Title: SYSTEM AND METHOD FOR REGISTERING A STRUCTURE USING FIBER-OPTICAL REALSHAPE DATA

(57) Abstract: A system and method for registering a structure (104) of a subject (103) to a coordinate system which includes a deformable registration device (102) having a deformable body (105) that features an optical fiber (108). A FORS system (110) measures a shape of the optical fiber when the deformable body contacts the structure of the subject to obtain positional points (106) for the structure. A pre-processing module (112) analyzes the positional points and determines which positional points are on-surface and off-surface with respect to the structure. A registration module (118) deletes the off-surface positional points and registers the device to the structure using the on-surface positional points. Positional points (142) from a shape (137) generated on a model which approximates points that would be measured by the deformable registration device of the structure may be combined with the positional points (106) acquired from the deformable body to provide an improved registration.
SYSTEM AND METHOD FOR REGISTERING A STRUCTURE
USING FIBER-OPTICAL REALSHAPE DATA

5 BACKGROUND:

Technical Field

This disclosure relates to medical devices and more particularly to a system and method for registration of a structure using Fiber-Optical RealShape™ data.

10 Description of the Related Art

Computer assisted surgery is frequently used to provide live navigational guidance during surgical procedures which allows for the optimal positioning of implants as well as improved intraoperative verification of the biomechanics of a structure. The registration of a structure of the subject, such as a bone or anatomy of interest, to the coordinate system of an imaging modality (e.g., CT, MRI, X-ray, etc.) or a real-world coordinate system is of vital importance for a computer assisted surgery. In order to register the structure to a coordinate system, the practitioner must hold the tip of a tracked pointer to certain landmarks on the anatomy, such as bony landmarks, and indicate to a computerized registration device when the pointer is at the designated landmark. After a series of landmark points are acquired in this fashion, a coarse registration is computed; the practitioner may also refine the registration by running the pointer over the surface, painting the anatomy and digitizing the surface into the tracking coordinate frame.

For example, in the current practice of registration in computer assisted surgery utilizing marker-based registration, fiducial markers need to be acquired in a certain order by the practitioner. In markerless registration or for refinement of the maker-based registration,
a series of points are sampled by sliding the tracked pointer on the surface of the bone.

These existing procedures are time-consuming because the tracked pointer must be moved to sample the desired number of landmarks. Furthermore, during this sampling procedure, the patient must remain still in order to avoid errors in the registration. The marker-based registration also requires the user to locate pre-defined fiducial markers in a particular order. Some tracking systems need one user to hold the pointer to sample the landmarks, and another user to operate the software for recording the sampling points. Sliding of the pointer over the surface of the structure similarly requires coordination between one user sliding the pointer and one user operating the software. Furthermore, the pointer may inadvertently disengage the surface during the sliding activity, introducing errors into the registration process. These factors prolong and complicate the workflow for an interventional procedure.

In order to provide a more efficient registration, a deformable registration device utilizing Fiber-Optical RealShape™ (also known as “Optical Shape Sensing”, “Fiber Shape Sensing”, “Fiber Optical 3D Shape Sensing”, “Fiber Optic Shape Sensing and Localization” or the like) may be used. A deformable registration device includes a deformable body that is configured to conform to the shape of the structure of the subject to be registered. The deformable registration device may further include an optical fiber for a Fiber-Optical RealShape™ (“FORS”) system which is configured to acquire a collection of samples along the surface of the deformable body in a single acquisition snapshot in order to obtain positional points for the structure.

A registration of the positional points obtained by FORS is performed to transform the positional points of the structure so that, for example, they correctly overlay the images of the structure obtained by the imaging modality. In order to ensure that the registration is
accurate, the deformable registration device must be flush against the structure of the subject. If the deformable registration device is not flush, point cloud/surface registration algorithms known in art, such as iterative closest point ("ICP") in its most widely used form, may provide errors in the registration. This is because ICP and other point cloud/surface registration algorithms use the cumulative Euclidean distance error between the input data sets as the optimization criterion and point samples that reside off of the surface of an object have large associated errors that lead to errors in the registration.

**SUMMARY**

In accordance with the present principles, a system for registering a structure of a subject to a coordinate system using FORS data includes a deformable registration device having a deformable body. The deformable body includes an optical fiber for a FORS system. The system further includes a FORS system that is configured to measure a shape of the optical fiber when the deformable body contacts the structure of the subject and obtain positional points for the structure. A pre-processing module is configured to analyze the positional points acquired by the FORS system and determine which positional points are on-surface and off-surface points with respect to the structure. A registration module is configured to delete the off-surface positional points and perform a registration using the on-surface positional points.

In another embodiment, a system for registering a structure of a subject to a coordinate system using FORS data includes a deformable registration device having a deformable body. The deformable body includes an optical fiber for a FORS system. A FORS system is configured to measure a shape of the optical fiber when the deformable body contacts the structure of the subject and obtain positional points for the structure. The system
further includes a workstation having one or more processors, memory and an interface. A pre-processing module is configured to analyze the positional points acquired by the FORS system and determine which positional points are on-surface and off-surface points with respect to the structure. A registration module is configured to delete the off-surface positional points and perform a registration using the on-surface positional points.

In another embodiment, a method for registering a structure of a subject to a coordinate system using FORS data includes the steps of placing a deformable registration device having a deformable body on a structure of the subject. Positional points for the structure are obtained by measuring a shape of the optical fiber using a FORS system. The positional points acquired by the FORS system are analyzed and a determination concerning which positional points are on-surface and off-surface points with respect to the structure is made. The off-surface positional points are deleted and the on-surface positional points are used to perform a registration.

These and other objects, features and advantages of the present disclosure will become apparent from the following detailed description of illustrative embodiments thereof, which is to be read in connection with the accompanying drawings.

**BRIEF DESCRIPTION OF DRAWINGS**

This disclosure will present in detail the following description of preferred embodiments with reference to the following figures wherein:

FIG. 1 is a block/flow diagram showing a system for registering a structure using FORS data in accordance with one illustrative embodiment;

FIG. 2 shows images of a deformable registration device held taut against the structure;
FIG. 3 shows images of the system determining on-surface and off-surface points using curvature detection;

FIG. 4 shows images of the contact sensing device on the structure;

FIG. 5 is a block/flow diagram showing a contact sensing device;

FIG. 6 shows images of a convex hull generated on a model of the structure and the deformable registration device positioned on the structure;

FIG. 7 shows images of a model of a structure and a convex hull generated from the model;

FIG. 8 shows images of an envelope generated on a model of the structure and the deformable registration device positioned on the structure;

FIG. 9 shows images of a correct alignment of the registration shape and the bone model and a misalignment of the shapes due to inclusion of off-surface points in registration;

FIG. 10 is a flow diagram showing a method for registering a structure using FORS data in accordance with one illustrative embodiment; and

FIG. 11 is a flow diagram showing a method for registering a structure using FORS data in accordance with another illustrative embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

In accordance with the present principles, a system for registering a structure using FORS data is provided. The system includes a deformable registration device having a deformable body that includes an optical fiber. The system further includes a FORS system configured to measure a shape of the optical fiber when the deformable body contacts the structure of the subject and obtain positional points for the structure. A pre-processing module is configured to analyze the positional points acquired by the FORS system and
determine which positional points are on-surface and off-surface points with respect to the
structure. A registration module is configured to delete the off-surface positional points and
register using the on-surface positional points.

The system allows for registration of the positional points acquired by the deformable
registration device without requiring the deformable device to be flush against the structure.
Positional points may be obtained from a shape generated on a model which approximates
points as would be measured by the deformable registration device when it is not flush
against the structure. The positional points obtained from the shape generated on a model
may be combined with the positional points acquired from the deformable body to provide an
improved registration. This provides a simpler, more efficient registration procedure for the
practitioner which requires less care and skill and improves the accuracy of the registration.

It should be understood that the present invention will be described in terms of
medical systems. However, the teachings of the present invention are much broader and in
some embodiments, the present principles are employed in complex biological or mechanical
systems. Furthermore, the present principles are applicable to internal procedures of
biological systems in all areas of the body such as the lungs, liver, brain, uterus, gastro-
intestinal tract, excretory organs, blood vessels, and any other solid organ tissue, tumor tissue
and homogenously or heterogeneously enhancing structures of the body. The elements
depicted in the FIGS. may be implemented in various combinations of hardware and software
and provide functions which may be combined in a single element or multiple elements.

The functions of the various elements shown in the FIGS. can be provided through the
use of dedicated hardware as well as hardware capable of executing software in association
with appropriate software. When provided by a processor, the functions can be provided by a
single dedicated processor, by a single shared processor, or by a plurality of individual
processors, some of which can be shared. Moreover, explicit use of the term “processor” or “controller” should not be construed to refer exclusively to hardware capable of executing software, and can implicitly include, without limitation, digital signal processor (“DSP”) hardware, read-only memory (“ROM”) for storing software, random access memory (“RAM”), non-volatile storage, etc.

Moreover, all statements herein reciting principles, aspects, and embodiments of the invention, as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents as well as equivalents developed in the future (i.e., any elements developed that perform the same function, regardless of structure). Similarly, it will be appreciated that various processes may be substantially represented in computer readable storage media and so executed by a computer or processor, whether or not such computer or processor is explicitly shown.

Furthermore, embodiments of the present invention can take the form of a computer program product accessible from a computer usable or computer-readable storage medium providing program code for use by or in connection with a computer or any instruction execution system. For the purposes of this description, a computer usable or computer readable storage medium can be any apparatus that may include, store, communicate, propagate, or transport the program for use by or in connection with the instruction execution system, apparatus, or device. The medium can be an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system (or apparatus or device) or a propagation medium. Examples of a computer readable medium include a semiconductor or solid state memory, magnetic tape, a removable computer diskette, a random access memory (RAM), a read-only memory (ROM), a rigid magnetic disk and an optical disk. Current examples of
optical disks include compact disk – read only memory (CD-ROM), compact disk – read/write (CD-R/W), Blu-Ray™ and DVD.

In accordance with the present principles, a system for registering a structure using FORS data is provided. Referring now to the drawings in which like numerals represent the same or similar elements and initially to FIG. 1, a system 100 includes a deformable registration device 102 which includes a deformable body 105 that is configured to conform to the shape of the structure 104 of the subject 103 to be registered.

As shown in FIG. 1, in one embodiment, the system 100 may include a workstation 101 from which the procedure is supervised and/or managed. The workstation 101 preferably includes one or more processors 107, memory 109 for storing programs and applications and a display 115 which permits a user to view images and interact with the workstation 101. The system 100 may further include an interface 123 which may feature a keyboard, mouse, a joystick, a haptic device, or any other peripheral or control to permit user feedback from and interaction with the workstation 101.

The deformable registration device 102 includes an optical fiber 108 for a FORS system. A Fiber-Optical RealShape™ system is a commercial name for systems developed by Koninklijke Philips, N.V. As used herein, the terms FORS and FORS systems are not, however, limited to products and systems of Koninklijke Philips, N.V., but refer generally to fiber optic(al) shape sensing and fiber optic(al) shape sensing systems, fiber optic(al) 3D shape sensing, fiber optic(al) 3D shape sensing systems, fiber optic(al) shape sensing and localization and similar technologies. FORS systems are also commonly known as “optical shape sensing systems”. FORS systems include one or more optical fibers 108 that are integrated within the registration device 102 in a set pattern or patterns. The FORS system is connected to a FORS interrogator device (not shown). In one embodiment, the optical fiber
may connect to a workstation 101 through cabling 117. The system may include a sensing
and interpretation module 113 that is configured to receive the FORS data 111 and interpret
this information. The FORS data 111 may be stored in the memory 109 of the system 100.

A FORS system uses light from the interrogator device along a multicore optical fiber
for providing FORS data concerning the shape of the optical fiber during a procedure such as
a surgical interventional procedure. The shape along the optical fiber begins at a specific
point along the sensor, known as the launch or zero position, and the subsequent shape
position and orientation are relative to that point.

The FORS system 110 with fiber optics may be based on fiber optic Bragg grating
sensors. A fiber optic Bragg grating (FBG) is a short segment of optical fiber that reflects
particular wavelengths of light and transmits all others. This is achieved by adding a periodic
variation of the refractive index in the fiber core, which generates a wavelength-specific
dielectric mirror. A fiber Bragg grating can therefore be used as an inline optical filter to
block certain wavelengths, or as a wavelength-specific reflector.

A fundamental principle behind the operation of a fiber Bragg grating is Fresnel
reflection at each of the interfaces where the refractive index is changing. For some
wavelengths, the reflected light of the various periods is in phase so that constructive
interference exists for reflection and, consequently, destructive interference for transmission.
The Bragg wavelength is sensitive to strain as well as to temperature. This means that Bragg
gratings can be used as sensing elements in fiber optical sensors. In an FBG sensor, the
measurand (e.g., strain) causes a shift in the Bragg wavelength.

One advantage of this technique is that various sensor elements can be distributed
over the length of a fiber. Incorporating three or more cores with various sensors (gauges)
along the length of a fiber that is embedded in a structure permits a three-dimensional form of
such a structure to be precisely determined, typically with better than 1 mm accuracy. Along
the length of the fiber, at various positions, a multitude of FBG sensors can be located (e.g., 3
or more fiber sensing cores). From the strain measurement of each FBG, the curvature of the
structure can be inferred at that position. From the multitude of measured positions, the total
three-dimensional form is determined.

As an alternative to fiber-optic Bragg gratings, the inherent backscatter in
conventional optical fiber can be exploited, such as Raleigh, Raman, Brillouin or
fluorescence scattering. One such approach is to use Rayleigh scatter in standard single-
mode communications fiber. Rayleigh scatter occurs as a result of random fluctuations of the
index of refraction in the fiber core. These random fluctuations can be modeled as a Bragg
grating with a random variation of amplitude and phase along the grating length. By using
this effect in three or more cores running within a single length of multi-core fiber, the 3D
shape and dynamics of the surface of interest can be followed.

The FORS system 110 allows for determination of the shape of the optical fiber 108
when the deformable body 105 of the deformable registration device contacts the structure
104 of the subject. The FORS system 110 using the shape of the optical fiber 108 is
configured to acquire positional points representing the position of the structure 104 of the
subject. While the system 100 is illustratively described as utilizing a FORS system 110,
other known shape sensor systems and sensors may be utilized for the system in accordance
with the present principles.

The deformable registration device 102 is normally required to be flush against the
structure of the subject to avoid acquiring erroneous positional points that are not on the
surface of the structure 104 and which do not represent a position of the structure. These off-
surface points lead to errors in registration of the structure to a coordinate system, such as the
coordinate system of the imaging device, a real-world coordinate system or another global coordinate system. For example, FIG. 2 displays a deformable registration device 102 held taut against a structure 104. The regions of the device 102 in solid lines are in contact or close proximity to the structure 104 and represent on-surface points 114. In contrast, the regions of the device 102 in dotted lines are not in contact or close proximity to the structure 104 and represent off-surface points 116. A registration of these off-surface points 116 by known registration algorithms such as ICP would result in errors in the registered structure. More specifically, with specific reference to ICP, the ICP algorithm uses as an optimization parameter that depends on the distance between each sampled point and its corresponding closest point of the structure. Accordingly, the ICP algorithm would analyze the acquired off-surface points and compute a local minimum that is not necessarily the global minimum for the structure 104.

The system 100 obviates the requirement for the deformable registration device 102 to be held flush against the structure 104 of the subject in order to accurately register the structure 104. The system 100 includes a pre-processing module 112 which is configured to analyze the positional points 106 acquired by the FORS system 110 and determine which points are on-surface 114 and off-surface points 116. A registration module 118 is then configured to register the acquired points of the structure 104 factoring in whether a point is an on-surface 114 or off-surface point 116. As shown in FIG. 3, the registration module 118 is configured to delete the off-surface points in order to avoid the distortion that would normally occur in the registration of the off-surface points 116. “Deletion” of positional points by the registration module 118 means that the positional points are either removed or are disregarded in the registration algorithm, such as ICP.

In one embodiment, the pre-processing module includes an interpolation module 120.
The interpolation module is configured to interpolate the positional points 106 from the FORS data and generate a smooth surface fit 121 along the points. For example, FIG. 3 shows positional points 106 acquired from the FORS system which are then interpolated to provide a smooth surface fit 121 over the points.

The pre-processing module includes a computation module 122 that is configured to compute surface metrics, such as curvature, slope, shape, axial strain, etc., along the surface of the smooth surface fit 121. The deformable body 105 of the deformable registration device typically contacts regions of the structure 104 that are more curved than regions of the deformable body that are off of the surface of the structure. Furthermore, flat regions of the structure 104 that are isolated from curved regions are more likely to provide off-surface positional points of the structure 104. Additionally, the further away that the flat regions of the structure are from the curved regions, the more likely that the flat regions will provide off-surface positional points. For example, as shown in FIG. 2, the flat taut portions of the device are off-surface of the concave surfaces of the structure 104 below the deformable body 105 of the device.

In one embodiment, the computation module 122 is configured to compute the curvature along the surface of the smooth surface fit developed by the interpolation module 120. A threshold curvature level is determined in which regions with a larger curvature are likely to be on-surface points 114 and regions below the threshold curvature level are likely to be off-surface points 116. The threshold curvature level may be developed by the use of models or the analysis of sample data.

The determination module 124 is configured to analyze the curvature level or other surface metric(s) determined by the computation module 122 in comparison to the threshold curvature level and determine if the curvature is above, equal to, or below the threshold. As
shown in FIG. 3, if the curvature level for a point is below the threshold curvature level, the
determination module identifies the point as an off-surface point 116. If the point is equal to
or above the threshold, the point is determined to be an on-surface point 114.

In another embodiment, the system 100 may utilize contact sensing information in
combination with the information provided by the determination module 124 to determine if
a positional point 106 acquired by the FORS system 110 is an on-surface point 114 or off-
surface point 116. In one embodiment, the contact sensing is performed by a contact sensing
device 126. As shown in FIGS. 4-5, the contact sensing device 126 may include an optical
fiber 127 of a FORS system that is in an overlapped configuration to form two parallel
segments. While the optical fiber is described as forming two parallel segments, in some
embodiments the optical fiber may form more than two segments and/or the fiber segments
may be positioned in a non-intersecting configuration which is not strictly parallel. The
contact sensing device 126 is configured to apply a pressure on the optical fiber 127 and the
optical fiber is placed on the structure 104. As shown in FIG. 4, when the optical fiber 127
contacts an on-surface region 114 of the structure, the distance between the parallel fibers
decreases due to the pressure applied on the optical fiber. Conversely, when the optical fiber
is in contact with an off-surface region 116, the distance between the fibers remains
approximately the same.

The contact sensing device 126 includes a detection device 130 that is configured to
compute the distance between the segments of the optical fiber 127 when it is pressed against
the structure 104. The contact sensing device 126 further includes an identification device
132 that is configured to receive the computation of the distance between segments from the
detection device 130 and provide contact sensing information 128 which identifies on-surface
and off-surface points. The identification device 132 is configured to identify points where
the distance between the segments remains approximately the same from the initial distance between the points as being off-surface points 116. The identification device 132 is configured to identify the points where the distance between the segments decrease as being on-surface points 114.

While the illustrative embodiment describes the system 100 as including a separate contact sensing device 126, in some embodiments the optical fiber may be configured within the deformable body 105 to enable the deformable body 105 to simultaneously perform the contact sensing function of the contact sensing device 126 and the registration function of the deformable registration device 102 within a single device.

The system 100 is configured to review the determination of on-surface points 114 and off-surface points 116 by both the determination module 124 and from the contact sensing information 128. In some embodiments, the system 100 may combine both the contact sensing information 128 and the determination from the determination module 124 using a weighted analysis or by other means known in the art.

In another embodiment, the system 100 includes a model 134 (FIG. 6) of the structure 104, such as a statistical atlas model, which is also utilized to identify positional points 142 (FIG. 1) of the structure. The system 100 includes a generation module 136 that is configured to generate a shape 137 (FIG. 8) on the model 134 which approximates points that would be acquired by the deformable registration device 102 on the structure 104 when the deformable registration device 102 is not flush against the surface of the structure 104. For example, as shown in FIGS. 6-7, the model may generate a convex hull shape 138 which approximates the position of the deformable registration device 102 if the deformable body 105 is held taut over a concave surface. Alternatively, as shown in FIG. 8, an envelope 140 with a maximum concave curvature which encloses the structure may be generated by the
generation module 136.

The pre-processing module 112 is configured to receive the positional points 142 (FIG. 1) obtained by the generation module 136 from the shape generated on the model 134 and determine which points are on-surface and off-surface points with respect to the structure 104.

The registration module 118 is configured to receive the positional points 106 acquired by the deformable registration device from FORS data and the positional points 142 acquired from the generation of a shape on the model 134 by the generation module and perform a registration to a coordinate system. In some embodiments, the registration module 118 is configured to solely utilize positional points from the deformable registration device or derived from the model 134 in order to perform the registration. However, in other embodiments both types of acquired positional points 106, 142 are utilized as this technique will generally increase the robustness of the registration.

For example, since the positional points 142 acquired from the model may be a convex hull 138 approximating the position of the deformable registration device 102 when it is held completely taut, the positional points obtained from the model may be used to register the model with positional points 106 obtained from the deformable registration device. This obviates the need for the deformable registration device 102 to be held completely taut when acquiring the positional points. Similarly, if the deformable registration device 102 has a maximum convex curvature that it can deform to, positional points acquired from the envelope 140 generated on the model may be used to register the model with positional points 106 obtained from the deformable registration device. The system 100 is also configured to replace positional points acquired by the model 134 with positional points 142 from the generation module 136. This allows the positional points 106 from the deformable
registration device 102 to morph a modified statistical model of the structure 104 to match the modified shape of the structure and to obtain registration therefor.

The registration module 118 is configured to perform registration of the positional points 106, 142 using standard registration algorithms known in the art, such as ICP. The registration module is configured to apply different weights or delete the positional points in order to avoid error in the registration. For example, as shown in FIG. 9, if a standard ICP algorithm is applied to the positional points 106, 142 from both the deformable registration device and the model without modifying the positional points, the registration shape resulting from the model and the deformable registration device may have an error, such having the positional points 106, 142 intersect with respect to each other.

In one embodiment, the registration module 118 is configured to perform registration using positional points 106 acquired by the deformable registration device 102 and the positional points 142 from the model. The registration module 118 is configured to delete or apply different weights to positional points 106 acquired from the deformable registration device 102 and the positional points 142 acquired from the model. In one embodiment, a weighted approach is applied wherein the positional points 106 from the deformable registration device 102 are weighted based on on-surfaceness and off-surfaceness confidence of the positional points 106 based on a curvature threshold. Alternatively, a weighted approach may be based upon the convexity/concavity of the model 134 or other criteria. For example, since FORS data from concave regions of the structure are likely to be off-surface and thus more erroneous, the registration module 118 may apply more weight to positional points acquired from convex regions and less weight to positional points acquired from concave regions of the model.

The device may further include a registration evaluation module 119 which is
configured to review the registration for accuracy. If the registration is not accurate, the registration evaluation module 119 is configured to generate a signal for the user to reposition the deformable registration device 102 and a new registration is performed by the system 100.

The system 100 may be configured in an integrated computerized and/or electronic unit wherein a registration performed by the workstation 101 is automatically triggered when the deformable body 105 is pressed against the structure 104, in response to a gesture performed by the user of the deformable registration device 102, the user pressing a button on the deformable registration device, etc.

Referring to FIG. 10, methods for registering a structure of a subject to a coordinate system using FORS data are illustratively shown in accordance with the present principles. In block 150, a deformable registration device 102 having a deformable body is placed on a structure 104 of the subject. In block 160, positional points for the structure are obtained by measuring a shape of the optical fiber 108 using a FORS system 110. In block 170 the positional points 106 acquired by the FORS system are analyzed and a determination concerning which positional points are on-surface 114 and off-surface points 116 with respect to the structure is made. In block 180, the off-surface 116 positional points are deleted and the on-surface 114 positional points are used in registration with the model 134.

In the embodiment shown in FIG. 11, the method further comprises the step in block 190 of generating a shape on a model of the structure that is configured to approximate points that would be measured by a deformable registration device of the structure if the deformable registration device was not flush against the surface of the structure. The approximated model from generation module 136 can then be used with all positional points 106 from the deformable registration device 102 to perform registration.

In block 210, the positional points 106, 142 are modified by applying different
weights or deleting at least one positional point to form a modified positional point set. For example, in one embodiment, more weight is applied to positional points from the model that are detected as on-surface points and less weight is applied to positional points that are detected as off-surface points. In block 220, the modified positional point set are registered.

As previously described with respect to the system 100, the method may further comprise the steps of interpolating the positional points from the FORS data to generate a smooth surface fit along the positional points. A surface metric, such as curvature, slope, shape, axial strain, etc., along the surface of the smooth surface fit is then computed and the positional points in which the surface metric is above a threshold level are identified as on-surface points. The positional points that are below a threshold level are identified as off-surface positional points.

In other embodiments of the method, contact sensing information, such as information obtained by a procedure performed by the contact sensing device 126 may be used in order to determine which positional points are on-surface and off-surface points.

This method for registering a structure of a subject to a coordinate system using FORS data allows for registration of the positional points acquired by the deformable registration device without requiring the deformable device to be flush against the structure. This provides a simpler, more efficient registration procedure for the practitioner which requires less care and skill and improves the accuracy of the registration. However, the system and method may be effectively utilized for registration of positional points acquired by a deformable registration device that is flush against the structure in accordance with the principles of this invention.

It is noted that modifications and variations can be made by persons skilled in the art in light of the above teachings. It is therefore to be understood that changes may be made in
the particular embodiments of the disclosure disclosed which are within the scope of the embodiments disclosed herein as outlined by the appended claims.

In interpreting the appended claims, it should be understood that:

a) the word "comprising" does not exclude the presence of other elements or acts than those listed in a given claim;

b) the word "a" or "an" preceding an element does not exclude the presence of a plurality of such elements;

c) any reference signs in the claims do not limit their scope;

d) several "means" may be represented by the same item or hardware or software implemented structure or function; and

e) no specific sequence of acts is intended to be required unless specifically indicated.

Having described preferred embodiments for the system and method for registering a structure using FORS data (which are intended to be illustrative and not limiting), it is noted that modifications and variations can be made by persons skilled in the art in light of the above teachings. It is therefore to be understood that changes may be made in the particular embodiments of the disclosure disclosed which are within the scope of the embodiments disclosed herein as outlined by the appended claims. Having thus described the details and particularity required by the patent laws, what is claimed and desired protected by Letters Patent is set forth in the appended claims.
CLAIMS:

1. A system for registering a structure (104) of a subject to a coordinate system using FORS data comprising:
   a deformable registration device (102) having a deformable body (105), said
   deformable body including an optical fiber (108) for a FORS system;
   a FORS system (110) configured to measure a shape of the optical fiber when the deformable body contacts the structure of the subject to obtain positional points (106) for the structure;
   a pre-processing module (112) configured to analyze the positional points acquired by the FORS system and determine which positional points are on-surface and off-surface points with respect to the structure; and
   a registration module (118) configured to delete the off-surface positional points and perform a registration using the on-surface positional points.

2. The system as recited in claim 1, wherein the system further includes:
   a model (134) of the structure of the subject; and
   a generation module (136) configured to generate a shape (137) on the model of the structure, said shape configured to approximate points which would be measured by the deformable registration device of the structure.

3. The system as recited in claim 2, wherein:
   the registration module (118) is configured to modify the positional points acquired by the deformable registration device and/or positional points acquired from the shape generated on the model by applying different weights or deleting at least one positional point
to form a modified positional point set; and

said registration module is configured to register the modified positional point set.

4. The system as recited in claim 2, wherein the shape (137) generated by the

generation module comprises a convex hull or envelope.

5. The system as recited in claim 3, wherein the registration module (118) is

configured to provide more weight to positional points from the deformable registration
device that are on the surface of the structure and less weight to positional points that are off

the surface of the structure.

6. The system as recited in claim 3, wherein the registration module (118) is

configured to provide more weight to positional points from convex regions of the model and

less weight to positional points from concave regions of the model.

7. The system as recited in claim 1 wherein the pre-processing module (112)

further includes:

an interpolation module (120) configured to interpolate the positional points from the

FORS data to generate a smooth surface fit along the positional points;

a computation module (122) configured to compute a surface metric along the surface

of the smooth surface fit; and

a determination module (124) configured to identify positional points in which the

surface metric is above a threshold level as being on-surface points and positional points that

are below a threshold level as being off-surface positional points;
8. The system as recited in claim 1, wherein the pre-processing module (112) further utilizes contact sensing information (128) in order to determine which positional points are on-surface and off-surface.

9. The system as recited in claim 1, wherein the system further includes a contact sensing device (126), comprising:
   an optical fiber (127) configured to form a plurality of non-intersecting segments;
   a detection device (130) configured to compute an initial distance between the segments and a distance between the segments when they are pressed against the structure; and
   an identification device (132) configured to identify positional points where the distance between the segments remains approximately the same as the initial distance as being off-surface positional points and positional points where the distance decreases as being on-surface positional points.

10. A system for registering a structure of a subject to a coordinate system using FORS data, comprising:
    a deformable registration device (102) having a deformable body (105), said deformable body including an optical fiber (108) for a FORS system;
    a FORS system (129) configured to measure a shape of the optical fiber when the deformable body contacts the structure of the subject and obtain positional points (106) for the structure;
    a workstation (101) including:
one or more processors (107), memory (109) and an interface (123);

a pre-processing module (112) configured to analyze the positional points acquired by the FORS system and determine which positional points are on-surface and off-surface points with respect to the structure; and

a registration module (118) configured to delete the off-surface positional points and perform a registration using the on-surface positional points.

11. The system as recited in claim 10, wherein the system further includes:

a model (134) of the structure of the subject stored in the memory; and

a generation module (136) configured to generate a shape (137) on the model of the structure, said shape configured to approximate points which would be measured by a deformable registration device of the structure of the subject.

12. The system as recited in claim 11, wherein:

the registration module (118) is configured to modify the positional points acquired by the deformable registration device and/or positional points acquired from the shape generated on the model by applying different weights or deleting at least one positional point to form a modified positional point set; and

said registration module is configured to register the modified positional point set.

13. The system as recited in claim 12, wherein the registration module (118) is configured to provide more weight to positional points from the deformable registration device that are on the surface of the structure and less weight to positional points that are off the surface of the structure.
14. The system as recited in claim 10, wherein the pre-processing module (112) further includes:

an interpolation module configured to interpolate the positional points from the FORS data to generate a smooth surface fit along the positional points;

a computation module configured to compute a surface metric along the surface of the smooth surface fit; and

a determination module configured to identify positional points in which the surface metric is above a threshold level as being on-surface points and positional points that are below a threshold level as being off-surface positional points;

15. A method for registering a structure of a subject to a coordinate system using FORS data comprising the steps of:

placing (150) a deformable registration device having a deformable body on a structure of the subject;

obtaining (160) positional points for the structure by measuring a shape of an optical fiber positioned within the deformable registration device using a FORS system;

analyzing (170) the positional points acquired by the FORS system and determining which positional points are on-surface and off-surface points with respect to the structure;

and

deleting (180) the off-surface positional points and registering the on-surface positional points.

16. The method as recited in claim 15, further comprising the step of generating
(190) a shape on a model of the structure which is configured to approximate points which would be measured by a deformable registration device of the structure.

17. The method as recited in claim 15, further comprising the steps of:
modifying (210) the positional points acquired by the deformable registration device and/or positional points acquired from the shape generated on the model by applying different weights or deleting at least one positional point to form a modified positional point set; and
registering (220) the modified positional point set.

18. The method as recited in claim 17, wherein the modifying step comprises applying more weight to positional points from the registration device that are on the surface of the structure and less weight to positional points that are off the surface of the structure.

19. The method as recited in claim 15, further comprising the steps of:
interpolating the positional points from the FORS data to generate a smooth surface fit along the positional points;
computing a surface metric along the surface of the smooth surface fit; and
identifying positional points in which the surface metric is above a threshold level as on-surface points and positional points that are below a threshold level as off-surface positional points;

20. The method as recited in claim 15, comprising the further step of utilizing contact sensing information in order to determine which positional points are on-surface and off-surface.
FIG. 2
1. Fit surface over samples

2. Find curvature along surface

3. Remove low-curvature data for ICP

FIG. 3
FIG. 10

Placing deformable registration device on structure

Obtaining positional points for structure from FORS data

Analyzing and determining which positional points are on-surface and off-surface points

Deleting off-surface positional points and registering on-surface positional points

FIG. 11

Generating a shape on a model of the structure that approximates points measured by the deformable registration device when it is not flush against the surface

Modifying positional points obtained from model and from FORS data

Registering the modified positional points
Detecting vital signs of the user \( 191 \)  
Selecting sleep aid technique \( 193 \)  
Updating dose-off time \( 194 \)  
Determining schedule for executing action \( 195 \)  
Executing action \( 196 \)  

FIG. 1B
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<th>Sensor/technique concept</th>
<th>Sensor*</th>
<th>220A</th>
<th>220B</th>
<th>220C</th>
<th>220D</th>
<th>220E</th>
<th>220F</th>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Inhale through left nostril</td>
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<td>x</td>
<td>x</td>
<td>x</td>
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<td>x</td>
<td></td>
</tr>
<tr>
<td>Squeeze and relax muscles</td>
<td>210B</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Try to stay awake</td>
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<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Rewind your day</td>
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<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
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<td>Roll your eyes</td>
<td>210E</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Just imagine</td>
<td>210F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Hum to yourself</td>
<td>210G</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
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<tr>
<td>Press here</td>
<td>210H</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Find your trigger</td>
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<td></td>
<td></td>
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<td>x</td>
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*Sensors includes both actual and virtual sensors

**FIG. 2B**
FIG. 2C

<table>
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<tr>
<th>Time after sleep</th>
<th>Environment trigger</th>
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<tbody>
<tr>
<td>0</td>
<td>Lock doors</td>
</tr>
<tr>
<td>1</td>
<td>Dim all lights to 0</td>
</tr>
<tr>
<td>1</td>
<td>Lower all audio device volumes to 0</td>
</tr>
<tr>
<td>...</td>
<td></td>
</tr>
</tbody>
</table>

FIG. 3
Wearable base GUI

Select sleep aid technique:

- Inhale through left nostril (410)
- Squeeze and relax muscles (415)
- Try to stay awake (420)
- Rewind your day (425)
- Roll your eyes (430)
- Just imagine (435)
- Hum to yourself (440)

Select post-sleep actions:

- Turn off lights (450)
- Lock doors (immediately) (455)
- Turn off audio (460)
- Turn down thermostat (465)

When? 1 minute

Start training (475)
Start sleep (480)
Cancel (490)

FIG. 4
Rewind your day 510

Sleep aid technique selected:

Instructions:

Starting with now, try to remember every mundane detail of the day.

Reset this technique 540

Switch technique (will open base GUI) 530
FIG. 6
Rewind your day 710

Think back over your day. Starting now, try to remember every mundane detail of the day.

720

Sleep aid technique selected: 

Instructions: 750

Time elapsed: 5 minutes 760

Alert: Sleep technique is currently not as effective as projected. What do you want to do? 740

Switch technique (will open base GUI) 730

Wearable go-to-sleep GUI 700
**FIG. 9A**

1. Receive initiation of software
2. Load data for selected sleep aid technique from user sleep profile
3. Display instructions to user for selected sleep aid technique in wearable training GUI
4. Receive sensor data from wearable sensors, write to wearable sensor data database
5. Receive user's doze data from doze software
6. Is user asleep?
   - Yes: Initiate wearable analysis software
   - No: Continue with next step

**FIG. 9B**

1. Receive initiation of software
2. Load wearable sensor data database
3. Select current day
4. Calculate rate of change of percent doze for data for hour before 100% doze
5. Determine data point when rate of change of percent doze at least doubles, write all data on that row to Tipping Point Database, record time before sleep, time after start
6. Records for all days reviewed?
   - Yes: Determine user Tipping Point by averaging all values for each technique data point type in Tipping Point Database, save to user sleep profile
   - No: Select previous day

*Sensor data is prefixed with sleep aid technique identifier*
FIG. 10A

1005

Wearable device-wearable software

1010

Receive user initiation of go-to-sleep software

1015

Load data for selected sleep aid technique from user sleep profile

1020

Display instructions for selected sleep aid technique in wearable go-to-sleep GUI

1025

Receive sensor data from wearable sensors, write to wearable sensor data database

1030

Did user begin to doze within predicted time before sleep?

1035

Y

1040

N

Initiate wearable analysis software

1040

Initiate wearable environment software

1040

*Sensor data is prefixed with sleep aid technique identifier
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<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>% Doze</th>
<th>Technique data type</th>
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<th>…</th>
<th>Technique data type</th>
<th>Technique data point</th>
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<td>2059</td>
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<td>R.W.Y.D Pulse</td>
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<td></td>
<td>R.W.Y.D Pulse</td>
<td>120/80</td>
</tr>
<tr>
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<td>2100</td>
<td>6</td>
<td>R.W.Y.D Pulse</td>
<td>63</td>
<td></td>
<td>R.W.Y.D Pulse</td>
<td>120/80</td>
</tr>
<tr>
<td>02 - 10 - 2015</td>
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<td>R.W.Y.D Pulse</td>
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<td>52</td>
<td></td>
<td>R.W.Y.D Pulse</td>
<td>100/65</td>
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</table>

**FIG. 11**
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Time before sleep (minutes)</th>
<th>Time after start (minutes)</th>
<th>% Doze</th>
<th>Technique data type 1</th>
<th>Technique data point 1</th>
<th>···</th>
<th>Technique data type n</th>
<th>Technique data point n</th>
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<tr>
<td>02-07-2015</td>
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<td>3</td>
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<td>RWYDBP</td>
<td>115/77</td>
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<td>59</td>
<td></td>
<td>RWYDBP</td>
<td>114/76</td>
</tr>
<tr>
<td>02-10-2015</td>
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<td>5</td>
<td>3</td>
<td>15</td>
<td>RWYD Pulse</td>
<td>60</td>
<td></td>
<td>RWYDBP</td>
<td>115/77</td>
</tr>
</tbody>
</table>

FIG. 12
<table>
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<tr>
<th>Wearable user sleep profile 1300</th>
<th>Sleep aid technique</th>
<th>Predicted time before sleep (minutes) 1320</th>
<th>Predicted time after start (minutes) 1330</th>
<th>Technique data type 1 1340</th>
<th>Technique average data point 1 1350</th>
<th>Technique data type n 1360</th>
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<tr>
<td>Inhale through left nostril</td>
<td>8</td>
<td>5</td>
<td>ITLNResp</td>
<td>40</td>
<td>ITLNBP</td>
<td></td>
</tr>
<tr>
<td>Squeeze and relax muscles</td>
<td>10</td>
<td>13</td>
<td>SRMPulse</td>
<td>65</td>
<td>SRMResp</td>
<td></td>
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<td>Try to stay awake</td>
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<td>6</td>
<td>TTSAVibrate</td>
<td>8</td>
<td>None</td>
<td></td>
</tr>
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<td>Rewind your day</td>
<td>5</td>
<td>3</td>
<td>RWyDPulse</td>
<td>60</td>
<td>RWyDBP</td>
<td></td>
</tr>
<tr>
<td>Roll your eyes</td>
<td>7</td>
<td>15</td>
<td>RYERolls</td>
<td>15</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Just imagine</td>
<td>10</td>
<td>25</td>
<td>JIQuest</td>
<td>3</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Hum to yourself</td>
<td>..</td>
<td>..</td>
<td>HTYMic</td>
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<td>Press here</td>
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<td>PHMuscleTension</td>
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**FIG. 13**
<table>
<thead>
<tr>
<th>Technique average data point n</th>
<th>Instructions to user</th>
</tr>
</thead>
<tbody>
<tr>
<td>116/79</td>
<td>Lie on your left side. Place a finger over your right nostril. Begin slow, deep breathing.</td>
</tr>
<tr>
<td>45</td>
<td>Lie on your back. Take slow, deep breaths. Starting with your toes and working toward your head, squeeze and release each muscle groups.</td>
</tr>
<tr>
<td></td>
<td>Keep your eyes wide open. Mentally challenge yourself to stay awake (don’t worry, your brain will try to do the opposite).</td>
</tr>
<tr>
<td>115/77</td>
<td>Think back over your day. Starting with now, try to remember every mundane detail of the day.</td>
</tr>
<tr>
<td></td>
<td>Close your eyes. Roll your eyes three times. Repeat as necessary</td>
</tr>
<tr>
<td></td>
<td>Imaging yourself in a ‘happy place’ such as a tropical paradise or a strawberry field.</td>
</tr>
<tr>
<td></td>
<td>Close your eyes, relax your shoulders, relax your jaw but keep your mouth closed. Hum out on each breath.</td>
</tr>
<tr>
<td></td>
<td>&lt;Display PressurePoint.jpeg&gt;. Press the pressure points indicated in the picture. Hold for 20 seconds, then press another.</td>
</tr>
<tr>
<td></td>
<td>Please perform your trigger action.</td>
</tr>
<tr>
<td></td>
<td>Synch your breath synchronizer device. Breathe in and out with the device.</td>
</tr>
<tr>
<td>115/77</td>
<td>Think through all the things that your need to do or are worrying about. Write down your list, if you want.</td>
</tr>
</tbody>
</table>

**FIG. 13** Continue
Method 1400

Providing a wearable device containing wearable software, wearable sensor data database, wearable tipping point database, wearable environment database, user sleep profile, wearable base GUI, wearable training GUI, wearable go-to-sleep GUI, clock, wearable sensor1-n, wearable comm, doze software, and doze sensors; the internet; and a plurality of sleep networks each containing a network comm, network technique info database and network software

Allowing a user to download from sleep network a user sleep profile containing sleep aid techniques and instructions

Allowing the user to train wearable to recognize effective dozing-off data of a plurality of sleep aid techniques

Allowing the user to select a trained sleep aid techniques prior to user attempting to go to sleep

Determining if the sleep aid technique is less effective than during training

Re-evaluating the sleep aid technique's effectiveness

Making pre-set changes to user's environment based on sleep state

FIG. 14
## INTERNATIONAL SEARCH REPORT

**A. CLASSIFICATION OF SUBJECT MATTER**
- INV. A61B34/20
- ADD.

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.

Electronically data base consulted during the international search (name of data base and, where practicable, search terms used)
- EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>X</td>
<td>WO 2014/167511 A1 (KONINKL PHILIPS NV [NL]; PHILIPS DEUTSCHLAND GMBH [DE])</td>
<td>1-6, 10-13</td>
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<tr>
<td></td>
<td>16 October 2014 (2014-10-16) page 10; figures 1,2,4</td>
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</tr>
<tr>
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<td>page 14 - page 15</td>
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<tr>
<td></td>
<td>page 17 - page 18; figures 1,2,3,4,12</td>
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<td>X</td>
<td>WO 2013/030764 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; MANZKE ROBERT [DE]; RAMACHANDRAN) 7 March 2013 (2013-03-07)</td>
<td>1,4</td>
</tr>
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<td></td>
<td>page 11 - page 12; figures 1,3</td>
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</tbody>
</table>

- Further documents are listed in the continuation of Box C.
- See patent family annex.

**Notes:**
- "A" document defining the general state of the art which is not considered to be of particular relevance.
- "E" earlier application or patent 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.
- "S" 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.
- "Z" document member of the same patent family.

**Date of the actual completion of the international search**
- 13 September 2016

**Date of mailing of the international search report**
- 22/09/2016

**Name and mailing address of the ISA/ European Patent Office, P.B. 5618 Patentlaan 2 NL: 2280 HV Vijfhuizen, Tel: (+31-70) 340-2040, Fax: (+31-70) 340-3016**

**Authorized officer**
- Hausmann, Alexander
### 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.: 15-20
   - because they relate to subject matter not required to be searched by this Authority, namely:
   - see FURTHER INFORMATION sheet PCT/ISA/210

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 5.4(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 fees, 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.
Continuation of Box II.1

Claims Nos.: 15-20

Rule 39.1(iv) PCT. The subject matter of claims 15-20 relates to a method for treatment of the human or animal body by surgery. Therefore a search is not required: Placing a deformable registration device having a deformable body on a structure of the subject. It is clear from the disclosure as a whole, see for example page 1 (references to bone). For a claimed method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise, no search is required. Rule 39.1 (iv) PCT. See also Rule 43 bis PCT.
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