature that compares clinical spinal measurements with biplanar radiographs. Adams et al (1986) found that recordings from the inclinometer are reproducible and correlate well with radiographs in flexion. Unfortunately, the reproducibility of lumbar spine flexion was only measured in one subject over 9 days. Larger sample size (at least ten subjects, measured over number of days) is recommended in research literature to carry out statistical tests that present ICCs and SEM when evaluating the reliability of a measurement tool. When correlating radiographic and clinical measurement of lumbar spine it has been argued that the variation in skin movements contributes to the considerable errors detected during measuring of lumbar flexion. However, it could be the discrepancies in location
of the point of reference, rather than the skin motion, that could contribute to the error.

The source of error when using an inclinometer was also investigated by Mayer et al (1997) who tested each potential source of error separately and found that the device error is negligible compared to the test process itself. The test administrator training deficiencies accounted for the largest source of error, including the ability to identify bony landmarks, the "wobble" of the inclinometer over the sacrum while the subject moved, and misplacement of the inclinometer sensor back at T12 after the subject moved. The magnitude of measured movement also influenced the accuracy of the inclinometer; measurement of a relatively small pelvic extension, for example, resulted in larger percentage error.

Brumagne et al (1999) tested the test re-test reliability of a lightweight piezoresistive accelerometer and 3-D video-analysis system. The accelerometer is attached to the skin over the sacrum as an electro-goniometer to determine a position of the sacrum during pelvic tilting. The Piezoresistive electrogoniometer was shown to have an accuracy of within 0.42 degree when measuring pelvic tilt (Fahrenberg J. 1997). The piezoresistive electrogoniometer measurements also correlated highly with three-dimensional video analysis system (ICC=0.84-0.97) when measuring pelvic tilt in standing where the standard error of measurement (SEM) was 0.40 degrees with 95% CI=0.78 for the electrogoniometer and 0.42 degrees with 95% CI=0.82 for the video analysis. This study unfortunately did not include the inter-tester reliability tests.
This omission could be quite significant as later studies demonstrated that the largest source of error when using such systems was related to the test administrator training deficiencies (Mayer et al, 1997).

One of the disadvantages of the above methods is their relative limitation of measuring only a fraction of the spinal movement, often limited to motion between only two vertebrae. Given the intricate anatomy and biomechanics of the spinal column, measurement limited to only few segments may not give the true motion patterns of the whole spine. A method that measures the whole spine would allow for more accurate assessment.

There have been some attempts to measure a larger proportion of the spine using flexicurve. Stokes et al, 1987 in Swinkels 98 (TO GET) compared flexicurve measurement to radiography and found only a reasonable accuracy +/-25.5%.

The discrepancies in this study could have been a result of measures taken on different days in different positions. A reliable way of measuring movement in the whole spine would allow for accurate assessment of interventions used in clinical practice.

However, the above methods are of questionable clinical usefulness because the most reliable only measure a relatively small proportion of the spine which is often limited to over few vertebrae. Measurement of spinal movements limited to few spinal segments may not truly reflect the movement behaviour of the whole spine and pelvis and therefore could be of limited clinical value. Given the
anatomical complexities of the spinal column and pelvis, a tool that measures the curvature of the whole spinal-pelvic structure i.e. movement of the whole spine relative to the pelvis, would arguably be very useful and relevant to clinicians.

Statements of Invention

Accordingly, in a first aspect, the invention concerns a non-invasive device for measuring spinal curvature comprising a wheel member attached to a handle in such a fashion that the wheel member is free to rotate when travelling along a surface to be measured and at least one reflective marker attached to, or integral with, the centre or near centre of the wheel.

Thus, in use, the device is held by a healthcare worker, using the handle, and the wheel is made to trace a path alongside, or over, the centre of the spine or spinal groove from a first selected position, such as vertebrae S1, to a second selected position at a selected distance therefrom such as the occipital groove.

Throughout this procedure an electro-magnetic signal is sent to the reflective marker which reflects same. This reflected signal is captured and recorded on a suitable camera so that an image of the path taken by the reflective marker is recorded and captured for future analysis. In its simplest context the reflective marker simply reflects light and therefore the methodology simply involves a camera taking a photographic image of the path traced by the device, and thus the marker, as it travels along the spinal path. Once captured the image can be
stored and processed, using conventional software, for the analysis of appropriate lines of curvature.

Alternatively, the reflective marker may reflect a selected wavelength of electro-magnetic energy and thus, a particular colour of light or a particular form of electro-magnetic radiation such as infra-red radiation.

Typically, more than one measurement is taken of an individual's spine and, preferably, in more than one position.

In a preferred embodiment of the invention the wheel member has a radius greater than 2 cm and more preferably still greater than 4 cm and more preferably still greater than 5 cm and, in any event, it has a radius which is able to protrude above any muscle or fat issue covering, or on either side of, the spinal column so that when the wheel traces its path along the spine a part thereof protrudes above the surface of any tissue. Moreover, the said reflective marker, although positioned at or near the centre of the wheel, extends across the surface of the wheel by an amount that ensures that the marker also protrudes above the surface of any human tissue when the wheel is made to trace a path along, over, by, or against the spinal column. Ideally, the reflective marker is made from conventional material known to reflect light or heat energy. More ideally still, the marker is provided on both sides of said wheel and of a suitable size and shape to perform its function, although typically, it will be in the form of a dot or disc extending outwards from the centre of the wheel. Ideally,
the marker is the same size and shape on both sides of the wheel, although this is not compulsory. Optionally, the wheel may be provided with a locking mechanism to prevent rotation when the wheel has reached a selected position.

According to a second aspect of the invention there is provided a system for measuring spinal curvature comprising a non-invasive device as afore described and associated camera and recording means whereby an image of the path travelled by the device over a selected spinal region can be recorded and stored for future assessment.

In a preferred embodiment of this second aspect of the invention the system also includes suitable software for analysing the images captured by the camera and recorded within the system for further analysis.

According to a further aspect of the invention there is provided a method for measuring spinal curvature comprising:

a) tracing a path alongside or over the centre of the spine or spinal groove of an individual from a first selected position to a second selected position at a predetermined distance therefrom using a non-invasive device comprising a wheel member rotatably attached to a handle wherein the wheel member has at least one reflective marker attached to, or integral with the centre or near centre of the wheel;

b) exposing said marker to an electromagnetic signal;
c) recording the reflection of said signal from said marker using a recordal device;

d) processing said recorded signal to obtain information concerning the path of travel of said marker from said first to said second positions whereby information concerning said path of travel provides information concerning spinal curvature of said individual.

In a preferred method of the invention said first position is just below, or at, SI spinous process or vertebrae S1 and said second position is just above, or at, the occipital groove, or vice versa.

An embodiment of the invention will now be described by way of example only with reference to the following methods and Figures wherein:

Figure 1 shows a device in accordance with the invention;

Figure 2 shows a flexicurve platform attached to a skeleton spine;

Figure 3 is a graphical representation of spinal curvature measurement (three trials) in a single subject;

Figure 4 shows a measure of intra-rater reliability using the device in accordance with the invention;

Figure 5 shows a measure of inter-rater reliability using the device in accordance with the invention; and

Figure 6 shows a measure of test, re-test reliability showing a device in accordance with the invention.
Study Design and Population

Observational study design was used to measure the spinal curvature during sitting and standing in 10 healthy volunteers (five females) recruited from the staff of School of Healthcare Studies, Cardiff. Ethical approval was obtained from South East Wales Ethics Committee. All subjects read the information sheet and signed the consent form. The subjects were asked to attend two sessions three days apart.

Development and use of the spinal wheel device

A free-wheeling plastic wheel with 10cm in diameter and 0.5cm width was custom-made and attached to an ergonomic handle allowing continual motion of the wheel in forward and backward direction with a no lateral displacement (Fig 1). A reflective marker was secured in the centre, ideally, the exact centre of the plastic wheel (Fig 1).

The spinal wheel is moved through the centre of the spinal groove from the S1 vertebra up the occiput. The measurement of the spinal curvature is produced by guiding the spinal wheel along the centre of the spine (or slightly paravertebral if the subject is particularly thin with protruding spinous processes). The continuous motion of the reflective marker secured to the spinal wheel was detected by Vicon 3-dimensional 512 kinematic movement analysis system. This provided an exact trace signal of the spinal curvature, in frontal and sagital plane. Reflective markers were attached to the spinous
processes of the S1, T12, C7 vertebrae to identify the thoracic and lumbar spine, and pelvis was marked by attaching reflective markers to the anterior and posterior superior iliac spines ASIS and PSIS. The information of the moving and static markers is then used to calculate position of thoracic and lumbar spine relative to the pelvis and the pelvic position is calculated relative to the external gravity-based reference system.

Pilot

Initial piloting aimed to validate the spinal wheel in measuring true angular values, where series of measurements were collected on number of static angles. The static angles were made using flexicurve that was shaped to 30, 45, 90 and 120 degree angles.

To determine the tool's sensitivity to conditions likely to be encountered when measuring a human spine (such as a body sway), measurements were collected on a skeleton spine with custom-made flexicurve platform securely attached to the spinal column (Fig 2) that was made to artificially sway in series of directions at different amplitudes.
In addition, the piloting was aimed at maximizing the quality of the data collection, finalizing the lighting systems, subject's clothing and marker placement. The procedure was tested on two volunteers to identify any weaknesses in the protocol before the actual data collection.

Following the piloting, the Matlab programme was finalised. The position of the subject within the data collection area was standardized to ensure a maximal camera detection of the moving marker. A bra strap crossing the middle part of the spine was shown to introduce an error in angular value to thoracic spine. To eliminate this error, female subjects wore a custom-made gown that allowed them to undo the bra strap for the data collection while maintaining their dignity. The lighting was adjusted as increased brightness interfered with the Vicon motion analysis system.

**Procedure**

The data collection took place in the Human Kinaesiology Laboratory at Cardiff University. Prior to data collection the equipment was switched on and calibrated and its position and was checked. Subjects were given explanation of the testing procedure, equipment used and were given an opportunity to ask any questions to express any concerning issues. The participants were asked to undress from the waist up, women wore a bra.
Each subject was assigned a unique code and randomized to establish the order of the assessors measuring his/her spinal curvature. The principal assessor identified left and right ASIS, PSIS and C7, T12 and S1 spinous processes and attached the reflective markers. Following anatomical calibration the subjects were asked to sit in their usual position with arms folded across the front of their chest to avoid obscuring the reflective markers. The chair height and position was identical for each subject for both visits to ensure that subjects sat in the same position during both visits. The three assessors (in random order) then measured the subject by guiding the spinal wheel from just below the marked S1 spinous process to the occipital groove. The signal was captured by Vicon 512 Kinematic System and saved on the hard drive under a unique code. The same procedure was then repeated in relaxed standing position. All three assessors (the principal assessor and two senior chartered physiotherapists) collected three sets of measurements in each position in every subject. Subjects were invited back to repeat the procedure three days later.

To assess intra-tester and inter-tester reliability three assessors collected three trials each on every subject in sitting and standing. To assess test re-test reliability one assessor measured each subject three times on two separate days in sitting and standing.

Data Analysis

Each trial was displayed in a form of moving reflective markers on a black screen. A marker set was attached to the collected footage, the data was
checked for any missing markers and saved on the hard drive. A programme
within the Matlab computer software was then used to analyze the data. The
motion of the pelvis was expressed in the global coordinates and spinal motion
was expressed in relation to the pelvic coordinates. Numerical and graph
representation of the thoracic, lumbar and pelvic angle for every trial were
calculated. The angular value was transferred and saved in the data collection
sheet.

SPSS 14.0 statistical software was used to calculate the descriptive statistics
and intra-class correlation coefficients (ICC) to determine the intra-rater, inter-
rater and test re-test reliability in measuring the thoracic, lumbar and pelvic
angle in sitting and standing positions.

Results

The study investigated the reliability of the spinal wheel in its ability to accurately
detect a given spinal shape in sitting and standing.

Intra-rater reliability within one and multiple raters

Intra-rater reliability which evaluates accuracy of one rater (assessor) in
measuring spine and pelvis three times is presented in Figure 4 and Table 1.
The mean values, standard deviation and intra-class coefficient (ICC) for
thoracic, lumbar and pelvis measures in sitting and standing is shown. The ICC
values in Table 1 were calculated for one rater and for multiple rater and range
from .978 to .998. According to Munro (2005) who states that r-value within a category .90 - 1.00, such values indicate a very high correlation.

**Inter-rater reliability**

Inter-rater reliability evaluated the agreement of three raters (assessors) in measuring identical spinal and pelvic position measurements. Figure 5 and Table 2 show the inter-rater mean values and standard deviations for thoracic, lumbar and pelvis measures in sitting and standing. Table 2 also presents the ICC scores that range between .979 - .998 and so again demonstrate very high reliability.

**Test re-test reliability**

The test re-test reliability evaluated the stability of the measures over time. Figure 6 and Table 3 presents the mean values, standard deviations and ICC scores for thoracic, lumbar and pelvis measures in sitting and standing taken on two separate days. Table 3 presents ICC scores that range between .822 - .980. Although pelvic measure in sitting (r=.822) and lumbar measure in standing (r=.883) shows slight reduction in the ICC scores, it is still indicated high reliability (Munro, 2005).

**Discussion**

The results indicate that this method of measuring the spine and pelvis is highly reliable when comparing scores of one assessor (intra-rater reliability) and comparing the level of agreement among three assessors (inter-rater reliability). The test re-test reliability was also shown to be very high for thoracic and lumbar
spine and high for pelvis measures in sitting. In standing, the thoracic and pelvis measures demonstrated very high test re-test reliability and high reliability for the lumbar spine.

The lower ICC scores of test re-test reliability of pelvis during sitting and lumbar spine during standing could be due to the position the subjects adopted during the two visits. Steps were taken to ensure that the tested position is standardized: The subjects were instructed to sit in a "normal relaxed sitting". Further instruction was not given to ensure minimal distraction from the usual sitting and standing posture each subject normally adopts. In addition, the chair height and position was standardized throughout the trial. It is not known however, whether the sitting and standing positions individuals adopt are exactly the same. Sitting and standing is dynamic in nature, that it requires continual adjustment to maintain balance and equilibrium and to avoid excessive stress on tissues. Given the demonstrated high accuracy of the tool, even minimal change in sitting and standing posture could present a potential error. The high ICC scores for the intra- and inter-rater reliability demonstrate that any potential variations in the positions tested within one session do not affect the reliability.

As for the location, pelvis and lumbar spine are relatively mobile structures compared to the thoracic region. The larger range of movement within low back and pelvis allows, perhaps, for larger margin of variability within the available range during sitting and standing.
Validity of the measurements

It is important to determine whether the device produces valid measures, in this case whether the reported angular values in this study truly represent the vertebral movement. One method of determining validity of a given device involves comparing the yielded angular values to a gold standard measure (Bland and Altman, 1986). Biplanar radiographs are generally considered to be the gold standard for measuring curvatures and range of movement in the spine (Ordway et al., 1997; Portek et al., 1983). However, reliability research reports wide intra- and inter-observer angular variability ranging from 2.8 to 10 degrees when measuring kyphosis and scoliosis (Cakir et al., 2006; Carman et al., 1990; Morrissy et al., 1990). This variability was reported to be a result of using different statistical methods (Bland and Altman, 1986), radiographic quality and determination of the spinal level (Panjabi et al., 1992), positioning of the patient during the X-ray (Mannion et al., 2004) and observer’s experience (Cakir et al., 2006). Nonetheless, such variability in the angular values was suggested to seriously question the use of radiographic spinal measures as a gold standard measure (Mannion et al., 2004).

To establish some level of agreement of the spinal wheel with other spinal measure devices (convergent validity) a comparison of the angular values (including radiography) was performed to establish whether the spinal wheel produces realistic values of lumbar lordosis and thoracic kyphosis. The literature review revealed that research investigating the spinal and pelvic angles in sitting would be impossible to compare with the present study due to the variability of
the sitting postures, such as upright, neutral, relaxed, slouched (Allison and Fukushima 2003; Brumagne et al. 1999a; Dankaerts et al. 2006; Dolan K.J. 2006; O'Sullivan et al. 2003). Therefore, only literature evaluating the standing spinal measures was reviewed. Angular values obtained by similar skin-surface device Spinal Mouse© and the movement tracking devices such as the electronic goniometer, 3Space Fastrack and inclinometer were selected for the review and are presented in Table 4.

Lumbar lordosis measures

Standing lumbar lordosis in this study reached mean value of 31 degrees. This compares favourably with majority of the studies (Dolan P. 1993; Hultman et al. 1992; Mannion et al. 2004) presented in Table 4. Slightly lower values ranging between 24 and 28 degrees, found by Ng et al (2001) and Bergennud et al (1989), could be related to the fact that these values are derived from measurements of male subjects only. Pinel-Giroux et al (2006) who presented much higher angles (62.5-67 degrees) attributed the large discrepancies to measuring patients with spondylolisthesis and scoliosis who frequently present with increased lumbar lordosis (Pinel-Giroux et al. 2006). In addition, radiographic values are likely to differ from those obtained by skin-surface device due to fat deposits over sacrum, for example, and the fact that skin-surface measurement follow the line of the skin and spinous processes rather than the vertebral bodies.

Thoracic spine measures
Standing thoracic kyphosis measured by the spinal wheel in this study was on average 30 degrees. This value compares favourably to some radiographic studies (Pinel-Giroux et al. 2006; Ravishankar et al,1998).

There are also studies where thoracic kyphosis angular means appear somewhat higher compared to this study (Table 4). Different methods used to calculate spinal angles from sagittal radiographs could contribute to this discrepancy. (Pinel-Giroux et al. 2006) study showed that although there is a high correlation between two different methods of measuring spinal curvatures on sagittal radiographs (ICCs of 0.88-0.94), they yield significantly different angular values. The traditional Cobb method, for example, where angles of specific vertebral end plates are marked to draw up an angle between them, produced thoracic curvatures of 40°, compared to the tangent circles method that produced mean angles of 36° (P=0.0014). The Cobb method was criticised, for problems with identifying the end-plates of thoracic vertebrae and for significant overestimations in thoracic kyphosis produced by changes in vertebral bodies architecture (Goh et al. 2000). The tangent circles method was designed to overcome the difficulties in identifying vertebral end-plates. The authors argue that the latter method is less susceptible to error as it models a global geometry of the curves by marking number of landmarks (Pinel-Giroux et al. 2006). High variability in one landmark does not affect the final angular value as much as in the Cobb method where inaccurate identification of the direction of one vertebral end-plate influences the accuracy of the final measure (Pinel-Giroux et al. 2006). Besides the discrepancies between the two methods, both of
them measure the spinal curvature from radiographs and so could yield very different values from a skin surface device such as spinal wheel.

Comparisons from a similar skin surface device, however, still produces a 15° difference between the mean thoracic kyphosis values produced by the spinal mouse® (45 degrees) and the spinal wheel (30 degrees). Number of factors could explain this discrepancy. Although the subject group in both studies had similar characteristics, activity levels and occupation, the subjects in this study were on average of a shorter stature, which may potentially contribute to differences in the overall thoracic kyphosis values.

In addition, as previously suggested, the accuracy of any skin-surface device is affected by the discrepancies in the method of measurement such as the speed, pressure exerted and the path followed while rolling the device in the spinal groove (Mannion et al. 2004). Such variables are difficult to control within a single study on a single day. It is entirely possible that such factors could have significantly contributed to the discrepancies between these two studies. Mannion et al (2004) stated that the potential for error in the thoracic region is smaller as there is typically less subcutaneous fat in that region. Although this is may be the case, it still does not rule out the potential for error in this region. Relative lack of landmarks in the thoracic region, for example, may lead to variance in the chosen path. Also, it was observed, that some subjects swayed slightly forwards while the device was guided through the thoracic region. It is
possible that these factors could have led to some discrepancies specifically in the thoracic spine.

**Conclusion**

Our spinal wheel and a Vicon motion analysis system demonstrated high to very high reliability in measuring the spine and pelvis in healthy individuals during sitting and standing. In addition, given the fact that low-load sitting and standing postures are thought to significantly contribute to low back pain in today’s society, this simple and user-friendly method could prove to be extremely valuable in terms of diagnosis and evaluation of rehabilitation outcomes. For example, spinal wheel could be very useful when evaluating NSLBP disorders, particularly when identifying particular subsets within LBP population based on current motor impairment classification models. Also, the device may be of value when evaluating assessing re-positioning accuracy in patients with low back pain.
References


Dankaerts, W. et al. 2006. Differences in sitting postures are associated with nonspecific chronic low back pain disorders when patients are subclassified. *Spine* 31(6), pp. 698-704.


Table 2. Intra-rater mean scores, standard deviation (SD) and intra-class correlation coefficients (ICC) for thoracic, spinal and pelvic measures in sitting and standing.

<table>
<thead>
<tr>
<th>Score 1 Mean (SD)</th>
<th>SITTING</th>
<th>STANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic</td>
<td>Lumbar</td>
<td>Pelvis</td>
</tr>
<tr>
<td>32 32 (12.96)</td>
<td>18.5 (14.2)</td>
<td>10.37 (6.94)</td>
</tr>
<tr>
<td>Score 2 Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32 32 (12.43)</td>
<td>18.7 (14.59)</td>
<td>10.47 (7.28)</td>
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<tr>
<td>Score 3 Mean (SD)</td>
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<td></td>
</tr>
<tr>
<td>32 32 (13.73)</td>
<td>18.67 (16.23)</td>
<td>9.86 (10.3)</td>
</tr>
<tr>
<td>ICC (r-value one rater)</td>
<td>0.993</td>
<td>0.987</td>
</tr>
<tr>
<td>ICC (r-value multiple rater)</td>
<td>0.995</td>
<td>0.979</td>
</tr>
</tbody>
</table>

Table 2. Inter rater mean scores, standard deviation (SD) and intra-class correlation coefficients (ICC) for thoracic, spinal and pelvic measures in sitting and standing.

<table>
<thead>
<tr>
<th>Rater 1 Mean (SD)</th>
<th>SITTING</th>
<th>STANDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic</td>
<td>Lumbar</td>
<td>Pelvis</td>
</tr>
<tr>
<td>34.20 (13.01)</td>
<td>18.63 (15)</td>
<td>10.24 (8.17)</td>
</tr>
<tr>
<td>Rater 2 Mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.02 (14.27)</td>
<td>19.79 (15.1)</td>
<td>20.28 (9.3)</td>
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<tr>
<td>Rater 3 Mean (SD)</td>
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<tr>
<td>35.78 (14.24)</td>
<td>14.63 (12.69)</td>
<td>20.3 (8.64)</td>
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<tr>
<td>ICC r-value</td>
<td>0.994</td>
<td>0.979</td>
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Table 3. Test re-test mean scores, standard deviation (SD) and intra-class correlation coefficients (ICC) for thoracic, spinal and pelvic measures in sitting and standing.

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<th>SITTING</th>
<th>STANDING</th>
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<tr>
<td></td>
<td>Thoracic r-value</td>
<td>Lumbar r-value</td>
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<td>Day 1 Mean (SD)</td>
<td>34.26 (13.01)</td>
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<td>Day 2 Mean (SD)</td>
<td>31.20 (9.64)</td>
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<td>ICC r-value</td>
<td>0.98</td>
<td>0.921</td>
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Table 4. Comparison of lumbar lordosis and thoracic kyphosis mean angular values in this study with mean angular values reported in literature using other methods of measurement.

<table>
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<th>Study</th>
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<th>Lumbar lordosis (°) Region measured</th>
<th>Thoracic kyphosis (°) Region measured</th>
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<td>Spinal Wheel©</td>
<td>31 (T12-S1)</td>
<td>30 (C7-T12)</td>
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<td>Mannion et al (2004)</td>
<td>Spinal Mouse©</td>
<td>32 (T12-S1)</td>
<td>45 (C7-T12)</td>
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<td>Isotrack</td>
<td>31 (L1-S1)</td>
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<td>Hultman et al (1999)</td>
<td>Debrunner Kyphometer</td>
<td>33 (L1-S1)</td>
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<td>Inclinometers</td>
<td>24-28 (T12-S1)</td>
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<td>Spinal pantograph</td>
<td>28 (T12-S1)</td>
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<td>Ng et al (2001)</td>
<td>X-ray Cobb angle</td>
<td>67 (T1-T12)</td>
<td>40 (T1-T12)</td>
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<td>Bergennud et al (1989)</td>
<td>X-ray Tangent circles technique</td>
<td>62.5 (T1-T12)</td>
<td>36 (T1-T12)</td>
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<td>Ravishankar et al (1998)</td>
<td>Xray</td>
<td>-</td>
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1. A non-invasive device for measuring spinal curvature comprising a wheel member attached to a handle in such a fashion that the wheel member is free to rotate when travelling along a surface to be measured and at least one reflective marker attached to, or integral with, the centre or near centre of the wheel.

2. A device as claimed in claim 1 further including an electro-magnetic signal generator for sending an electro-magnetic signal to the reflective marker, which in use reflects the signal when the wheel travels in a path across the surface to be measured.

3. A device as claimed in claim 2 further including a camera or other means for capturing and recording an image of the reflected signal as the wheel moves along the path.

4. A device as claimed in any one of the preceding claims wherein, the reflective marker reflects electromagnetic radiation in the form of visible light and said camera or other means records one or a series of images of the path traced by the marker, as the wheel travels along the path.

5. A device as claimed in claim 4 further including apparatus for storing and analysing the captured image or images to determine spine curvature.

6. A device as claimed any one of claims 1 to 3 wherein, the reflective marker reflects a selected wavelength or wavelengths of electro-magnetic radiation

7. A device as claimed in claim 6 wherein the selected wavelength is a coloured light or infra-red.
8. A device as claimed in any one of the preceding claims wherein, the wheel member has a radius greater than 2 cm.

9. A device as claimed in claim 8 wherein the wheel member has a radius greater than 4 cm.

10. A device as claimed in claim 9 wherein the wheel member has a radius greater than 5 cm.

11. A device as claimed in any one of the preceding claims wherein the wheel member has a radius which is able to protrude above any muscle or fat issue covering, or on either side of, the spinal column so that when the wheel traces its path along the spine a part thereof protrudes above the surface of any tissue.

12. A device as claimed in any one of the preceding claims wherein the said reflective marker, positioned at or near the centre of the wheel, extends across the surface of the wheel by an amount that ensures that the marker protrudes above the surface of any human tissue when the wheel is made to trace a path along, over, by, or against the spinal column.

13. A device as claimed in any one of the preceding claims wherein the reflective marker is made from material which reflects light or heat energy.

14. A device as claimed in any one of the preceding claims wherein, the marker is provided on both sides of said wheel and is in the form of a dot or disc extending outwards from the centre of the wheel in an axial direction.

15. A device as claimed in claim 14 wherein, the marker is the same size and shape on both sides of the wheel.
16. A device as claimed in any one of the preceding claims wherein, the wheel may be provided with a locking mechanism to prevent rotation when the wheel has reached a preselected position.

17. A system for measuring spinal curvature comprising a non-invasive device as claimed in any one of the preceding claims and associated camera and recording means whereby an image or images of the path travelled by the device over a selected spinal region can be recorded, and stored for future assessment.

18. A system for measuring spinal curvature wherein, the system also includes software for analysing the image or images recorded or stored.

19. A method for measuring spinal curvature comprising:

   a) tracing a path alongside or over the centre of the spine or spinal groove of an individual from a first selected position to a second selected position at a predetermined distance therefrom using a non-invasive device comprising a wheel member rotatably attached to a handle wherein the wheel member has at least one reflective marker attached to, or integral with the centre or near centre of the wheel;

   e) exposing said marker to an electromagnetic signal;

   f) recording the reflection of said signal from said marker using a recordal device;

   g) processing said recorded signal to obtain information concerning the path of travel of said marker from said first to said second positions whereby information concerning said path of travel provides information concerning spinal curvature of said individual.
20. A method as claimed in claim 19, wherein, said first position is just below, or at, S1 spinous process or vertebrae S1 and said second position is just above, or at, the occipital groove, or vice versa.

21. A method as claimed in claim 19 or 20 wherein, the steps a) to c) at least are repeated for different spinal articulations.

22. A method as claimed in any one of the preceding claims 19 to 21 wherein, the tracing of the path is carried out manually.

23. A device, system or method substantially as described herein with reference to the drawings.
Fig. 3
Intra-rate mean scores of spinal and pelvic measures in sitting and standing

Fig. 4
Fig. 5

Inter-rater scores for spinal and pelvic measures in sitting and standing.
Fig. 6

Test re-test scores for spinal and pelvic measures in sitting and standing

Day 1  Day 2

Pelvis

Lumbar

Thoracic

SITTING  STANDING
# INTERNATIONAL SEARCH REPORT

## A. CLASSIFICATION OF SUBJECT MATTER

**INV. A61B5/107**

According to International Patent Classification (IPC) or to both national classification and IPC.

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched.

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
<th>Citation of document, with indication, where appropriate of the relevant passages</th>
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<td>4, 5, 8-12, 16, 17, 19-22</td>
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Further documents are listed in the continuation of Box C

* Special categories of cited documents
  * "A" document defining the general state of the art which is not considered to be of particular relevance
  * "E" earlier document but published on or after the International filing date
  * "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  * "O" document referring to an oral disclosure, use, exhibition or other means
  * "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"A" document member of the same patent family

Date of the actual completion of the international search

9 February 2009

Date of mailing of the international search report

23/02/2009

Name and mailing address of the ISA/ European Patent Office, P B 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel (+31-70) 340-2040

Fax (+31-70) 340-3016

Authorized officer

Mohrs, Sascha

Form POT/ISA/210 (second sheet) (April 2005)
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<td>EP 0 251 911 A (MENETRIEUX STEPHANE [FR]; CHAMAILLARD GUY [FR]; MENETRIEUX CLAUDE [FR]) 7 January 1988 (1988-01-07) abstract figures 1-3 column 1, line 48 - column 2, line 31 column 2, line 45 - column 3, line 2 column 3, line 20 - column 3, line 58 column 5, line 7 - line 20</td>
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<td>WO 85/05175 A (RIJLAARSDAM CORNELIS ELIZABETH) 21 November 1985 (1985-11-21) abstract figure 5 page 5, line 20 - line 30</td>
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<td>DE 44 02 562 A1 (SEICHERT NIKOLA DR RER NAT [DE]) 3 August 1995 (1995-08-03) abstract figures 9-12 column 4, line 42 - line 47 column 6, line 6 - column 10, line 16 column 11, line 23 column 12, line 1 - line 41</td>
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</table>
INTERNATIONAL SEARCH REPORT

Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23 because they relate to subject matter not required to be searched by this Authority, namely:

   Rule 6.2 References to Other Parts of the International Application

2. [ ] Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.

Remark on Protest

- [ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- [ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- [ ] No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (April 2005)
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<td>DE 69408452 T2</td>
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