



## (51) International Patent Classification:

*A61B 5/00* (2006.01)      *A61B 17/70* (2006.01)  
*A61B 17/60* (2006.01)      *A61B 17/72* (2006.01)  
*A61B 17/68* (2006.01)      *A61B 17/80* (2006.01)

## (21) International Application Number:

PCT/GB2014/052779

## (22) International Filing Date:

12 September 2014 (12.09.2014)

## (25) Filing Language:

English

## (26) Publication Language:

English

## (30) Priority Data:

1316263.1      12 September 2013 (12.09.2013)      GB  
 1413401.9      29 July 2014 (29.07.2014)      GB

(71) Applicant (for all designated States except US): **IN-MEDICA D.O.O.** [SI/SI]; Levicnikova cesta 34, 8310 Šentjernej (SI).

## (72) Inventors; and

(71) Applicants (for US only): **OGRODNIK, Peter Jan** [GB/GB]; c/o Metaphysis, Welsh Bridge, 1 Frankwell, Shrewsbury, Shropshire SY3 8LG (GB). **THOMAS, Peter Brian MacFarlane** [GB/GB]; c/o Metaphysis, Welsh Bridge, 1 Frankwell, Shrewsbury, Shropshire SY3 8LG (GB).

(74) Agent: **BOOTH, Catherine**; Mathys & Squire LLP, The Shard, 32 London Bridge Street, London, Greater London SE1 9SG (GB).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

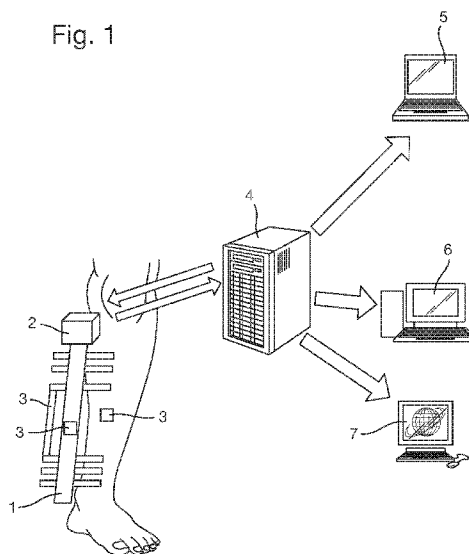
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

## Published:

- with international search report (Art. 21(3))
- with amended claims (Art. 19(1))

## (54) Title: BONE FIXATION SYSTEM AND ASSOCIATED METHOD

Fig. 1



(57) Abstract: A method of monitoring a bone fracture in an individual. The method comprises the steps of: measuring a first parameter indicative of the load on said bone fracture; measuring a second parameter indicative of the activity level of said individual; obtaining a plurality of values for said first and second parameters; correlating said values to determine a measure of bone fracture condition; monitoring a change in said correlation over time; and determining a measure of the change in bone fracture condition over time. A bone fixation system implements this method of monitoring a bone fracture in an individual. The method and system provide a more accurate and reliable measure of bone fracture condition and of the progression of healing of the bone fracture.

### **Bone fixation system and method**

The present invention relates to a method of monitoring a bone fracture in an individual and to a bone fixation system which can perform said method.

5 All vertebrates with a solid skeletal frame can suffer a fracture of one or more bones. The natural healing process of long bones creates callus as a product of inter-fragmentary movement; the callus mass builds until the movement comes to rest. At this point the bone is healed. However, there are complications and congenital issues that could delay this process. When treating a human with, say, a fractured tibia the surgeon has a variety of choices of  
10 treatment regime. Stable fractures (those that do not shorten under axial loading) are treated in plaster-of-paris casts; unstable fractures are treated surgically using external fixation or internal fixation. But they are all bound by the same questions: is the fracture healing as it should? Is the fracture heading towards a non-union? Is the fracture healed and is it time to remove the fixation? At present, all of these questions are answered by examining patients at  
15 regular clinics.

Typically a patient suffering say a tibial fracture, would be required to visit about 4-6 clinics over a period of several months. However this is a cumbersome approach; it involves transportation to and from hospitals, and dictates the use of resources to staff clinics. As an example, for the tibia, the surgeon would start to assess healing after about 7 weeks. This  
20 involves examination of x-ray images and physical manipulation of the fracture. Of course, in between clinics the patient is self diagnosing by observing for infections etc. The clinic therefore is a synthesis of a variety of data to decide whether the fracture healing is progressing 'normally'. In the early stages the decision concerns how the healing is progressing and whether there are any complications (such as mal-union, infection or non-  
25 union ensuing). In the latter stages the decision concerns whether the fracture is healed or not. In both cases early intervention of any complication is of paramount importance. In the case of early detection of a complication the benefits are self evident. In the case of fracture healing detection a patient's fracture could be considered healed one day after their last clinic. Being missed by one day, the fixation could be in place for a number of weeks longer than it  
30 needs to be; or the patient cannot return to normal activity for longer than necessary. Any improvement in the situations described above would realise cost benefits for the healthcare provider and personal benefits for the patient.

- 2 -

EP-A-0740927 and US-A-5738684, previously filed by the inventors of the present invention, provide basis for a fixation system in concept concerned with obtaining continuous information about use of a bone fixation system on a patient, and particularly concerned with determining the degree of relative movement between fractured bones.

5 Other documents have not taken the concept much further and have not extended the technology, but have demonstrated the need for an improved system. US-A-2012277746 presents an instrumented IM nail, and US-A-2012065548 presents an instrumented plate, and US-A-2012163683 is similarly presented for an implant, but these do not improve on the technology of EP-A-0740927 and US-A-5738684. WO-A-2013044174 presents a telemetric  
10 implant for condition monitoring of said implant, and concentrates on the design of the implant itself. EP-A-1905388 and US-A-2012071735 disclose systems concerned with tele-health associated with implants, the former is not an automatic system and relies on a call centre, the latter is concerned with data within a hospital environment only. However, none of these documents disclose the technology required for successful implementation of an  
15 independent data-logging and monitoring system i.e. an intelligent fixation system.

The present invention is set out in the appended claims. Embodiments of the present invention are generally concerned with correlating parameters associated with a bone fracture and the individual, as it has been found that this provides a more accurate and reliable measure of bone fracture condition. Additionally, embodiments of the present invention may  
20 monitor a change in that correlation over time, since it has been found that this provides a more accurate and reliable measure of the progression of healing of the bone fracture.

Embodiments of the present invention proposes a system that incorporates sensors, data logging, transmission and analysis of data, and personalised (secure) data presentation that, in the first instance, can be used to monitor the progression of healing of a fracture but  
25 which can be used as a platform for the monitoring of a variety of clinical outcomes away from the hospital/clinical environment.

According to the present invention there is provided a method of monitoring a bone fracture in an individual, the method comprising the steps of:

30 measuring a first parameter indicative of the load on said bone fracture;  
measuring a second parameter indicative of the activity level of said individual;  
obtaining a plurality of values for said first and second parameters;  
correlating said values to determine a measure of bone fracture condition;  
monitoring a change in said correlation over time; and

- 3 -

determining a measure of the change in bone fracture condition over time.

This method may provide a more accurate and reliable measure of bone fracture condition than prior art methods and a more accurate and reliable measure of the progression of healing of the bone fracture. It may allow for self monitoring of a patient with a bone fracture.

5 It may allow for checks linked to the healing of the bone fracture to be carried out remotely and regularly to ensure that the patient can enhance their rate of recovery and capture any complications quickly, or even as they occur. If a patient is alerted to complications quickly, they are more likely to be able to correct them quickly, minimising the delay to recovery. The method may allow for complications to be resolved remotely so the patient may not need to  
10 wait until they can get an appointment at a clinic to have them resolved. As such, the method may reduce the number of clinics a patient needs to attend, reducing the burden on the healthcare provider and the potential inconvenience to the patient in getting to the clinic.

The first parameter may be, but is not limited to: inter-fragmentary movement; deformation; acceleration; pressure; strain; and any combination(s) thereof. Such parameters may  
15 be able to give an indication of whether bones at the bone fracture site are moving an appropriate amount. The first parameter may provide a measure of deformation at the fracture site. The first parameter may be measured continuously. This would allow for constant monitoring of the fracture so would be effective in identifying any issues that may arise quickly. Alternatively, the first parameter may be measured intermittently.

20 The second parameter may be, but is not limited to: limb (e.g. hip) movement; acceleration; orientation; and any combination(s) thereof. Such parameters may be able to provide information on whether the patient is, for example, walking quickly, sitting down, very active, not active enough. The second parameter may be measured continuously. Alternatively, the second parameter may be measured intermittently.

25 The method may further comprise the steps of:  
measuring a third parameter associated with said bone fracture;  
obtaining a plurality of values for said third parameter;  
correlating said values to determine a measure of bone fracture condition;  
monitoring a change in said correlation over time; and  
30 determining a measure of the change in bone fracture condition over time.

Measuring a third parameter may allow for an even more accurate and reliable measure of bone fracture condition and/or an even more accurate and reliable measure of the progression of healing of the bone fracture.

The third parameter may be, but is not limited to: temperature; lactic acid level; limb (e.g. hip) movement; acceleration; orientation; strain; pressure; oxygen level; tension; and any combination(s) thereof. Such parameters may provide an indication of whether a bone fracture is healing correctly. Such parameters may be able to provide an indication of whether the fracture site has become infected. The third parameter may be any other parameter associated with the patient and/or their fracture. The third parameter may be measured continuously. Alternatively, the third parameter may be measured intermittently. There may be multiple further parameters and this is not intended to be limiting.

On measuring at least one of said parameters to obtain a value, the method may further comprise the step of: comparing said at least one measured parameter value to at least one threshold value. An event may be recorded when this at least one threshold is exceeded. This may generate a useful parameter related to movement of the patient. For instance, the number of events measured per day may be used to indicate patient activity levels and/or mobility at the fracture site. This can give important indications of whether a patient is moving a correct amount to encourage healing and/or whether a fixator applied at the fracture site may be applied too tightly or not tightly enough such that it is hindering the healing process. An indicating means may be activated when said threshold is exceeded. This may be helpful in identifying problems which may arise with the fracture. For instance, if the temperature at the fracture site exceeded a threshold, this may be indicative of an infection. The indicating means may alert the patient to attend a clinic as soon as possible. The indicating means may be, but is not limited to, a loudspeaker, display, LED, an alarm or any other suitable indicating means.

Correlating said values may involve plotting a graph. This may be a useful way of identifying trends.

Determining a measure of the change in bone fracture condition over time may further comprise the step of: comparing said correlated data with pre-determined data typical of healing bone fractures. This may make it easy to identify the progression of healing and/or if there are any associated problems. The pre-determined data may comprise any, some or all of average, upper and lower boundaries for values of said correlated data typical of healing bone fractures. This may be particularly useful when the correlated data is plotted on a graph and the boundaries may be plotted as data curves on the graph. This may increase positivity and morale in a patient if they know that their fracture is healing well. It may also motivate the patient to correct their behaviour if this is having a negative effect on the healing. For instance, if the graph shows that the patient is not being active enough, it may motivate the patient to be more active.

The method may further comprise the step of: using a database as a basis for generating the pre-determined data, wherein said database is updated at regular intervals. The regular intervals may be pre-determined and/or may be controlled by activation means. The activation means may be a switch which may be controlled by the patient and/or by a physician/clinician caring for the patient. The database may be updated via wireless connections. The wireless connection may be the Internet. All data generated by such methods may be sent to a main server which uploads data to the database. The database may always contain the most up-to-date data, particularly useful when determining average, upper and lower boundary values of the correlated data, typical of healing bone fractures.

10 The method may further comprise the step of: providing an output based on at least one of said determinations. The output may be in the form of: text; graphic; sound; tactility; light; as any combination(s) thereof or any other suitable form. Particular forms of output may be more useful depending on the parameters measured and/or the patient/physician/clinician may have a preference as to how they would like to receive/view information. Providing an output may  
15 involve providing feedback on any, some or all of: whether the bone fracture is healing; the progression of healing of the bone fracture; predicting the endpoint of the healing process; whether a problem has developed with the bone fracture; whether the patient is not active enough or is too active. Predicting the endpoint of the healing process may comprise the steps of: extrapolating said correlated data to a point representing a healed bone fracture based on said pre-  
20 determined data; and calculating a time period over which the fracture can be expected to reach said point. The time period may be calculated directly as a result of the extrapolation, and/or may be calculated based on any, some or all of: known rates of healing; how far along the patient is into the healing process based on measured parameters or otherwise; how the healing is progressing based on correlated or monitored data or otherwise; when the fracture occurred;  
25 and/or how long a bone fixator may have been applied for.

The method may further comprise the steps of: detecting whether there is a problem associated with a bone fixator applied to the bone fracture based on at least one of said determinations; and, if a problem is detected, identifying said problem and sending feedback commands to an actuation means for manipulating said bone fixator based on the identified  
30 problem. The bone fixator may be internal or external. The steps of identifying said problem, sending feedback commands and manipulating said bone fixator, may be automatically controlled. Alternatively, or additionally, actuation may be manually controlled. This may help speed up the rate of recovery since the patient may not need to attend a clinic in order to correct a problem.

The present invention provides a bone fixation system operable to implement the method as described above.

The present invention provides a bone fixation system comprising:

a bone fixator for application to a bone fracture site;

5 a first sensor for measuring a first parameter indicative of load on said bone fracture and generating associated first parameter data;

a second sensor for measuring a second parameter indicative of the activity level of said individual and generating associated second parameter data;

a processing means for correlating said first and second parameter data to determine a  
10 measure of bone fracture condition, and for determining a change in said correlation over time to determine a measure of the change in bone fracture condition over time.

The bone fixation system provides the same and/or similar advantages as those of the method of the present invention.

The first sensor may be, but is not limited to: an accelerometer; a strain gauge; a  
15 pressure gauge; a capacitive sensor; or any combination(s) thereof. The first sensor may take measurements continuously. The first sensor may take measurements intermittently.

The second sensor may be, but is not limited to: a pedometer; an accelerometer; a gyroscope; a GPS sensor; or any combination(s) thereof. The second sensor may take measurements continuously. The second sensor may take measurements intermittently.

20 The bone fixation system may further comprise a third sensor. The third sensor may be, but is not limited to: an accelerometer; a strain gauge; a pressure gauge; a capacitive sensor; a pedometer; a gyroscope; a GPS sensor; a thermometer; or any combination(s) thereof. The third sensor may take measurements continuously. The third sensor may take measurements intermittently.

25 The processing means may compare any, some or all of said measured parameters to at least one threshold and record an event when this at least one threshold is exceeded. Additionally or alternatively, the processing means may compare any, some or all of said measured parameters to at least one level of activity and record an event when this activity level is met. The bone fixation system may further comprise an indicating means which may be operable to  
30 automatically activate when the at least one threshold is exceeded and/or the at least one level of activity is met.

The processing means may be able to identify a problem associated with the bone fracture or bone fixator applied thereto.

The bone fixation system may comprise an actuation means, such that the processing means may be able to send data commands to said actuation means based on an identified problem, and said actuation means may be operable to move at least a part of said bone fixator in response to said data commands. The bone fixation system may further comprise injecting, and/or  
5 stimulating means, operable to inject medication and/or antibiotics, and/or stimulate a body part, in response to said data commands. The stimulation may be electrical, thermal or any other physical stimulation. The processing means may be able to check that that the data commands and response thereto have corrected any problem with the bone fracture and/or the bone fixator.

The bone fixation system may further comprise an output means for providing an output  
10 based on at least one of said determinations. The output means may be, but is not limited to, a display, a speaker, or a combination thereof.

The bone fixation system may comprise a data storage means. The system may comprise a communication means and a device, wherein said communication means communicates data with said device. The communication means may be operable to communicate said data with said  
15 device synchronously. The communication means may be operable to communicate said data with said device asynchronously. The data may be communicated with said device via a wireless connection. The data may be communicated via the internet. In the situation where the communication means cannot send data to the device as soon as it is measured, for lack of an internet connection or otherwise, one or more of these features would allow for later  
20 transmission of the data to the device.

The device may be attached to the bone fixator. The device may be at a remote location. The device may be a server. The server may have the ability to assimilate and collate patient data into normal data for the population.

The bone fixator may have a unique identification number associated with it and any data  
25 communicated from said communication means may be communicated with this number. This may ensure that any data communicated from the bone fixation system could be traced to that particular system/fixator and/or patient. This may be helpful for a clinician observing the data remotely and/or may allow a system to automatically recognise the system/fixator and/or user for which data would need to be stored and/or where to send any data back to. Data  
30 communicated from the communication means may additionally, or alternatively, be sent anonymously.

The communication means and/or the device may be operable to push and pull data from one another. This is particularly useful when someone wants to analyse the progress of a

patient since they could request data to be transmitted from the bone fixation system at will in a pull mode, but also if the bone fixation system detects the onset of a complication then the system could contact someone, such as a clinician, in a push mode.

The device may be operable to collect said data from said communication means at  
5 regular intervals; analyse said data; store said data; and communicate the results of said analysis back to said communication means for outputting on an output device. The data may be stored anonymously for use in creating graphs to display typical recovery information. The patient to whom the data corresponds may alternatively be stored with the data, which may be particularly useful if the information is to be sent onto a clinician for example.

10 The communication means and/or the device may be operable to receive data or other information so as to update at least one algorithm associated with the device, the algorithm being used to determine the measure of the change in bone fracture condition over time, the progress of the healing of the bone fracture, etc. The communication means and/or the device may be operable such that the algorithm is updated remotely, for example by a physician or  
15 clinician, for example over the Internet or via other communication such as short or long range wireless communication. The communication means and/or the device may be operable with more than one algorithm (any one or more of which may be updateable as discussed above), the different algorithms being configured to provide the same and/or different results, end points or targets. This may be particularly advantageous for redundancy purposes and/or  
20 for error checking between the algorithms and/or for comparative methodologies, etc.

The device may further comprise a storage means for storing data and a programmable processing means operable to use said stored data to plot graphs related thereto. The programmable processing means may be operable to calculate a data point on one of said graphs, from data communicated to said device from said communication means, and plot this  
25 point on said graph. This may be useful in comparing an individual patient's data to grouped data based on results considered normal for a healing fracture. The programmable processing means may be operable to automatically update said storage means on communication of data to said device. This would mean the storage means was regularly updated and would provide an up-to-date database for plotting graphs therefrom.

30 Additionally, or alternatively, the processing means may be operable to perform any of the functions as described for any part of the device. Additionally, or alternatively, parts of the device may be operable to perform any of the functions as described for the processing

means. Where the processing means and device perform the same operations, one may be used as a back up system.

It should be understood that the bone fixation system of the present invention may incorporate any, some or all of the features of the method of the present invention as is  
5 desired or appropriate. Any steps in the method of the present invention may be performed by the relevant features of the bone fixation system, and the above described inventive method encompasses and may be implemented with any embodiments or any features described in connection with the previously discussed inventive bone fixation system, as long as those embodiments or features are compatible with the method.

10 Advantages of embodiments of the present invention may include:

- Reducing the number of clinics a patient needs to attend (indeed it is possible to eliminate the need for any clinics) this reduces burden on the healthcare provider and on the patient themselves;
- Monitoring progression of healing with a view to the capture of complications as  
15 quickly as possible;
- Transmitting and presenting data such that the surgeon / clinician is able to compare progression against 'norms';
- Transmitting and presenting data such that the patient can see their progress against norms and thus have the opportunity to be motivated.

20

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, of which:

Figure 1 shows an embodiment of a bone fixation system operable to implement the method of the present invention;

25 Figures 2-4 show embodiments of a bone fixation system for intramedullary nails, plates and plaster-of-paris casts;

Figure 5 shows an embodiment of a bone fixation system for ring fixation systems (frames) used for manipulation of the frame configuration;

Figure 6 shows the embodiment of Figure 1 in communication with a local server;

30 Figure 7 shows an example registration of a data-logging system;

Figure 8 shows a typical profile for analysis;

Figure 9 shows 'pull mode' of data inspection for patient and healthcare provider;

- Figure 10 shows how the system may be used to provide early indication of a potential complication;
- Figure 11 shows how the system may be used to provide automatic medicinal intervention;
- 5 Figure 12 shows an example of a standard profile for a graph of fracture movement versus time;
- Figure 13 shows an example of three potential complications that could be detected using the graph in Figure 12;
- Figure 14 shows another data set indicating potential complications using normal, and  
10 upper and lower quartile data curves;
- Figure 15 shows the detection of a catastrophic event;
- Figure 16 shows the use of the upper lower quartile data curves detecting further potential complications;
- Figure 17 shows another data set where a patient has been motivated by the data;
- 15 Figure 18 shows the use of data-fit equations to predict a healing end point.

Figure 1 is a typical embodiment of the bone fixation system. The bone fixation system is operable to implement the method of the present invention. A bone fixator (1) (for the sake of clarity this is illustrated as an external fixator but could be any fixation system such as an intramedullary nail, a plate or any other applicable fixation method) is used to fix a  
20 fracture. Attached to the fixation is a data-logging system (2). This has the ability to log data in a variety of forms, store this data and transmit this data. The data logging system could be integral to the fixation, or it could be a stand alone item. In addition to item (2) a variety of one or more sensors will be required to measure parameters of the patient, which are of importance (3). These parameters may be, but are not limited to, interfragmentary movement,  
25 pedometer data, fracture site temperature, lactic acid levels, measured strain, compartmental pressure, elevation and/or orientation and/or attitude of the fracture and/or of the patient, e.g. a limb of the patient. The sensors themselves could be wired directly to the data-logging unit (2) or could be connected wirelessly. The data-logging unit (2) would be required to collect the data from the sensors (3), and this could be in any form for example time-domain,  
30 frequency domain or tabular, and then store this locally until it is required. One method of data analysis would be to upload the data to a main server (4), or host computer (not shown). The uploading could be conducted using wired technology, wireless technology (such as

Zigbee or Bluetooth), or using internet (or cloud) technology (for example 3G, 4G or WiFi). It is anticipated, however, that the greatest strength of the invention will be the use of internet based communication to a main server (4). The uploading could be synchronous or asynchronous.

5 In another embodiment, a processing means (not shown) connected to the bone fixator (1) and data-logging unit (2) could perform data-analysis. The raw logged data and/or processed data could then be sent to the main server (4), or host computer (not shown), for storage and/or to provide a back-up analysis of the logged data.

Another embodiment is a complete, stand alone data-logging system with all  
10 diagnostics pre-programmed on-board.

The main server (4) has a number of main tasks. The first task will be to collect the data from patients on a regular basis. This could be in either push or pull modes. For example, the data-logging system could detect an open Wi-Fi zone and then use this internet service to upload data to the server (push); alternatively the server could 'dial' the data-logging unit and  
15 then enforce uploading of data (pull). The server's 2<sup>nd</sup> task will be to analyse and store the data that has been uploaded. This data could be numerical, or it could be graphical (some examples are given later); equally it could be a diagnostic result. However all data may need to be stored anonymously. To this end the third task of the server will be registration of the data-logging system such that only the patient and their healthcare practitioner have access to  
20 the data (described later). The fourth task of the server will be to communicate the data to the patient (5), the healthcare provider (6) and the healthcare community (7); the preferred methodology is described more fully later. It is suggested that this communication is once again push and pull. In the context of data interrogation 5,6 and 7 would interrogate their data at will in a pull mode; however if the system detected the onset of a complication then the  
25 system would contact the healthcare provider in push mode.

Figures 2, 3 and 4 illustrate further embodiments for the system illustrated in Figure 1. Figure 2 is an intramedullary nail (8); Figure 3 is a plate (9); and Figure 4 a plaster-of-paris (or other appropriate material) cast (10).

Figure 5 illustrates how the system could be used to provide feedback to a bone  
30 fixation system, in this case a 'ring-fixation' system (11), in order to provide manipulation commands. Ring fixators are commonly used to provide an aid to reconstruction. If the relative positions of a number of rings are data-logged via one or more suitable sensors (12)

and the structure of the ring-system (or frame) is known then the server (4) is able to provide commands for the manipulation of the frame in order to provide the planned alignment of the rings. This could be instructions to the patient who can manipulate the components manually; equally it could be commands to active components that would manipulate the components  
5 automatically. The active components could automatically manipulate the components at pre-determined time intervals dependent on how long the bone fixator has been applied for and/or in response to data collected by the bone fixation system. Manipulations to aid healing include stiffening and adjusting the alignment for example. Further to this, the bone fixation system could be used in reconstruction devices to control fixation parameters, to lengthen,  
10 align or perform bone transport for example.

Figure 6 illustrates an embodiment of a system using local servers (13). In this embodiment the data-logging system would communicate with a local server (for example the healthcare provider's or the patient's desktop computer), this local server would store and analyse the data but would receive regular updates from the main server (14). Operating much  
15 like a standard virus-detection system, local detection and analysis is conducted on the standalone system using a database of information (12). The database of information is updated, regularly, from a main server (14). In turn that main server is updated from the information stored on the stand-alone system and thus analyses the data on a global scale.

Figure 7 illustrates the registration of a new data logging system. To ensure patient  
20 confidentiality it is envisaged that each data logging unit should have a unique serial number (15); and it is this serial number that is used for all communication and storage of data (16). The only people to know this serial number would be the patient and the healthcare provider. However, as data security increases it could be envisaged that the 'patient ID' could well include pertinent personal details. Registration of the data-logger should incorporate pertinent  
25 patient data (17), for example: age, sex, body weight, fracture classification, smoker/non-smoker, alcohol consumption. This data is important for the data analysis that is to follow.

Figure 8 illustrates how a typical 'profile' may be established. In this instance movement of the fracture is analysed. Whilst the data could come in time domain form (Figure 8a) in this case the data has been analysed to count the number of events per day  
30 (frequency domain) by counting how many times a trigger level (17) was exceeded. This data in itself may be useful, but a further plot of events/day versus time (Figure 8b) could be drawn. Once again this data may be useful in itself, but having the ability to compare it

against norms is of greater value. Upper and lower quartile graphs (18) would be derived from the analysis of global data discussed previously and could be presented as data-sets based on age, sex smoker etc. The benefits of the global approach of data analysis is that these 'normal' curves could be updatable on a regular basis; this is far more powerful than having a single algorithm fixed in time. Hence Figure 8c illustrates how the data could be presented. An individual patient's 'curve' (19) could then be compared with these norms. Any variance from the norm could be an indicator of a non-compliance, a complication, or a failure (described more fully later). It is easy to envisage that this is not restricted to fracture movement, nor is it restricted to frequency domain data. This power of the data lies in the ability to compare any of the variety of measured parameters for individuals, or groups of individuals, against constantly updated norms.

Figure 9 illustrates how the patient and the healthcare provider would see this data. In this situation the data would be in 'pull' mode. The patient (20), for example, would log onto the system using their unique serial number described earlier. They could then examine their own 'profile' versus norms. They would not be able to see any other individual profile, and no one but their healthcare provider could see theirs. The healthcare (21) provider would also log onto the system but could examine any of the patients' data in their care, either individually or as a group. In this way they could see the progress of an individual patient but also how their own patients, as a whole, compare with the norms.

Figure 9 also illustrates how the data presented in Figure 8 could be used as a motivational tool for the patient. For example, the data presented (22) could be number of pedometer events per day versus number of fracture movement events per day. A sedentary patient would not have many pedometer events hence the levels will remain low whereas the upper and lower quartile norms should increase with time to a constant plateau. A patient seeing this data could be motivated to be less sedentary. Equally the same data could be viewed by the clinician as a potential issue related to pain and may wish to discuss this with the patient; but not on an ad hoc basis. There is potential to include an alarm in the data-logger to alert the patient to inactivity that only stops once acceptable activity levels have been achieved. The data-logger may be programmable with pre-determined thresholds such that the alarm is activated when such a threshold is exceeded or not reached. The alarm may be an audio alarm, a visual alarm or both.

Analysis of the data and comparison with norms will enable the system to predict when a fracture is healed; it will also detect the point when the fracture is healed. The system could then warn the healthcare provider to contact the patient, equally it could inform the patient to contact the healthcare provider. With greater confidence in the system it is possible  
5 for the system to inform the patient and who would then use the equivalent of a district nurse to remove their fixation.

One of the hidden benefits is the early detection of complications. Figure 10, for example, early detection of compartment syndrome could be accommodated using lactic acid and compartment pressure sensors. Detection could lead to a direct alarm to the healthcare  
10 provider. Other examples are the early detection of hypertrophic non-union, atrophic non-union, infection, and fixation failure. In this case the server would communicate an alarm (23) to the healthcare provider. Although this could be an immediate alarm time-zones makes this impractical and unnecessary. It is more practical for the healthcare provider to receive an email, text-message (or other electronic data form) from the server (24) at the start of the  
15 working day – in their time zone. If the alarm is urgent this could be in the form of a text message to the clinician directly.

Figure 11 illustrates a system that incorporates a medical intervention. In this example an ambulatory infusion pump (25) is activated when an infection is detected and suitable medication is administered. A similar system could also inject stimulants in the case of a non-  
20 union. It could also start stimulation using electrical, electromagnetic, mechanical, thermal or any other appropriate system.

In an embodiment of the present invention, the bone fixator is a hollow, or cannulated, fixator pin. In this embodiment, a pin may contain one or more transducers, in the form of sensors or otherwise, and these could detect physical, physiological or biological parameters  
25 within the bone or limb. Sensors that measure temperature, pressure, oxygen level or tension may be used for example. The cannulated pin may contain means for dispensing or injecting medication, and/or antibiotics, locally to the fracture site. Injection/dispense of the medication and/or antibiotics may be automated. Commands may be sent to active components in the means for dispensing/injecting, providing automated release of the medication/antibiotics.

30 Figure 12 illustrates an example of a standard graph to be used to assess fracture healing. In this case it is a graph of fracture movement events versus time. The number of events per day have been plotted as individual points (26). The standard curve (27) illustrates

4 phases. In phase 1 (28) the fracture is painful hence fracture movement is minimal. As pain subsides and confidence grows the number of events increase until a plateau of normal activity is achieved (29). As the fracture begins to heal events decrease (30) whilst ambulation is maintained. Eventually all fracture movement ceases and the fracture may be considered  
5 healed (30); in the case of the tibia this should be no later than 24 weeks or a delayed union may be indicated.

Figure 13 is the graph as illustrated by Figure 12 but in this case three different scenarios are presented. If the data reaches the plateau but does the movement does not subside (31) then the fracture could be progressing to a non-union, early intervention is  
10 essential. Another scenario is that at the start of the pain phase the slope of the graph is abnormally low (32), this could be indicating a delayed union. An extension of 32 is a slope close to zero (33); in this case it could be a sedentary patient or a fixation that is too stiff. In both cases early intervention is highly beneficial.

Figure 14 is an extension of Figure 12; in this case the standard graph is illustrated  
15 using normal, and upper and lower quartiles (34) as presented in Figures 8 and 9. This individual patient's (35) data is falling below the lower quartile and may be indicating a delayed union (36).

Figure 15 illustrates another scenario. In this case the patient activity suddenly stops  
20 (37). This is a catastrophic failure alarm and could be due to onset of severe pain, it could be the patient has had an accident or is severely ill, or the fixation has catastrophically failed or seized. Early intervention is required. Figure 16 is the opposite and is indicating too much movement (38); this could be indicating that the fixation is too flexible (which in turn could lead to a mal-union) or it could be that the fracture is progressing to a non-union.

Figure 17 illustrates how the data can provide motivation. In this case the patient has  
25 noticed that their activity levels are low (39) and decide to become more mobile. As a consequence their activity returns to within the normal boundaries and their healing pattern is normal.

Figure 18 illustrates how data-fitting can be used to predict healing end-point. As normal data gets collected a known equation can be fitted to predict the overall profile. In  
30 Figure 18(a) the data has only just started (40) and hence a first data-fit (41) obtains a rough estimate of healing end-point, T (42). As more data is collected (43), as in Figure 18(b), the fitted data produces a curve (44) which will settle to a more consistent estimate for healing

end-point, T (45). This information not only informs the healthcare team of the potential appointment for fixation removal but can also motivate patients.

The bone fixation system may comprise a plurality of sensors, which may measure a plurality of parameters. This may be useful in detecting the rate of healing and/or the onset of  
5 any particular problems which may be associated with the bone fixation system.

Sensors may include a strain gauge, which may enable the measurement of strain on the bone fixation to be used to assess fracture site excursions. In one embodiment, the fixator body comprises a composite material re-inforced with glass fibres and these fibres may be used as optical strain gauges. Sensors that measure a combination of linear and torsional  
10 strains may be used, which may enable measurement of motion in all degrees of freedom at the fracture site. This may be helpful in providing an accurate measure of patient activity level and/or movement at the fracture site.

Combinations of other measurements may be used to assess the rate of healing and/or any problems associated with the bone fixation system. A pedometer, associated with the  
15 bone fixation system, may be used to measure the activity of the patient. Activity of the wearer may be helpful in providing a more accurate and reliable measure of bone fracture condition and/or a measure of the progression of healing of the bone fracture. Any temperature monitoring means, associated with the bone fixation system, may be used to measure temperature at the fracture site. Parameters may have thresholds associated with  
20 them that enable a reading to be classed as 'high' or 'low', which may depend on the length of time for which the bone fixation system has been applied and/or on how long it has been since the fracture occurred. A processing means may compare the measured data to these thresholds.

Measurement of patient activity, when combined with measurement of the fracture  
25 activity, may be beneficial as it may be used to assess the progression of the healing, onset of non-union and/or any subsequent failure of the fixation system. For example, if the patient activity is measured to be high, the fracture activity is measured to be low, and the number of weeks for which the bone fixation system has been applied is less than 7, this may suggest over-stiff fixation has been applied. Alternatively, if the patient activity is measured to be low,  
30 the fracture activity is measured to be high, and the number of weeks for which the bone fixation system has been applied is less than 7, this may suggest an unstable fixation or that

- 17 -

the fixation is too flexible. Alternatively, if the patient activity is high, the fracture activity is high and the fracture activity is not decaying, this may indicate an atrophic non-union.

In another example, if the patient activity is low, the fracture activity is high and the fracture site temperature is high, this may suggest hypertrophic non-union.

5        Acceleration of the bone fixation system may also be measured, by way of a one-axis accelerometer connected to the bone fixation system, or otherwise. This may be used to assess whether the bone fixation system, and/or bone or part connected thereto is in a raised position. Measurement of acceleration may be used to assess fracture stiffness; this may be performed by multiplying the acceleration by a bodyweight factor, measuring the bend in the bone  
10    fixator and combining these results.

In an embodiment of the present invention, the fixator pin is electrically insulated. This may enable measurement of the potential difference across the fracture site, which may provide indications of the progression of healing.

In any embodiment of the invention, an indicating means, such as an alarm, may  
15    additionally be associated with the bone fixation system and may be used to indicate a problem to the user if the measured data is not as expected, if it exceeds or does not reach a threshold for example.

The above embodiments are described by way of example only. Many variations are possible without departing from the scope of the invention as defined in the appended claims.

20

**CLAIMS**

1. A method of monitoring a bone fracture in an individual, the method comprising the steps of:

5           measuring a first parameter indicative of the load on said bone fracture;  
          measuring a second parameter indicative of the activity level of said individual;  
          obtaining a plurality of values for said first and second parameters;  
          correlating said values to determine a measure of bone fracture condition;  
          monitoring a change in said correlation over time; and  
10          determining a measure of the change in bone fracture condition over time.

2. A method as claimed in claim 1 wherein said first parameter is any one of: inter-fragmentary movement; deformation; acceleration; pressure; strain; and any combination(s) thereof.

15

3. A method as claimed in any preceding claim wherein said second parameter is any one of: hip movement; acceleration; orientation; and any combination(s) thereof.

4. A method as claimed in any preceding claim wherein the method further comprises the steps of:

20

          measuring a third parameter associated with said bone fracture;  
          obtaining a plurality of values for said third parameter;  
          correlating said values to determine a measure of bone fracture condition;  
          monitoring a change in said correlation over time; and  
25          determining a measure of the change in bone fracture condition over time.

5. A method as claimed in claim 4 wherein said third parameter is any one of: temperature; lactic acid level; hip movement; acceleration; orientation; strain; pressure; oxygen level; tension; and any combination(s) thereof.

30

6. A method as claimed in any preceding claim wherein on measuring at least one of said parameters to obtain a value, the method further comprises the step of: comparing said at least one measured parameter value to at least one threshold value; and activating an

- 19 -

indicating means when said at least one threshold value is exceeded.

7. A method as claimed in any preceding claim wherein determining a measure of the change in bone fracture condition over time further comprises the step of: comparing said correlated data with pre-determined data typical of healing bone fractures.
8. A method as claimed in claim 7 wherein said pre-determined data comprises any or all of average, upper and lower boundaries for values of said correlated data typical of healing bone fractures.
9. A method as claimed in any preceding claim wherein the method further comprises the step of: providing an output based on at least one of said determinations.
10. A method as claimed in claim 9 wherein providing an output involves providing feedback on any, some or all of: whether the bone fracture is healing; the progression of healing of the bone fracture; predicting the endpoint of the healing process; whether a problem has developed with the bone fracture; whether the patient is not active enough or is too active.
11. A method as claimed in claim 10, when dependent directly or indirectly on claim 7, wherein predicting the endpoint of the healing process comprises the steps of: extrapolating said correlated data to a point representing a healed bone fracture based on said pre-determined data; and calculating a time period over which the fracture can be expected to reach said point.
12. A method as claimed in any preceding claim wherein the method further comprises the steps of: detecting whether there is a problem associated with a bone fixator applied to the bone fracture based on at least one of said determinations; and, if a problem is detected, identifying said problem and sending feedback commands to an actuation means for manipulating said bone fixator based on the identified problem.
13. A method as claimed in claim 12, wherein the steps of identifying said problem, sending feedback commands and manipulating said bone fixator, are automatically controlled.

- 20 -

14. A bone fixation system operable to implement the method as described in any preceding claim.

15. A bone fixation system comprising:

- 5                   a bone fixator for application to a bone fracture site;  
                  a first sensor for measuring a first parameter indicative of load on said bone fracture and generating associated first parameter data;  
                  a second sensor for measuring a second parameter indicative of the activity level of said individual and generating associated second parameter data;  
10                  a processing means for correlating said first and second parameter data to determine a measure of bone fracture condition, and for determining a change in said correlation over time to determine a measure of the change in bone fracture condition over time.

15   16. A bone fixation system as claimed in claim 15, wherein the processing means compares at least said first parameter to a threshold and records an event when this threshold is exceeded.

20   17. A bone fixation system as claimed in claim 16, the system further comprising an indicating means operable to automatically activate when an event is recorded.

18. A bone fixation system as claimed in any of claims 15 to 17 wherein the system further comprises an output means for providing an output on at least one of said determinations.

**AMENDED CLAIMS**  
**received by the International Bureau on 15 January 2015 (15.01.2015)**

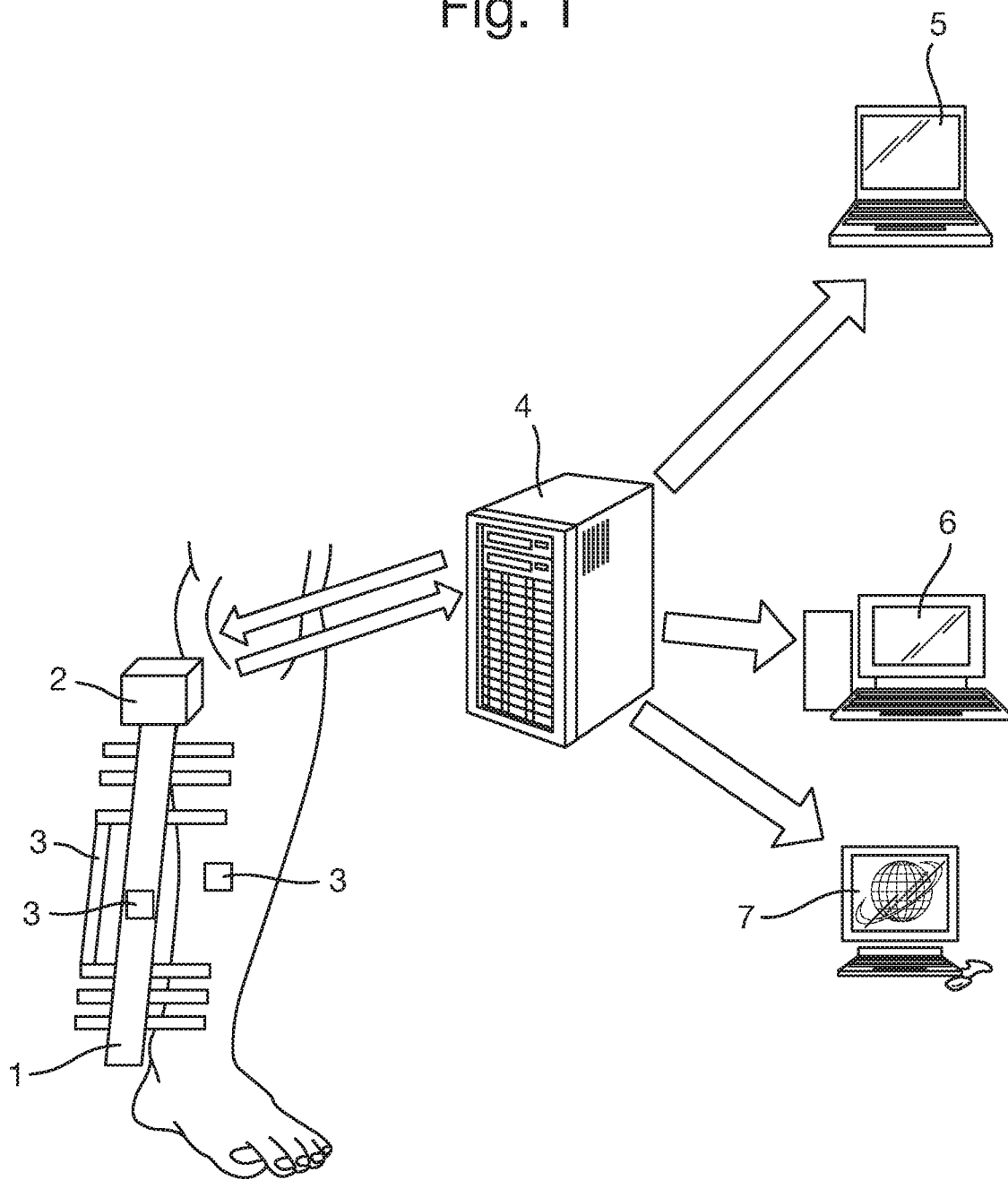
1. A method of monitoring a bone fracture in an individual, the method comprising the steps  
of:  
5           measuring a first parameter indicative of the load on said bone fracture;  
            measuring a second parameter indicative of the activity level of said individual;  
            obtaining a plurality of values for said first and second parameters;  
            correlating said values to determine a measure of bone fracture condition;  
            monitoring a change in said correlation over time; and  
10           determining a measure of the change in bone fracture condition over time.
2. A method as claimed in claim 1 wherein said first parameter is any one of: inter-  
fragmentary movement; deformation; acceleration; pressure; strain; and any  
combination(s) thereof.
- 15           3. A method as claimed in any preceding claim wherein said second parameter is any one of:  
            hip movement; acceleration; orientation; and any combination(s) thereof.
4. A method as claimed in any preceding claim wherein the method further comprises the  
20           steps of:  
            measuring a third parameter associated with said bone fracture;  
            obtaining a plurality of values for said third parameter;  
            correlating said values to determine a measure of bone fracture condition;  
            monitoring a change in said correlation over time; and  
25           determining a measure of the change in bone fracture condition over time.
5. A method as claimed in claim 4 wherein said third parameter is any one of: temperature;  
lactic acid level; hip movement; acceleration; orientation; strain; pressure; oxygen level;  
tension; and any combination(s) thereof.
- 30           6. A method as claimed in any preceding claim wherein on measuring at least one of said  
            parameters to obtain a value, the method further comprises the step of: comparing said at  
            least one measured parameter value to at least one threshold value; and activating an

indicating means when said at least one threshold value is exceeded.

7. A method as claimed in any preceding claim wherein determining a measure of the change in bone fracture condition over time further comprises the step of: comparing said correlated data with pre-determined data typical of healing bone fractures.
8. A method as claimed in claim 7 wherein said pre-determined data comprises any or all of average, upper and lower boundaries for values of said correlated data typical of healing bone fractures.
9. A method as claimed in any preceding claim wherein the method further comprises the step of: providing an output based on at least one of said determinations.
10. A method as claimed in claim 9 wherein providing an output involves providing feedback on any, some or all of: whether the bone fracture is healing; the progression of healing of the bone fracture; predicting the endpoint of the healing process; whether a problem has developed with the bone fracture; whether the patient is not active enough or is too active.
11. A method as claimed in claim 10, when dependent directly or indirectly on claim 7, wherein predicting the endpoint of the healing process comprises the steps of: extrapolating said correlated data to a point representing a healed bone fracture based on said pre-determined data; and calculating a time period over which the fracture can be expected to reach said point.
12. A method as claimed in any preceding claim wherein the method further comprises the steps of: detecting whether there is a problem associated with a bone fixator applied to the bone fracture based on at least one of said determinations; and, if a problem is detected, identifying said problem and sending feedback commands to an actuation means for manipulating said bone fixator based on the identified problem.
13. A method as claimed in claim 12, wherein the steps of identifying said problem, sending feedback commands and manipulating said bone fixator, are automatically controlled.

14. A bone fixation system comprising a bone fixator, a first sensor, a second sensor and a processing means, the bone fixation system operable to implement the method as described in any preceding claim.
- 5 15. A bone fixation system comprising:
- a bone fixator for application to a bone fracture site;
  - a first sensor for measuring a first parameter indicative of load on said bone fracture and generating associated first parameter data;
  - a second sensor for measuring a second parameter indicative of the activity level
  - 10 of said individual and generating associated second parameter data;
  - a processing means for correlating said first and second parameter data to determine a measure of bone fracture condition, and for determining a change in said correlation over time to determine a measure of the change in bone fracture condition over time.
- 15 16. A bone fixation system as claimed in claim 15, wherein the processing means compares at least said first parameter to a threshold and records an event when this threshold is exceeded.
- 20 17. A bone fixation system as claimed in claim 16, the system further comprising an indicating means operable to automatically activate when an event is recorded.
18. A bone fixation system as claimed in any of claims 15 to 17 wherein the system further comprises an output means for providing an output on at least one of said determinations.

Fig. 1



2/14

Fig. 2

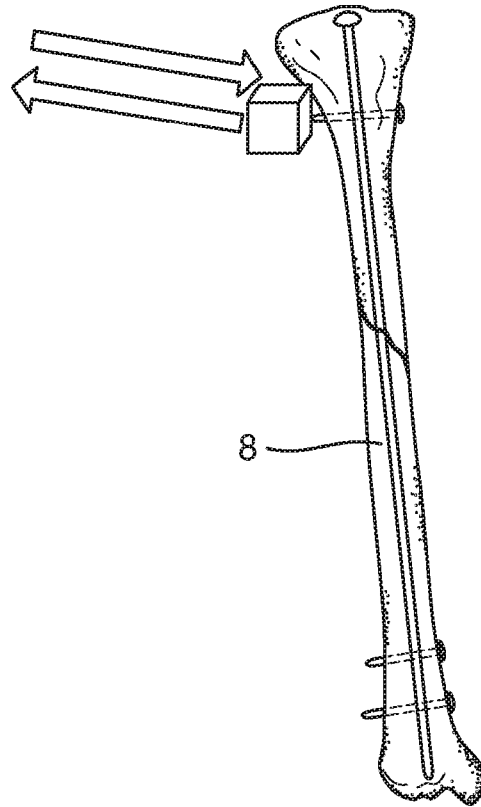


Fig. 3

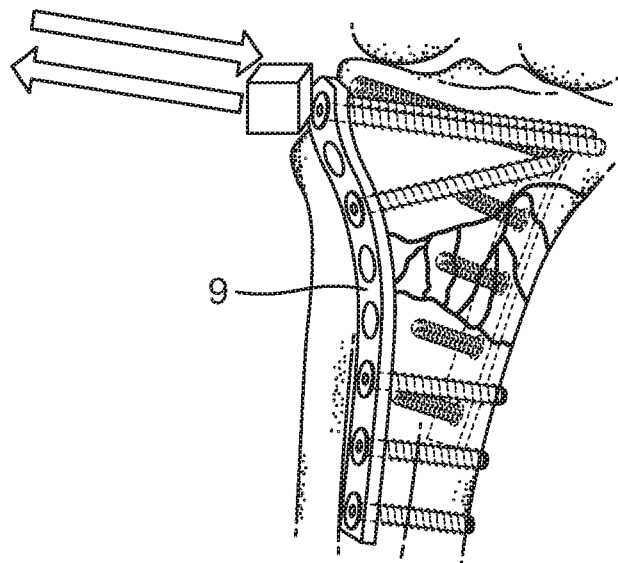


Fig. 4

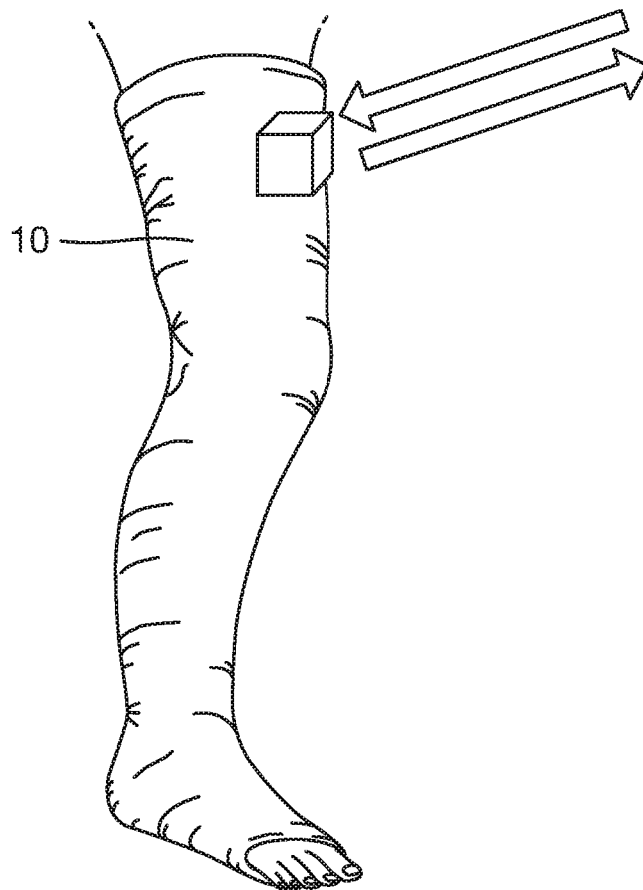


Fig. 5

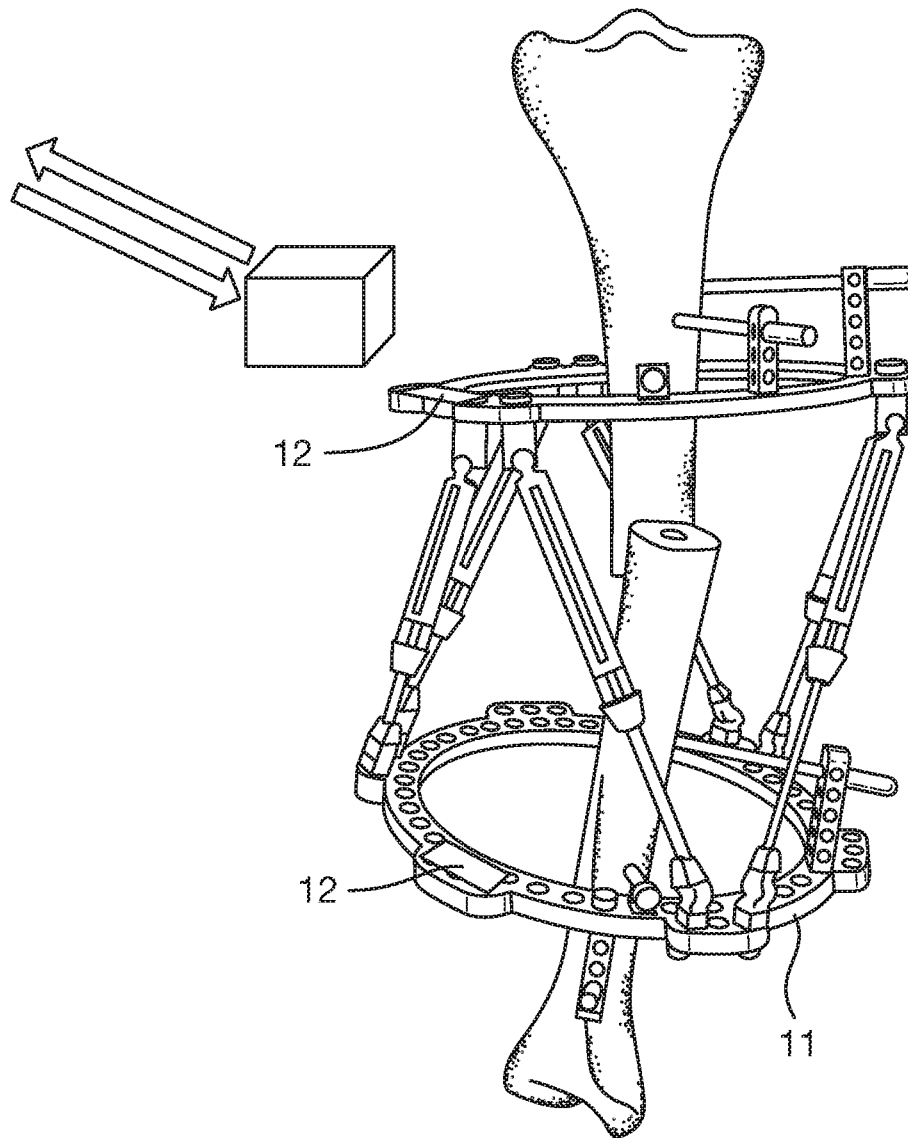
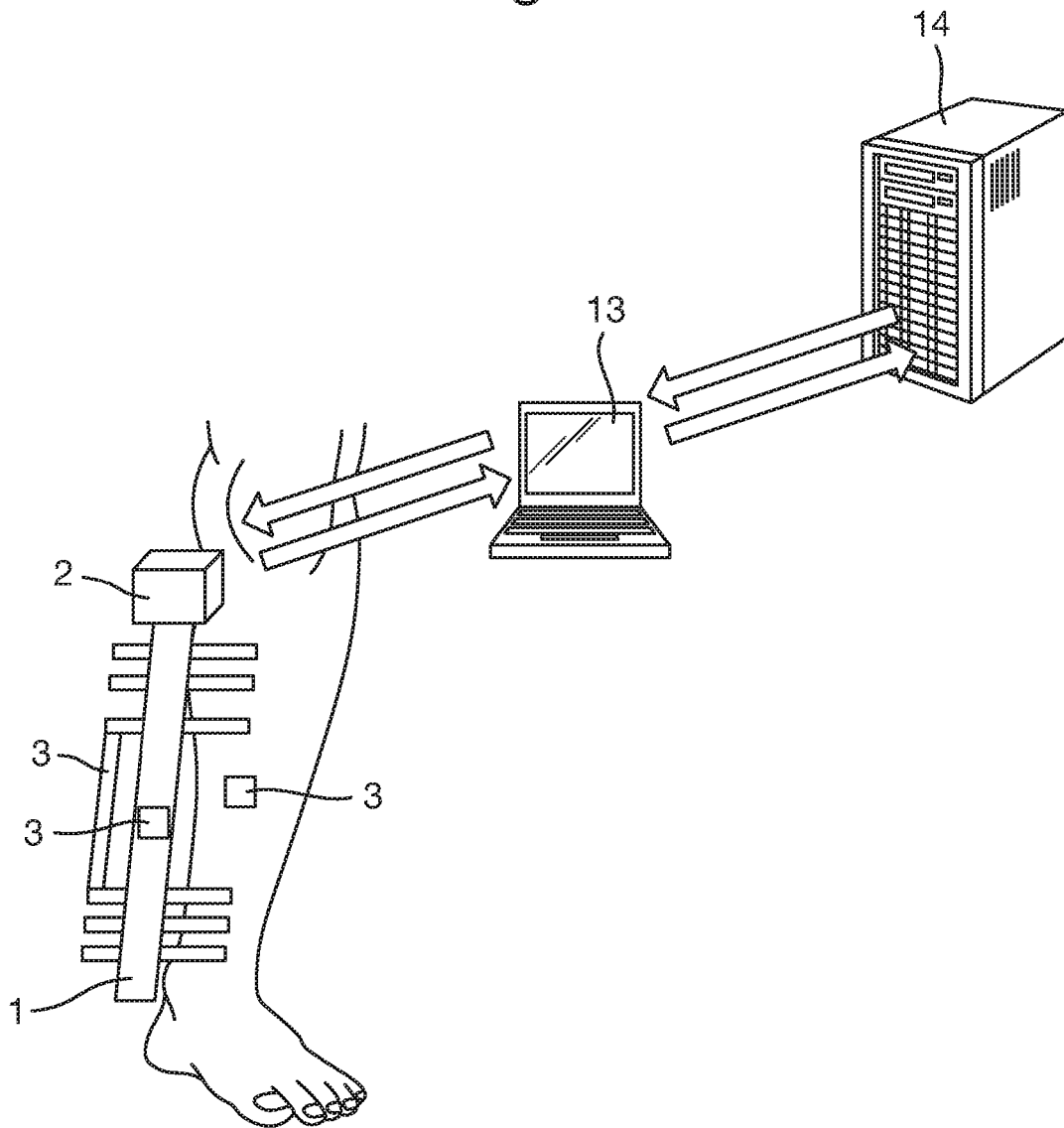
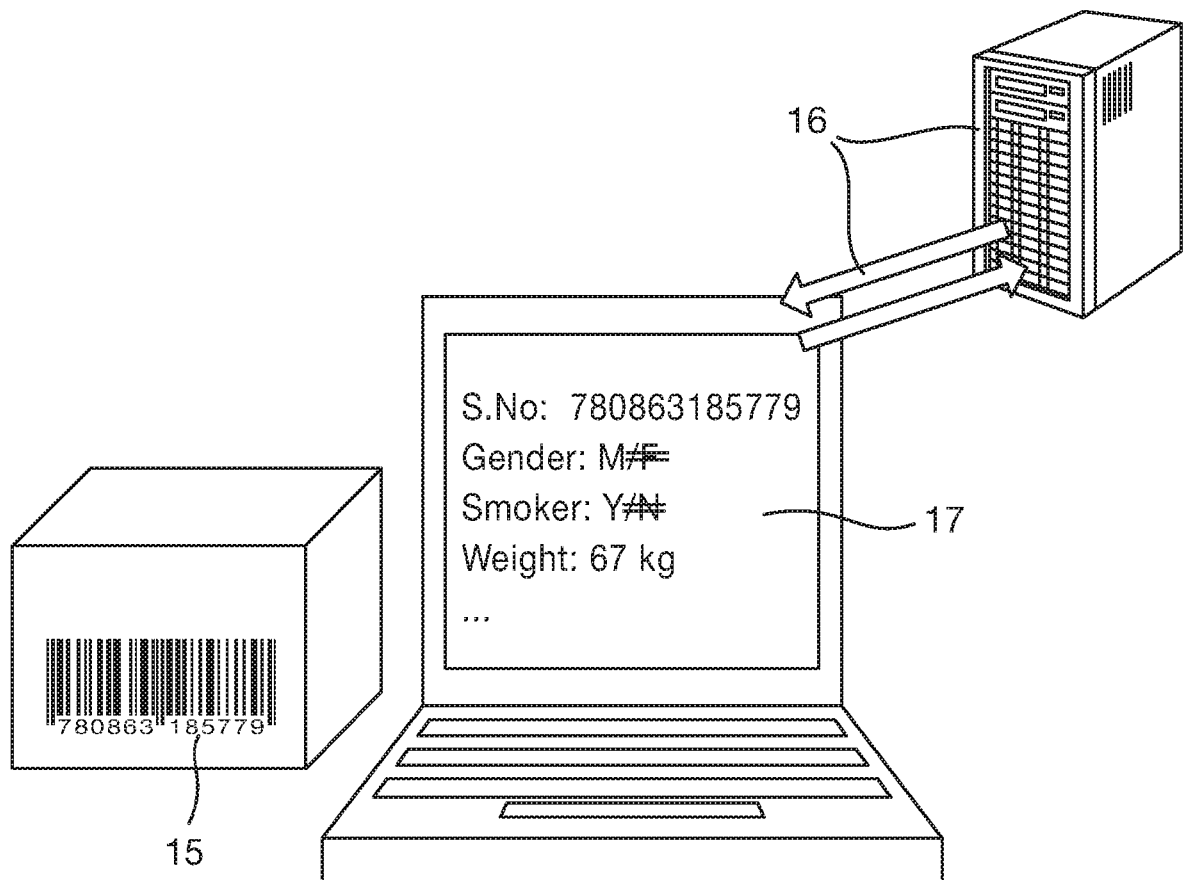


Fig. 6



6/14

Fig. 7



7/14

Fig. 8(a)

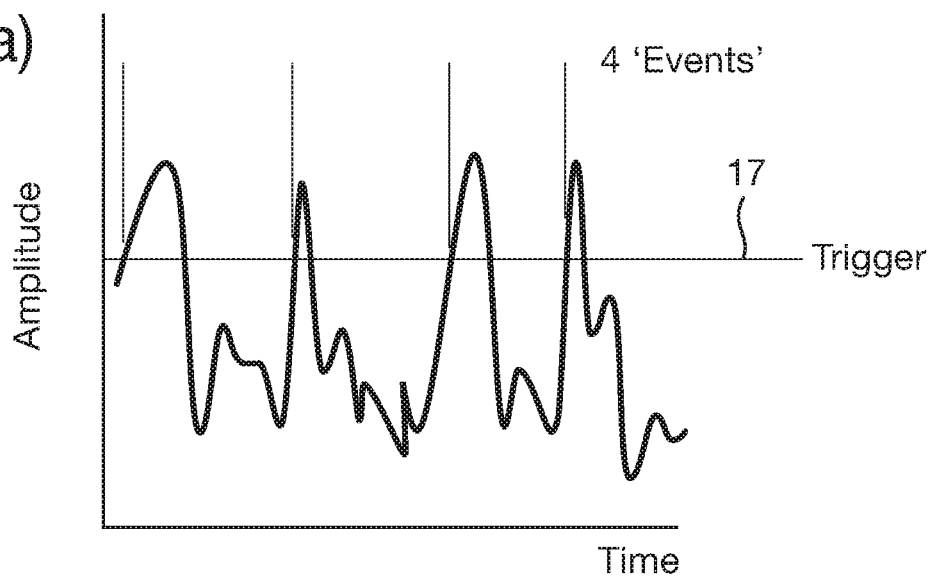


Fig. 8(b)

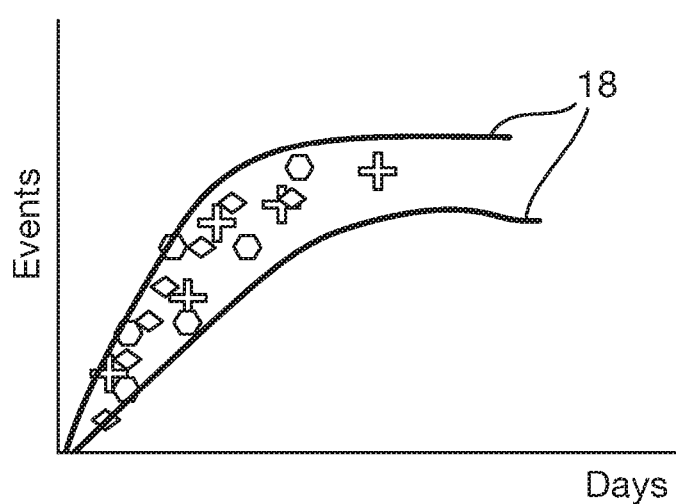


Fig. 8(c)

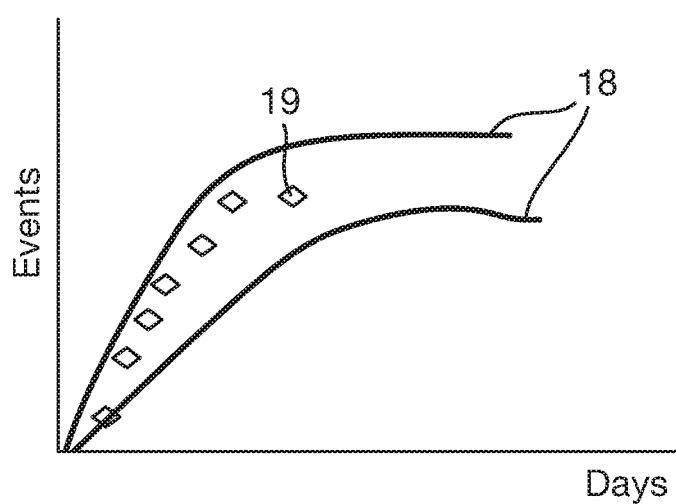
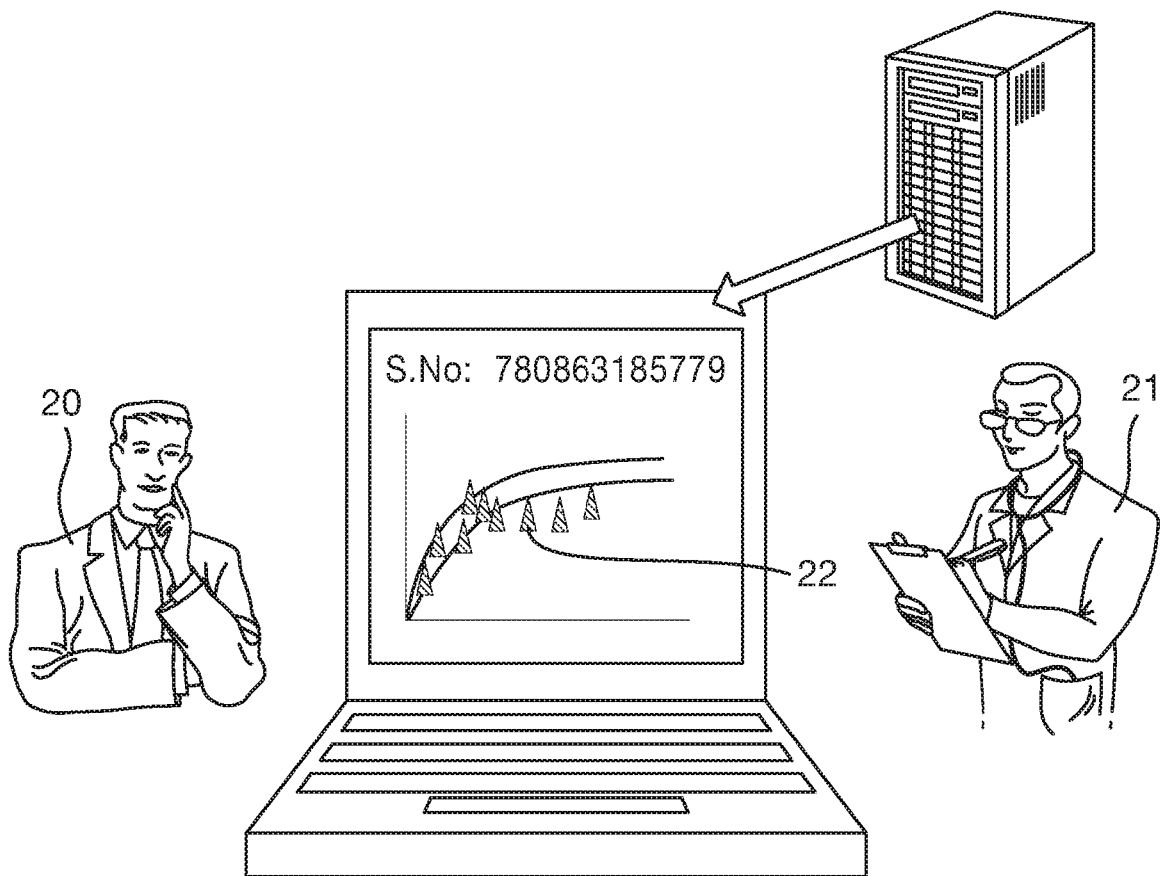


Fig. 9



9/14

Fig. 10

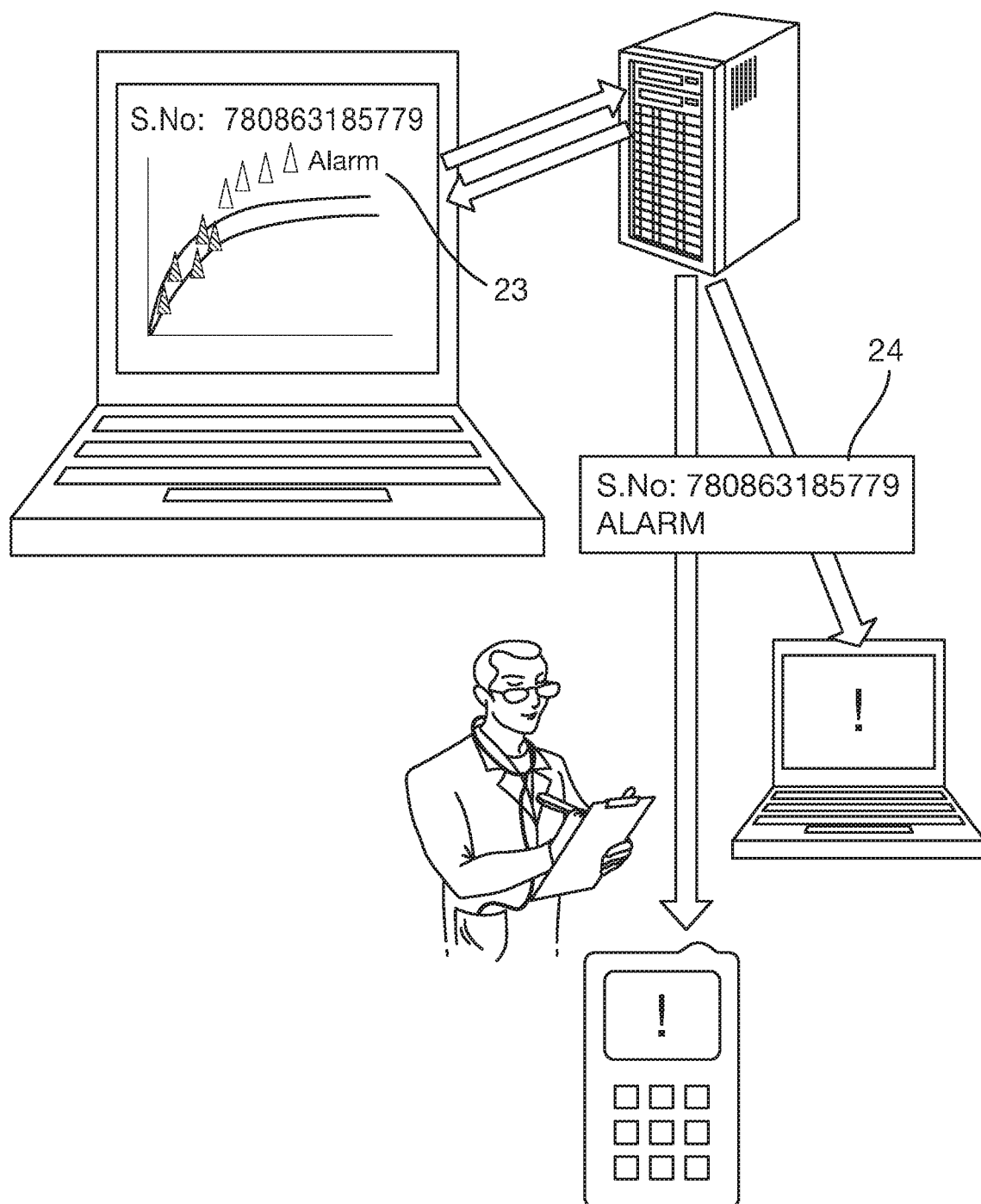
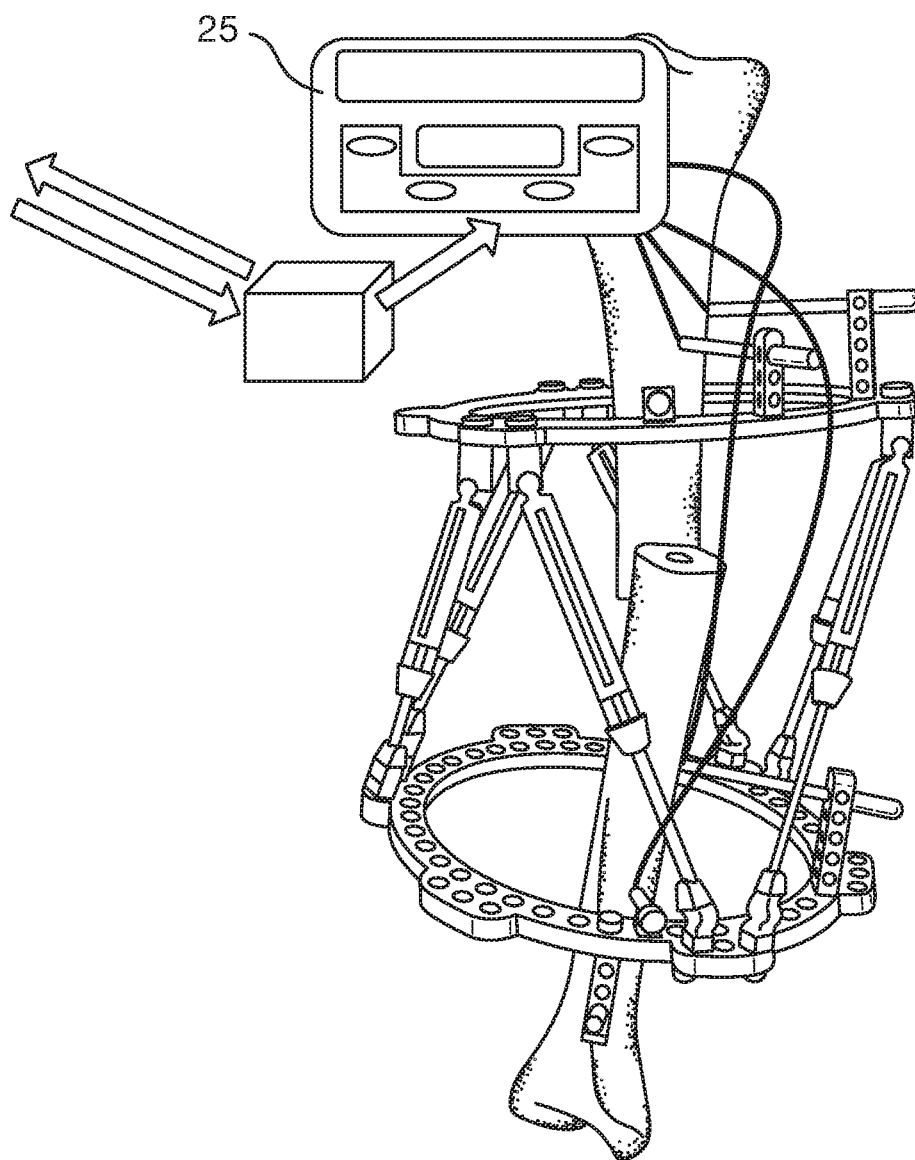


Fig. 11



11/14

Fig. 12

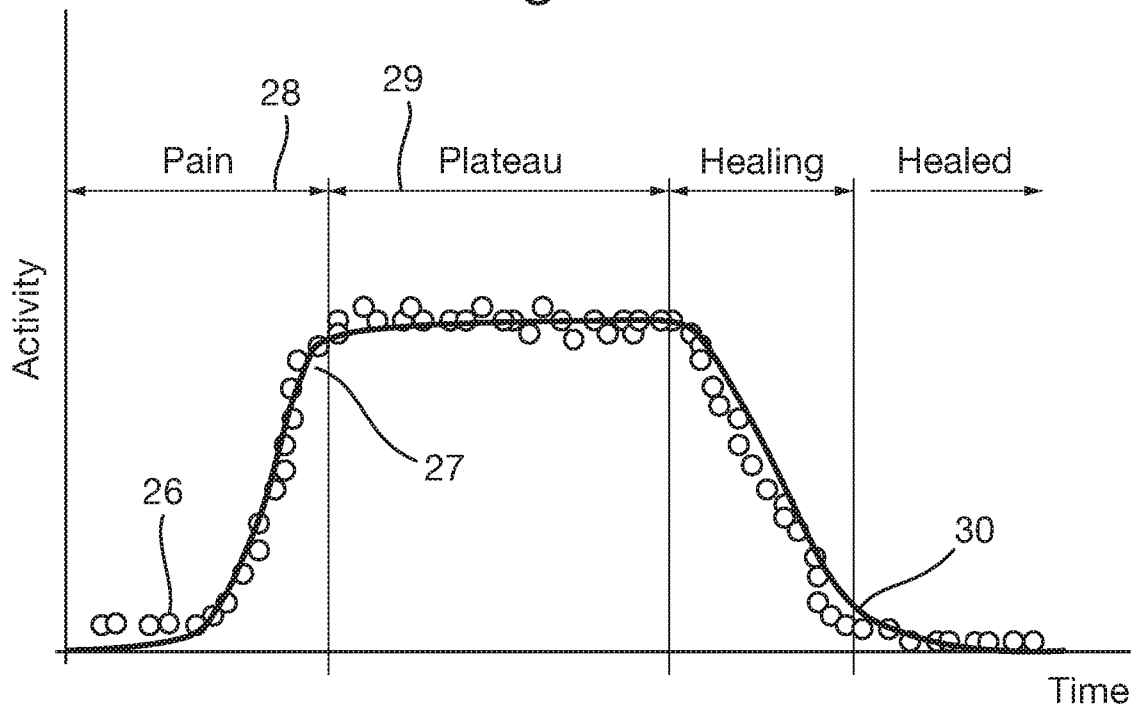
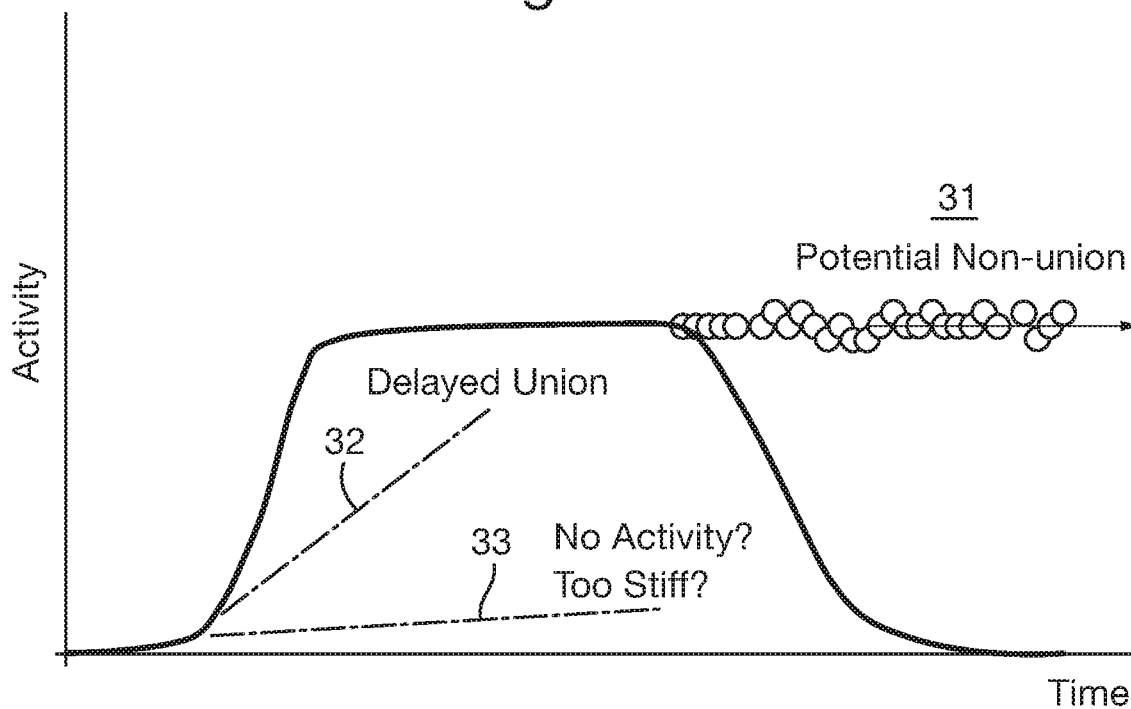


Fig. 13



12/14

Fig. 14

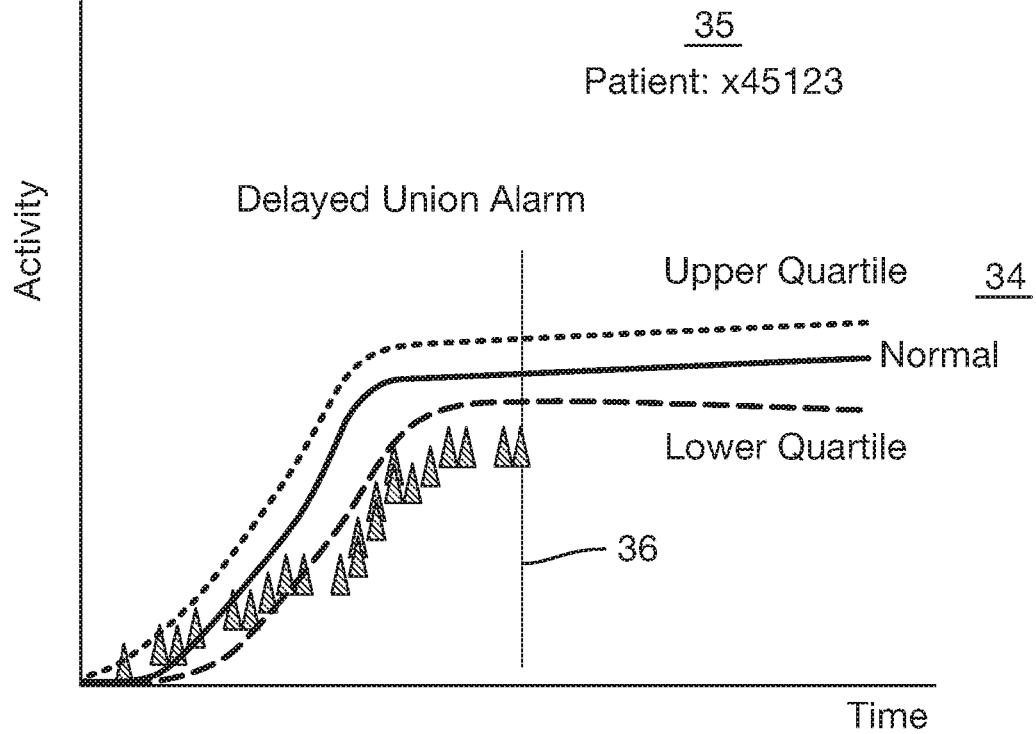
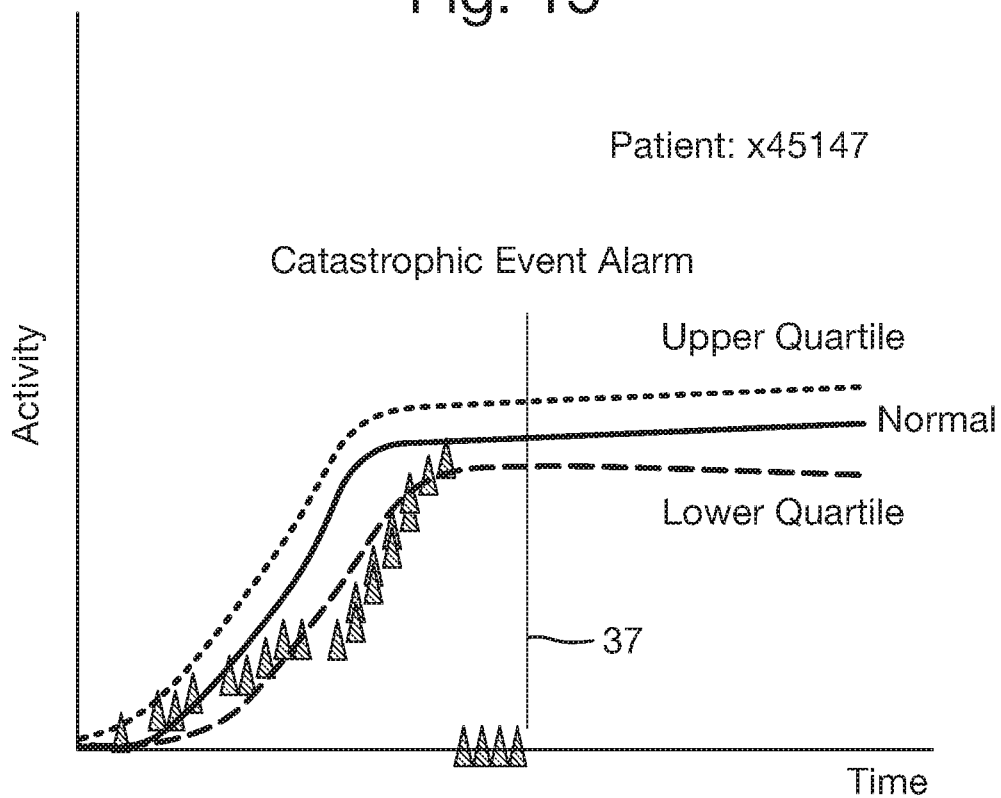


Fig. 15



13/14

Fig. 16

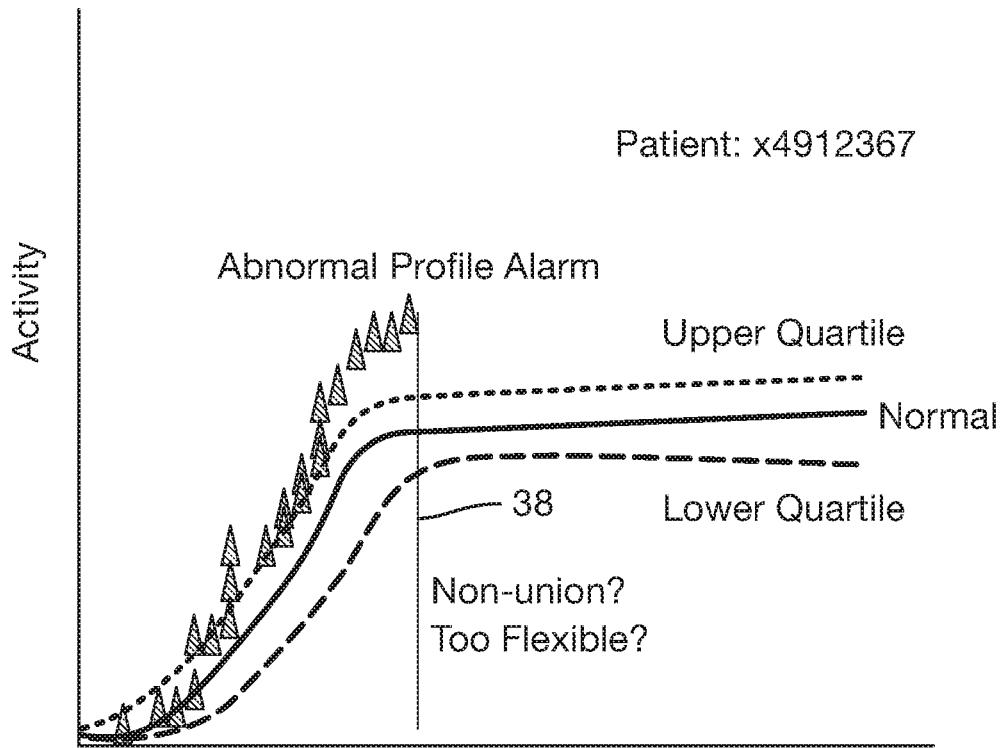
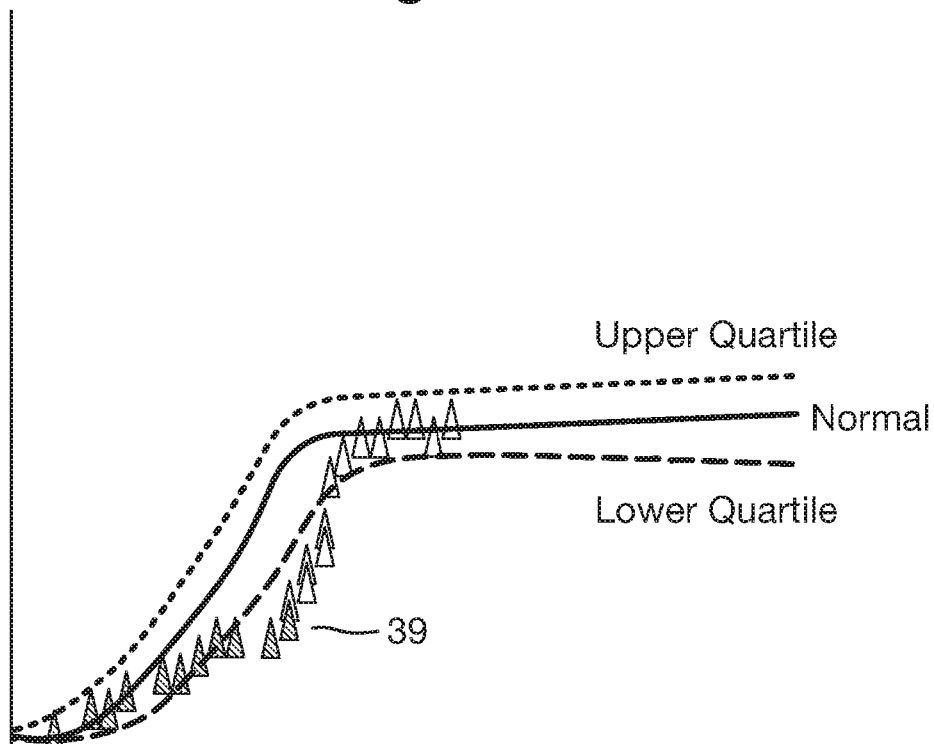


Fig. 17



14/14

Fig. 18(a)

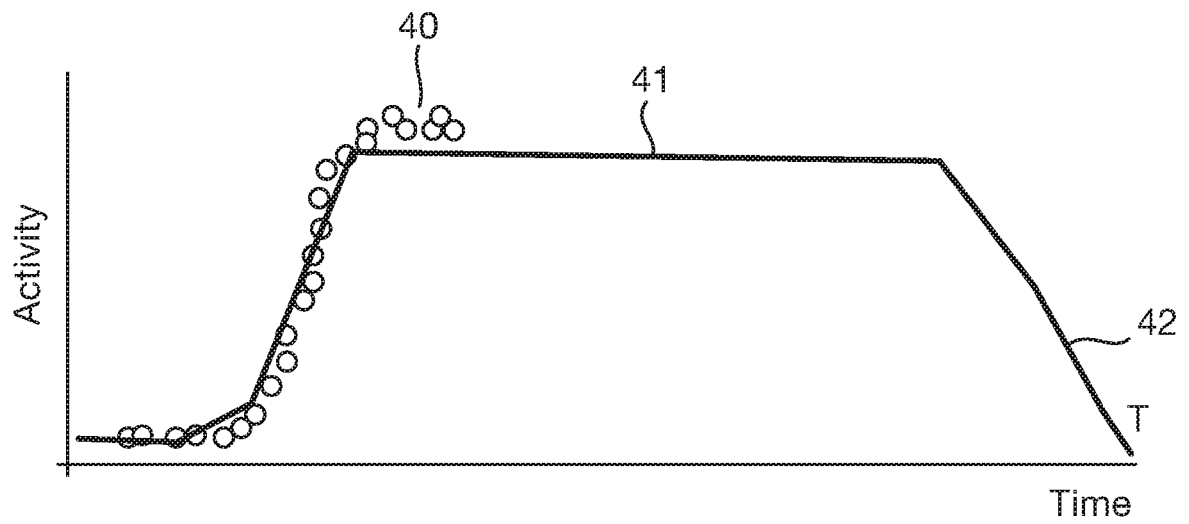
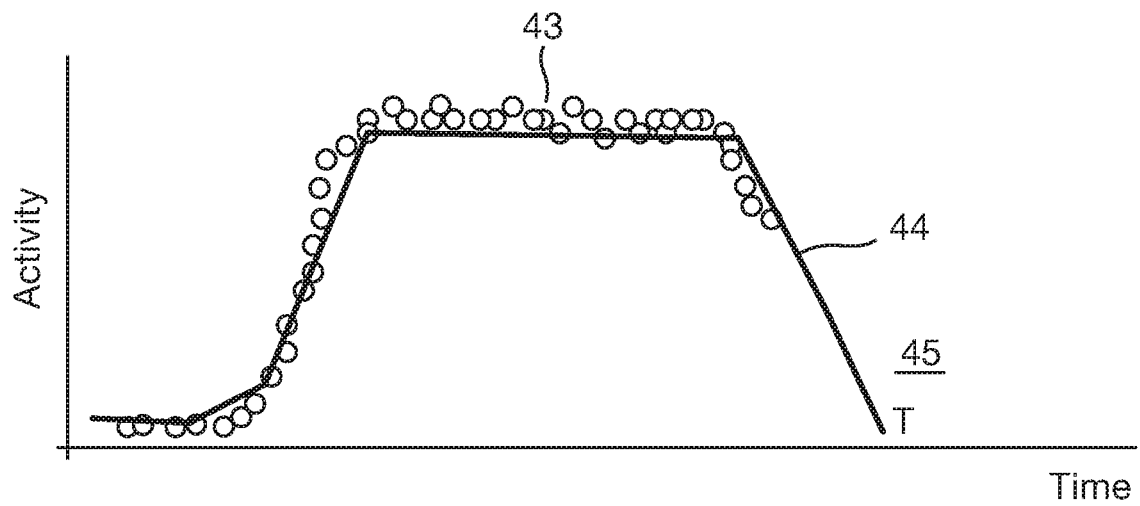


Fig. 18(b)



# INTERNATIONAL SEARCH REPORT

International application No  
PCT/GB2014/052779

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>INV. A61B5/00 A61B17/60 A61B17/68 A61B17/70 A61B17/72<br>A61B17/80<br>ADD.<br>According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|---|---------------------------------------------------------------------------------------------------------------------------------|----|---|--------------|-------|
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>A61B<br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>EPO-Internal, WPI Data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%; padding: 5px;">Category*</th> <th style="width: 70%; padding: 5px;">Citation of document, with indication, where appropriate, of the relevant passages</th> <th style="width: 20%; padding: 5px;">Relevant to claim No.</th> </tr> </thead> <tbody> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">           WO 2007/025191 A1 (SMITH &amp; NEPHEW INC [US]; MORGAN ROBERT L [GB]; WICKHAM MARK D [GB]; BR) 1 March 2007 (2007-03-01) paragraphs [0064], [0074], [0087], [0088]; figure 1<br/>           -----         </td> <td style="text-align: center; vertical-align: top; padding: 5px;">14-18</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">           WO 2011/044220 A1 (UNIV MASSACHUSETTS MEDICAL [US]; WIXTED JOHN J [US]) 14 April 2011 (2011-04-14) page 2, lines 14-20; figures 1-3 page 7, lines 5-20 page 8, line 24 - page 10, line 23<br/>           -----         </td> <td style="text-align: center; vertical-align: top; padding: 5px;">14,15,18</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">           US 6 034 296 A (ELVIN NIELL [US] ET AL) 7 March 2000 (2000-03-07) column 4, line 54 - column 5, line 67; figures 2,3,7<br/>           -----         </td> <td style="text-align: center; vertical-align: top; padding: 5px;">14</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">           -----<br/>           -/-         </td> <td style="text-align: center; vertical-align: top; padding: 5px;">15-18</td> </tr> </tbody> </table> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                | Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Relevant to claim No. | X | WO 2007/025191 A1 (SMITH & NEPHEW INC [US]; MORGAN ROBERT L [GB]; WICKHAM MARK D [GB]; BR) 1 March 2007 (2007-03-01) paragraphs [0064], [0074], [0087], [0088]; figure 1<br>----- | 14-18 | X | WO 2011/044220 A1 (UNIV MASSACHUSETTS MEDICAL [US]; WIXTED JOHN J [US]) 14 April 2011 (2011-04-14) page 2, lines 14-20; figures 1-3 page 7, lines 5-20 page 8, line 24 - page 10, line 23<br>----- | 14,15,18 | X | US 6 034 296 A (ELVIN NIELL [US] ET AL) 7 March 2000 (2000-03-07) column 4, line 54 - column 5, line 67; figures 2,3,7<br>----- | 14 | A | -----<br>-/- | 15-18 |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Relevant to claim No.                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | WO 2007/025191 A1 (SMITH & NEPHEW INC [US]; MORGAN ROBERT L [GB]; WICKHAM MARK D [GB]; BR) 1 March 2007 (2007-03-01) paragraphs [0064], [0074], [0087], [0088]; figure 1<br>-----                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 14-18                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | WO 2011/044220 A1 (UNIV MASSACHUSETTS MEDICAL [US]; WIXTED JOHN J [US]) 14 April 2011 (2011-04-14) page 2, lines 14-20; figures 1-3 page 7, lines 5-20 page 8, line 24 - page 10, line 23<br>-----                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 14,15,18                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | US 6 034 296 A (ELVIN NIELL [US] ET AL) 7 March 2000 (2000-03-07) column 4, line 54 - column 5, line 67; figures 2,3,7<br>-----                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 14                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | -----<br>-/-                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 15-18                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| <input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| * Special categories of cited documents :<br><table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;">           "A" document defining the general state of the art which is not considered to be of particular relevance<br/>           "E" earlier application or patent but published on or after the international filing date<br/>           "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)<br/>           "O" document referring to an oral disclosure, use, exhibition or other means<br/>           "P" document published prior to the international filing date but later than the priority date claimed         </td> <td style="width: 50%; vertical-align: top;">           "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<br/>           "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<br/>           "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<br/>           "&amp;" document member of the same patent family         </td> </tr> </table>                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                | "A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"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)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<br>"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<br>"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<br>"&" document member of the same patent family |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| "A" document defining the general state of the art which is not considered to be of particular relevance<br>"E" earlier application or patent but published on or after the international filing date<br>"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)<br>"O" document referring to an oral disclosure, use, exhibition or other means<br>"P" document published prior to the international filing date but later than the priority date claimed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<br>"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<br>"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<br>"&" document member of the same patent family |                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| Date of the actual completion of the international search<br><br><div style="text-align: center; font-weight: bold;">11 November 2014</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Date of mailing of the international search report<br><br><div style="text-align: center; font-weight: bold;">19/11/2014</div> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |
| Name and mailing address of the ISA/<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Authorized officer<br><br><div style="text-align: center; font-weight: bold;">Fourcade, Olivier</div>                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                       |   |                                                                                                                                                                                   |       |   |                                                                                                                                                                                                    |          |   |                                                                                                                                 |    |   |              |       |

# INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2014/052779

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                             | Relevant to claim No. |
|-----------|--------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | WO 2005/120203 A2 (MORGAN CHAD; HALL HARRY<br>T IV [US]; GREEN JAMES M [US]; FLEXNER<br>GEOFFRE) 22 December 2005 (2005-12-22) | 14                    |
| A         | paragraphs [0034], [0035], [0036],<br>[0040]; figures 1-4,6<br>-----                                                           | 15-18                 |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2014/052779

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)                                                                                                                                                                                                                  | Publication<br>date                                                                                                                                                                |
|-------------------------------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| WO 2007025191 A1                          | 01-03-2007          | AU 2006282828 A1<br>CA 2620247 A1<br>CN 103637840 A<br>EP 1924211 A1<br>JP 5518335 B2<br>JP 2009505751 A<br>JP 2013039444 A<br>US 2008300597 A1<br>US 2012277746 A1<br>WO 2007025191 A1                                                     | 01-03-2007<br>01-03-2007<br>19-03-2014<br>28-05-2008<br>11-06-2014<br>12-02-2009<br>28-02-2013<br>04-12-2008<br>01-11-2012<br>01-03-2007                                           |
| WO 2011044220 A1                          | 14-04-2011          | US 2012253345 A1<br>WO 2011044220 A1                                                                                                                                                                                                        | 04-10-2012<br>14-04-2011                                                                                                                                                           |
| US 6034296 A                              | 07-03-2000          | NONE                                                                                                                                                                                                                                        |                                                                                                                                                                                    |
| WO 2005120203 A2                          | 22-12-2005          | AU 2005251808 A1<br>BR PI0511838 A<br>CA 2569605 A1<br>CN 101060815 A<br>EP 1765204 A2<br>JP 4874970 B2<br>JP 2008501488 A<br>KR 20070049136 A<br>NZ 552049 A<br>US 2006052782 A1<br>US 2012065548 A1<br>WO 2005120203 A2<br>ZA 200700096 A | 22-12-2005<br>15-01-2008<br>22-12-2005<br>24-10-2007<br>28-03-2007<br>15-02-2012<br>24-01-2008<br>10-05-2007<br>25-09-2009<br>09-03-2006<br>15-03-2012<br>22-12-2005<br>28-05-2008 |

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB2014/052779

### 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. ☒ Claims Nos.: **1-13**  
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 6.4(a).

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

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional 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.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Claims Nos.: 1-13

Claims 1-13 relate to subject-matter considered to be covered by the provisions of Rule 39.1(iv) PCT (Method for treatment of the human or animal body by surgery), see in particular claim 1 : "measuring a first parameter indicative of the load on said bone fracture". In order to measure a parameter indicative of the load on the bone fracture, it is necessary to have a solid connection between a measuring mean (sensor) and said bone. This can only be achieved either by directly implanting the measuring mean, or by connecting the measuring mean to a fixation device attached to the bone: the implantation of the fixation device or of the sensor is done through surgery. The above-mentioned method step therefore implies a surgical step: implanting the fixation mean and/or implanting the measuring mean. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims which are also not searched.

|                |                                                                                                                                                                                                                                                                                                                                                                                 |         |            |
|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------|
| 专利名称(译)        | 骨固定系统和相关方法                                                                                                                                                                                                                                                                                                                                                                      |         |            |
| 公开(公告)号        | <a href="#">EP3043695A1</a>                                                                                                                                                                                                                                                                                                                                                     | 公开(公告)日 | 2016-07-20 |
| 申请号            | EP2014771951                                                                                                                                                                                                                                                                                                                                                                    | 申请日     | 2014-09-12 |
| [标]申请(专利权)人(译) | 在MEDICA D 2 OÒ                                                                                                                                                                                                                                                                                                                                                                  |         |            |
| 申请(专利权)人(译)    | 在.公司，公司                                                                                                                                                                                                                                                                                                                                                                         |         |            |
| 当前申请(专利权)人(译)  | 在.公司，公司                                                                                                                                                                                                                                                                                                                                                                         |         |            |
| [标]发明人         | OGRODNIK PETER JAN<br>THOMAS PETER BRIAN MACFARLANE                                                                                                                                                                                                                                                                                                                             |         |            |
| 发明人            | OGRODNIK, PETER JAN<br>THOMAS, PETER BRIAN MACFARLANE                                                                                                                                                                                                                                                                                                                           |         |            |
| IPC分类号         | A61B5/00 A61B17/60 A61B17/68 A61B17/70 A61B17/72 A61B17/80                                                                                                                                                                                                                                                                                                                      |         |            |
| CPC分类号         | A61B5/6812 A61B5/00 A61B5/0022 A61B5/0024 A61B5/01 A61B5/1036 A61B5/11 A61B5/1118 A61B5/1121 A61B5/1126 A61B5/14542 A61B5/14546 A61B5/4504 A61B5/4836 A61B5/4848 A61B5/486 A61B5/6846 A61B5/6847 A61B5/6878 A61B5/7246 A61B5/7282 A61B17/60 A61B17/68 A61B17/70 A61B17/72 A61B17/80 A61B2562/0219 A61B2562/0247 A61B2562/0252 A61B2562/0261 A61B2562/0266 A61M5/142 A61M2210/02 |         |            |
| 优先权            | 2013016263 2013-09-12 GB<br>2014013401 2014-07-29 GB                                                                                                                                                                                                                                                                                                                            |         |            |
| 外部链接           | <a href="#">Espacenet</a>                                                                                                                                                                                                                                                                                                                                                       |         |            |

#### 摘要(译)

一种监测个体骨折的方法。该方法包括以下步骤：测量指示所述骨折上的负荷的第一参数;测量指示所述个体的活动水平的第二参数;获得所述第一和第二参数的多个值;关联所述值以确定骨折状况的量度;监测所述相关性随时间的变化;并确定骨折状况随时间变化的量度。骨固定系统实施这种监测个体骨折的方法。该方法和系统提供了更准确和可靠的骨折状况测量和骨折愈合进展。