



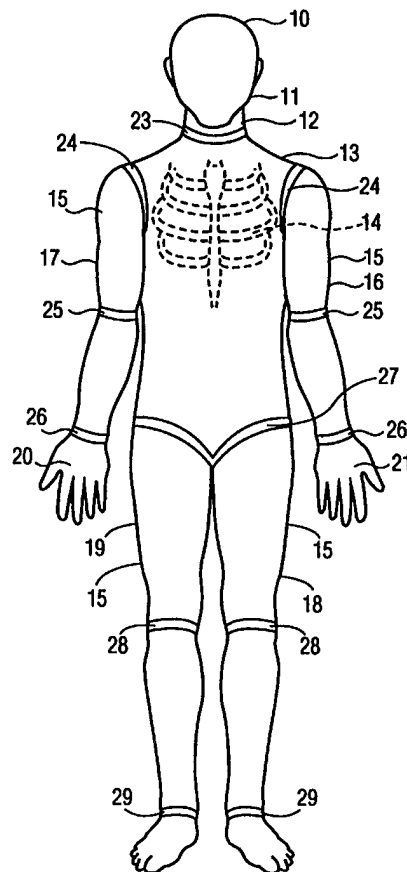
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(54) Title: METHOD AND APPARATUS FOR TESTING THE EFFICACY OF PATIENT SUPPORT SYSTEMS

(57) Abstract

This invention is an anthropomorphic model (10) for ascertaining the presence of certain forces within flexible human skin material covering the model. The anthropomorphic model can simulate the major dynamic characteristics of a human. The anthropomorphic model is adaptably representative of specific classes of human body form as regards body build, and including flexible human skin simulating materials including a cutaneous region, and a subcutaneous region covering at least parts of the model. The anthropomorphic model includes sensing means (32, 33, 34) located within the flexible human skin simulating materials for measuring physical parameters such as pressure, shear and friction forces acting on the anthropomorphic model, and means for detecting signals from the sensing means for ascertaining at least one of the pressure, shear and friction forces existing within the flexible skin simulating materials. The anthropomorphic model may be used to test the efficacy of support structures in the prevention and treatment of decubitus or pressure ulcers and related conditions.



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METHOD AND APPARATUS FOR TESTING
THE EFFICACY OF PATIENT SUPPORT SYSTEMS

1 BACKGROUND OF THE INVENTION

2

3 A decubitus ulcer, or pressure ulcer as it is
4 more commonly known, is a localized wound of
5 variable depth caused by prolonged pressure in a
6 patient allowed to lie too still in bed over an
7 extended period of time. Sustained compression of
8 the cutaneous and subcutaneous tissue between the
9 bony prominences of the patient's body and the
10 support structure, e.g. the mattress, has been cited
11 as a primary cause of pressure ulcer formation.
12 Thus, the sites most often affected in bed-ridden
13 patients include the sacrum, greater trochanter,
14 heel and scapula - these are the sites which usually
15 experience higher pressures or loads due to body
16 weight distribution.

17

18 From the treatment of patients in acute care
19 facilities to their care in the home setting, the
20 incidence of pressure ulcer development, and the
21 degeneration of tissues associated with such ulcers,
22 once formed, present a significant health care
23 problem both in terms of the amount of financial
24 resources expended in treatment and, more

1 importantly, in the morbidity and mortality
2 associated with the complications which often arise.
3 Depending on the severity of the pressure ulcer and
4 the medical condition of the patient, it has been
5 estimated that the cost of treatment can be as high
6 as \$40,000 (Brandeis et.al., JAMA 264:2905-2908
7 (1990)). In one study it was reported that the rate
8 of occurrence of bacteremia associated with pressure
9 ulcers was 3.5 events per 10,000 hospital
10 discharges. The hospital mortality rate from this
11 complication alone was estimated to be 50% (Allman,
12 Decubitis 2:30-33 (1989)).

13

14 Although current understanding of pressure
15 ulcer etiology is incomplete, it is known that the
16 development of such ulcers is the result of a myriad
17 of factors which often interact with one another in
18 a complex manner. It has been recognized that
19 purely conservative measures can be used to control
20 one or more of these factors and that these measures
21 alone can result in the prevention of pressure ulcer
22 development and in more effective treatment of those
23 which have developed. One conservative measure
24 which has been identified to be of critical
25 importance in this regard, is the choice of
26 effective support surfaces, such as wheelchair
27 cushions as well as other seating devices and, more
28 importantly, mattresses, which are utilized in the
29 day-to-day patient care. In the following

1 discussion, the general term "support structure"
2 will encompass such varied products as beds,
3 mattresses, cushions, mattress overlays and covers,
4 and sheets, in addition to operating room tables and
5 other types transitional structures i.e. all types
6 of products with which a patient might have contact.

7 All of the products mentioned above impinge
8 upon defined areas of a patient's body and so
9 present their own unique set of problems and
10 concerns for healthcare workers and researchers in
11 the field of pressure ulcer prevention. For
12 example, the areas at risk of pressure ulcer
13 development as a result of inadequately designed
14 seating devices center primarily around the ischium
15 but can involve the posterior regions of the knee
16 joints and lower thigh. More generalized areas are
17 at risk of pressure ulcer development however, when
18 the design of operating room tables and other
19 transitional structures is examined.

20

21

22 **FACTORS TO BE CONSIDERED IN THE DESIGN OF A SUPPORT**
23 **STRUCTURE**

24 There is no universal support surface which can
25 be effectively used with every patient who might be
26 at risk of developing a pressure ulcer. Indeed, the
27 criteria for developing any type of support
28 structure transcend the purely practical constraints
29 of economy, durability and ease of use. The factors

1 which prevent the design of the universal support
2 structure are those associated with the individual
3 patient such as diagnosis; tissue history (previous
4 incidence of tissue breakdown, surgical repair or
5 stress); and body build (percentage of body fat and
6 its distribution or localization). In the design of
7 any type of support structure for the prevention, or
8 treatment, of pressure ulcers, the interaction
9 between these and other patient-related variables
10 together with the three mechanical forces of
11 pressure, shear and friction, all of which have been
12 implicated in the cause or exacerbation of pressure
13 ulcers, is of great importance. A review of the
14 three mechanical forces and their interaction with
15 the support structure, as well as a discussion of
16 the means used to measure them, is informative at
17 this juncture.

18

19 (1) Contact Pressure

20 Contact pressure is that force exerted on the
21 cutaneous and subcutaneous tissues by the patient's
22 body weight and bony prominences on one side and the
23 support structure on the other. The incorporation
24 of material into a support structure which has the
25 ability to reduce, redistribute or modify the
26 pressure forces generated by a patient's body weight
27 and bony prominences is of obvious importance in the
28 design of an effective support structure for the
29 prevention or treatment of pressure ulcers.

1 At present there are a number of devices which
2 are routinely utilized by designers of support
3 structures to measure the ability of their products
4 to reduce contact pressure. These devices range
5 from simple pneumatic types to the more complex,
6 which utilize electro-pneumatic and electro-
7 resistive means. Such devices may employ algorithms
8 to sense pressure change. The pressure change, so
9 detected, is translated by the device and displayed
10 in a standardized form. Some measuring devices use
11 fluids instead of air to sense changes in pressure.

12

13 Pneumatic and electro-pneumatic measuring
14 devices consist essentially of a pressure-reading
15 instrument connected to a probe. The probe consists
16 of an inflatable bladder in the pneumatic devices
17 or, in the electro-pneumatic devices, an inflatable
18 bladder containing a wire grid on each of its two
19 opposing walls (electrical connection is broken when
20 the grids are separated). The uninflated pneumatic-
21 type probes are placed beneath the body site to be
22 measured and air is supplied until, in the electro-
23 pneumatic devices, the two grids are separated or,
24 in the pneumatic devices, until internal pressure is
25 equal to external loading pressure. The contact
26 pressure is calculated as that pressure which
27 corresponds to the pressure between the body site
28 and the underlying support structure as measured by
29 the attached pressure-reading instrument.

1 Electro-resistive devices for measuring contact
2 pressure consist of a probe containing sensors
3 composed of materials whose electrical resistance
4 properties vary with the pressure which is applied
5 to their surface. Such electro-resistive devices
6 for measuring contact pressure can contain single-,
7 or multiple-sensor-probes. Strain gages or strain
8 gage assemblies are usually included as component
9 parts of such pressure measuring instruments. Just
10 as in the pneumatic-type devices, the change in
11 resistance of the sensor(s) is measured by
12 appropriate instrumentation and, by virtue of
13 calibration methods, the contact pressure between
14 the body site and underlying support structure can
15 be estimated from the change in resistance as
16 recorded on the attached instrumentation.

17

18 (2) Shear

19 Shear is defined as a mechanical stress which
20 is applied parallel to a plane of interest. Shear
21 is proportional to the pressure at any given site.
22 Like pressure, it exerts a degree of trauma on
23 cutaneous and subcutaneous tissues, thereby
24 compromising circulation and, as such, it is likely
25 to be an important factor in so-called "pressure
26 ulcer" formation.

27

28 The majority of support structures are
29 contained in an external covering material to

1 protect the interior from patient discharges. The
2 external covering material can produce shear stress
3 and one manifestation of such shear stress is the
4 so-called "hammock effect." The hammock effect
5 occurs when the support structure external covering
6 material supports the bulk of the patient's body
7 weight in a manner which is independent of the
8 interior of the support structure. In this
9 situation, the external covering material has a
10 tendency to cause relative movement of the cutaneous
11 and subcutaneous tissues along the sides of the
12 contact area between the external covering material
13 and the patient's body. Shear forces and stress are
14 also generated when the head region of a patient's
15 hospital-type bed is raised relative to the lower
16 portions resulting in slippage of the patient's
17 lower body regions.

18

19 Although clinical literature discusses the
20 significance of shear forces in the development and
21 progression of pressure ulcers in bed-ridden
22 patients, it does not define specific means for
23 measuring the shear forces which cause the observed
24 clinical effects. Indeed, to date, no procedures
25 have been described which will accurately measure
26 the total shear forces experienced by various sites
27 on a patient's body. Nor are there any means
28 presently available which are capable of determining
29 how much of what is presently recorded as a

1 "pressure" effect is, in actual fact, a shear
2 effect.

3

4 As stated previously, strain gages are often
5 used as the primary means of detection in devices
6 which are used to measure different types of force.
7 The principle upon which the operation of the strain
8 gage is based is, in essence, a simple one: the load
9 placed on the gage or housing which contains the
10 gage produces a force; the force causes the gage to
11 strain or stretch in response to its application;
12 the force alters the physical properties of the gage
13 such that there is a change in its electrical
14 properties such as resistance; this resistance
15 change can be detected and converted into an
16 accurate measurement of force.

17

18 For the above reasons, strain gages are
19 particularly suited for use in instrumentation for
20 the direct measurement of shear forces. The
21 tendency of tissue to deform due to shear can be
22 detected by the change in such properties as
23 electrical resistance in the attached gage. In this
24 regard, the Y series of encapsulated foil strain
25 gages and G series of foil strain gage manufactured
26 by Omega Engineering, Inc. of Stamford, Connecticut;
27 and the semiconductor strain gages such as types C,
28 D, E, F, G, H, and L supplied by Kulite

1 Semiconductor Products, Inc. of Leonia, New Jersey
2 are useful.

3

4 (3) Friction

5 Friction is defined as the force generated
6 between two surfaces as they move across one
7 another. As such, it is a factor which is
8 considered to be of some importance in not only the
9 formation of pressure ulcers, but also in the
10 progressive deterioration of tissues which occurs as
11 a result of their development. When, for example,
12 the external covering of the support structure,
13 described earlier, moves relative to the skin of a
14 patient, frictional forces are generated. When such
15 frictional forces are exerted on the patient's skin,
16 the skin is exposed to frictional drag which causes
17 abrasion of its outermost layers.

18

19 When examining the forces of friction, two
20 factors must be considered - the actual force with
21 which the patient's body is pushing against the
22 external covering material and the relative
23 smoothness, softness or lubricity of the external
24 covering material which contacts the skin.

25

26 The coefficient of friction is the product of
27 such support structure properties as external
28 covering material smoothness, softness and lubricity
29 and the clinical characteristics of the opposing

1 external skin. Current methods for measuring
2 friction usually involve dragging a weighted sled,
3 with the material of interest on its contact side,
4 across the surface of the skin.

5

6 Frictional drag produces a strain on tissue and
7 so an alternative means of measuring its magnitude
8 would be by the use of localized force indicators
9 such as strain gages.

10

11 CONCLUSION

12 From the foregoing discussion of the importance
13 of contact pressure, shear and friction in "pressure
14 ulcer" development and progression, as well as that
15 regarding the methods available for their
16 measurement, it is apparent that, at the present
17 time, a support structure's ability to reduce the
18 incidence and severity of pressure ulcers cannot be
19 accurately determined prior to it being marketed.
20 The current pre-marketing test procedures used to
21 determine contact pressure, shear and friction are
22 inadequate or nonexistent - there are no universally
23 accepted means of, or procedures for, measuring
24 contact pressure in this context. Reproducibility
25 of results from both within and between testing
26 centers is impractical; the various pressure
27 measuring devices, discussed earlier, produce
28 different readings under the same test conditions.
29 Likewise, the determination of frictional drag,

1 mentioned above, is not universally applicable. In
2 addition, there are no methods currently available
3 to measure shear in this context.

4
5 As a result of the current inadequacies in pre-
6 market testing, patients are exposed to an unknown
7 risk of developing "pressure" ulcers while being
8 treated in healthcare facilities and precious
9 healthcare resources are being potentially wasted on
10 equipment with no measure of efficacy in the area of
11 pressure ulcer prevention or amelioration.

12 13 **TOWARDS A UNIVERSAL TESTING SCHEME**

14 As discussed previously, the choice of a
15 suitable support structure for the patient at risk
16 of developing so-called "pressure ulcers" is vital
17 in the prevention of this serious and potentially
18 life-threatening condition. As an initial
19 preventative measure, it not only is the most
20 effective means of controlling the problem, but also
21 the most economical. Unfortunately, there are no
22 universally accepted means currently available to
23 test the various types of commercially available
24 support structures before they are introduced into
25 hospitals and other healthcare institutions.
26 Moreover, the majority of testing procedures which
27 are presently utilized, only take into account the
28 contribution of contact pressure in the development

1 of pressure ulcers and so, in light of the foregoing
2 discussion, are deficient.

3

4 Most initial evaluations of support structures
5 are performed using individual volunteer subjects of
6 varying physical characteristics of weight, height,
7 anatomical frame, gender and age. The results of
8 such evaluations cannot be duplicated or
9 extrapolated to different physiognomies.
10 Furthermore, such evaluations are performed merely
11 to provide the documentation required to introduce
12 the support structures into the healthcare facility.

13

14 In reality, at the present time, the true
15 efficacy parameters of the product can only be
16 determined from its actual performance once in-use
17 in the facility. Not only are such means of
18 assessing efficacy undesirable, exposing, as they
19 do, patients to an unknown risk of developing
20 pressure ulcers, but they also provide a potentially
21 meaningless assessment. Even in well-designed,
22 randomized clinical trials, great care must be
23 exercised to ensure strict adherence to the study
24 protocol. Such studies are usually conducted over
25 extended periods of months or even years and involve
26 a large expenditure of financial resources. Failure
27 to comply with the study protocol can result in
28 invalidation of the results and so negate the value

1 of the study for use in justifying clinical
2 outcomes.

3

4 Pressure sore development, as discussed
5 previously, occurs as a result of the interaction of
6 a variety of factors. The presence of these various
7 factors, or their interaction, cannot be assessed in
8 the scientifically uncontrolled environment of the
9 healthcare facility.

10

11 As a result of the inability of current
12 methodologies and procedures to accurately assess
13 the efficacy of support structures used in the
14 prevention and treatment of pressure ulcers,
15 valuable healthcare resources are being drained from
16 an already overburdened system. Resources are being
17 wasted not only in the purchase of products whose
18 efficacy is largely unknown, but also in the
19 treatment of pressure ulcers which develop as a
20 result of exposing patients to products which are
21 not efficacious.

22

23 A preferred methodology for testing support
24 structures to determine their ability to prevent
25 pressure ulcer formation would be one which is both
26 uncomplicated in its utilization and universal in
27 nature i.e., one which would give reproducible
28 results no matter where in the world testing was
29 conducted. In addition, given the earlier

1 discussion of the present inability to accurately
2 measure the three mechanical forces which have been
3 cited as being of importance in pressure ulcer
4 formation, such testing methodology would also
5 include, at a minimum, some means of accurately
6 measuring contact pressure, shear and friction.

7
8 The present invention contemplates provision of
9 a standardized testing system and method for
10 evaluation of the efficacy of support structure
11 products in the prevention and treatment of pressure
12 ulcers. The manner in which this has been achieved
13 is by the incorporation of sensors of contact
14 pressure, shear and friction into the design of an
15 anthropomorphic model which is representative of the
16 human body in respect to such features as anatomical
17 contours; height, weight and weight distribution;
18 and compliance, flexibility and tissue thickness.

19
20 As a result of the flexible and adaptable
21 nature of its design, the present invention can also
22 be adapted to include an assessment of other factors
23 which might be considered important in the
24 development of pressure ulcers. The effect of these
25 factors on pressure ulcer development can be
26 assessed alone or in conjunction with other
27 variables such as those of contact pressure, shear
28 and friction already mentioned. Examples of such
29 other factors are temperature and moisture

1 accumulation within the skin due to sweating, normal
2 moisture loss from the body and moisture
3 accumulation due to uncontrolled factors such as
4 incontinence. In this regard, the physical
5 properties of the material or materials used to
6 simulate human skin and subcutaneous tissues in the
7 anthropomorphic model combined with the ability to
8 incorporate means of simulating normal moisture loss
9 and sweating within the model e.g. fluid reservoirs
10 and heating filaments, would enable clinical
11 investigators or researchers to examine and monitor
12 the role of these factors in the formation and
13 progression of pressure ulcers.

14

15 In the past, anthropomorphic devices have found
16 extensive use in studies of various aspects of motor
17 vehicle safety and, in a related context, as parts
18 of model systems designed to assess the effects of
19 motor vehicle accidents on the vehicle occupants.
20 As such, the idea of placing sensors of various
21 types on the surface of, and within, the
22 anthropomorphic device, is not of itself new.
23 However, one novel aspect of the present invention,
24 and one which distinguishes it from the
25 anthropomorphic systems proposed to date, is its
26 placement of particular sensing means at various
27 experimentally-predetermined positions of
28 physiological importance to the development and
29 clinical progression of pressure ulcers. The

1 placement of the sensing means is of such sensitive
2 nature that their output as regards contact
3 pressure, shear and friction can be correlated to
4 the actual forces acting on the cutaneous and
5 subcutaneous tissues in vivo. In this way, the
6 anthropomorphic model of the present invention can
7 be used to accurately assess, in a standardized
8 manner, the external factors which will predispose
9 an individual to pressure ulcer formation and their
10 pathological progression.

11

12 This ability to accurately assess the role of
13 external factors in pressure ulcer development and
14 pathological progression imparted by the
15 anthropomorphic model of the present invention is
16 especially valuable when it is remembered that many
17 pressure ulcers are initiated beneath the surface of
18 the skin, usually in the deeper tissue regions. By
19 the time these pressure ulcers are visible on the
20 surface of the skin, they have usually already
21 severely undermined large areas of tissue between
22 the bone and skin surface, often forming channels,
23 sinus tracts and large areas of dead or missing
24 tissue. An understanding of the way in which
25 external factors translate into internal forces
26 beneath the surface of the skin is critical to not
27 only the assessment of the efficacy of new support
28 structures, but also to an understanding of the

1 pathology of pressure ulcer development and
2 progression.

3

4 In addition, the positioning of the various
5 sensors within the anthropomorphic model combined
6 with the ability to manufacture the model to a
7 variety of specifications which are representative
8 of the varied forms of the human body allows the
9 contribution of the various forces to be accurately
10 assessed for an infinite variety of body types. The
11 system is thus capable of separating the various
12 forces in a manner which has not been possible up
13 until the present time. Such an ability is an
14 invaluable component of not only a testing system,
15 but also any system designed to investigate the
16 individual and combined effect of such variables as
17 contact pressure, shear, friction, moisture
18 accumulation and temperature in pressure ulcer
19 development and progression.

20

21 The design of the anthropomorphic model system
22 also lends itself to testing and study programs
23 involving actual human tissue. Sections of human
24 tissue may be introduced into the compartmentalized
25 structure of the anthropomorphic model and tissue
26 viability assessed over time relative to the
27 application of various support structures. The
28 viability of the sections of human tissue will be
29 proportional to the forces acting upon them and so

1 indicative of the efficacy of the support structure
2 being tested.

3

4 **SUMMARY OF THE INVENTION**

5 The present invention achieves its objectives
6 in a simple, straightforward yet elegant manner.
7 The anthropomorphic model is of stable construction
8 and composed of durable materials so that it will
9 retain over an extended period of time, its
10 characteristics of human-like contour; weight and
11 weight distribution; tissue compliance, flexibility
12 and thickness. Its specifications can be so rigidly
13 delineated that it is capable of being manufactured
14 in a reproducible manner in different shapes, sizes
15 and weights which are representative of various
16 classes of male and female body types.

17

18 The sensor means capable of measuring contact
19 pressure and shear are placed at discrete,
20 predetermined locations on the surface of the
21 anthropomorphic model and at experimentally
22 predetermined depths of physiological importance
23 within the portions of the model which correspond to
24 the inner tissues. Sensor means capable of
25 measuring friction are also located on or near the
26 surface of the model at experimentally predetermined
27 positions of physiological importance. Although,
28 the location of the sensor means correspond to those
29 areas of a patient's body where pressure ulcers are

1 known to develop, the flexibility of the testing
2 system is such that sensor means may also be easily
3 located at positions which normally experience lower
4 loadings. This permits the actual measurement of
5 forces at an almost infinite variety of sites both
6 before and after the anthropomorphic model has been
7 placed on a support structure. Placement of sensor
8 means at discrete positions on the surface of the
9 anthropomorphic model as well as at predetermined
10 positions of clinical importance within the model
11 enable the three forces of contact pressure, shear
12 and friction to be measured in as close to the real
13 life situation as is possible.

14

15 The sensor means are placed so that they are
16 easily accessible and so can be removed to check
17 accuracy or replaced when no longer functional by
18 relatively unskilled individuals. The output of
19 each sensor is measured, processed and recorded by
20 suitable instrumentation equipped with programs to
21 collate the data in a form that can be easily
22 interpreted. If desirable, the means for
23 transmitting the data obtained from the sensing
24 means can be located entirely within the model,
25 thereby obviating the need for the attachment of any
26 external means for signal transduction.

27

28 It is therefore an object of the present
29 invention to provide an anthropomorphic model which

1 embodies a standardized testing system which
2 produces quantifiable measurements of contact
3 pressure, shear and friction for the evaluation of
4 the efficacy of support structures designed to
5 prevent pressure ulcers or reduce the trauma
6 associated with existing pressure ulcers, so that
7 manufacturers and healthcare facilities alike can
8 determine the efficacy of support structures in a
9 reproducible manner for all types of patient.

10

11 It is a further object of this invention to
12 provide an anthropomorphic model which will enable
13 clinical investigators and researchers to delineate
14 the role of, and assess the efficacy of support
15 structures in decreasing the effect of other factors
16 e.g. temperature and moisture accumulation, which
17 have been implicated in pressure ulcer development
18 and progression.

19

20 It is a further object of this invention to
21 provide an anthropomorphic model which simulates the
22 various forms of the human body in such a manner
23 that quantitative measurements of contact pressure,
24 shear and friction can be obtained at predetermined
25 positions corresponding to areas of the human body
26 at risk of pressure ulcer development in order to
27 facilitate research into the relationship of these
28 three mechanical forces to the development of
29 pressure ulcers.

1 It is another object of the present invention
2 to provide an anthropomorphic model from which
3 quantifiable measurements of contact pressure, shear
4 and friction can be obtained under conditions which
5 mimic those which would be experienced by a
6 hospitalized patient such that various clinical
7 parameters of importance to the choice and useful
8 life of support structures can be measured in the
9 controlled environment of the laboratory.

10

11 **BRIEF DESCRIPTION OF THE DRAWINGS**

12 FIG. 1 is a front elevational view of the
13 anthropomorphic model of this invention.

14

15 FIG. 2 is a side elevational view of a typical
16 joint in the limbs.

17

18 FIG. 3 is a side elevational view of the
19 anthropomorphic model of Fig. 1.

20

21 FIG. 4 is an expanded schematic model of the
22 placement of sensors for detecting contact pressure,
23 shear and friction forces in the human skin and
24 subcutaneous layers simulating material.

25

26 FIG. 5(a) is a schematic representation of an
27 arrangement of sensors for detecting contact
28 pressure, shear and friction forces; the data
29 receiving module, composed of signal processing

1 circuits and a signal transmitting terminus
2 assembly; data storage and retrieval modules; and
3 computer processing assembly.
4

5 FIG. 5(b) is a schematic representation of one
6 embodiment of
7 the signal detection, transmitting and processing
8 pathway depicted in Fig. 5(a) within a limb of the
9 anthropomorphic model.
10

11 Fig. 5(c) is a schematic representation of an
12 alternative embodiment of the signal detection,
13 transmitting and processing pathway depicted in Fig.
14 5(a) within a limb of the anthropomorphic model. In
15 this embodiment, the data receiving module is
16 attached by signal transmitting wires to the data
17 storage and retrieval module which is located at a
18 position outside the anthropomorphic model.
19

20 DESCRIPTION OF THE PREFERRED EMBODIMENT

21 A preferred embodiment of the invention
22 incorporates a number of features. The specific
23 form of those features presented in the preferred
24 embodiment of the invention is in accordance with
25 its use as a model system for testing various
26 support structures for their ability to prevent the
27 formation of pressure ulcers. This application has
28 been selected because of its importance. In other

1 applications, other specific forms may be
2 preferable.

3
4 Reference will now be made to the drawings,
5 whereby like parts are designated by like numerals.
6 The anthropomorphic model 10 includes head means 11,
7 neck means 12, and body means 13 which includes
8 chest/rib defining means 14. Limb means 15 include
9 a pair of arms 16, 17, a pair of legs 18, 19, and a
10 pair of hands 20, 21. Joint means 22 provide low
11 friction or frictionless articulated connections at
12 a neck joint 23, shoulder joints 24, elbow joints
13 25, wrist joints 26, hip joints 27, knee joints 28,
14 and ankle joints 29. Incorporation of the joint
15 means 22 into the design and structure of the
16 anthropomorphic model 10 enables the anthropomorphic
17 model 10 to be manipulated into a variety of
18 positions which have a direct relationship to the
19 human form and to changes in loading which result
20 from changes in relative positions of various body
21 parts. The anthropomorphic model 10 can be
22 manufactured in a variety of size and weight classes
23 so that representatives of each class of human body
24 size and shape can be made available for testing.
25 A given model 10 may also be provided with means
26 (not shown), internal to the model, for attaching
27 discrete concentrated weights, for example in the
28 vicinity of the shoulder blades, buttocks, hips,

1 heels, etc. to simulate various weight classes using
2 single models.

3
4 Detachable portions 30 of the anthropomorphic
5 model 10 of this embodiment are composed of layers
6 100, 200, 300 of a flexible material 31 simulating
7 human skin and subcutaneous tissue. The flexible
8 material 31 simulating human skin and subcutaneous
9 tissue may be uni- or multi-layer depending upon the
10 precise application and testing procedures employed.

11
12 The layers of flexible skin and subcutaneous
13 tissue simulating material 31 which make up the
14 detachable portions 30 of the anthropomorphic model
15 10 are especially adapted to support or contain
16 various types of sensing means 32, 33, 34. Mounted
17 on the outer surface 100 of the skin and
18 subcutaneous tissue simulating material 31 are
19 contact pressure sensing means 32, shear force
20 sensing means 33 and friction sensing means 34. The
21 middle layer 200 of skin and subcutaneous tissue
22 simulating material 31 contains contact pressure
23 sensing means 32 and shear force sensing means 33.
24 The innermost layer 300 of skin and subcutaneous
25 tissue simulating material 31 contains contact
26 pressure sensing means 32 and shear force sensing
27 means 33.

28

1 Sensing means 32, 33, 34 are incorporated into
2 the anthropomorphic model 10 in such a way as to
3 facilitate ease of detachment and replacement even
4 by those unskilled in the art.

5
6 Each sensing means 32, 33, 34 is of modular
7 design and construction and is coupled to or is
8 integral with a data receiving module 35 composed of
9 a signal processing circuit 36 and a signal
10 transmitting terminus assembly 37, the latter being
11 connected by a plurality of leads 38 or a data bus
12 to data storage and retrieval modules 39 located in
13 predetermined parts of the anthropomorphic model 10
14 which do not interfere with the ability of the
15 system to take the necessary measurements. The data
16 storage and retrieval modules 39 are each enclosed
17 in a cushioned and rugged protective housing 40.
18 The data storage modules 39 receive and store the
19 output signals from the various sensors and transmit
20 them to a computer terminal 41. The computer 41 is
21 programmed to read the data supplied by each sensing
22 means 32, 33, 34, in a conventional manner.
23 Appropriate algorithms for performing mathematical
24 summing, averaging, statistical analysis or other
25 operations on the data generated by the various
26 sensors to be collated and displayed may be
27 conducted in a manner known to one of ordinary skill
28 in the art.

1 In an alternative embodiment of the invention,
2 each sensing means 32, 33, 34 is of modular design
3 and construction and consists of a data receiving
4 module 35 composed of a variety of signal processing
5 circuits 36 and a signal transmitting terminus
6 assembly 37 which is connected by a plurality of
7 leads 38 to data storage and retrieval modules 39
8 located at a position external to the
9 anthropomorphic model 10.

10

11 Commonly available "off-the-shelf" items can be
12 used to sense and record contact pressure, shear and
13 friction. For example, suitable devices for sensing
14 shear forces are the RY21, RY61 and Y series of
15 strain gages manufactured by Omega Engineering, Inc.
16 of Stamford, Connecticut; suitable devices for
17 measuring contact pressure are those in the 170
18 series manufactured by Omega Engineering, Inc.; and
19 suitable devices for measuring friction are also
20 strain gages manufactured by Omega Engineering, Inc.

21 In addition, commonly available components can
22 be utilized to measure other variables,
23 quantification of which might be considered
24 desireable. For example, temperature measuring
25 instruments such as thermistors and thermocouples of
26 suitable dimensions for placement within the
27 anthropomorphic model are available from Cole-Parmer
28 of Niles, Illinois. Also, devices for measuring
29 skin moisture such as the Dermal Phase Meter are

1 manufactured by Nova Technology Corporation of
2 Gloucester, Massachusetts.

3

4

WHAT IS CLAIMED IS:

1. An anthropomorphic model system comprising:

an anthropomorphic model simulating the major dynamic characteristics of a human, said anthropomorphic model being adaptably representative of specific classes of human body form as regards body build and including flexible human skin and subcutaneous tissue simulating materials comprising a cutaneous region and a subcutaneous region covering at least parts of the model;

sensing means located at predetermined positions on, and in the vicinity of, the surface of the skin defining the cutaneous region and within the subcutaneous region, within the interior of said anthropomorphic model, said sensing means for measuring physical parameters acting on said anthropomorphic model when arranged in life-like positions resting on a support structure, such physical parameters including pressure, shear and friction forces; and

means for detecting and displaying signals from said sensing means whereby decreased or increased signals from said sensing means are indicative of the forces existing at and within the cutaneous and subcutaneous regions.

2. The anthropomorphic model system of Claim 1 wherein said anthropomorphic model comprises at least one of:

head means;

neck means;

body means which include chest and rib
defining means;

limb means which include arm, leg and hand
means;

a plurality of joint means providing
articulated connection means at least at one of
neck, shoulder, elbow, wrist, hip, knee and ankle
means;

detachable means composed of said flexible
human skin simulating materials, said flexible
human skin and subcutaneous tissue simulating
materials being layered, said detachable means
containing force sensing means situated on the
surface of said human skin and subcutaneous tissue
simulating materials and at varying depths within;

sensing means comprising data receiving means
and signal transmitting means; and

data storage and retrieval means.

3. The anthropomorphic model of Claim 1
wherein said sensing means comprises a strain gage.

4. The anthropomorphic model of Claim 1
wherein said flexible human skin simulating
materials simulate human skin and subcutaneous
tissues as to at least one of the properties of:
compliance, elasticity; porosity; surface friction;
and thickness.

5. The anthropomorphic model of Claim 2
wherein said flexible human skin simulating
materials simulate the human skin and subcutaneous

tissues as to at least one of the properties of: compliance, elasticity; porosity; surface friction; and thickness; said human skin and subcutaneous tissue simulating materials being disposed at least on areas of said anthropomorphic model which correspond to said detachable means containing said sensing means.

6. The anthropomorphic model system of Claim 2 wherein said detachable means containing said sensing means are removable and said sensing means are replaceable.

7. The anthropomorphic model system of Claim 2 wherein said detachable means are interchangeable between different types of anthropomorphic models which are representative of different forms of human body.

8. The anthropomorphic model system of Claim 2 wherein said detachable means are specific to anthropomorphic models which are representative of a specific form of human body.

9. The anthropomorphic model system of Claim 1 wherein said sensing means includes a plurality of sensors which are incorporated with at least one of: the outer surface of said human skin and subcutaneous tissue simulating material situated on the surface of said detachable means, said sensing means capable of measuring at least one of temperature, moisture accumulation, pressure, shear or friction;

the middle layer of said human skin and subcutaneous tissue simulating material, said sensing means capable of measuring at least one of temperature, moisture accumulation, pressure and shear;

the innermost layer of said human skin and subcutaneous tissue simulating material, said sensing means capable of measuring at least one of temperature, moisture accumulation, pressure or shear.

10. The anthropomorphic model system of Claim 1 wherein said anthropomorphic model contains:

sensing means capable of signal transduction in response to activation of said sensing means by the generation of force or other physical phenomena;

data transmitting means for transmitting said signal to data receiving and storage means, said transmitting means being contained entirely within said anthropomorphic model and free of any external transmitting means physically attached thereto except said anthropomorphic model;

and data receiving and storage means within said anthropomorphic model for receiving said signal from said sensing means and storing said signal within memory means.

11. The anthropomorphic model system of Claim 1 wherein said anthropomorphic model contains:

sensing means for signal transduction in response to activation of said sensing means by the generation of physical parameters including force;

data transmitting means for transmitting said signal to data receiving and storage means, said transmitting means being located at a point external to said anthropomorphic model and connected by signal transmitting means to said anthropomorphic model;

and data receiving storage means outside said anthropomorphic model for receiving said signal from said sensing means and storing said signal within memory means.

12. The anthropomorphic model system of Claim 1 wherein said anthropomorphic model contains internal means for simulating moisture losses to atmosphere which are normal for a variety of physiological states corresponding to different size and weight classes of the human body.

13. The anthropomorphic model of Claim 1 wherein said model contains an internal framework means, such internal framework means having prominences at positions corresponding to at least one of: occiput; scapula; sacrum; trochanter; heel; ankle; knee; and ischium.

14. The anthropomorphic model of Claim 1 wherein said anthropomorphic model contains an internal framework composed of simulated bones having a soft core encased in fiberglass reinforced plastic material.

15. The anthropomorphic model of Claim 1 wherein said anthropomorphic model contains

compartments at positions corresponding to at least one of: heel, ankle, knee, trochanter, sacrum, scapula, ischium or cranium; said compartments having the ability to hold blocks of live tissue of human or animal origin.

16. The anthropomorphic model system of Claim 1, wherein said sensing means includes a plurality of sensors.

17. The anthropomorphic model system of Claim 1, wherein said system is designed for testing the efficacy of a support structure in the prevention and treatment of decubitus or pressure ulcers and related conditions; said system including the placement of said anthropomorphic model on a support structure to be tested and wherein the signals from said sensors are indicative of the efficacy or lack thereof of said support structure.

18. The anthropomorphic model as claimed in Claim 1, wherein said flexible human skin and subcutaneous tissue simulating materials comprise a single layer.

19. The anthropomorphic model as claimed in Claim 1, wherein said flexible human skin and subcutaneous tissue simulating materials comprise at least two layers.

20. A method for measuring the efficacy parameters of support structures to be used in the prevention and treatment of decubitus or pressure

ulcer formation comprising:

resting an anthropomorphic model simulating the major dynamic characteristics of a human and having flexible human skin and subcutaneous tissue simulating materials including a cutaneous region and a subcutaneous region;

placing sensing means at specific locations on and within said cutaneous and subcutaneous regions of said model on a support structure to be tested for efficacy, said sensing means capable of measuring physical parameters comprising at least one of temperature, moisture accumulation, pressure, shear and friction; and

means for collecting and interpreting data obtained from said sensing means to determine loading at sensing locations to thereby determine likelihood of injury to a human resting on such support.

21. The method of Claim 20 wherein said anthropomorphic model component is contacted with said support structure component such that signals are generated by said plurality of sensing means located within said anthropomorphic model and said signals are collected and interpreted as indicative of the efficacy, or lack thereof, of said support structure.

22. The method of Claim 20 wherein said anthropomorphic model component is interchangeable such that all classes of human size and weight forms, as represented by said anthropomorphic models of differing specifications, can be included

in the test procedure.

23. The method of Claim 20 wherein said testing system is standardized by the manufacture of said anthropomorphic models representative of all human size and weight classes, said anthropomorphic models capable of being reproducibly manufactured to predetermined, uniform specifications.

24. The method of Claim 20 wherein said anthropomorphic model contains blocks of live tissue of human or animal origin at various positions corresponding to at least one of the positions identified at risk for the development of pressure or decubitus ulcer formation.

25. The method of Claim 20 wherein said anthropomorphic model contains blocks of live tissue is contacted with said support structure and assessment of the viability of said block of live tissue is indicative of the efficacy, or lack thereof, of said support structure.

26. The method of Claim 20 wherein said testing system is used to obtain quantitative measurements of physical parameters, including but not limited to, at least one of temperature, moisture accumulation, contact pressure, shear and/or friction in research procedures aimed at studying the etiology of, or methods for treatment and/or prevention of decubitus or pressure ulcer formation.

27. An anthropomorphic model simulating the major dynamic characteristics of a human, said anthropomorphic model being adaptably representative of specific classes of human body form as regards body build and including flexible human skin simulating materials including a cutaneous region and a subcutaneous region covering at least parts of the model;

sensing means located within the flexible human skin simulating materials of said anthropomorphic model for measuring physical parameters such as pressure, shear and friction forces acting on said anthropomorphic model; and

means for detecting signals from said sensing means for ascertaining at least one of the pressure, shear and friction forces existing within the flexible skin simulating materials.

28. An anthropomorphic model as claimed in claim 27, wherein the sensing means located within the flexible human skin simulating materials is located within the subcutaneous region and wherein said means for detecting signals determine the pressure, shear and friction forces existing within the subcutaneous region.

29. An anthropomorphic model as claimed in claim 27, wherein said sensing means includes sensors located at a number of predetermined positions on, and in the vicinity of, the surface of the flexible human skin and within the subcutaneous region located within the interior of said anthropomorphic model; said sensors for

sensing at least one of the pressure, shear and friction forces existing at the surface of the skin and within the subcutaneous tissue.

30. An anthropomorphic model as claimed in Claim 29, wherein said sensors are disposed on, and within the subcutaneous tissue of the model for measuring pressure, shear and friction forces acting on said anthropomorphic model when arranged in life-like positions resting on a support structure; and wherein said means for detecting signals from said sensing means are indicative of the efficacy, or lack thereof, of said support structure.

31. The anthropomorphic model as claimed in Claim 29, wherein said means for detecting signals also includes means for displaying the signals.

32. The anthropomorphic model as claimed in Claim 31, wherein said sensing means for measuring pressure includes means for measuring contact pressure between the surface of the skin and any underlying support structure and internal pressure within the flexible human skin simulating materials.

33. The anthropomorphic model as claimed in Claim 27, wherein said cutaneous and subcutaneous regions of said flexible human skin simulating materials comprise a single layer.

34. The anthropomorphic model as claimed in

Claim 27, wherein said cutaneous and subcutaneous regions of said flexible human skin simulating materials comprise at least two layers.

35. A method for measuring the external and internal pressures and forces sensed by parts of an anthropomorphic model simulating the major dynamic characteristics of a human, said anthropomorphic model including flexible human skin simulating materials with a cutaneous region and a subcutaneous region comprising:

placing sensing means at specific locations on, and within, said flexible human skin of said model; said sensing means capable of measuring physical parameters comprising at least one of temperature, moisture accumulation, pressure, shear and friction;

resting said anthropomorphic model on a support structure; and sensing and interpreting data obtained from said sensing means to determine at least one of temperature, moisture accumulation, pressure, shear and friction at a sensing location on, and within, said flexible human skin.

36. A method as claimed in claim 35 wherein the placing of sensing means at specific locations includes the placing of a sensing means within the subcutaneous region of said flexible human skin for sensing at least one of temperature, moisture accumulation, pressure, shear and friction present within the subcutaneous region.

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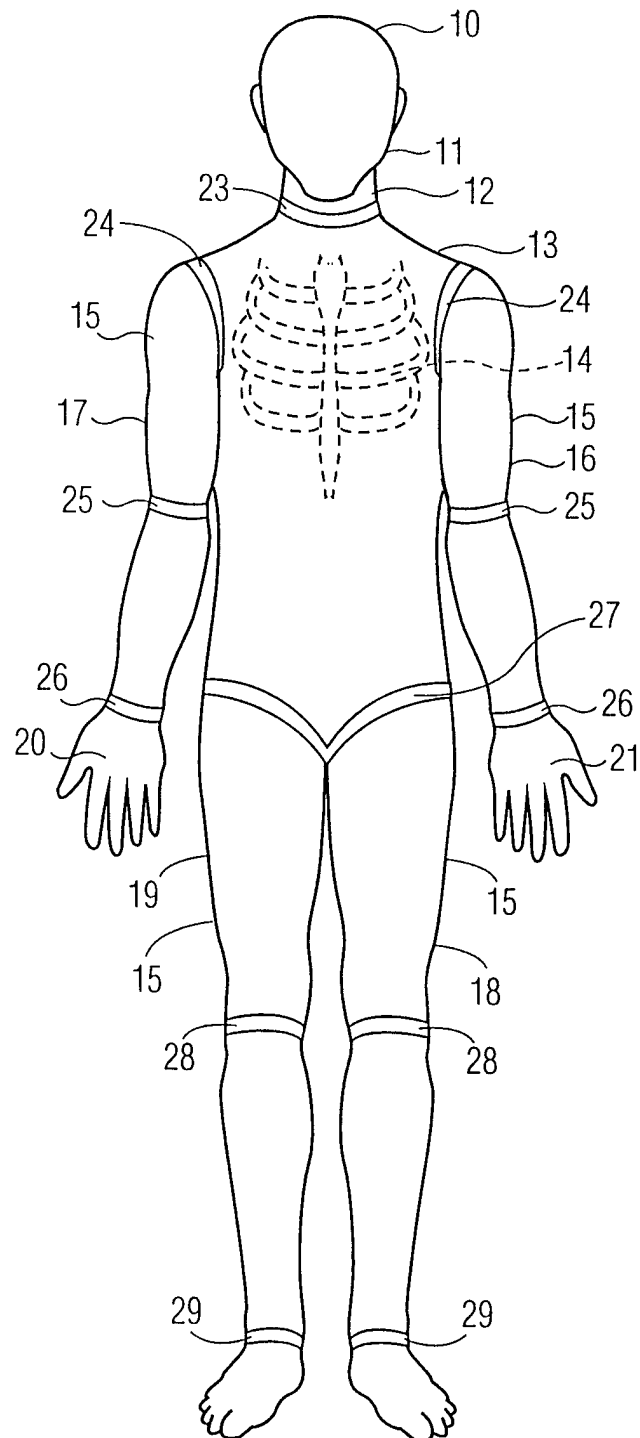


FIG. 1

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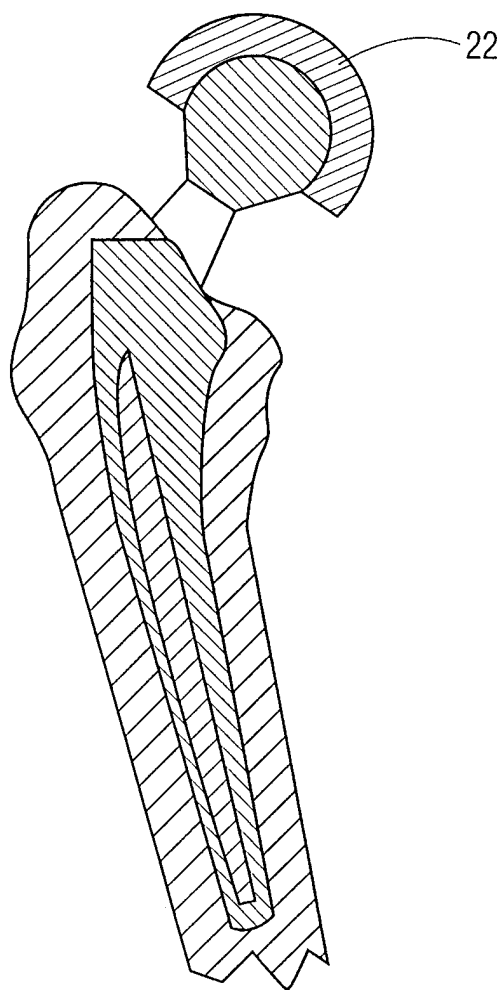


FIG. 2

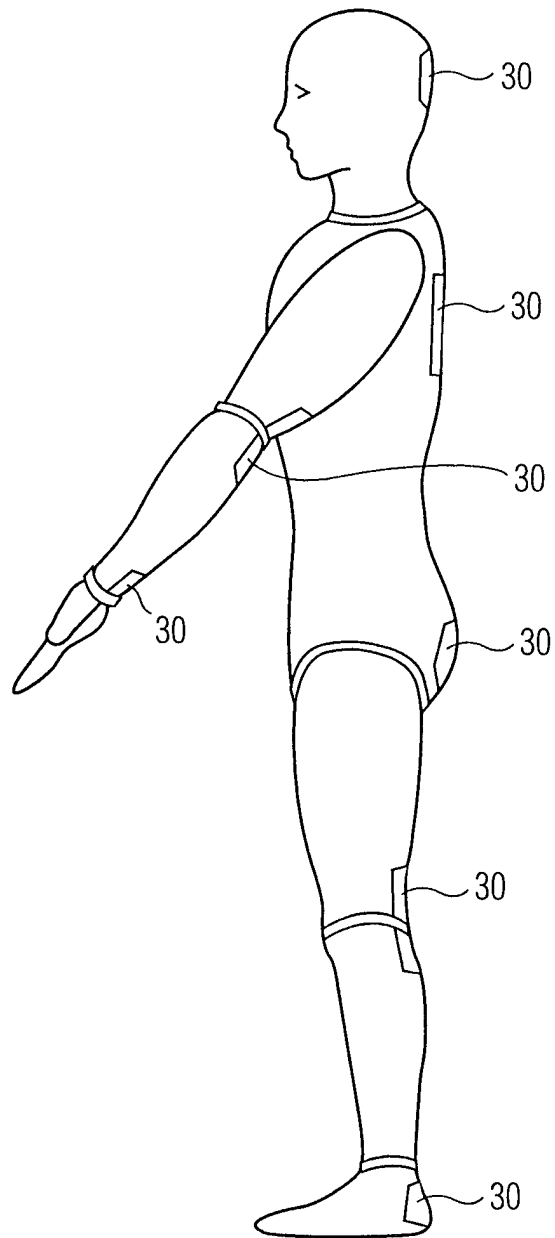


FIG. 3

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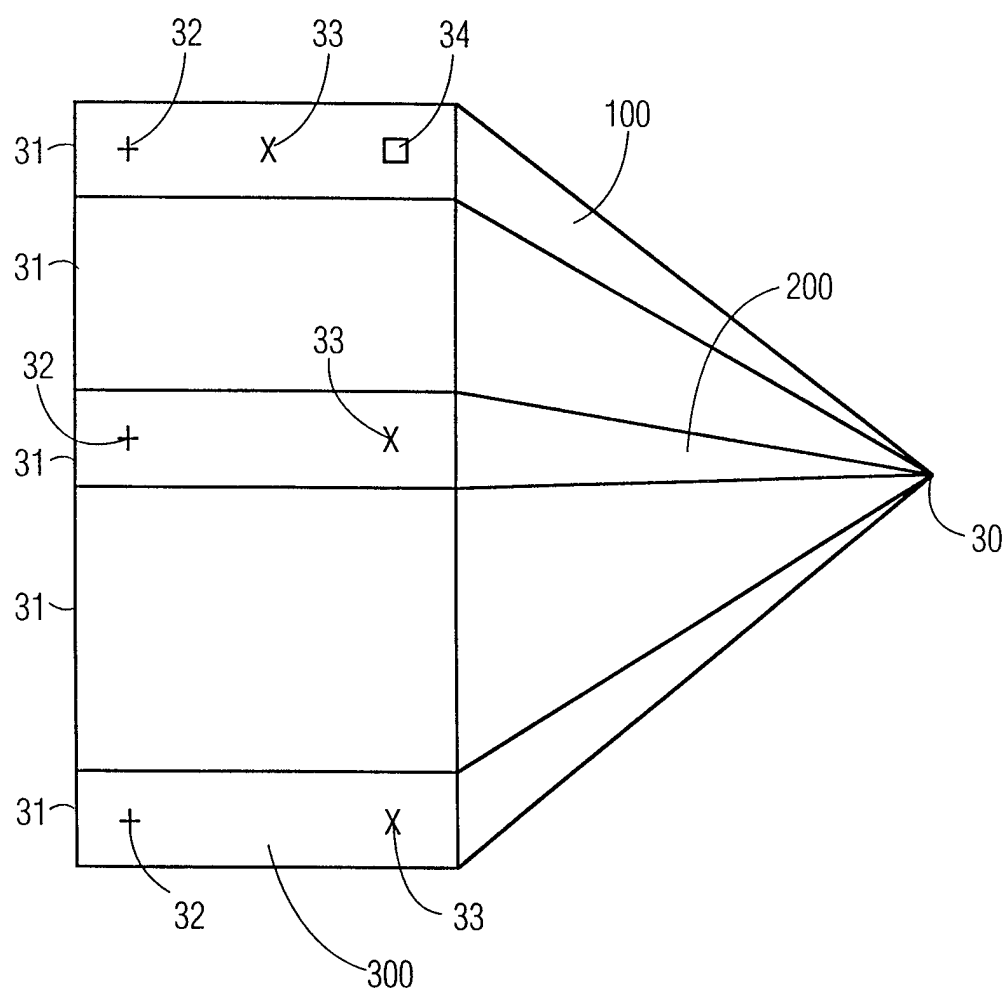
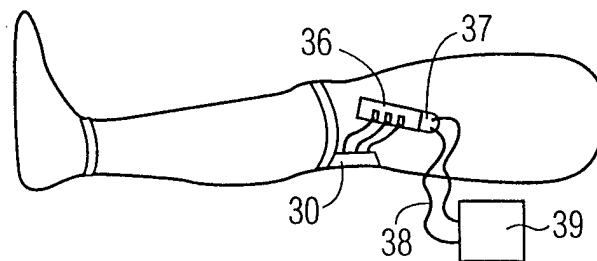
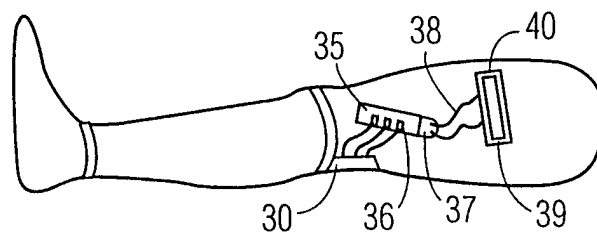
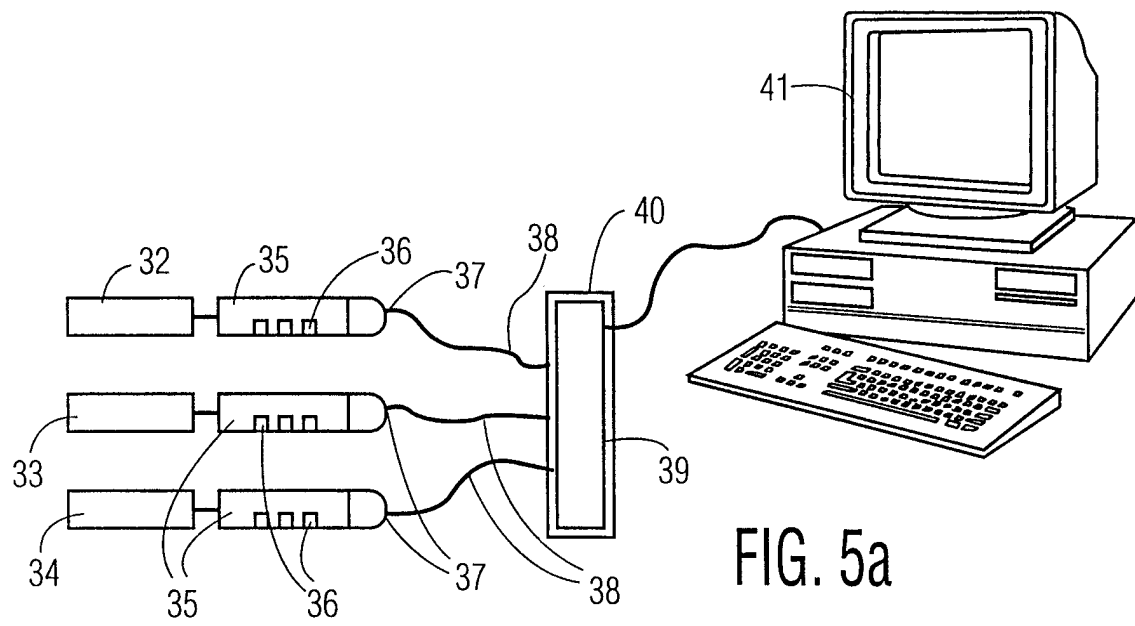


FIG. 4

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/00813

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G09B 23/28

US CL :434/262, 267, 272, 274

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 434/262, 267, 272, 274

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

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

Please See Extra Sheet.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	HIGASHI, H. et al. Design of an Anthropomorphic Model to Simulate the Vibration Response of the Surface for the Human Body; Audio Engineering Society Preprint 76th. Publ, New York, NY USA 2154, 12 pages, October 1984. See Abstract.	1-36
Y	BRIENZA, D. M. et al. System for the Analysis of Seat Support Surfaces Using Surface Shape Control and Simultaneous Measurement of Applied Pressures; IEEE Transactions on Rehabilitation Engineering, Vol. 4, No. 2, June 1996, pages 103-113. See Abstract.	1-36



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier document published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

15 MAY 1997

Date of mailing of the international search report

10 JUL 1997

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INTERNATIONAL SEARCH REPORT

 International application No.
 PCT/US97/00813

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	ALLEN V. et al. Repeatability of Subject/Bed Interface Pressure Measurements, Journal of Biomedical Engineering, Vol. 15, No. 4, July 1993, pages 329-332. See abstract.	1-36
Y	US 5,589,651 A (VIANO et al.) 31 December 1996, Fig. 1, Background of the Invention, and Summary of the Invention	1-36
Y	SU 1820406 A (DNERP MED INST) 07 June 1993, Abstract.	1-36
Y	US 5,509,810 A (SCHERTZ et al.) 23 April 1996, Figs. 1 and 6; and cols. 7 and 8	1-36
Y	CH 646 538 A (VIGNOLA) 30 November 1984, Abstract, and figures.	1-36
Y	US 4,777,599 A (DOROGI et al.) 11 October 1988, col. 1, lines 34-48; col 2, lines 3-13; col. 3, lines 1-19; and cols. 5 and 6.	1-36
Y	US 4,503,705 A (POLCHANINOFF) 12 March 1985, Abstract; Figs. 8-10; col. 1, lines 10-14; col. 2, lines 6-12 and 20-26.	1-36
Y	US 3,147,617 A (KAPTUR, JR. et al.) 08 September 1964, Fig. 1, and title.	1-36
Y	US 4,701,132 A (GROESCH et al) 20 October 1987, Abstract; and col. 2, lines 11-13.	1-36 -
Y,E	US 5,609,485 A (BERGMAN et al.) 11 March 1997, Fig. 1.	1-36

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/00813

B. FIELDS SEARCHED

Electronic data bases consulted (Name of data base and where practicable terms used):

APS, ABI-INFORM, AEROSPACE, COMPENDEX, EUROPATFULL, HEALSAFE, INPADOC, JAPIO, JGRIP, JICST-EPLUS, JPNEWS, MEDLINE, PATOSWO, SOLIDSTATE, WPIDS, USPATFULL

Search Terms: anthropomorphic, skin, decubitus, model, simulate, simulation, pressure, ulcer, dummy, measure, force, body, human, animal, sensing, sensor, shear, friction, temperature, moisture, seat compression, ergonomic.