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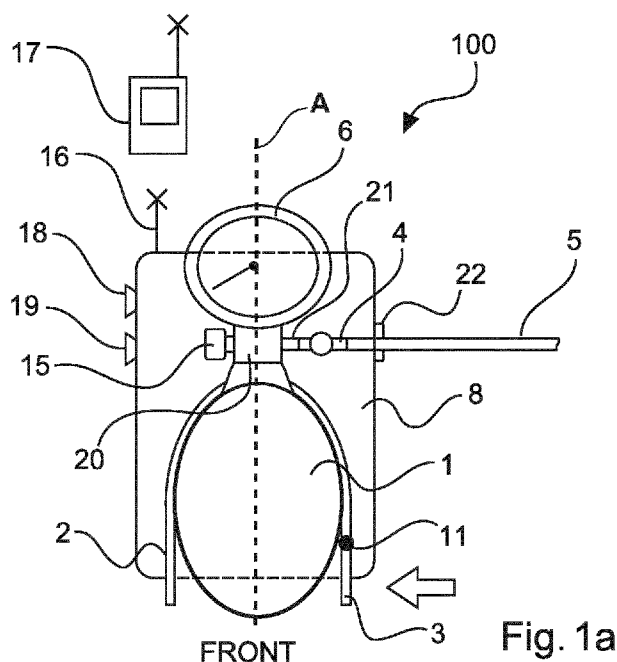
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(57) Abstract: The system of the present invention is based on a conventional cuff-based blood pressure measurement system, in which the connector coupling the bulb of the cuff is detachably engaged with a handle assembly. The handle assembly comprises a compressible handle, adapted to squeeze or compress the bulb during cuff inflation. An electrical generator mechanically coupled to the bulb and handle converts the compression/squeezing motion of the bulb and handle during inflation into electrical energy, which is stored in an energy storage element. The cuff is provided with an electronic pressure sensor. In a preferred embodiment the system further comprises a trigger element. By actuating the trigger element, the operator temporarily energizes the system to acquire, by means of the electronic pressure sensor, a pressure measurement and store it in a data storage device for subsequent transmittal to a remote device or server.

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RETROFITTABLE KIT FOR A MANUAL BLOOD PRESSURE MEASUREMENT SYSTEM

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FIELD OF THE INVENTION

The invention relates to blood pressure measurements. More specifically, the present invention relates to a retrofittable kit for a manual blood pressure measurement system, a system for blood pressure measurement, a method for enabling a manual blood pressure measurement system to perform an automated blood pressure measurement, and a method for measuring the blood pressure of a subject.

BACKGROUND OF THE INVENTION

Hypertension, a medical condition in which the blood pressure (BP) is persistently elevated, may be considered as one of the risk factors for premature death worldwide and may be associated with an increased risk of developing cardiovascular diseases, such as ischemic heart disease, strokes, peripheral vascular disease, heart failure, aortic aneurysms, diffuse atherosclerosis, chronic kidney disease, pulmonary embolism, etc.

As a result of this, hypertension screening at a population level has been recognized globally as an important disease prevention tool. In addition, hypertension screening is further motivated by the fact that high blood pressure usually has no symptoms, which means it may be difficult to detect unless measured.

In practice, measurement of BP in many rural and resource-constrained settings may be performed using a manually operated BP cuff. In many developing countries, which have limited resources, significant efforts are being made to conduct routine hypertension screening at the population level, using community health volunteers and nurses. There are many challenges to be faced in this context, such as limited training and education level of the community health volunteers, difficulties in correctly performing the BP measurement, electrical grid unreliability, as well as consistent reporting of recorded BP data.

BP data may typically be recorded by hand, before being manually input into

an information and communications technology (ICT) system via a hand-held device or computer. This may present a burden to health workers, who are often unfamiliar with ICT systems.

In the context of the present invention, a manual blood pressure measurement system or manual sphygmomanometer refers to the fact that the measurement system is to be used in conjunction with a stethoscope for auscultation and requires the intervention of a practitioner, as it is the case in mercury sphygmomanometers or in mechanical-type aneroid sphygmomanometers including a dial. In contrast, electronic blood pressure measurement systems typically use oscillometric measurements and electronic calculations rather than auscultation, and can obtain a blood pressure measurement in an automated manner without the intervention of a practitioner.

US patent application publication 2013/0211267 A1 relates to a battery-free cuff-based blood pressure measuring apparatus that comprises a generator-driving structure attached to a bulb, which enables electrical power generation and cuff inflation by the bulb at the same time, and measuring the blood pressure with the generated electrical power.

Document US 2013/0245391 A1 describes a blood pressure cuff coupled to an energy-generating apparatus configured to generate energy from a depressurization of the cuff, while US 2008/0319329 A1 discloses a manually-driven inflation-powered electronic blood pressure measuring apparatus.

SUMMARY OF THE INVENTION

It may be desirable to have a blood pressure measurement system, which is operable in a reliable way and reduces the risk that wrong blood pressure values are recorded.

A first aspect of the invention relates to a retrofittable kit for a manual blood pressure measurement system. The manual blood pressure measurement system comprises a cuff which is configured to be placed around a limb of a subject, e.g. a person, a mechanical pressure gauge comprising a gauge dial, the mechanical pressure gauge being configured to measure a pressure inside the cuff and provide a pressure value on the gauge dial which is related to the measured pressure inside the cuff, and a bulb coupled via a connector to the mechanical pressure gauge and to the cuff, for example via a flexible hose, and configured to

inflate the cuff when cyclically compressed.

The retrofittable kit comprises a handle assembly, an electric generator, an energy storage element, an electronic pressure sensor and a data storage device.

The handle assembly is configured to detachably engage with the connector
5 along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb. In some embodiments said angle is preferably between 45 and 135 degrees, more preferably between 60 and 120 degrees, and even more preferably about 90 degrees (i.e., a direction that is substantially perpendicular to the direction of coupling of the connector to the bulb).

10 The handle assembly comprises a handle that is configured to perform a compression movement, i.e. a forward movement, when it is actuated by an external force, such as a pressure force by a user's hand. The forward movement starts at an extended position and moves on to a compressed position, thereby exerting a compression force on the bulb. The handle is further configured to perform a return movement, when released, to the
15 extended position, thus ceasing the compression force on the bulb.

In this manner, the handle assembly can advantageously engage with the connector of the manual blood pressure measurement system without interfering with the elements of the manual blood pressure measurement, and in particular with the already existing bulb of said system. Similarly, once installed, the handle assembly can be disengaged
20 from said connector also along said direction. For example, the handle assembly can be slid in along a perpendicular direction to the direction of coupling of the connector to the bulb (typically the longitudinal axis of the bulb) and installed on the connector, so that a compressible handle of the handle assembly is brought into place without colliding with bulb. Once installed, the handle assembly can be disengaged from said connector by sliding it out
25 perpendicularly to the longitudinal axis of the bulb.

The kit of the present invention can then be retrofitted on a manual blood pressure measurement system without requiring disassembling the elements of the manual system, or even having to replace some of those elements by others in order to make it compatible with the retrofittable kit. Therefore, the present invention provides an easy-to-use
30 and convenient solution which can be quickly added on (and subsequently removed from) an

existing manual blood pressure measurement system without disrupting the normal operation of said system.

The handle is mechanically coupled to an electrical generator, wherein the electrical generator is configured to convert the forward movement and/or the return
5 movement of the (compressible) handle into electrical energy.

The electrical generator may be a linear or a rotary alternator. A linear alternator may be used to directly convert a linear motion of the compression/squeezing of the bulb and handle during inflation into electrical energy. Alternatively, a rotary alternator may be used, if the handle is linked via a crank or step-up gear to a rotatable flywheel, e.g. a
10 flywheel magnet rotor, connected to a dynamo with a commutator. The commutator may be used for rectifying the alternating current to direct current. A linear alternator may be preferred in order to make the device more compact and less bulky.

The energy storage element is electrically coupled to the electrical generator and configured to store the electrical energy generated by the electrical generator. It may be
15 adapted in form of a capacitor or super-capacitor or a battery for storage of the harvested energy.

The electronic pressure sensor is electrically coupled to the energy storage element and configured to measure the pressure inside the cuff. It may be arranged close to the bulb.

20 In the context of the present invention, the term electronic pressure sensor (also referred to as pressure transducer) preferably refers to a sensor capable of converting a pressure applied on the sensor into an electrical signal or into a change in an electrical property. In contraposition, a mechanical pressure gauge preferably refers to a device in which an applied pressure leads to a mechanical change in the device, or to a change of a
25 mechanical property of an element included in the device, which change is typically used to represent the measured pressure on a gauge dial comprised in the device.

The data storage device is configured to store a blood pressure value, which is related to the measured pressure inside the cuff. The blood pressure value may be equal to the pressure measured by the pressure sensor. However, the retrofittable kit may also be
30 configured to convert the pressure measured by the pressure sensor into a blood pressure

value, thereby taking into account that the actual blood pressure is related to but may not be equal to the pressure measured by the pressure sensor. The retrofittable kit may also be adapted to store the pressure value measured by the pressure sensor, in order to have it converted into an actual blood pressure value at a later time, which may be performed by an external device.

A second aspect of the invention relates to a system for blood pressure measurement, which comprises a cuff configured to be placed around a limb of a subject, a bulb coupled via a connector to the cuff and configured to inflate the cuff when cyclically compressed, a handle assembly, an electrical generator, an energy storage element, an electronic pressure sensor and a data storage device, as described above with respect to the retrofittable kit.

According to an embodiment of the second aspect, the system comprises a manual blood pressure measurement system, retrofitted with the above described retrofittable kit.

A third aspect of the invention relates to a method for enabling a manual blood pressure measurement system to perform a semi-automated or electronically assisted blood pressure measurement. The manual blood pressure measurement system comprises a cuff configured to be placed around a limb of a subject, a mechanical pressure gauge comprising a gauge dial and configured to measure a pressure inside the cuff and provide a pressure value on the gauge dial which is related to the measured pressure inside the cuff, and a bulb coupled via a connector to the mechanical pressure gauge and to the cuff and configured to inflate the cuff when cyclically compressed.

A handle assembly is detachably engaged with the connector along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb, wherein the handle assembly comprises a handle configured to perform a forward movement, when actuated by an external force, from an extended position to a compressed position, thereby exerting a compression force on the bulb, and a return movement, when released, to the extended position, ceasing the compression force on the bulb. The handle is mechanically coupled to an electrical generator, which is configured to convert the forward movement and/or the return movement of the compressible handle into electrical energy. The electrical

generator is electrically coupled to an energy storage element, which is configured to store the electrical energy generated by the electrical generator. An electronic pressure sensor is coupled to the pressure inside the bulb, wherein the electronic pressure sensor is connected to the energy storage element to receive electric energy from the energy storage element, and
5 configured to measure the pressure inside the cuff. Also, a data storage device is provided which is configured to store a pressure value, which is related to the pressure measured by the pressure sensor, i.e., the pressure inside the cuff.

A fourth aspect relates to a method for measuring the blood pressure of a subject. First, a handle of a handle assembly which is engaged with a connector coupling a
10 bulb of a manual blood pressure measurement system to a cuff of said manual blood pressure measurement system is actuated. The handle assembly is detachably engagable with the connector along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb. The handle is configured to perform a forward movement, when actuated upon, from an extended position to a compressed position, thereby exerting a
15 compression force on the bulb, and a return movement, when released, to the extended position, ceasing the compression force on the bulb, thereby generating electrical energy and building up pressure inside the cuff.

Then, the generated electrical energy is stored in an energy storage element and a first blood pressure measurement is triggered, after which a second blood pressure
20 measurement is triggered. Both measurements may be performed by an electronic pressure sensor electrically connected to the energy storage element. A first blood pressure value, acquired by the first blood pressure measurement, and a second blood pressure value, acquired by the second blood pressure measurement, are stored in a data storage device.

According to an embodiment, the handle assembly comprises engaging means
25 for detachably engaging the handle assembly with the connector. Preferably, the engaging means are selected from the list comprising screwing means, fastening means, clipping means and clamping means.

According to an embodiment, the first blood pressure measurement is triggered by manually operating a first switch. Also, the second blood pressure measurement
30 may be triggered by manually operating the first switch again.

Thus, electric energy may be saved since the pressure sensor does not have to be operated during the whole blood pressure measurement cycle, but only when it is in fact needed for recording pressure data, i.e., when the systolic blood pressure or the diastolic blood pressure has been reached. In case of an oscillometric BP measurement, the pressure sensor may be operating for the complete deflation cycle, not only around the systolic blood pressure (SBP) or the diastolic blood pressure (DBP).

According to another embodiment, a transmission of data stored on the data storage device to an external receiver, such as, for example, a handheld computer or smartphone, or a central server is triggered by manually operating a second switch. This may, again, save energy, since the system, which may be configured for wireless data transmission, such as, for example, Bluetooth or other short range, low energy data transmission techniques, does not try to transmit data when there is no need for a data transmission or when data transmission is simply not possible, because no external receiver is within reach. When using NFC, a configuration may be possible, where no energy at all is needed from the energy storage. The energy required may be generated by an NFC reader reading the NFC accessible memory with the blood pressure measurement values.

It should be noted that the features which are described above and in the following with respect to the retrofittable kit may also be implemented in the system for measuring blood pressure and, on the other hand, features of the system to measure blood pressure may be also features of the retrofittable kit.

According to an embodiment, the retrofittable kit comprises a microphone which is configured to detect Korotkoff sound signals for triggering the first and second blood pressure measurements. Thus, no stethoscope has to be used, thereby simplifying operation of the blood pressure measurement system.

According to another embodiment, the retrofittable kit comprises a first manual switch which is configured to trigger the pressure sensor to perform a first blood pressure reading and/or a second blood pressure reading,. Thus, electrical energy may be saved.

According to another embodiment, the retrofittable kit further comprises a processor which is operatively connected to the electronic pressure sensor and receives

electric energy for its operation from the energy storage element. The processor is configured to acquire a pressure signal from the electronic pressure sensor and to determine the blood pressure value for the subject based on the acquired pressure signal.

This blood pressure value may then, according to an embodiment, be stored on
5 the data storage device. However, according to another embodiment, the system may be configured to first store the two pressure values acquired by the electronic pressure sensor. After the blood pressure measurement cycle has been completed and the system is ready for data transmission to the external device, the processor determines the blood pressure values for the subject from the stored pressure values. This may save electric energy during the
10 blood pressure measurement cycle. The raw pressure data is converted into blood pressure values after the measurement cycle has been successfully performed.

According to an embodiment, the retrofittable kit also comprises a valve which is operatively connected to the processor and configured to be operatively coupled to the cuff. The valve is configured to enable a deflation of the cuff in response to a control signal from
15 the processor. For example, if the processor determines that the pressure in the cuff is high enough, deflation of the cuff is initiated. This deflation may also be triggered by pressing a manual switch, such as the switch described above, or an additional switch.

According to an embodiment of the second aspect, the system may also comprise a mechanical pressure gauge, which may be part of the manual blood pressure
20 measurement system. The mechanical pressure gauge is observed by the user during the BP measurement cycle, and when the user determines during the blood pressure measurement cycle that a sufficiently high pressure has been reached, he may actuate a manual switch to initiate deflation of the cuff, after which the valve is operated by the processor to allow a reduction of the pressure inside the cuff and thus a measurement of the systolic and the
25 diastolic blood pressure values. Triggering the valve operation manually may save electric energy.

According to another embodiment, the retrofittable kit comprises a data transmission interface configured to transmit data stored on the data storage device to an external receiver, such as a smartphone, a handheld device or a central server.

30 The data transmission interface may be a wireless interface and, according to

another embodiment, a further manual switch may be provided which is configured to trigger the data transmission. Alternatively, only one switch may be provided which serves for triggering data transmission and also for triggering systolic and diastolic blood pressure measurements and/or the valve operation. When using NFC, no such trigger for data
5 transmission is needed.

According to another embodiment, the retrofittable kit further comprises a T-piece connector or junction, configured to be connected between a flexible tube of the manual blood pressure measurement system and the connector, thereby pneumatically connecting the retrofittable kit with the bulb and the cuff. Also, the valve may be arranged in the T-piece
10 connector.

The retrofittable kit may comprise a housing, in which the electronic pressure sensor, the electrical generator, the energy storage element and/or the data storage device are arranged. The housing may be connected to the movable handle, by a mechanical transmission element which connects the movable handle to the generator, and by a rigid pipe
15 or tube which connects the T-piece connector to the electronic pressure sensor inside the housing.

The T-piece connector and the rigid pipe may be adapted to firmly connect the housing to a central portion of the manual BP measurement system, which is arranged between the bulb and the analog pressure sensor (i.e., the mechanical pressure gauge) of the
20 manual blood pressure measurement system.

The retrofitted blood pressure measurement system is capable of harvesting and storing electric energy during the manual inflation of the blood pressure cuff and then discharging this energy in a controlled manner to power sensors, which support the health worker in accurately performing the blood pressure measurement as well as in transmission
25 of the acquired data to an external device.

In the following, embodiments of the invention are described with reference to the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a system for blood pressure measurement according to an

embodiment of the invention.

Fig. 1B shows the system of Fig. 1A in a side view.

Fig. 2 shows a schematic illustration of a cuff-based blood pressure measurement.

5 Fig. 3 shows a flow-chart of a method according to an exemplary embodiment.

Fig. 4 shows a flow-chart of a method according to another exemplary embodiment.

DETAILED DESCRIPTION OF EMBODIMENTS

10 The drawings are schematically and not to scale.

Currently many community health volunteers and nurses in rural and low resource settings use manually inflatable blood pressure cuffs along with a stethoscope to listen to the Korotkoff heart sounds to perform blood pressure measurements. A procedure, which is typically followed when the measurement is performed, is schematically illustrated in Fig. 2. The blood pressure cuff is inflated to a pressure well above the systolic blood pressure (SBP) and is then slowly deflated until the first Korotkoff sounds are heard via the stethoscope. This indicates that the SBP has been reached. The value on the mechanical pressure gauge is then (mentally) noted before continuing the cuff deflation to the point at which no Korotkoff sounds are heard. At this point, the diastolic blood pressure (DBP) has been reached, and the value on the pressure gauge is (mentally) noted. The blood pressure cuff is then fully deflated and the SBP and DBP readings are manually recorded in a health register or notebook.

Fig. 1A shows a system for performing blood pressure measurements according to an embodiment of the invention. The system 100 comprises a bulb 1 and a mechanical pressure sensor and gauge 6 which are connected to the bulb via a connector 20. The connector 20, which is arranged between the mechanical pressure sensor 6 and the bulb 1, comprises a valve which is operated by a rotating knob 15. The connector has an opening 21, to which a T-piece connector 4 is connected, which, in turn, is connected to a flexible tube or hose 5, which connects the bulb to a cuff armband (not shown).

The system comprises a handle assembly that detachably engages with the connector 20. In particular, the handle assembly comprises a handle 2, which may firmly be connected to the housing, and a movable handle 3, which can perform a forward movement towards the fixed handle, when actuated by an external force, from the extended position
5 shown in Fig. 1A to a compressed position (not shown), thereby exerting a compression force on the bulb, and a return movement, when released, to the extended position, ceasing the compression force on the bulb.

The T-piece connector 4 is also connected to a stiff pipe 7, which connects to an electronic pressure sensor 14. The pipe 7 enables the electronic pressure sensor 14 to
10 measure the pressure inside the flexible tube, and thus inside the bulb 1 and the cuff armband.

A valve, which is adapted to be actuated electronically, may be included in the T-piece connector 4. This valve is configured to ventilate the system, i.e., to release air from the bulb 1 and the cuff armband, when a pressure measurement cycle is performed.

The pipe 7 is connected to a housing 8, which contains the electronic pressure
15 sensor 14, the controller or processor 9 (which may contain a data storage device), an energy storage element 10, such as a supercapacitor or a battery, and the electric generator 12, 13. The electric generator 12, 13 is connected to the movable handle 3 via a mechanical transmission element 11. Also, a data transmission interface 16 may be provided, for example a wireless interface and/or a wire interface.

20 Also, a first, second and/or third manual switch 18, 19, 22 may be provided on the housing 8, for triggering a blood pressure measurement, triggering operation of the electric valve and/or for triggering data transmission.

An external receiver 17 may be provided, for receiving measurement data acquired by the system, in particular blood pressure measurement values. The system may be
25 adapted to acquire and store exactly two blood pressure measurement values, i.e., the systolic value and the diastolic value, and transmit the two values to the external receiver 17, either via a wireless data transmission or a wire-bound data transmission.

Fig. 1B shows a side view of the system of Fig. 1A.

The connector 20 is directly coupled to the bulb 1 defining a direction of
30 coupling represented by line A, which would correspond to a longitudinal axis of the bulb 1.

The bulb 1 may not touch the housing 8 and the handle 3 is arranged in parallel to the top surface of the housing. The pipe 7 may be as short as possible and arranged perpendicularly to the front surface of the housing and the longitudinal axis of the handle 3.

On the other hand, the handle assembly is configured to detachably engage
5 with the connector 20 (e.g. by means of clipping) along a direction represented by line B, which is perpendicular to line A. In this manner, when installing the handle assembly on the connector 20, the fixed handle 2 and the movable handle 3 of the handle assembly do not interfere with the bulb 1, or with the mechanical pressure sensor and gauge 6. That is, the handle assembly can be engaged with the connector 20 while maintaining the coupling of the
10 bulb 1 with the mechanical pressure sensor and gauge 6 via the connector 20.

The processor 9 controls the pressure sensor, data acquisition, data storage and data transmission.

The data transmission interface 16 may comprise a near field communication module (NFC), a Bluetooth low energy module, a low power WiFi module or a ZigBee
15 transmitter for wireless data transmission to the external device 17. Data transmission may also be accomplished via wired means, for example using a bit-serial cable.

Data storage, such as temporary or erasable data storage, for example in form of a micro SD card or an NFC tag, is provided by the processor or an additional data storage device, for storing all blood pressure data that will be transmitted to the external device, i.e., a
20 smartphone, a tablet, a computer or a cloud.

Also, permanent data storage is provided, for storing, for example, the blood pressure module functions and signal processing algorithms.

Also, a real time clock (RTC) may be provided with a battery to permit time stamping of acquired blood pressure data. Further, an NFC enabled basic feature phone 17, a
25 smartphone or tablet may be provided for receiving transmitted data and sharing with an information and communication technology (ICT) system, such as, for example, a cloud-based system.

The system may also comprise a microphone for recording heart sounds to measure Korotkoff sounds for automatic determination of the systolic and the diastolic blood
30 pressure values. Still further, an electronically operated valve may be provided, to enable an

automatic cuff deflation. The electronically operated valve may be included in the T-piece connection (see above).

A key aspect of the proposed invention is to harvest and store mechanical energy generated from the pumping of the bulb during inflation of the BP cuff, and then to discharge this energy for control of the recording of two blood pressure measurements (SBP and DBP) during cuff deflation, as well as the transmission of the recorded information to another location or device via a lower power means, NFC, Bluetooth low energy, low-power Wi-Fi. This may be accomplished in the following way:

A handle assembly comprising a flexible, squeezable or compressible handle is mounted on the manual BP measurement system, in particular, detachably engaged with the connector 20. When the handle 3 is squeezed together with the bulb, this motion is converted into electrical energy via conversion of the kinetic energy of the handle into electrical energy through a linear or rotary alternator (according to Faraday's law of induction), in a similar manner to the Knijpkat flashlight. This induced electrical energy is then stored in a (super-)capacitor or battery, for later use during cuff deflation. Following the current health worker workflow, the BP cuff is steadily inflated, generating power, until a pressure above SBP has been reached. The typical manual cuff inflation time required to do this is estimated to be approximately 5-20 s. Based on values for human energy harvesting from squeezing, the power and energy generated during cuff inflation can be estimated:

Assuming a gripping force of 200-250 N (roughly half of the maximum gripping force of a 30 year old male), and application of this force over a distance of 10 mm during squeezing of the bulb at a rate of 1 Hz the following power output is obtained:

$$P = f * F * d = 1 \text{ Hz} * 200-250 \text{ N} * 10.0 \times 10^{-3} \text{ m} = \pm 2.0 - 2.5 \text{ W} \quad (1)$$

where P = power output, f = squeezing frequency, F = gripping force and d = handle displacement during squeezing.

The total energy, E_{total}, harvested over the 5-20s period is therefore:

$$E_{total} = P * (5-20 \text{ s}) = \pm 10 - 50 \text{ J} \quad (2)$$

Next, following the BP measurement workflow, the cuff is deflated manually until the first Korotkoff sounds are heard (via listening to the stethoscope – following the current health worker workflow), indicating that SBP has been reached. At this moment the operator triggers the pressure sensor to acquire a pressure measurement by pressing a switch,
5 button or other means on the cuff to record the SBP. This is accomplished by powering the pressure transducer, located at the mouth of the bulb, for a small time duration (typically less than 0.1s) which requires approximately 0.05 W of power and consumes 5mJ of energy. The processor is also powered to store the measured pressure value over a 0.5 s period, which requires 0.024 W and consumes 12 mJ. After further cuff deflation this process is repeated
10 when the Korotkoff sounds are no longer heard (consuming an additional 17 mJ), indicating that the DBP has been reached. A key advantage of this approach to data acquisition is that the BP values are automatically, electronically recorded without the need for manual entry by the health worker. This eliminates errors due to poor memory recall or incorrect readings made by the operator and due to manual data entry.

15 The stored SBP and DBP values may then be transmitted via Bluetooth, low power Wi-Fi or NFC to a nearby mobile device or to the cloud. The power requirement for low-power Wi-Fi /ZigBee is 36 mJ per 24 bytes of data, for Bluetooth low energy it is 0.147 mJ. For a NFC transmitter energy is harvested from an external NFC reader (e.g., in a feature or smartphone) so it does not consume any energy harvested during cuff inflation. Also the
20 valves of the manual BP cuff do not consume power during inflation and deflation when operated manually. Any remaining energy above that consumed by the pressure sensor, processor, data transmission and storage, can be stored in the (super-)capacitor or battery for later use in additional measurements.

In a simple case, data from the BP cuff can be transmitted to an NFC-enabled
25 basic feature phone, which is widely available throughout Africa and other resource limited settings. However, a smartphone, tablet or portable computer may also be used. The battery of the external device may be used to provide additional energy the BP measurement system. In instances in which no such devices are present (e.g., due to the unavailability of a reliable electrical supply) the BP data may be stored on the device or an SD card, over an extended
30 period of time for later data extraction.

Based on the above description, the energy feasibility of the proposed invention can be confirmed by a simple energy budget calculation as follows:

$$\text{Net energy generated} = \text{Energy harvested during inflation} - ([\text{Energy consumed during data acquisition} + \text{data storage} + \text{data transmission}] + \text{energy losses}) \quad (3)$$

Assuming a minimum inflation time of 5s, ZigBee or low-power WiFi data transmission and estimated energy losses of 50 mJ this yields:

$$\text{Net energy generated} = \pm 10\text{J} - (10\text{ mJ} + 24\text{ mJ} + 36\text{mJ} \pm 50\text{ mJ}) = 9.88\text{ J} \quad (4)$$

Even more energy (9.92 J) may be generated, if NFC is used for data transmission, since energy is instead harvested from an external NFC reader (e.g., a smartphone). It should also be noted, that gripping forces of up to 400N and bulb displacements large than 10 mm are possible, and longer cuff inflation times (up to 30s) may occur, which means that larger amounts of energy may be generated. The bulb stiffness/compliance may be adjusted to increase the force required to inflate the bulb and thereby increase the amount of energy harvested.

The system may comprise an emergency mode in which the bulb is operated to harvest energy without the cuff being pressurized.

In a further embodiment, a microphone is added to record the Korotkoff sounds, which are then processed using an algorithm to enable automatic determination of SBP and DBP (eliminating the need for a user-triggered button or switch). This embodiment may also be used to improve the accuracy of the oscillometric method of BP measurement. This embodiment has the advantage that an inexperienced/non-expert health worker no longer needs to use the stethoscope to listen for the sounds thereby enhancing the reliability of the BP measurement. To enable this embodiment, an additional power of 0.05 W may be required by the microphone sensor and 0.024W by the processor, over a period of 20-30s. This corresponds to $\pm 1.48 - 2.22\text{ J}$ of energy, which can be drawn from the excess energy harvested during cuff inflation. To further enable this embodiment, it would be advantageous for the processor to automatically control the valve deflation. Powering the valve(s) may

require an additional 0.35W power over 15-20s, which consumes 5.25-7J of energy.

Based on the above, the energy feasibility of this embodiment can be confirmed by a simple energy budget calculation as follows:

5

Net energy generated = Energy harvested during inflation – ([Energy consumed during microphone operation + valve operation + data acquisition + data storage + data transmission]+ energy losses) (5)

10

Assuming a minimum inflation time of 5s, ZigBee or low-power WiFi data transmission and estimated energy losses of 100 mJ this yields:

Net energy generated = $\pm 10J - (2.22J + 7J + 10 \text{ mJ} + 24 \text{ mJ} + 36\text{mJ} \pm 500 \text{ mJ}) = 0.56 \text{ J}$ (6)

15

More energy (0.60 J) may be generated, if NFC is used for data transmission, since energy is instead harvested from an external NFC reader (e.g., a smartphone).

20

In a further embodiment, the proposed invention may be applied as a retrofit or augmentation to existing manual BP cuffs by adding to the existing bulb a retrofittable kit integrating all essential components, including the handle assembly with a compressible handle, electronics, the pressure sensor, (super-)capacitor or battery, and energy harvesting elements (i.e., electrical generator), etc., in a single compact unit. The fact that the handle assembly is detachably engagable with a connector coupling the bulb and the mechanical pressure gauge to the cuff, along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb, makes it possible to install the handle assembly without having to disconnect or take apart the existing bulb manual BP measurement system. Of course, despite not being necessary in view of the advantages of the present invention, the user may still replace the existing bulb with a new bulb already retrofitted with the retrofittable kit of the present invention if he or she so desires.

25

In a further embodiment, a real-time clock powered by a 150 to 200 mAh button cell battery can be used to timestamp the acquired BP data for identification purposes. Alternatively the BP data may be linked to a patient identifier via optical character

30

recognition (OCR), a bar code, or QR code scanned by the phone camera or via manual input of a patient number using the phone or computer keypad. A key advantage of this method of BP data transmission is that it is seamless and does not require manual input of the BP data from the health worker thereby minimizing the risk of data errors. It is also important to note
5 that a button cell battery typically has a lifetime of several years.

Fig. 3 shows a flow-chart of a method according to an embodiment of the invention. In step 301, a handle assembly is detachably engaged with a connector coupled to a bulb and to a mechanical pressure gauge of a manual blood pressure measurement system. The handle assembly comprises a movable handle which can be used to compress the bulb
10 when actuated. In step 302, the handle is mechanically coupled to an electrical generator configured to convert the forward movement and to the return movement of the handle into electrical energy. In step 303, the electrical generator is electrically coupled to an energy storage element which is configured to store the electrical energy generated by the generator. In step 304, an electronic pressure sensor is coupled to the atmosphere inside the bulb and in
15 step 305, the electronic pressure sensor is connected to the energy storage element. In step 306, a data storage device is provided configured to store a pressure value from the electronic pressure sensor, which is related to the measured pressure inside the cuff.

It should be noted that the above steps may also be performed in a different order. For example, the last step may be the step of connecting the electronic pressure sensor
20 to the atmosphere inside the bulb (by installing the T-piece connection), and the step before that may be the step of coupling the handle assembly to the connector.

Fig. 4 shows a method for measuring the blood pressure of a subject with the above described system. In step 401, the movable handle of a handle assembly engaged with a connector coupling a bulb of a manual blood pressure measurement system to a cuff of said
25 manual blood pressure measurement system is actuated. The handle assembly is detachably engagable with the connector along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb. The handle is configured to perform a forward movement, when actuated upon, from an extended position to a compressed position, thereby exerting a compression force on the bulb, and a return movement, when released, to the
30 extended position, ceasing the compression force on the bulb, thereby generating electrical

energy and building a pressure inside the cuff. In step 402, the generated electrical energy is stored in an energy storage element and, in step 403, a first blood pressure measurement is triggered after enough pressure has been built up inside the cuff. Triggering of the first blood pressure measurement may be performed by pressing a button. In step 404, pressure is released by a valve and in step 405, a second blood pressure measurement is triggered by pressing the same button (for the second time). Both pressure values are stored and in step 406, further energy is generated by actuating the handle again. After enough energy has been stored, a further switch (or the same switch) is pressed to trigger a wireless data transmission, thus transmitting the stored pressure values to an external receiver.

It should be noted that embodiments of the invention are described with reference to different subject-matter. In particular, some embodiments are described with reference to method-type features, whereas other embodiments are described with respect to apparatus-type features. A person skilled in the art will gather from the above description, that, unless otherwise notified, in addition to any combination of features belonging to one type of subject-matter, also any combination between features relating to different subject-matter is considered to be disclosed within this application.

It should be noted that the term “comprising” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality. Let it further be noted that features described with reference to one of the above embodiments can also be used in combination with other features of other embodiments described above. Moreover, while at least one embodiment has been presented in the foregoing summary and detailed description, it should be appreciated that a vast number of variations exist. It should also be appreciated that the embodiment or embodiments are only examples, and are not intended to limit the scope, applicability, or configuration in any way. Rather, the foregoing summary and detailed description will provide those skilled in the art with a convenient road map for implementing an exemplary embodiment, it being understood that various changes may be made in the function and arrangement of elements described in an embodiment without departing from the scope as set forth in the appended claims and their legal equivalents. Any reference signs in the claims should not be construed as limiting the scope of the claims.

CLAIMS:

5

1. A retrofittable kit for a manual blood pressure measurement system, wherein the manual blood pressure measurement system comprises:

- a cuff configured to be placed around a limb of a subject,
- a mechanical pressure gauge (6) comprising a gauge dial, the mechanical

10 pressure gauge being configured to measure a pressure inside the cuff and provide a pressure value on the gauge dial which is related to the measured pressure inside the cuff, and

- a bulb (1) coupled via a connector (20) to the mechanical pressure gauge (6) and to the cuff, the bulb being configured to inflate the cuff when cyclically compressed, the retrofittable kit comprising:

15 a handle assembly (2, 3) configured to detachably engage with the connector (20) along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb, the handle assembly comprising a handle (3) configured to perform a forward movement, when actuated by an external force, from an extended position to a compressed position, thereby exerting a compression force on the bulb, and a return
20 movement, when released, to the extended position, ceasing the compression force on the bulb;

an electrical generator (12, 13) mechanically coupled to the handle, the electrical generator being configured to convert the forward movement and/or return movement of the handle into electrical energy;

25 an energy storage element (10) electrically coupled to the electrical generator, the energy storage element configured to store the electrical energy generated by the electrical generator;

an electronic pressure sensor (14) connected to the energy storage element and configured to measure the pressure inside the cuff; and

30 a data storage device (9) configured to store a blood pressure value, which is

related to the measured pressure inside the cuff.

2. The retrofittable kit according to claim 1, further comprising:

a first manual switch (18) configured to trigger the electronic pressure sensor
5 (14) to perform a first blood pressure measurement or a second blood pressure measurement.

3. The retrofittable kit according to claim 1 or 2, further comprising:

a processor (9) operatively connected to the electronic pressure sensor (14)
and the energy storage element (10), the processor being configured to acquire a pressure
10 signal from the electronic pressure sensor and to determine the blood pressure value for the
subject based on the acquired pressure signal.

4. The retrofittable kit according to one of the preceding claims, further
comprising:

15 a data transmission interface (16) configured to transmit data stored on the
data storage device (9) to an external receiver (17).

5. The retrofittable kit according to claim 4,

wherein the data transmission interface (16) is a wireless interface.

20

6. The retrofittable kit according to claim 4 or 5, further comprising:

a second manual switch (19) configured to trigger the data transmission.

7. The retrofittable kit according to one of the preceding claims, further

25 comprising:

a microphone configured to detect Korotkoff sound signals for triggering a
first and a second blood pressure measurement.

8. The retrofittable kit according to claim 3 or to one of claim 4 to 7 when

30 dependent on claim 3, further comprising:

a valve operatively connected to the processor (9) and configured to be operatively coupled to the cuff;

wherein the valve is configured to enable deflation of the cuff in response to a control signal from the processor.

5

9. The retrofittable kit according to claim 8, further comprising:

a T piece connector (4) configured to be connected between a flexible tube (5) of the manual blood pressure measurement system (100) and the connector (20), thereby connecting the bulb (1) with the cuff and the electronic pressure sensor (14); and

10 wherein preferably the valve is arranged in the T piece connector (4).

10. The retrofittable kit according to one of the preceding claims, further comprising:

15 a housing (8), in which at least one of the electronic pressure sensor (14), the electrical generator (12, 13), the energy storage element (10) and the data storage device (9) is arranged.

11. A system (100) for blood pressure measurement, comprising:

a cuff configured to be placed around a limb of a subject;

20 a bulb (1) coupled via a connector (20) to the cuff, the bulb being configured to inflate the cuff when cyclically compressed;

a handle assembly (2, 3) configured to detachably engage with the connector (20) along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb, the handle assembly comprising a handle (3) configured to perform a forward movement, when actuated by an external force, from an extended position to a compressed position, thereby exerting a compression force on the bulb, and a return movement, when released, to the extended position, ceasing the compression force on the bulb;

30 an electrical generator (12, 13) mechanically coupled to the handle, the electrical generator being configured to convert the forward movement and/or return

movement of the compressible handle into electrical energy;

an energy storage element (10) electrically coupled to the electrical generator, the energy storage element being configured to store the electrical energy generated by the electrical generator;

5 an electronic pressure sensor (14) connected to the energy storage element and being configured to measure the pressure inside the cuff; and

a data storage device (9) configured to store a pressure value which is related to the measured pressure inside the cuff.

10 12. A method for enabling a manual blood pressure measurement system to perform a semi-automated blood pressure measurement, wherein the manual blood pressure measurement system comprises:

- a cuff configured to be placed around a limb of a subject,

15 - a mechanical pressure gauge (6) comprising a gauge dial, the mechanical pressure gauge being configured to measure a pressure inside the cuff and provide a pressure value on the gauge dial which is related to the measured pressure inside the cuff, and

- a bulb (1) coupled via a connector (20) to the mechanical pressure gauge (6) and to the cuff, the bulb being configured to inflate the cuff when cyclically compressed, the method comprising the steps of:

20 detachably engaging (301) a handle assembly (2, 3) with the connector (20) along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb, the handle assembly comprising a handle (3) configured to perform a forward movement, when actuated by an external force, from an extended position to a compressed position, thereby exerting a compression force on the bulb, and a return movement, when
25 released, to the extended position, ceasing the compression force on the bulb;

wherein the handle (3) is mechanically coupled (302) to an electrical generator (12, 13), the electrical generator being configured to convert the forward movement and/or return movement of the handle into electrical energy;

30 wherein the electrical generator (12, 13) is electrically coupled (303) to an energy storage element (10), the energy storage element being configured to store the

electrical energy generated by the electrical generator;

coupling (304) an electronic pressure sensor (14) to the atmosphere inside the bulb (1);

wherein the electronic pressure sensor is connected (305) to the energy storage element and configured to measure the pressure inside the cuff; and

providing (306) a data storage device (9) configured to store a pressure value, which is related to the measured pressure inside the cuff.

13. A method for measuring the blood pressure of a subject, the method comprising the steps of:

actuating (401) a handle (3) of a handle assembly (2, 3) engaged with a connector (20) coupling a bulb (1) of a manual blood pressure measurement system to a cuff of said manual blood pressure measurement system, wherein the handle assembly is detachably engagable with the connector along a direction that is at an angle with respect to a direction of coupling of the connector to the bulb, wherein the handle (3) is configured to perform a forward movement, when actuated upon, from an extended position to a compressed position, thereby exerting a compression force on the bulb, and a return movement, when released, to the extended position, ceasing the compression force on the bulb, thereby generating electrical energy and building up pressure inside the cuff;

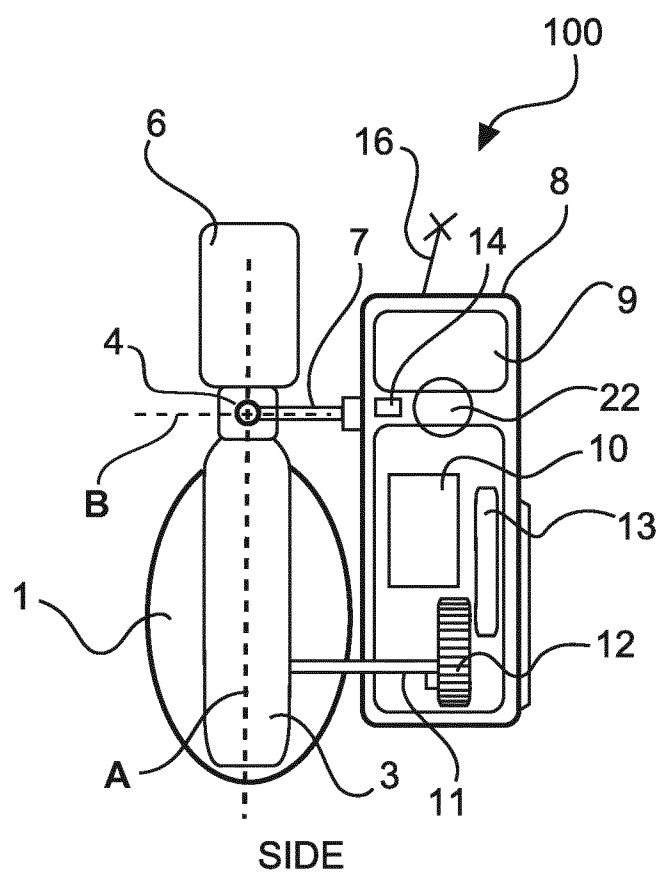
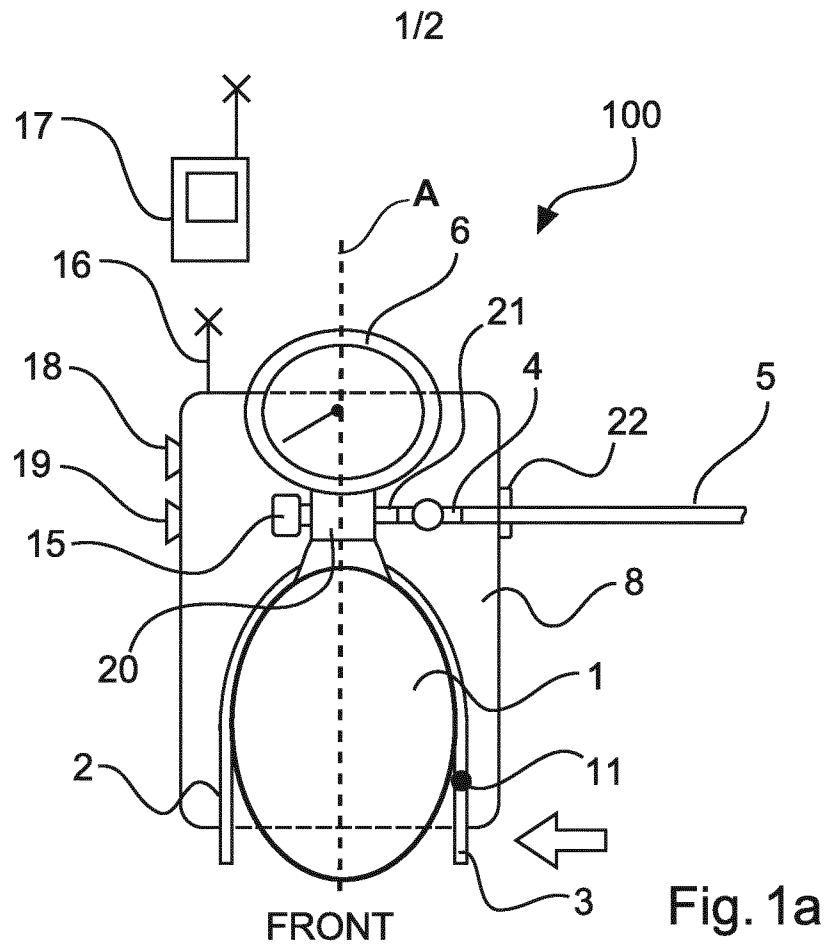
storing (402) the generated electrical energy in an energy storage element (10); performing (403, 404, 405) a first blood pressure measurement and a second blood pressure measurement by an electronic pressure sensor (14) connected to the energy storage element;

storing (406) a first blood pressure value and a second blood pressure value acquired by the first blood pressure measurement and the second blood pressure measurement, respectively.

14. The method of claim 13, wherein the first blood pressure measurement is triggered by manually operating a first switch (18); and

wherein the second blood pressure measurement is triggered by manually operating the first switch again.

15. The method of claim 13 or 14, further comprising the step of:
triggering a transmission of data stored on the data storage device (9) to an external receiver (17) by manually operating a second switch (19).



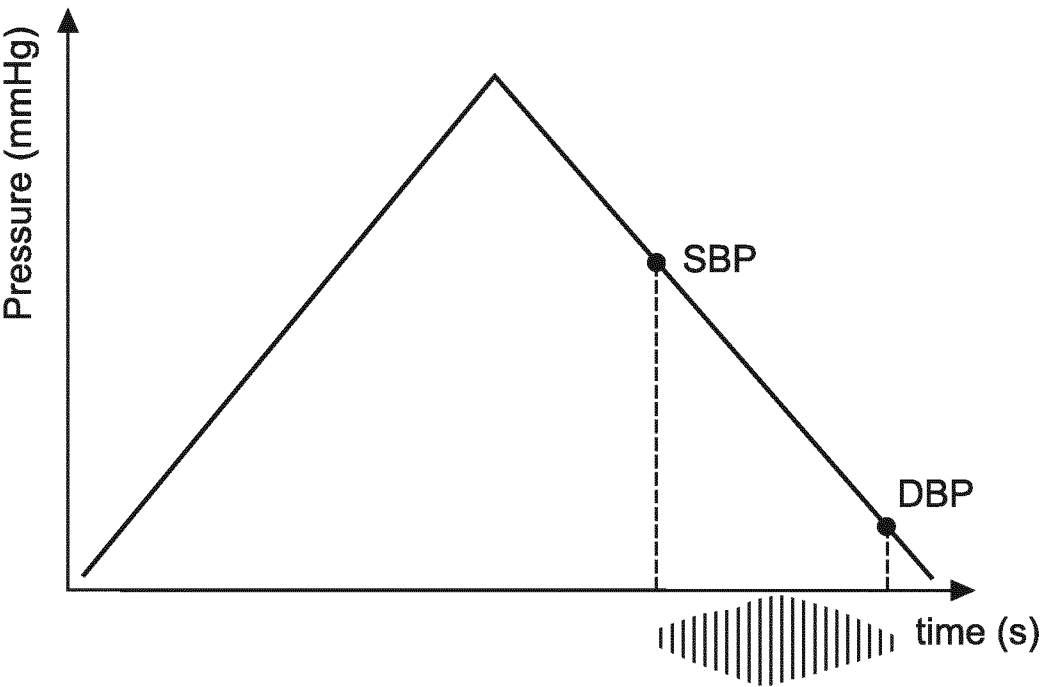


Fig.2

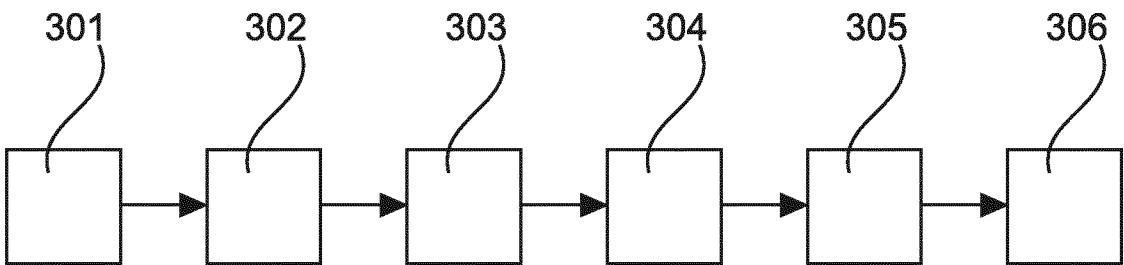


Fig.3

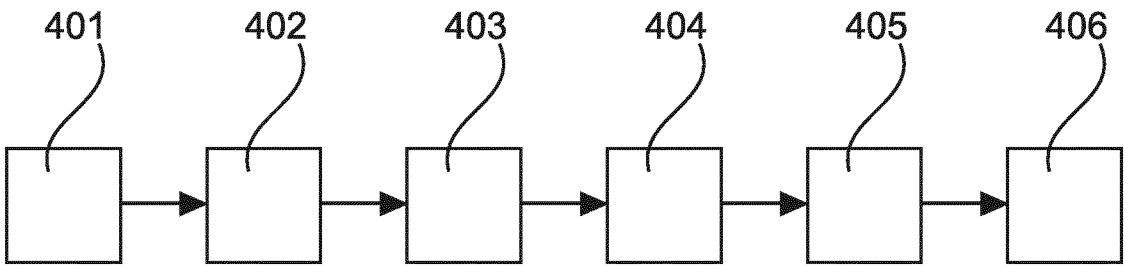


Fig.4

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/058890

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/021 A61B5/022
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/211267 A1 (WANG TIANREN [US] ET AL) 15 August 2013 (2013-08-15) the whole document	1-15
Y	US 2006/217618 A1 (LIA RAYMOND A [US] ET AL) 28 September 2006 (2006-09-28) the whole document	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search

19 July 2017

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Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2017/058890

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013211267	A1	15-08-2013	NONE

US 2006217618	A1	28-09-2006	CN 101299960 A 05-11-2008
		EP 2462865 A2 13-06-2012	
		JP 2009508577 A 05-03-2009	
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