Sensor Device for Detecting Extravasation

Technical Field

The present disclosure relates, in general terms, to a sensor device for detecting extravasation.

Background

Intravenous (IV) cannulation is a routine procedure for most hospital patients for drug or fluid administration. Successful delivery of drugs and fluids depends on the cannula remaining in the vein at all times. Extravasation refers to the accidental leakage of IV drugs from the vein to the surrounding tissues. This can occur for a variety of reasons such as (1) incorrect placement of the cannula, (2) fragile veins (especially in infants and the elderly), (3) excessive movement from the patient resulting in the cannula being pulled out and (4) excessive pressure from the infusion pump used to infuse fluids, damaging the vein or dislodging the cannula. Extravasation begins with the drug accumulating in the subcutaneous tissue distal to the cannula, creating a bulky area. Complications related to extravasations may be quite severe and may include irritation, congestion, blistering and even necrosis of the tissue. Severe cases may result in prolonged hospital stays, cosmetic defects, functional impairment and require reconstructive surgery to repair.

Extravasation is frequently detected late when a large subcutaneous "bump" is noticed at the IV cannulation site, indicating that a large amount of infused fluid had infiltrated the surrounding tissues. This is a particular problem in the operating room with anaesthetized children, as it is often impossible to visualize the cannula site when patients are under surgical drapes. The severity of extravasation injury depends on the volume/type of drug extravasated and the time lapse before the extravasation is detected.

Conventionally, extravasation is physically discovered by healthcare personnel who have a busy workload. This often led to late detection, especially during the night. When a patient is infused with chemotherapeutic drugs, late detection of IV extravasation may damage surrounding tissue of the patient as the drugs are often toxic. In more serious cases, undesirable consequences such as irreversible tissue death and amputation results.

It is important to detect extravasation early for two main reasons. Firstly, early detection will limit any potential damage to the surrounding tissues. This is of crucial importance during infusion of vesicant drugs which cause tissue destruction or irritant drugs which in turn cause pain or inflammation in the tissues. Secondly, early detection of extravasation will ensure that the drugs/fluids administered will reach the patient's intravascular space as intended, failure of which can jeopardize medical management and compromise patient care.

Currently available devices to detect extravasation are expensive, bulky, cumbersome and not for routine use. The occlusion alarms provided by conventional infusion pumps are neither sensitive nor specific enough to detect extravasation. Occlusion pressure limit cannot reliably detect extravasation especially at sites with high compliance, low flow rates, even when pump is set to low occlusion limits.

It would be desirable to overcome or ameliorate at least one of the above-described problems.

Summary

The present disclosure provides a sensor device, comprising:

a) a sensor patch comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film;

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag; and

b) a reader configured to wirelessly read the output from the NFC tag and/or to wirelessly transmit a current to the transponder chip.

Disclosed herein is a sensor device, comprising:

a) a sensor patch comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film;

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag;

iv) a hard backing at a point of connection between the transponder chip and the at least one sensing electrode; and

b) a reader configured to wirelessly read the output from the NFC tag and/or to wirelessly transmit a current to the transponder chip.

In some embodiments, the sensor patch comprises a backing at a point of connection between the transponder chip and the at least one sensing electrode;

wherein the backing is characterised by a flexural modulus of elasticity of more than 1 GPa.

In some embodiments, the backing is made from a material selected from polyimide and/or polyethylene terephthalate (PET).

In some embodiments, the at least one sensing electrode is configured to detect the force acting on the elastic film at at least three sections of the at least one sensing electrode.

In some embodiments, the output is an electrical signal.

In some embodiments, the NFC tag is an active NFC tag.

In some embodiments, the transponder chip is positioned on the one side of the elastic film and adjacent to the at least one sensing electrode.

In some embodiments, the transponder chip is characterised by a lateral dimension of less than about 40 mm.

In some embodiments, the NFC tag comprises an antenna, wherein the antenna extends substantially along a side of the sensor patch or surrounds the at least one sensing electrode.

In some embodiments, the transponder chip is configured to convert the detected change in electrical resistance in a step wise manner.

In some embodiments, the elastic film further comprises an adhesive layer on another side of the elastic film.

In some embodiments, the at least one sensing electrode comprises conductive carbon.

In some embodiments, the at least one sensing electrode is characterized by a

thickness of about 0.05 μm to about 0.2 μm.

In some embodiments, the at least one sensing electrode is characterized by a length of about 50 cm to about 100 cm.

In some embodiments, the at least one sensing electrode is patterned to cover at least about 60% of the surface of the elastic film.

In some embodiments, the sensor patch further comprises a coin battery.

In some embodiments, the sensor patch further comprises at least one pair of bonding pads electrically coupled to the at least one sensing electrode.

In some embodiments, the sensor patch further comprises a frame attached to the elastic film, wherein the transponder chip is sandwiched between the elastic film and the frame.

In some embodiments, the sensor device further comprises a second reader configured to receive the output from the reader.

The present disclosure also provides a sensor patch, comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film; and

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag.

Disclosed herein is a sensor patch, comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film;

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag; and

iv) a hard backing at a point of connection between the transponder chip and the at least one sensing electrode.

The present disclosure also provides a sensing system for detecting extravasation in a patient using the sensor device as disclosed herein, wherein the change in electrical resistance of the at least one sensing electrode is detectable by the transponder chip, convertable to an output that is readable from the NFC tag and wirelessly transmittable to the reader, and based on a magnitude of the change in electrical resistance of the at least one sensing electrode, the reader determines whether an action is necessitated concerning the patient, and provides a notification to a predetermined user.

Disclosed herein is a sensing system for detecting extravasation in a patient, the sensing system comprising a sensor device as disclosed herein, wherein the change in electrical resistance of the at least one sensing electrode is detectable by the transponder chip, convertable to an output that is readable from the NFC tag and wirelessly transmittable to the reader, and based on a magnitude of the change in electrical resistance of the at least one sensing electrode, the reader determines whether an action is necessitated concerning the patient, and provides a notification to a predetermined user.

In some embodiments, the magnitude of change in electrical resistance is calibrated against a calibration plot.

In some embodiments, the notification is a visual alert and/or audio output means.

The present disclosure also provides a method for detecting extravasation in a patient in need thereof using the sensor device as disclosed herein, comprising:

a) positioning the sensor patch adjacent to an IV infusion site on the patient; and

b) wirelessly monitoring the change in electrical resistance of the at least one sensing electrode via the reader.

Disclosed herein is use of the sensor device as disclosed herein, comprising the steps of:

a) positioning the sensor patch adjacent to an IV infusion site on the patient; and

b) wirelessly monitoring the change in electrical resistance of the at least one sensing electrode via the reader.

The present disclosure also provides a sensor device as disclosed herein for use in detecting extravasation.

Brief description of the drawings

Embodiments of the present invention will now be described, by way of non-limiting example, with reference to the drawings in which:

Figure 1A shows the components of the sensor patch.

Figure 1B shows an exemplary sensor patch in use.

Figure 2 shows a comparator and an embodiment of the present disclosure.

Figure 3 shows a schematic of an embodiment of the present disclosure. The transponder chip is represented as RF430FRL152H.

Figure 4 shows a schematic of another embodiments of the present disclosure.

Figure 5 shows a schematic of another embodiment of the present disclosure.
Figure 6 shows how a bump increases the length of sensing electrode.

Detailed description

There is a clinical need for a small, portable, practical and/or cost-effective device to detect extravasation. The device may trigger a warning, may be independent of rate of infusion and which may be universally applied to all patients.

The present disclosure is predicated on the understanding that wearable built on integrated sensors hold huge potential in the healthcare industry because of the potential for autonomous monitoring and the reliance on healthcare workers is reduced. Such wearable may also be non-obstructive. In this regard, various types of sensors with low-power electronics and wireless radio communication interfaces may be integrated into wearables.

Without wanting to be bound by theory, the inventors believe that it is desirable for disposable medical devices to be integrated with a wireless module. For example, disposable medical devices may be configured to auto-detect intravenous infusion (IV) leakage (i.e. extravasation), which is desirable as it has a high rate occurrence. This may ease the workload of healthcare professionals and allow for on time treatment when required.

The present disclosure provides a sensor device, comprising:

a) a sensor patch comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film;

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing

electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag;

b) a reader configured to wirelessly read the output from the NFC tag and/or to wirelessly transmit a current to the transponder chip.

The sensor device comprises a reusable reader device, which may be in the form of a wearable watch having integrated circuits build on PCB, and a sensor patch configured to sense a strain. The sensor patch may be applied to an IV injection site of the patient. This sensor patch may be a consumable ie. disposable. Hence, the reader may be transferred to another patient for use with a new sensor patch.

As shown in Figure 1A, the sensor patch 10 comprises an elastic film 102 and at least one sensing electrode 104. The sensing electrode 104 is disposed on the elastic film 102. The sensing electrode 104 may be adhered to the elastic film 102, or printed (such as screen-printed) onto the elastic film 102. The elastic film 102 may comprise an adhesive surface for adhering to a skin of a patient. The adhesive surface may be protected by a protecting layer 110 before use. The protecting layer 110 may be removed such that the user can adhere the adhesive surface to the skin of the patient. When the skin of the patient is strained (such as being stretched), the strain force acts on the at least one sensing electrode, which in turn causes an electrical resistance of the at least one sensing electrode. The magnitude of the electrical resistance depends on the amount of force acting on the at least one sensing electrode. The change in the electrical resistance is transmitted to the transponder chip 106, which may be integral on the sensor patch 10 (as shown in Figure 1) or forms an external circuit module. The change in the electrical resistance is converted into an output by the transponder chip 106. The transponder chip 106 also comprises a near field communication (NFC) tag, which comprises an antenna. The NFC tag may thus wireless transmits the output as data to a reader in responds to instructions from the reader. The sensor patch 10 may further comprise a frame

108. The frame 108 forms a border around the elastic film. The frame 108 may be adhered to the elastic film 102, or laminated to the elastic film 102. The frame 108 prevents the elastic film 102 and thus sensing electrode 104 from crinkling when attaching to a user's body.

The sensing electrode 104 may be further protected by a protective layer. In this regard, the sensing electrode 104 may be sandwiched between the elastic film 102 and a protective layer. This prevents or minimizes damage to the sensing electrode 104. The protective layer may be a second elastic film.

The transponder chip 106 is affixed on the elastic film 102. For example, the transponder chip 106 may be adhered to the elastic film 102. The transponder chip 102 may be further soldered to the at least one sensing electrode 104 in order to electrically connect with the sensing electrode 104. The point of connection (or connector) 112 between the transponder chip 106 and the at least one sensing electrode 104 may further comprise a backing. The backing may be a hard and/or firm backing, such as from a hard material. The material may be polyimide or polyethylene terephthalate (PET). It was found that this improves the connectivity between the transponder chip 106 and the at least one sensing electrode 104, and also reduces the possibility of electrical breakage when the elastic film is stretched. The transponder chip 106 may also be adhered to the backing. It was further found that by limiting the backing to the connection 112 and/or the transponder chip 106, the sensor patch remains flexible to conform to the contours of a patient's body or limb.

The backing may have a shore hardness of more than 60D, or 70D, 80D, 90D or 100D.

The backing may have a flexural modulus of elasticity of more than 1 GPa, or 1.3 GPa, 1.4 GPa, 1.5 GPa, or 1.6 GPa. The flexural modulus may be between 1GPa to 1.6 GPa. Flexural modulus is defined as a measure of stiffness during the initial bending process. It is also known as the modulus of elasticity in

bending and is represented by the slope of the stress-strain curve's initial straight line portion.

Figure 1B shows an exemplary sensor patch in use, adhered on a skin of a patient.

Figure 2 shows a comparator and an embodiment of the present disclosure. The comparator sensor device comprises a wired connection between a receiver and the sensor patch. The embodiment of the present disclosure shows a wireless connection between the reader (receiver) and the sensor patch. Wireless communication occurs between the reader and the sensor patch. The wireless communication may be via NFC protocol. The receiver may be a wearable device.

The basic components of a contactless system are a reader (or Proximity Coupling Device (PCD)) and a tag. The reader comprises an antenna connected to an electronic circuit. The reader forms the active part of the system, as it “reads” (or processes) information, from which a specific response may be triggered. The response may be predefined, or may be input manually by a user. It may also provide power and sends commands to the transponder (tag). A tag consists of an inductive antenna and a chip having an integrated circuit connected to the ends of the antenna. The combination reader-tag behaves as a transformer. An alternating current passes through a primary coil (reader antenna) that creates an electromagnetic field, which induces a current in the secondary coil (transponder antenna). The tag converts the electromagnetic field (or RF field) transmitted by the contactless reader (PCD) into a DC voltage by means of a diode rectifier. This DC voltage may power the transponder's internal circuits. Data may also be exchanged; the reader is constantly emitting a signal; when a tag comes in range, it receives the signal and responds to the reader with the information requested.

As mentioned, the at least one sensing electrode is electrically communicated with a transponder chip. The transponder chip receives an input in the form of a change in electrical resistance from the at least one sensing electrode and converts the input to an output signal. The output may be an electrical signal such as a current or voltage. The at least one sensing electrode may be electrically communicated or coupled to the transponder chip via a readout circuit. The transponder chip may comprise the readout circuit. In this way, the change in the electrical resistance is convertible to an electrical output signal, which is receivable by the transponder chip. Accordingly, the readout circuit aids in allowing the input from the at least one sensing electrode to be transmitted to the transponder chip.

The transponder chip comprises a near field communication (NFC) tag. The NFC tag comprises an antenna. In this regard, the transponder chip may be electrically communicated with a wireless antenna. The wireless antenna may be for NFC. In some embodiments, the wireless antenna may surround the at least one sensing electrode. This enlarges the footprint and hence the communication range of the NFC. Alternatively, the antenna may be configured to be at an edge of the sensor patch such that it may be in close proximity to the reader. For example, the antenna may extend substantially along a side of the sensor patch. The wireless antenna is for communicating contactlessly and/or wirelessly with a reader device.

The NFC tag may be a single interface NFC chip. A single-interface NFC chip is a passive device embedded in an NFC tag, which only communicates with the reader. Once it is activated by the reader, the single-interface NFC chip sends data received from the tag to the reader, when they are brought in close proximity. These devices do not process any information sent from other sources, and cannot connect to other passive components. Accordingly, the sensor patch may further comprise a battery for powering the NFC tag.

For example, the sensor patch may comprise a coin battery. This provides power for the transponder chip to work without depending on communication with the reader. The transponder chip sends data to the reader without energy harvesting. In this instance, the distance for wireless transfer between the reader and the transponder chip may be less than 100 cm, or less than 50 cm, 20 cm, 15 cm, 10 cm, 8 cm, 5 cm or 2 cm.

The NFC tag may be a dual interface NFC chip. A dual-interface tag is an active device and is coupled with a microcontroller through a wired interface (I2C for example), thereby offering a second communication interface in addition to the NFC wireless link. An NFC Dynamic Tag chip enables two-way, wireless communication between two electronic systems (i.e. send and receive data), even when no power is supplied to the object carrying the NFC Dynamic Tag. An NFC Dynamic Tag acts as a bridge between two electronic systems and is able to exchange data and harvest energy from the NFC RF field to power up a microcontroller. For example, when an NFC-enabled smartphone is brought within reading distance of an electronic device (such as a Bluetooth™ computer), the BLE pairing is automatically performed without any additional user operation. The NFC reader (smartphone) detects the NFC Dynamic tag embedded in the computer and recovers the information that enables the BLE pairing.

Accordingly, the NFC tag may allow for two way wireless communication between the reader and the transponder chip. Data may be received by the reader from the transponder chip, and the transponder chip may be wirelessly powered by the reader.

In addition to their ability to read and write data, NFC chip also support specific features, such as tamper detection mechanisms and digital signature, which is suitable for identification and authentication of the sensor patch.

The NFC tag may be adhered to the transponder chip and hence the sensor patch by an adhesive.

Figure 3 shows a schematic of an embodiment of the present disclosure. The at least one sensing electrode is a strain sensor electrically connected to the transponder chip (RF430FRL152H). A change in strain results in a change in electrical resistance (R_{strain}), which is sent as data to the transponder chip. R_1 may be calibrated so that the range of R_{strain} may be measured accurately. The collected data is subsequently sent to a reader device such as a watch via the antenna coil of the NFC tag, which may further wirelessly transfer the data to a further reader device such as a mobile phone by WIFI. The mobile phone may be carried by the healthcare professionals within the hospital compound.

The transponder chip may further comprise a capacitor. The capacitor may store electrical charge, for powering the NFC chip.

Figure 4 shows a schematic of another embodiment of the present disclosure. The reader device is a bedside device which is NFC-enabled. The reader may be a device which is wearable on a patient's wrist such as a watch, or a tablet or a laptop. Collected data at bedside device may then be wirelessly transfer to a further reader device such as a mobile phone or centralised monitoring system by WIFI. The mobile phones could be carried by the healthcare professionals within the hospital compound.

Figure 5 shows a schematic of another embodiment of the present disclosure. The reader device is a mobile phone accessible by and/or near to the patient.

The sensor patch may be employed for detecting extravasation. In use, stretched tissue and/or swollen tissue trigger resistance change of conductive electrodes which act as strain sensors and generates signal change captured by the integrated transponder chip. Using wireless or Near Field Communication (NFC) technology, the transponder chip may be micro-powered by a nearby

NFC-enabled devices such as watch, bedside device or mobile phones. Simultaneously, wireless data is transferred from the transponder chip to a nearby NFC-enabled device.

As the change in electrical resistance is a variable value (i.e. may increase over time), the output from the transponder chip may also be a variable value. Accordingly, the NFC tag is configured to handle this change in information such that the reader is constantly updated in real time. In this regard, any size of output is transmitted to the reader.

Alternatively, the transponder chip may be configured to convert the detected change in electrical resistance in a step wise manner. For example, when the change in electrical resistance is changed by a fixed amount, a fixed output is generated in the transponder chip. This fixed output is sent to the NFC tag for reading by the reader.

Alternatively, when the electrical resistance of the sensing electrode is equal to or more than a first predetermined threshold level, or when a change (from an initial electrical resistance value) in the electrical resistance of the sensing electrode is equal to or more than a second predetermined threshold level, the change is sent to the transponder chip which then converts the detected change to an output readable by the NFC tag.

Accuracy validation may be performed for every sensor patch. In addition, before usage, the sensor patch may be calibrated to reduce deviation resulting from skin contact and/or crinkling of the sensor patch.

The reader may be a device which is wearable on a patient's wrist as a watch. A second reader may also be configured to wirelessly receive an output from the watch (first reader). The second reader may be a computer, configured to receive the output from the watch via Bluetooth. Alternatively, the second reader may be a smartphone. For the reader to be able to receive data and/or

wirelessly communicate with the tag, the reader may also include a NFC antenna.

The transponder chip is electrically coupled to the at least one sensing electrode. The transponder chip may be electrically coupled to the at least one sensing electrode via connectors. Changes to the electrical resistance of the at least one sensing electrode is sent to the transponder chip, which may be converted into an electrical signal to be relayed to the reader via a Near Field Communication (NFC) tag through an antenna. Accordingly, the transponder chip comprises the Near Field Communication (NFC) antenna for receiving a NFC protocol.

Near-field communication (NFC) is a set of communication protocols that enables communication between two electronic devices over a distance of 10 cm or less. NFC offers a low-speed connection through a simple setup that can be used to bootstrap more capable wireless connections. NFC is based on inductive coupling between two antennas present on NFC-enabled devices, communicating in one or both directions using a frequency of 13.56 MHz in the globally available unlicensed radio frequency ISM band using the ISO/IEC 18000-3 air interface standard at data rates ranging from 106 to 848 kbit/s.

The transponder chip may be a passive transponder chip in that it does not have a power source. Instead, the transponder chip may be powered by electromagnetic energy transmitted from the reader. The electromagnetic energy may be received by the active NFC tag.

In various embodiments, the transponder chip is positioned on the sensor patch. In this regard, the transponder chip is not external to the elastic film, but may be adhered to a surface of the elastic film. The transponder chip may be adjacent to the at least one sensing electrode. The transponder chip may be positioned to an edge of the elastic film. It was found that this setup provides convenience to the patient in that there are no loose component which may be accidentally ripped off.

The transponder chip may have a small lateral dimension (length and/or width) of less than about 50 mm, or less than about 40 mm, 30 mm, 20 mm, 10 mm, or about 4 mm. This allows the sensor patch to be still substantially flexible to conform to the contours of a patient's arm. Alternatively, the transponder chip is sized such that it is less than about 10% relative to a surface of the elastic film.

The transponder chip may be soldered to the sensing electrode on the sensor patch.

An electrical resistance (or impedance) of the at least one sensing electrode may be changeable in response to a force acting or exerted on the at least one sensing electrode. This may mean that the at least one sensing electrode may be configured to exhibit a change in electrical resistance in response to a force acting on or exerted on the at least one sensing electrode. The force may also act on the elastic film. The force may originate from a strain in the skin. The at least one sensing electrode may not or does not need contact with a skin surface for extravasation detection.

The at least one sensing electrode may define a sensing area (or detecting area) of the sensor patch. The sensing area may be defined by the shape and/or size of the at least one sensing electrode. For example, the area of the sensor patch provided with the at least one sensing electrode may correspond to the sensing area.

In various embodiments, the at least one sensing electrode is patterned to substantially cover a surface of the elastic film. Alternatively, the at least one sensing electrode may cover at least about 90% of the elastic film, at least about 80%, at least about 70%, at least about 60%, at least about 50%, or at least about 40%.

In various embodiments, the force acting on the at least one sensing electrode may cause a change in at least one dimension (e.g., length and/or width) of the at least one sensing electrode, thereby causing a change in the electrical resistance of the at least one sensing electrode.

In various embodiments, where the sensor patch with the at least one sensing electrode is positioned on a surface, a change in a contour (or topography or shape) of the surface, e.g., resulting in a bump, may cause a force to act on or to be exerted on the at least one sensing electrode. As a result, the electrical resistance of the at least one sensing electrode may change. Changes in the contour of the surface may be conveyed by the elastic film to the at least one sensing electrode.

As a non-limiting example, the sensor patch with the at least one sensing electrode may be positioned on a skin surface of a subject (or patient), over a cannulation site. In the event that extravasation occurs, the contour (or topography or shape) of the skin surface over the cannulation site may change (e.g., resulting in a bump), and the at least one sensing electrode may experience a force acting on it, causing a change in at least one dimension (e.g., length and/or width) of the at least one sensing electrode, thereby changing its electrical resistance. For example, when a protrusion (e.g., a bump) occurs in the skin or skin surface, the electrical resistance of the at least one sensing electrode may increase. When extravasation occurs, changes in the skin or skin surface, for example, swelling, may stretch the sensor patch. This may result in a change in the electrical resistance of the at least one sensing electrode, due to a change in at least one dimension (e.g., length and/or width and/or thickness) of the at least one sensing electrode, as a result of stretching of the at least one sensing electrode. Therefore, skin swelling caused by extravasation may be detected through the sensor patch.

For example, extravasation occurrence may be observed as a bump on the skin. This stretches the adhered elastic film, and corollary the carbon electrodes on

the elastic film, resulting in the sensing electrode's length to be longer, causing resistance to increase.

The elastic film may be made of an elastic polymer. The elastic film may further be flexible. For example, the elastic film may be a polyurethane film. For example, the elastic film may be Tegaderm™.

In various embodiments, the elastic film may be adapted to conform to a contour (or topography or shape) of a surface on which the sensor patch is positioned. This may mean that the sensor patch may be a conformal sensor patch.

In various embodiments, the sensor patch may be stretchable. This may mean that the elastic film may be stretchable. Correspondingly, the at least one sensing electrode may also be stretchable. The elastic film and the at least one sensing electrode of the sensor patch may be stretchable for sensing extravasation bump formation. In various embodiments, the elastic film may be made of an elastic and stretchable material.

In various embodiments, the elastic film may be a flexible elastic film or substrate which may be stretchable, and the at least one sensing electrode may be a stretchable sensing electrode or sensing element disposed on the flexible elastic film.

In various embodiments, the elastic film may be formed from a polymer. The polymer for the elastic film may include polyethylene, silicone, urethane polymer, acrylate resin, Rayon, parylene, polyimide etc.

The sensor patch comprises at least one sensing electrode which may provide a single (one) sensing site. Alternatively, when the sensor patch comprises a plurality of sensing electrodes, multiple sensing sites may be present. The

sensing sites may be located at different sites on the sensor patch, or may converge at a central region of the sensor patch.

In various embodiments, the at least one sensing electrode may include a strain gauge. This may mean that the sensor patch may be a strain-gauge sensor patch.

In various embodiments, the at least one sensing electrode may include a piezoresistive material. This may mean that the at least one sensing electrode may exhibit piezoresistive effect. In this way, a piezoresistive type sensor patch for extravasation detection may be provided.

In various embodiments, the at least one sensing electrode may be disposed on one side of the elastic film. For example, the at least one sensing electrode may be provided (e.g., directly) on a surface (e.g., top surface) of the elastic film.

In various embodiments, the sensor patch may further include an adhesive layer provided on another side of the elastic film. For example, the adhesive layer may be provided (e.g., directly) on a second surface (e.g., bottom surface) of the elastic film, opposite to the top surface comprising the at least one sensing electrode. The adhesive layer may provide an adhesive surface to be placed over a skin surface, without any strap, arm band or housing, to secure the sensor patch on the body of a subject or patient.

In various embodiments, the at least one sensing electrode may be stretchable and patterned on the elastic film, which may be reused at the same site before peeling the sensor patch from the skin of a subject.

In various embodiments, the sensor patch may further include at least one pair of bonding pads electrically coupled to the at least one sensing electrode. The at least one pair of bonding pads may be electrically coupled or connected to a readout circuit (e.g., an external readout circuit) for determining the electrical

resistance or the change of the electrical resistance of the at least one sensing electrode. In this way, the at least one sensing electrode may be electrically coupled to a readout circuit via the at least one pair of bonding pads. In various embodiments, a respective pair of bonding pads may be electrically coupled to a respective (one) sensing electrode.

In various embodiments, the at least one sensing electrode may be printed on the elastic film. The at least one sensing electrode may be printed directly on the elastic film without any glue or adhesive between the at least one sensing electrode and the elastic film. In various embodiments, the at least one sensing electrode may be patterned on the elastic film.

In various embodiments, the at least one sensing electrode may be formed into an arrangement having at least one of a linear pattern, a curved pattern, a meander pattern, a zig zag pattern or a spiral pattern. For example, the meander pattern may have at least 5 fingers (Figure 6).

In some embodiments, the at least one sensing electrode is configured to detect the force acting on the elastic film at at least three sections of the at least one sensing electrode. For example, the at least one sensing electrode may detect the bump at 3, 4, 5 or multiple sections of the at least one sensing electrode. For example, as shown in Figure 6, the bump is detected at three sections of the at least one sensing electrode. It was found that this increase in detection footprint improves the accuracy of detection, as well as minimizes error and/or noise due to the adhering and crinkling of the sensor patch.

In various embodiments, the at least one sensing electrode may include at least one of metal, liquid metal alloy or conductive polymer. Non-limiting examples of metals that may be used for the at least one sensing electrode 204 may include titanium (Ti), gold (Au), nickel (Ni), copper (Cu), chromium (Cr), aluminium (Al), indium (In), platinum (Pt), silver (Ag) and tin (Sn).

Non-limiting examples of liquid metal alloys that may be used for the at least one sensing electrode may include Galinstan which may have a composition including gallium, indium, and tin.

Conductive polymers or intrinsically conducting polymers that may be used for the at least one sensing electrode may include organic polymers that conduct electricity. The compounds used may have metallic conductivity or may be semiconductors, such as silver, graphite, copper powder, carbon black or carbon nanotubes, etc.

In some embodiments, the at least one sensing electrode comprises electroconductive carbon. The carbon may be provided as a paste, comprising carbon-based materials (e.g., carbon black, graphite), a binder (e.g., PVDF, ethyl cellulose), a solvent (e.g., NMP, acetone), additives, and, optionally, conductivity enhancers like silver nanoparticles. Other functional agents, like thickeners, dispersants, and surfactants, to enhance performance, stability, or adhesion.

In various embodiments, the at least one sensing electrode may be formed as a single layer or as a stacked layer arrangement of different layers. For example, the at least one sensing electrode may be a single metal layer or a double layer arrangement having different metals in different layers.

In various embodiments, a width, w, of the at least one sensing electrode may be between about 0.5 mm and about 10 mm, for example, between about 0.5 mm and about 5 mm, between about 0.5 mm and about 2 mm, between about 2 mm and about 10 mm, between about 2 mm and about 5 mm, between about 5 mm and about 10 mm. The width, w, of the at least one sensing electrode may be at least substantially uniform throughout the at least one sensing electrode.

In various embodiments, a thickness, t, of the at least one sensing electrode may be about 0.2 μm or less (i.e., < 0.2 μm), e.g., < 0.15 μm, < 0.1 μm, or < 0.05 μm. The thickness, t, of the at least one sensing electrode may be at least substantially uniform throughout the at least one sensing electrode. The thickness of the at least one sensing electrode may be a less than 0.2 μm metal thin film to detect extravasation with high sensitivity. The very thin (0.2 μm) layer may be printed on the elastic (stretchable) film. This ensures that electrical connectivity is not broken when the elastic film is stretched.

For example, the at least one sensing electrode may be a metal and/or carbon layer of a thickness of about 0.2 μm. As a non-limiting example, a very thin (0.2 μm) metal and/or carbon layer (as the sensing electrode) printed on an elastic (stretchable) film may have an average (N = 9) resistance change of about 31 Ω/ml of saline infusion without the use of additional bridge network. In a general case, 2 ml of infusion may be considered as early extravasation. The sensor patch of various embodiments may be more sensitive and may have a high signal to noise ratio (e.g., > 4.1), which may detect slight skin swelling and tension caused by an early extravasation injury.

In various embodiments, the sensitivity of the sensor patch may be determined by the width, w, and/or the thickness, t, of the at least one sensing electrode.

In various embodiments, a length of the at least one sensing electrode may be between about 5 cm and about 100 cm, for example, between about 5 cm and about 50 cm, between about 5 cm and about 20 cm, between about 10 cm and about 50 cm, between about 20 cm and about 100 cm, between about 50 cm and about 100 cm, or between about 20 cm and about 40 cm. It was found that having a suitable length of the sensing electrode reduces the variance of electrical resistance.

In various embodiments, the electrical resistance of the at least one sensing electrode may be changeable in response to at least one of a normal force (e.g.,

due to skin swelling) or a shear force (e.g., due to skin stretching or tension) acting on the at least one sensing electrode.

In various embodiments, the electrical resistance of the at least one sensing electrode may be changeable in response to one or more forces acting on the at least one sensing electrode in x-, y- and z-directions of a three-dimensional Cartesian coordinate system. The electrical resistance of the at least one sensing electrode may be changeable in response to a force acting on the at least one sensing electrode in the x-direction, a force acting on the at least one sensing electrode in the y-direction, and a force acting on the at least one sensing electrode in the z-direction, as well as a force having force components acting on the at least one sensing electrode in at least two directions of the x-, y- and z-directions. This may mean that the sensor patch having the at least one sensing electrode may be able to detect skin deformation (e.g., tension/swelling) in 3 axes (x-y-z directions). Therefore, the sensor patch may detect skin tension and/or skin swelling, in the x-y-z directions, caused by (early) extravasation injury.

In various embodiments, the sensor patch may include a single (one) sensing electrode. In various embodiments, the sensor patch may include a plurality of sensing electrodes, e.g., two sensing electrodes, three sensing electrodes or any higher number of sensing electrodes. The plurality of sensing electrodes may be electrically isolated from each other.

In various embodiments, the sensor patch may be a planar sensor patch.

In various embodiments, the sensing patch includes a readout circuit for determining the electrical resistance of the at least one sensing electrode of the sensor patch. The readout circuit may determine the absolute value of the electrical resistance of the at least one sensing electrode and/or the change in the electrical resistance of the at least one sensing electrode. The readout circuit may be electrically coupled to the at least one sensing electrode, for example

via an electrical interconnection (e.g., wire or cable). The readout circuit may be incorporated within the transponder chip. The readout circuit may be external to the sensor patch. The readout circuit may be a microprocessor.

A "circuit" may be understood as any kind of a logic implementing entity, which may be special purpose circuitry or a processor executing software stored in a memory, firmware, or any combination thereof. Thus, in an embodiment, a "circuit" may be a hard-wired logic circuit or a programmable logic circuit such as a programmable processor, e.g. a microprocessor (e.g. a Complex Instruction Set Computer (CISC) processor or a Reduced Instruction Set Computer (RISC) processor). A "circuit" may also be a processor executing software, e.g. any kind of computer program, e.g. a computer program using a virtual machine code such as e.g. Java. Any other kind of implementation of the respective functions which will be described in more detail below may also be understood as a 'circuit' in accordance with an alternative embodiment.

In some embodiments, the reader only reads the NFC tag and determines, from the reading, the change in electrical resistance, which may result from a force applied to the film or the amount of stretch of the film.

In various embodiments, the sensing device may further include at least one of a visual means (e.g., a visual alert LED) or an audio output means. The audio output means may be electrically coupled to the readout circuit. The audio output means may be an alarm or a buzzer. As a non-limiting example, the audio output means may be activated to provide an audio signal, for example, when the electrical resistance of the at least one sensing electrode is equal to or more than a first predetermined threshold level, or when a change (from an initial electrical resistance value) in the electrical resistance of the at least one sensing electrode is equal to or more than a second predetermined threshold level. This may provide a warning or an indication to a clinician or a doctor that there may be extravasation.

A further threshold may be applied to the electrical resistance or change in electrical resistance, such that a reading above this particular threshold will in turn give rise to an alert. This may provide a warning or an indication to a clinician or a doctor that the cannula or sensor patch may be dislodged.

The visual means and/or audio output means may be provided in the reader. Accordingly, the clinician or doctor does not have to be constantly monitoring the patient at a bedside.

In various embodiments, the sensing device include a radio frequency (RF) wireless module such as a NFC transponder chip electrically coupled to the readout circuit. The RF wireless module may include at least one of a transmitter or a receiver. As a non-limiting example, the RF wireless module may transmit information or data obtained by the readout circuit wirelessly to a reader (remote device or processor), or to receive a signal wirelessly from a reader (remote device or processor) to activate the sensor device to perform sensing.

In various embodiments, the sensor patch comprises another elastic film. The at least one sensing electrode, transponder chip and other components may be sandwiched between the two elastic film. This provides better protection to the electrical components.

In an embodiment, the (conformal) sensor patch may include an elastic film and a sensing electrode made of a piezoresistive material provided on the elastic film. The elastic film may act as a substrate for the sensing electrode. The sensing electrode may be patterned on the elastic film. The sensing electrode may be provided on an upper surface of the elastic film. The sensing electrode may be arranged in a meander pattern. The sensing electrode of piezoresistive material may act as a strain sensing element, and may be used, for example, for sensing tissue skin stretch. The elastic film may convey or conduct tissue skin tension to the piezoresistive sensor. The electrical resistance of the sensing electrode of piezoresistive material may be changeable or variable, in response

to a force acting on it, for example, as a result of skin stretching. The material of the sensing electrode may be chosen as metal and/or conductive polymer. A sensing area (e.g., extravasation sensing area) may be defined by the sensing electrode, for example, by the arrangement, pattern or shape of the sensing electrode. The sensing area may be defined by a single sensing electrode or by a multi-electrode arrangement (i.e., plurality of sensing electrodes). A pair of bonding pads may be provided electrically coupled to the sensing electrode. For example, one bonding pad may be connected to one end of the sensing electrode while another bonding pad may be connected to another (opposite) end of the sensing electrode. The bonding pads of the patch may be used for interconnection with a reader circuitry. An adhesive layer may be provided on one side of the elastic film, for example, on the bottom surface of the sensor patch. The adhesive layer may be used to conformally attach the sensor patch on the skin of a subject or patient.

In some embodiments, the sensor patch comprises a frame attached to the elastic film. The frame borders the elastic film to provide additional support to the elastic film. The transponder chip may be sandwiched between the elastic film and the frame to provide additional protection to the electrical components. The transponder chip may be laminated to either or both the frame and the elastic film, or adhered to either or both the frame and the elastic film.

In use, the reader or phone which are equipped with NFC will wirelessly power the transponder chip on the sensor patch via the NFC tag which is connected to the transponder chip. When a change in electrical resistance is detected in the sensor patch, the transponder chip will transmit an output as data wirelessly by NFC via NFC tag to reader or phone which are at a distance of up to about 1 m. The reader or mobile app in the phone may trigger an alarm at the set point. The data may be displayed, which may be either by software on a computer wirelessly connected to reader via Bluetooth; or the data may be displayed on mobile app of mobile phone. The transponder chip receives power from the reader via the NFC tag.

Fabrication and packaging of the sensor patch of various embodiments will now be described.

The sensing electrode may be screen printed using carbon ink onto the elastic film. This makes the sensor patch more scalable and cheaper to manufacture. Screen printing is a printing technique where a mesh is used to transfer ink (or dye) onto a substrate, except in areas made impermeable to the ink by a blocking stencil. A blade or squeegee is moved across the screen to fill the open mesh apertures with ink, and a reverse stroke then causes the screen to touch the substrate momentarily along a line of contact. This causes the ink to wet the substrate and be pulled out of the mesh apertures as the screen springs back after the blade has passed.

Here, one of many technologies that may be employed to form the sensor patch of various embodiments is presented, and it should be appreciated that the manufacturing process or techniques of the sensor patch may be changed, for example, depending on the fabrication cost and/or quantities of production.

The present disclosure also provides a sensing system for detecting extravasation in a patient using the sensor device as disclosed herein, wherein the change in electrical resistance of the at least one sensing electrode is transmitted to transponder chip and wirelessly to the reader, and based on a magnitude of the change in electrical resistance of the at least one sensing electrode, the reader determines whether an action is necessitated concerning the patient, and provides a notification to a predetermined user.

In some embodiments, the magnitude of change in electrical resistance is calibrated against a calibration plot.

In some embodiments, the notification is a visual alert and/or audio output means.

The present disclosure also provides a method for detecting extravasation in a patient in need thereof using the sensor device as disclosed herein, comprising:

a) positioning the sensor patch adjacent to an IV infusion site on the patient; and

b) wirelessly monitoring the change in electrical resistance of the at least one sensing electrode via the reader.

The present disclosure also provides a sensor device as disclosed herein for use in detecting extravasation.

It will be appreciated that many further modifications and permutations of various aspects of the described embodiments are possible. Accordingly, the described aspects are intended to embrace all such alterations, modifications, and variations that fall within the spirit and scope of the appended claims.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising”, will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

Throughout this specification and the claims which follow, unless the context requires otherwise, the phrase "consisting essentially of", and variations such as "consists essentially of" will be understood to indicate that the recited element(s) is/are essential i.e. necessary elements of the invention. The phrase allows for the presence of other non-recited elements which do not materially affect the characteristics of the invention but excludes additional unspecified elements which would affect the basic and novel characteristics of the method defined.

The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

Claims

1. A sensor device, comprising:

a) a sensor patch comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film;

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag;

iv) a hard backing at a point of connection between the transponder chip and the at least one sensing electrode; and

b) a reader configured to wirelessly read the output from the NFC tag and/or to wirelessly transmit a current to the transponder chip.

2. The sensor device according to claim 1,

wherein the hard backing is characterised by at least one of the following:

i) a flexural modulus of elasticity of more than 1 GPa; and

ii) a Shore hardness of more than 60D.

3. The sensor device according to claim 1 or 2, wherein the hard backing is made from a material selected from polyimide and/or polyethylene terephthalate (PET).

4. The sensor device according to any one of claims 1 to 3, wherein the at least one sensing electrode is configured to detect the force acting on the elastic film at at least three sections of the at least one sensing electrode.

5. The sensor device according to any one of claims 1 to 4, wherein the

transponder chip is positioned on the one side of the elastic film and adjacent to the at least one sensing electrode.

6. The sensor device according to any one of claims 1 to 5, wherein the transponder chip is characterised by a lateral dimension of less than about 10 mm.

7. The sensor device according to any one of claims 1 to 6, wherein the NFC tag comprises an antenna, wherein the antenna extends substantially along a side of the sensor patch or surrounds the at least one sensing electrode.

8. The sensor device according to any one of claims 1 to 7, wherein the transponder chip is configured to convert the detected change in electrical resistance in a step wise manner.

9. The sensor device according to any one of claims 1 to 8, wherein the elastic film further comprises an adhesive layer on another side of the elastic film.

10. The sensor device according to any one of claims 1 to 9, wherein the at least one sensing electrode is characterized by at least one of the following:

i) a thickness of about 0.05 μm to about 0.2 μm; and

ii) a length of about 50 cm to about 100 cm.

11. The sensor device according to any one of claims 1 to 10, wherein the at least one sensing electrode is patterned to cover at least about 60% of the surface of the elastic film.

12. The sensor device according to any one of claims 1 to 11, wherein the sensor patch further comprises at least one of the following:

i) a coin battery;

ii) at least one pair of bonding pads electrically coupled to the at least

one sensing electrode;

iii) a frame attached to the elastic film, wherein the transponder chip is sandwiched between the elastic film and the frame; and

iv) a second reader configured to receive the output from the reader.

13. A sensor patch, comprising:

i) an elastic film;

ii) at least one sensing electrode printed on a surface of the elastic film, the at least one sensing electrode configured to produce a change in electrical resistance in response to a force acting on the elastic film;

iii) a transponder chip comprising a near field communication (NFC) tag, the transponder chip electrically connected to the at least one sensing electrode, the transponder chip configured to detect the change in electrical resistance, convert the detected change in electrical resistance to an output that is readable from the NFC tag; and

iv) a hard backing at a point of connection between the transponder chip and the at least one sensing electrode.

14. A sensing system for detecting extravasation in a patient, the sensing system comprising a sensor device according to any one of claims 1 to 12, wherein the change in electrical resistance of the at least one sensing electrode is detectable by the transponder chip, convertable to an output that is readable from the NFC tag and wirelessly transmittable to the reader, and based on a magnitude of the change in electrical resistance of the at least one sensing electrode, the reader determines whether an action is necessitated concerning the patient, and provides a notification to a predetermined user.

15. Use of the sensor device according to any one of claims 1 to 12, comprising the steps of:

a) positioning the sensor patch adjacent to an IV infusion site on a patient; and

b) wirelessly monitoring the change in electrical resistance of the at least one sensing electrode via the reader.