(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) **World Intellectual Property Organization**
International Bureau

(43) **International Publication Date**
17 May 2001 (17.05.2001)

PCT

(10) **International Publication Number**
WO 01/34016 A2

(51) **International Patent Classification⁷:** **A61B**

(21) **International Application Number:** PCT/IB00/01609

(22) **International Filing Date:**
6 November 2000 (06.11.2000)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) **Priority Data:**
60/164,467 10 November 1999 (10.11.1999) US

(71) **Applicant** *(for all designated States except US)*: **EEG, LTD.** [ZA/ZA]; 38 De La Rey Street, Observatory, 2198 Johannesburg (ZA).

(72) **Inventors; and**
(75) **Inventors/Applicants** *(for US only)*: **ELVIN, Alex** [ZA/ZA]; 38 De La Rey Street, Observatory, 2198 Johannesburg (ZA). **ELVIN, Niell** [US/US]; PO Box 397123, Cambridge, MA 02139 (US).

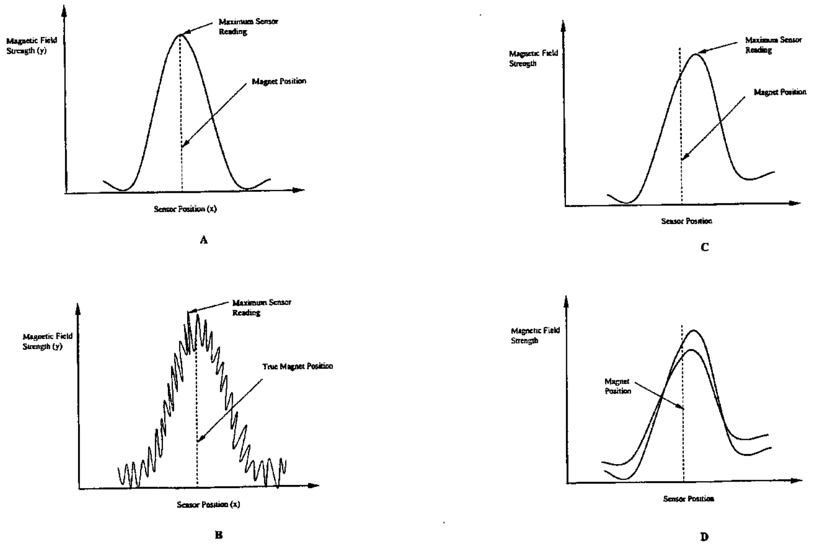
(81) **Designated States** *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** METHOD FOR LOCATING HOLES IN ORTHOPAEDIC DEVICES



(57) **Abstract:** A method for locating holes in orthopaedic devices, consisting of a mechanical arm which is able to sweep over the plane of deformation of the orthopaedic device. A magnet is rigidly attached to the orthopaedic device and a plurality of magnetic sensors which are attached to the moveable rigid arm are used to sense the magnetic field strength. The outputs of the magnetic sensors as well as a position sensor attached to the moveable arm are in communication with a central processing unit which is able to store and process the acquired data. The central processing unit is capable of subtracting the magnetic sensor outputs, curve fitting the acquired data and indicating the position of the maximum magnetic field which corresponds to the position of the magnet. Once the position of the magnet is located, a drill template connected to the mechanical arm is used to drill the holes.

WO 01/34016 A2

METHOD FOR LOCATING HOLES IN ORTHOPAEDIC DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

Not applicable

BACKGROUND –FIELD OF INVENTION

This invention relates a method of locating holes in orthopaedic devices, specifically to aid positioning screws for orthopaedic hardware such as intramedullary nails.

BACKGROUND—DESCRIPTION OF PRIOR ART

Orthopaedic devices that are inserted into the intramedullary canal have become a standard method of treating various conditions of long bones, for example to stabilize complex fractures of the femur, and tibia. One such device, known as the intramedullary nail (IM nail), typically requires fixation to the bone by means of screws. Since the nail lies in the hollow intramedullar canal, the screw holes in the nail cannot be seen from outside the bone. In general, when the nail is driven into the intramedullary canal it becomes distorted and this geometric matching from outside the body cannot be done. Great accuracy is needed in drilling the holes through the bone that match the holes in the nail to prevent any of the nail material being damaged during drilling and thus possibly affecting the healing process.

Several positioning devices have been proposed. Below the mode of operation of these devices will be discussed briefly:

(a) The most common method of locating the holes in the nail is by means of an X-ray apparatus (often called an image intensifier). In this method the holes are located by position the image intensifier directly in-line with the holes. The surgeon then aligns the drill with the axis of the image intensifier to drill the holes. The problem with this technique is that it requires accurate positioning of the large and bulky image intensifier with the holes and great skill from the person performing the operation to align the drill with the image intensifier. A further drawback is that the radiation of the high intensity image converter has serious disadvantages to its continued use by the medical personnel. Still a further drawback of this technique is that operating time increases due to the above mentioned problems with this method.

(b) In order to overcome the above mentioned disadvantage with the traditional method a rigid mechanical fixation has been proposed that is fixed to one end of the nail. This location instrument includes a drilling jig with guide holes that are geometrically matched to the screw holes in the nails. The problem with this method of hole location is that the nail undergoes deformation during insertion into the bone in order to conform with the bone's geometry. This deformation is sufficient to misalign the holes in the drilling jig with the holes in the nail.

(c) Magnetic location methods have also been proposed. In these methods magnets (or other sources of magnetic radiation such as inductive coils) are positioned with a probe down hollow nails and aligned with the holes in the nail. The magnetic field is then detected by means of an external magnetic sensor that indicates the position of the hole.

In general the magnetic location method has problems with trying to align the drill with the 4 degrees of freedom (namely 2 translations and two rotations) by free-hand while looking at a computer monitor display. These methods are thus highly susceptible to hand-jitter making them difficult and time consuming to use. Furthermore, each hole has to be individually located and drilled, i.e. a template is not used to locate subsequent holes after the first drill hole is located. Since certain nails do not deform in the axial or torsional mode (due to their closed cross-section) movable mechanical jigs (that account for the bending deformation of the nail) have been proposed that eliminate hand jitter problems

However, to-date this method has unsuccessful since in order to overcome such effects as ambient magnetic noise and the effect of the earth's magnetic field, the generated magnetic field must be very large compared to these error sources. For example, Figure 1A shows the ideal magnetic field strength with drill jig position when moving along one axis transverse to the magnet. It can be seen that the position of the maximum magnetic strength corresponds to the position of the magnet (and this the drill hole). However, Figure 1B shows the effect of ambient magnetic field (for example due to the earth). It can be seen that in general this causes a distortion of the field and introduces error in the measurement. Similarly the effect of ambient magnetic noise (such as from operating room machinery) can be seen in Figure 1C. n this case the magnetic noise can also significant sources of error when the signal-to-noise ratio is small. Thus to minimize the errors caused by ambient magnetic fields and noise, previously larger signal strengths have been used (i.e. magnetic field strengths much larger than the ambient magnetic field of noise).

Such large sources of magnetic field require either very large and powerful magnets or relatively large inductive currents. Both sources of magnetic field require probes to be placed down the hollow nail, which in turn means that the cross-section of the nail has to allow for the positioning of the probe and might not necessarily be biomechanically optimum. Further, the use of probes means that the person performing the operation needs to drill and place the distal screws first, before moving to the proximal screws. This requires as yet an unproven change in surgical technique which many surgeons are unwilling to adopt.

(d) Although several other methods of hole location have been tried, they in general either require very expensive equipment or suffer from the same problems as discussed above.

SUMMARY

In accordance with the present invention a method of overcoming magnetic noise and earth magnetic field distortions by means of dual magnetic sensor system and theoretical calculation.

Objects and Advantages

Accordingly, several advantages of the present invention are:

(a) to reduce the radiation exposure required for hole location that the medical personal will be subjected to during the operation;

(b) to reduce the time required to locate the holes;

(c) to provide a drilling capable of taking into account the flexural deflections of the nail, but nevertheless to remove the problem of hand-jitter associated with other "free-hand" techniques;

(d) to provide a means of overcoming the ambient drift problem associated with other magnetic hole targeting techniques;

(e) to provide a means of overcoming magnetic noise problems that can introduce errors in magnetic hole targeting;

(f) to allow for hole location in various cross-sectional nails (including solid nails) without the use of a nail probe;

(g) to allow for the location and drilling of the holes in any sequence that the person performing the operation chooses;

(h) to allow the drilling of a succession of drill holes once the first drill hole is located.

It must be noted that the method presented herein is general and can also be readily used with a probe.

DRAWING FIGURES

In the drawings, closely related figures have the same number but different alphabetic suffixes.

Figure 1A to 1D show typical magnetic field strength with position graphs including the effects of ambient magnetic fields and noise.
Figure 2 shows the hole locator jig, nail with associated electronics
Figure 3A to 3B show various embodiments of the mechanical jig to account for deflection of the nail
Figure 4 shows a detail of the magnet, magnetic field, and sensor configuration

Figure 5 shows a flow-chart of the algorithm required to minimize the effect of the ambient magnetic field and noise

Reference Numerals in Drawings

10	Bone
12	Intramedullary Nail
14	Orthopaedic Screws
16	Drill Hole
18	Magnet
20	Magnetic Field Sensors
22	Central Processing Unit with Display Unit
24	Position Sensor
26	Sweeping Mechanism
28	Mechanical Arm
30	Sensor Connecting Wire
32	Drill Sleeve
34	Mechanical Connector between Intramedullary Nail and Mechanical Jig
36	Direction of Mechanical Sweep
40	Magnetic Field

DESCRIPTION – Figs. 1A and 1D – Typical Magnetic Field Strength

Fig 1A is a typical idealized curve showing the variation of magnetic field (y) strength with position from the magnet (x) when a magnetic field sensor 20 such as shown in Figure 4 sweeps over a magnet 16 as shown in Figure 3 in the sweep direction 36. In this idealized curve, the maximum magnetic field corresponds to the position of the magnet. Conventional methods have relied on detection of the peak value of the curve to locate the magnet position. However others in the field US 5,584,838 have shown that detecting the peak value is difficult due to the flatness of the curve at that point. US 5,584,838 thus suggests using points with greater slope for detecting the position of the magnet. It must be noted that the discussion presented in Figures 1B and 1C are applicable to detection of both peak and off-peak values.

Figure 1B shows the effect of ambient magnetic field (such as that of the earth) on the idealized curve of the strength of the magnetic field shown in Fig. 1A. The ambient magnetic field has the effect of shifting the idealized curve so that the maximum magnetic field no longer corresponds to the position of the magnet. (The same is true for locating points off the maximum as described in Fig. 1A).

Figure 1C shows the effect of magnetic noise (such as from operating room equipment) on the idealized curve of the strength of the magnetic field shown in Fig. 1A. It can be seen that the maximum point is difficult to locate and can correspond to points on the curve with higher noise levels.

Figure 1D shows two magnetic field curves (with the effect of ambient magnetic field only) corresponding to increasing distance from the magnet. It can be seen that in general the magnetic field can change significantly with distance from the magnet and the peaks of the two curves may not necessarily be coincident. In general this figure also shows the problem with “free-hand” techniques since it is virtually impossible for the operator to keep their hand steady (with respect to distance from the magnet), the field strength tends to continuously change making it difficult to use the device.

Figure 2 and 4 – General Locator Concept

Figure 2 shows the general locating method. After the nail 12 has been inserted into the bone 10, the moveable targeting jig 28 is rigidly attached to the proximal end of the nail through a mechanical coupling 34. It is assumed that the nail is torsionally rigid and only deflects in the bending plane. The jig thus constrains all movement except in the direction of the bending as shown in Figure 3A. Figure 3B shows an alternative embodiment of the sweeping mechanism. A magnet 18 is attached to the nail near the location of the holes that need to be drilled. The magnetic field from the magnet 18 is detected by magnetic sensors 20. The magnetic sensor information are stored and processed in the central processing unit 22. A position sensor 24 such as an encoder is used to measure the position of the moveable arm, and is connected through a wire 30 to the central storage and processing unit 22. After the position of the magnet is located, a drill sleeve 32 is attached to the moveable arm 28 that allows for the drilling of the nail holes 16. It must be noted that once the magnet 18 has been detected, all drill holes 16 can be located at the same time by providing a template of holes on the moveable mechanical arm 28 that match the holes in the nail 16.

Figure 4 shows the detail of the locator operation near the position of the magnet. A display unit on the central processing unit 22 such as the Left 22a, Right 22c and Stop 22b LEDs informs the surgeon in which direction to move the arm and when the magnet has been located.

In general the system will operate as follows. After insertion of the nail 12 into the bone 10, the moveable rig 28 is attached to the nail. The central processing unit 22 is then attached to the rig. The position sensor 24 is attached to the rig and connected to the central processing unit 22 through a connecting wire 30. The central processing unit 22 is switched on. The operator then does one calibration sweep over the whole range of allowable movement of the arm. The position and sensor data is collected and processed in the central processing unit 22. Calculations are continuously performed by the central processing unit 22 as described in Figure 6. After the magnet position has been calculated, the display panel then indicates to the operator in which direction he/she needs to move the arm by the central processing unit LEDs (22a to 22 c).

An audible and visual signal (such as a buzzer and the STOP LED 22b) are activated by the CPU when the correct position is reached. The operator then attaches the drill sleeve 32 and drills the holes.

Figure 6 Flow Chart for Calculating Magnet Position

Figure 6 shows the flow-chart for calculating magnet location. The steps consist of acquiring the arm sweep position (x) using a position sensor such as an encoder. Magnetic field strengths (y_1, y_2, y_3, etc.) are sensed at various distances from the magnet using magnetic sensors such as magnetometers. Information for the sensor position (x) and magnetic strengths (y_i) are sent to the central processing unit. In general the magnetic field consists of components due to the magnetic field of (a) the locator magnet, (b) ambient magnetic fields such as those of the earth, and (c) magnetic noise such as those caused by electrical equipment.

Since the sources of the ambient magnetic field and magnetic noise occur relatively far from the sensors (as compared with the locator magnet which can be considered as a "near-field" magnetic source), the effect of the "far-field" magnetic fields will be constant for all magnetic sensors. The "near-field" magnetic field strength due to the locator magnet however will rapidly decrease with distance from the locator magnet. By subtracting the magnetic field strength from various pairs of magnetic sensors (say for example between magnetic sensors (1) and (2)), the magnetic "far-field" effects will cancel each other out leaving only the effect of the locator magnet. The subtraction of the electrical signals from the magnetic sensors is a standard electrical engineering technique and can be performed either through software or hardware in the central processing unit. The subtracted electrical signals from the various pairs of sensors are labeled Y_1, Y_2, etc. in Figure 5 and are similar to the one shown in Figure 1A.

The subtracted signals (Y_1 to Y_k) are then mathematically approximated using least square polynomial fitting. Other mathematical fitting techniques (for example Gaussian and Lorentzian curves) can also be used. For polynomial fitting the magnetic field for sensor (i) is modeled using

$$Y_i = A_i x^n + B_i x^{n-1} + \ldots + Z_I$$

Where Y is the mathematically derived magnetic field strength, x is the sensor position, n is the order of the polynomial approximation, and A_i to Z_i are the coefficients of the polynomial.

Figure 1A shows that the ideal magnetic field should be symmetrical about the location of the magnet center. However, the polynomial Y_i includes both even (symmetric) and odd (anti-symmetric) terms. The odd terms are due to small, residual ambient magnetic fields that have not been completely cancelled by the magnetic subtraction routine. By ignoring the anti-symmetric parts of the polynomial fit, the effect of the ambient magnetic fields can be still further reduced. reducing the mathematical magnetic field to the symmetric magnetic field Y_i^*.

The maximum position of the curves Y_i^* then correspond to calculated position of the locator magnet. Due to errors in the sensors, position and residual magnetic fields, the magnet position calculated for the various sensor combinations will not be exactly the same. A more accurate estimate of the magnet position can be derived by calculating a weighted average of all estimated magnetic positions. The weighting factors (w_i) can take on various forms, one example is to relate the weighting factors to the distance of the sensor from the magnet.

Conclusion, Ramifications and Scope

Accordingly, the reader will see that the magnetic, hole targeting method of this invention can be used to locate the holes in orthopaedic hardware without the errors associated with ambient magnetic signal or magnetic noise. In addition, the method allows for the rapid location of the holes without need of interpretation by the person performing the operation. Furthermore, the hole locating method has the additional advantages in that

- it does not require the use of x-rays for image enhancement, thus reducing the medical staff's exposure to harmful radiation;
- it takes into account the deflection of the orthopaedic device during insertion by providing a movable rigid arm which can sweep over the possible range of nail deflection.
- it provides a rigid drill guide thus eliminating the problem of hand-jitter;
- due to the geometric matching between the moving mechanical sweeping arm and the nail, it allows all closely spaced holes to be drilled after the first hole

location, thereby reducing the operation time required to locate each hole individually;

- it allows for the locating of holes in solid nails without the use of a probe;
- it allows the person performing the operation to drill holes in any sequence and not the distal holes first as is required by several existing methods requiring probes.
- It allows for the person performing the operation to drill all holes using a template on the moveable rigid once the magnet is located, thereby reducing the time it takes to locate each hole individually.

Although the description above contains many specifications, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. For example, the method can have other rigid arm sweeping methods; other magnetic sensors; other position sensors, such as potentiometers, rotary switches, etc.; and even other sources of magnetic fields such as inductive coils.

Thus the scope of the invention should be determined by the appended claims and their legal equivalents, rather than by the examples given.

Claims

1. Assembly for positioning a drill guide (32) for a intramedullary nail carrying a magnetic field source aligned with holes in the nail, comprising:
   - coupling means (34) adapted to be coupled to the intramedullary nail inserted into a bone,
   - support means (28) adapted to be attached to the coupling means and providing support for one or more magnetic sensors (20), the magnetic sensors (20) being movable in a direction (36) essentially transverse to the extension of the intramedullary nail coupled to the coupling means,
   - a position sensor (24) for sensing the position of the magnetic sensors with respect to the coupling means,
   - a processing unit (22) receiving the sensed data of the magnetic sensors and of the position sensor, wherein the processing unit determines the position of the magnetic field source from data sensed in at least two different positions of the magnetic sensors,
   - and indicator means being in communication with the processing means for indicating the position of the support means with respect to the magnetic field source such that the drill guide attached to the support means being aligned with the holes of the intramedullary nail.

2. Assembly of claim 1, wherein the support means (28) comprise a rigid arm (28), pivoted at the coupling means.

3. Assembly of claim 1, wherein the support means (28) comprise a rigid arm and a transverse guiding element (Fig. 3B) for guiding the magnetic sensors (20) transverse to the rigid arm.

4. Assembly according to one of the preceding claims, wherein the processing unit (22) uses subtracted signals from pairs of magnetic sensors whereby reducing the effect of ambient magnetic fields.

5. Assembly according to one of the preceding claims, wherein the processing unit collects the sensed data of the magnetic sensors and of the position sensor, wherein the processing unit fits the collected data to one or more determined curves to approximate the distribution of the magnetic field strength, and wherein the processing unit determines the position of the magnetic field source using one or more maximum values of the fitted curves for the magnetic field strength.

6. Assembly according to claim 5, wherein the processing unit uses polynomials as predetermined curves, preferably polynomials with even exponents.

7. Assembly according to claim 5 or 6, wherein the processing unit fits more than one polynomial curve to the sensed data.

8. Assembly according to claim 7, wherein the processing unit uses different maximum values from different fitted curves in a weighted sum in order to determine the position of the magnetic field source.

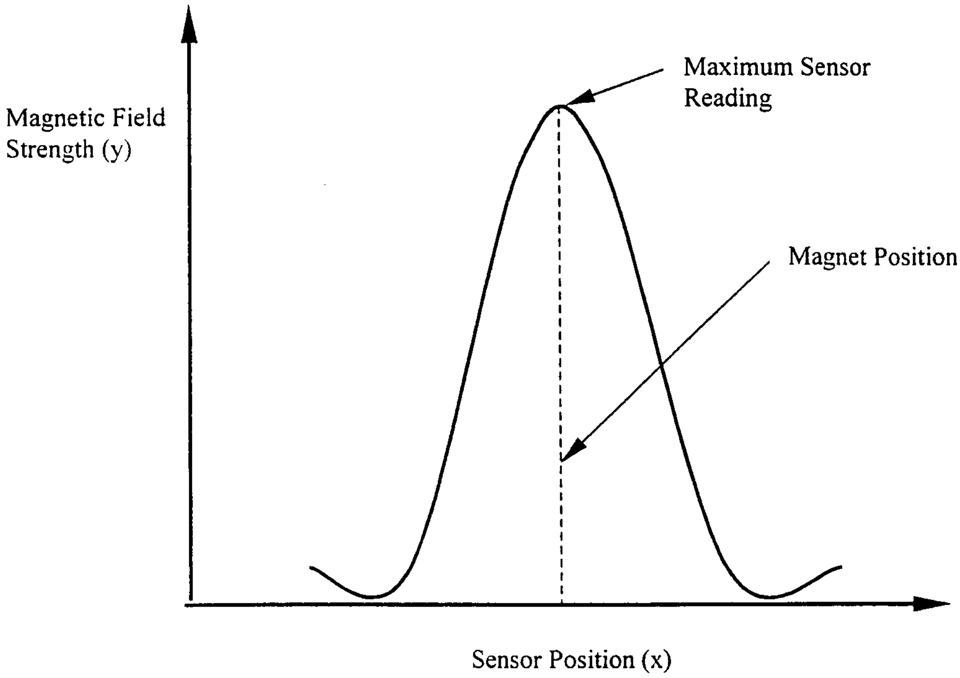

Maximum Sensor Reading
Magnetic Field Strength (y)
Magnet Position
Sensor Position (x)

FIG. 1A

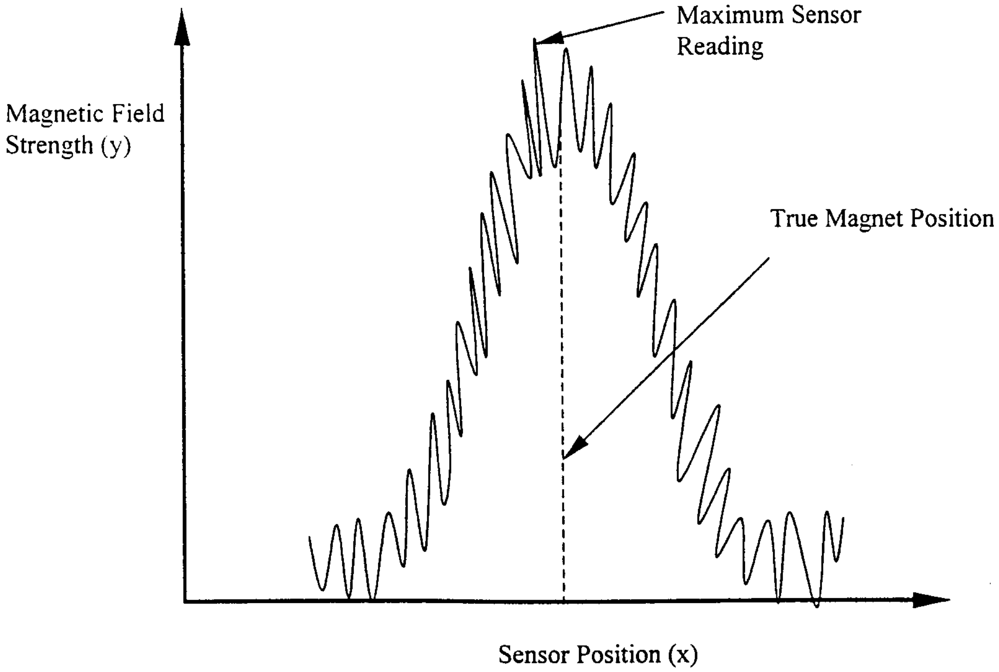

Maximum Sensor Reading
Magnetic Field Strength (y)
True Magnet Position
Sensor Position (x)

FIG. 1B

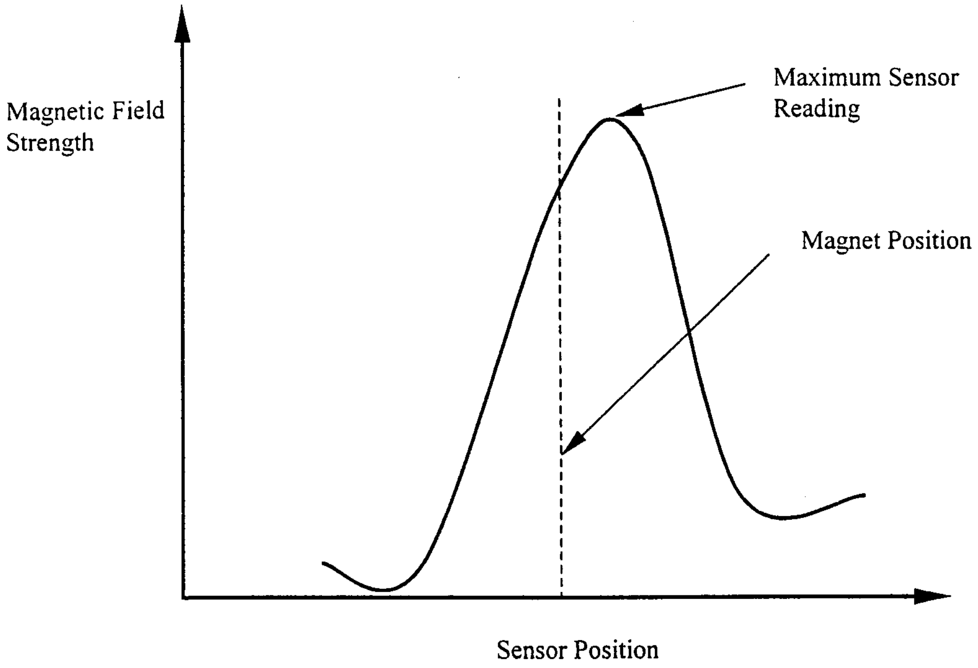

Magnetic Field Strength
Maximum Sensor Reading
Magnet Position
Sensor Position

FIG. 1C

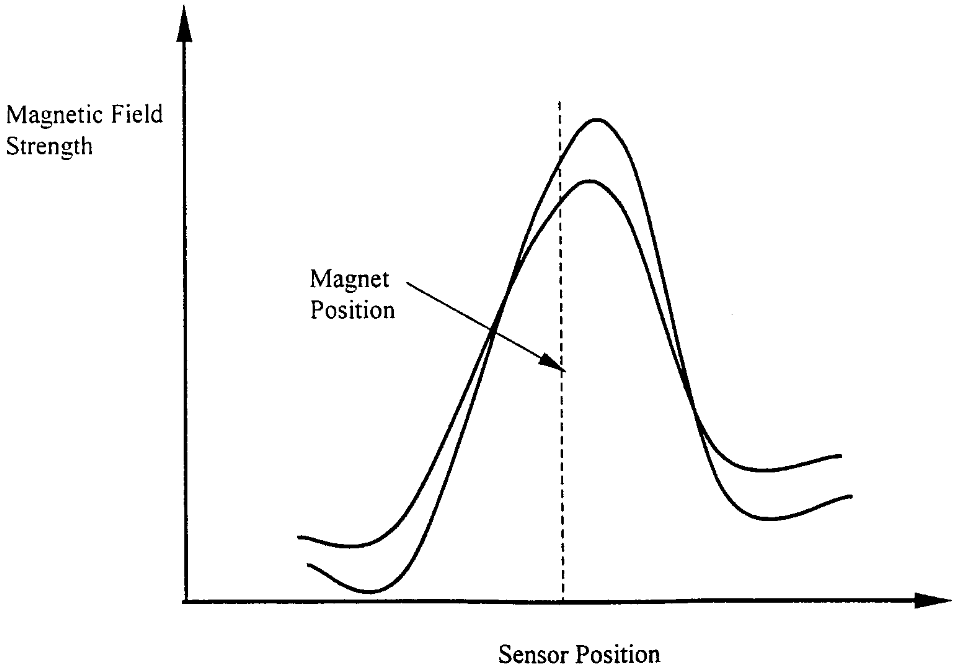

Magnetic Field Strength
Magnet Position
Sensor Position

FIG. 1D

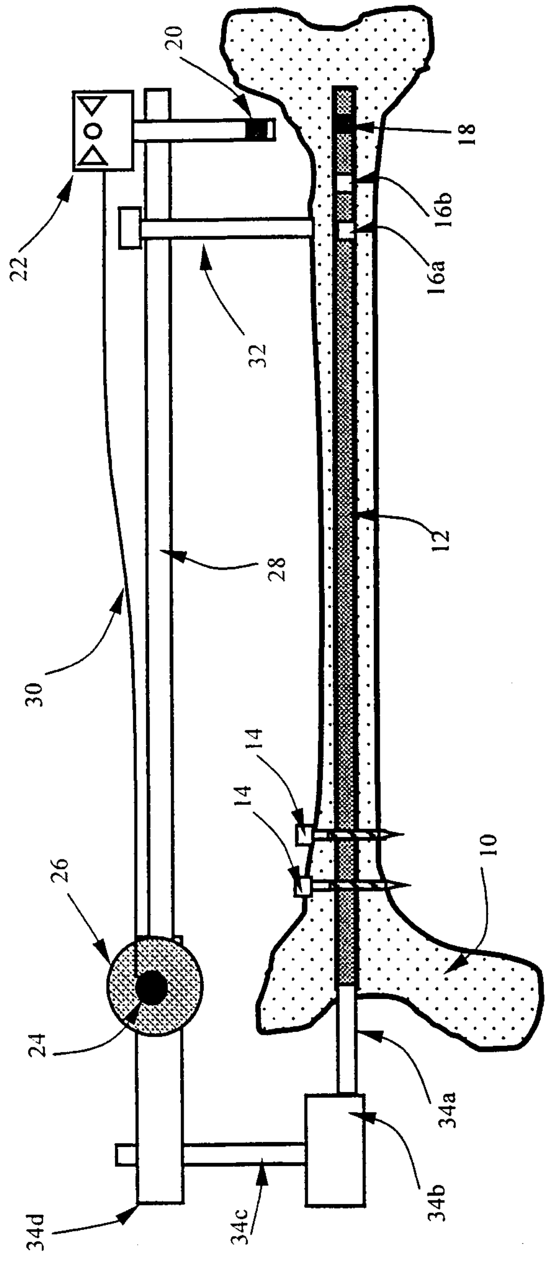

20
22
18
16b
16a
32
12
28
30
14
14
10
26
24
34a
34b
34c
34d

FIG. 2

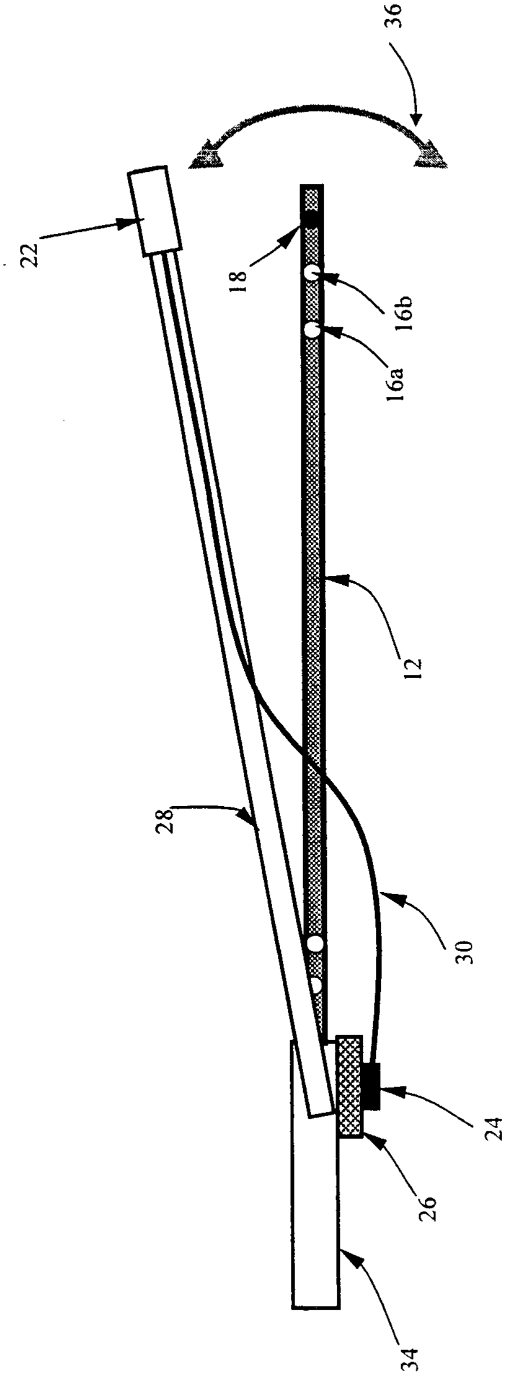

36
22
18
16b
16a
12
28
30
24
26
34

FIG. 3A

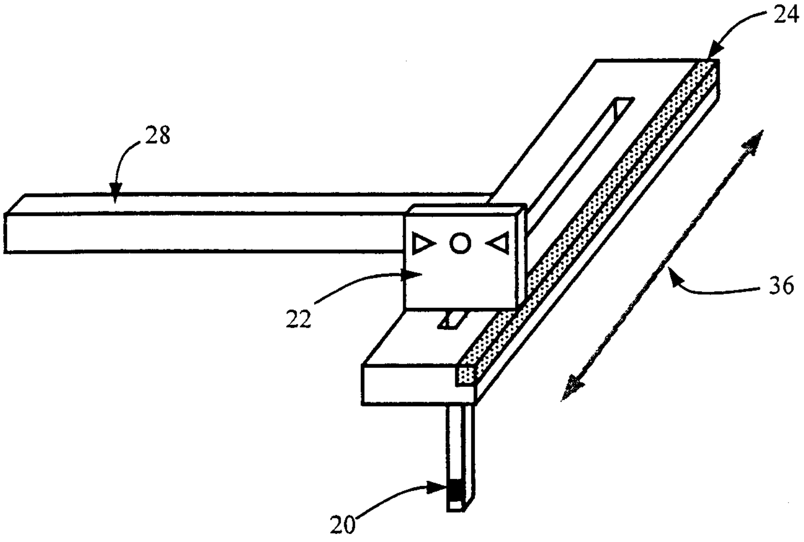


FIG. 3B

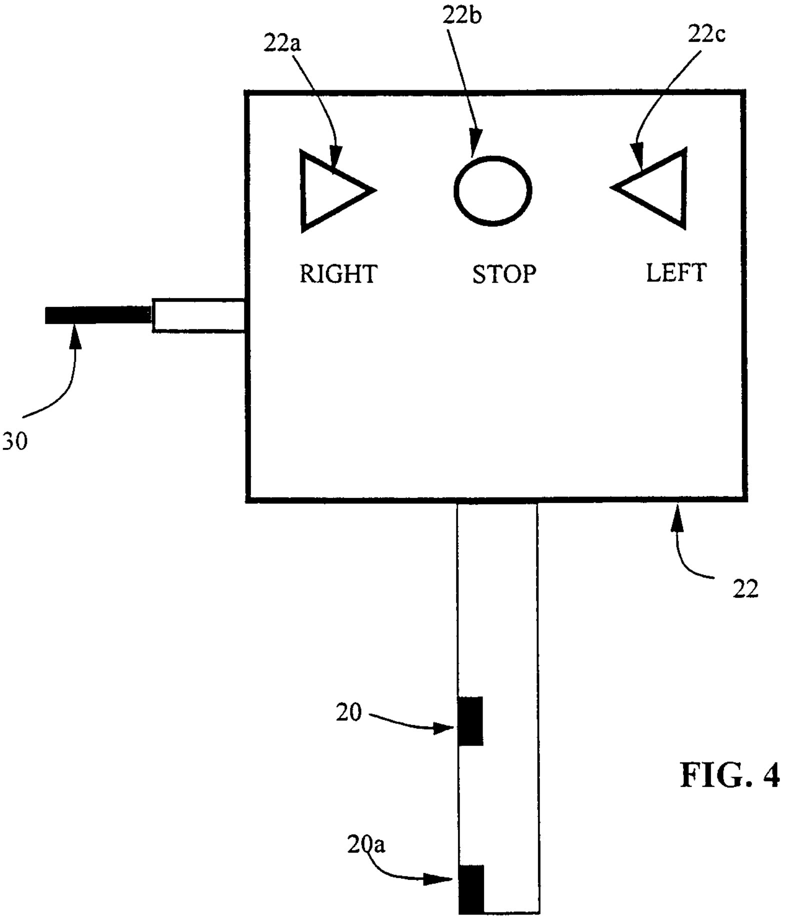


FIG. 4

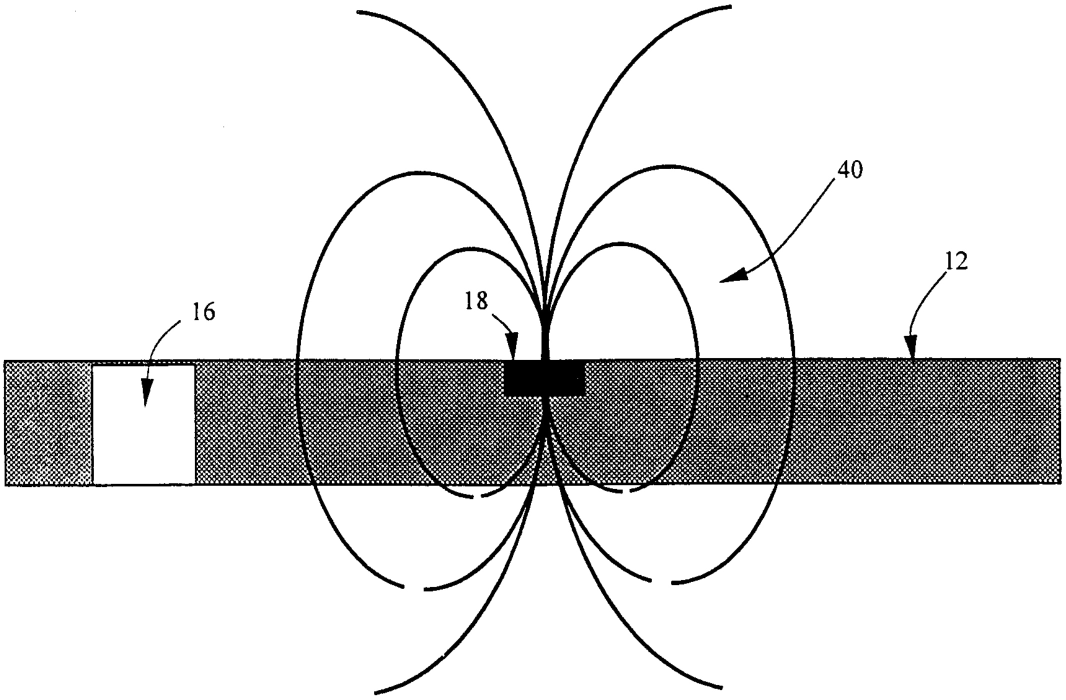


FIG. 5

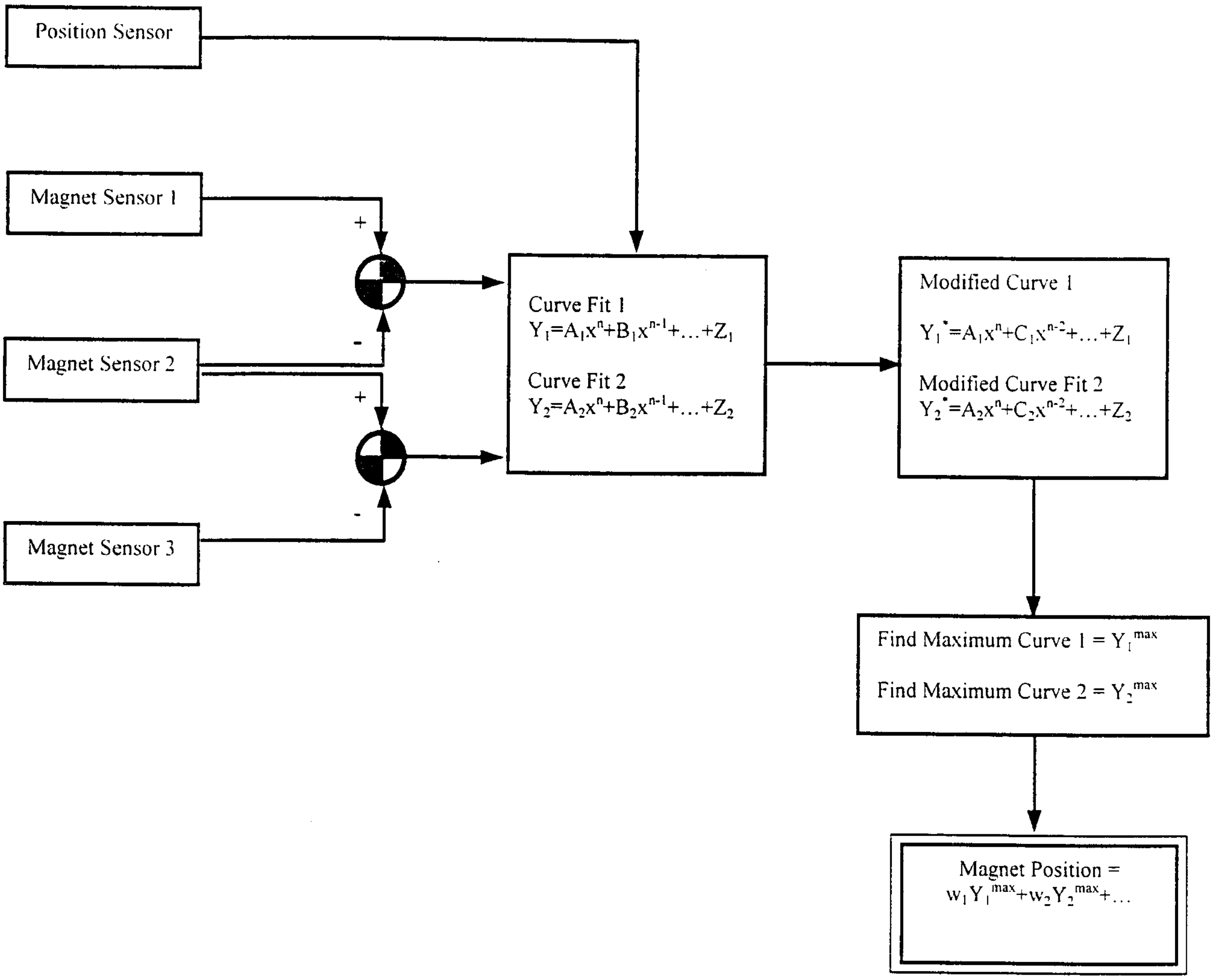

Position Sensor
Magnet Sensor 1
Magnet Sensor 2
Magnet Sensor 3
+
-
+
-
Curve Fit 1
$Y_1=A_1x^n+B_1x^{n-1}+\ldots+Z_1$
Curve Fit 2
$Y_2=A_2x^n+B_2x^{n-1}+\ldots+Z_2$
Modified Curve 1
$Y_1^*=A_1x^n+C_1x^{n-2}+\ldots+Z_1$
Modified Curve Fit 2
$Y_2^*=A_2x^n+C_2x^{n-2}+\ldots+Z_2$
Find Maximum Curve 1 = Y_1^{max}
Find Maximum Curve 2 = Y_2^{max}
Magnet Position =
$w_1Y_1^{max}+w_2Y_2^{max}+\ldots$

FIG. 6