Methods and devices for monitoring a skin adhesive layer

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(54) **Title:** METHODS AND DEVICES FOR MONITORING A SKIN ADHESIVE LAYER

(57) **Abstract:** Electronic device and method of monitoring an adhesive layer is disclosed, the method comprising obtaining sensor data comprising first sensor data from a first electrode pair associated with the adhesive layer; determining, based on the sensor data, a first parameter indicative of a first electrical property of the adhesive layer; determining, based on the sensor data, a second parameter indicative of a second electrical property of the adhesive layer; determining, based on the first parameter and the second parameter, an operating state of the adhesive layer; and outputting the operating state via an interface.

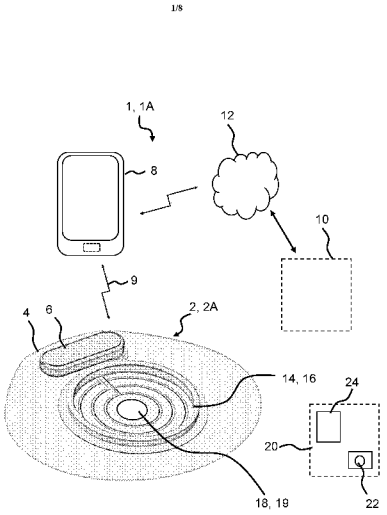

Fig. 1

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METHODS AND DEVICES FOR MONITORING A SKIN ADHESIVE LAYER

The present disclosure relates to monitoring of adhesive layer, and in particular to methods and electronic devices for monitoring an adhesive layer, such as a skin adhesive layer. In particular, the present disclosure relates to determining an operating state of an adhesive layer. The adhesive layer may be an adhesive layer of a medical device, such as an ostomy appliance or a wound dressing.

Brief Description of the Drawings

The accompanying drawings are included to provide a further understanding of embodiments and are incorporated into and a part of this specification. The drawings illustrate embodiments and together with the description serve to explain principles of embodiments. Other embodiments and many of the intended advantages of embodiments will be readily appreciated as they become better understood by reference to the following detailed description. The elements of the drawings are not necessarily to scale relative to each other. Like reference numerals designate corresponding similar parts.

Fig. 1 illustrates an exemplary monitor system being an ostomy system,
Fig. 2 illustrates an exemplary personal care system being a wound dressing system,
Fig. 3 illustrates an exemplary monitor device according to the present disclosure,
Fig. 4 is a flow diagram of an example method of monitoring an adhesive layer according to the present disclosure,
Fig. 5A shows graph of measurement of artificial sweat and NaCl solutions,
Fig. 5B shows graph of measurement of artificial sweat and NaCl solutions,
Fig. 5C shows graph of measurement of artificial sweat and NaCl solutions,
Fig. 5D shows graph of measurement of artificial sweat and NaCl solutions,
Fig. 6A shows graph of measurement of stomal output and NaCl solution,
Fig. 6B shows graph of measurement of stomal output and NaCl solution,
Fig. 6C shows graph of measurement of stomal output and NaCl solution,
Fig. 6D shows graph of measurement of stomal output and NaCl solution,
Fig. 7A shows graph of measurement of stomal output and NaCl solution,
Fig. 7B shows graph of measurement of stomal output and NaCl solution,
Fig. 7C shows graph of measurement of stomal output and NaCl solution,

Fig. 7D shows graph of measurement of stomal output and NaCl solution,
Fig. 8A shows graph of measurement of stomal output and NaCl solution,
Fig. 8B shows graph of measurement of stomal output and NaCl solution,
Fig. 8C shows graph of measurement of stomal output and NaCl solution, and
Fig. 8D shows graph of measurement of stomal output and NaCl solution.

Detailed Description

Various exemplary embodiments and details are described hereinafter, with reference to the figures when relevant. It should be noted that the figures may or may not be drawn to scale and that elements of similar structures or functions are represented by like reference numerals throughout the figures. It should also be noted that the figures are only intended to facilitate the description of the embodiments. They are not intended as an exhaustive description of the invention or as a limitation on the scope of the invention. In addition, an illustrated embodiment needs not have all the aspects or advantages shown. An aspect or an advantage described in conjunction with a particular embodiment is not necessarily limited to that embodiment and can be practiced in any other embodiments even if not so illustrated, or if not so explicitly described.

Throughout this disclosure, the words “stoma” and “ostomy” are used to denote a surgically created opening bypassing the intestines or urinary tract system of a person. The words are used interchangeably, and no differentiated meaning is intended. The same applies for any words or phrases derived from these, e.g., “stomal”, “ostomies” etc. Also, the solid and liquid wastes emanating from the stoma may be referred to as both stomal “output,” “waste(s),” and “fluids” interchangeably. A subject having undergone ostomy surgery may be referred to as “ostomist” or “ostomate” – moreover, also as “patient” or “user”. However, in some cases “user” may also relate or refer to a health care professional (HCP), such as a surgeon or an ostomy care nurse or others. In those cases, it will either be explicitly stated, or be implicit from the context that the “user” is not the “patient” him- or herself.

In the following, whenever referring to proximal side or surface of a layer, an element, a device or part of a device, the referral is to the skin-facing side or surface, when a user wears the appliance. Likewise, whenever referring to the distal side or surface of a layer, an element, a device or part of a device, the referral is to the side or surface facing away from the skin, when a user wears the appliance. In other words, the proximal side or surface is the side or surface closest to the user, when the appliance is fitted on a user

and the distal side is the opposite side or surface – the side or surface furthest away from the user in use.

The axial direction is defined as the direction of the stoma, when a user wears the appliance. Thus, the axial direction is generally perpendicular to the skin or abdominal surface of the user.

The radial direction is defined as perpendicular to the axial direction. In some sentences, the words "inner" and "outer" may be used. These qualifiers should generally be perceived with respect to the radial direction, such that a reference to an "outer" element means that the element is farther away from a centre portion of the ostomy appliance or wound dressing than an element referenced as "inner". In addition, "innermost" should be interpreted as the portion of a component forming a centre of the component and/or being adjacent to the centre of the component. In analogy, "outermost" should be interpreted as a portion of a component forming an outer edge or outer contour of a component and/or being adjacent to that outer edge or outer contour.

The use of the word "substantially" as a qualifier to certain features or effects in this disclosure is intended to simply mean that any deviations are within tolerances that would normally be expected by the skilled person in the relevant field.

The use of the word "generally" as a qualifier to certain features or effects in this disclosure is intended to simply mean – for a structural feature: that a majority or major portion of such feature exhibits the characteristic in question, and – for a functional feature or an effect: that a majority of outcomes involving the characteristic provides the effect, but that exceptional outcomes do not provide the effect.

The present disclosure relates to a personal care system and devices thereof, such as a personal care appliance, an electrode assembly, a sensor patch for attachment to the personal care appliance, electronic devices, such as a monitor device and/or one or more accessory devices. Further, methods related to the personal care system and devices thereof are disclosed. An accessory device (also referred to as an external device), may be a mobile phone, a smart device, such as a smartphone, or other handheld device, such as a tablet computer. An accessory device may be a personal electronic device, e.g., a wearable, such as a watch or other wrist-worn electronic device. The personal care system may comprise a server device. The server device may be operated and/or controlled by the personal care appliance manufacturer and/or a service centre. The

monitor device and/or a primary accessory device are optionally configured to establish a primary connection therebetween. The primary connection may be a Bluetooth connection or other wireless connection.

The present disclosure provides a personal care system and devices thereof, such as a personal care appliance, e.g. an ostomy appliance, a wound dressing, or a sensor patch, a monitor device, and optionally one or more accessory devices which either alone or together facilitate reliable classification, determination and monitoring of the nature, severity and/or rapidness of moisture propagation and/or moisture type in the personal appliance, such as in an adhesive layer provided for attaching, e.g., a personal care appliance, to the skin of a user. The adhesive layer may be an adhesive layer of a medical device, such as an ostomy appliance or a wound dressing. Typically, the adhesive layer and the internal state or operating state of the adhesive layer cannot readily be decided by a user during use, e.g., without peeling off the adhesive layer, which often requires a change in the appliance. Depending on the operating state of the adhesive layer, the personal care system and devices thereof enable providing information to the user about a liquid type wetting the adhesive layer, and in turn enable providing an indication to the user of the severity and thus the remaining time frame for replacing the personal care appliance without experiencing severe leakage and/or skin damage.

The adhesive layer may be a skin adhesive layer, i.e., an adhesive layer configured to adhere to the skin of a user. The adhesive layer may form a part of a personal care system, such as a base plate of an ostomy appliance, a part of a wound dressing comprising an absorbent core, or a part of a sensor patch for attachment to the base plate or the wound dressing, such as to the proximal side or surface of the base plate or the wound dressing.

In embodiments, the adhesive layer is made of a first composition. The first composition can comprise one or more polyisobutenes and/or styrene-isoprene-styrene. The first composition can comprise one or more hydrocolloids. The first composition can comprise one or more water soluble or water swellable hydrocolloids. The first composition can be a pressure sensitive adhesive composition suitable for medical purposes comprising a rubbery elastomeric base and one or more water soluble or water swellable hydrocolloids. The first composition can comprise one or more polybutenes, one or more styrene copolymers, one or more hydrocolloids, or any combination thereof. The combination of the adhesive properties of the polybutenes and the absorbing properties of the hydrocolloids renders the first composition suitable for use in personal care appliances,

including ostomy appliances. The styrene copolymer can for example be a styrene-butadiene-styrene block copolymer or a styrene-isoprene-styrene block copolymer. Preferably, one or more styrene-isoprene-styrene (SIS) block type copolymers are employed. The amount of styrene block-copolymer can be from 5 % to 20 % of the total adhesive composition. The butene component is suitably a conjugated butadiene polymer selected from polybutadiene, polyisoprene. The polybutenes are preferably present in an amount of from 35 – 50 % of the total adhesive composition. Preferably, the polybutene is polyisobutylene (PIB). Suitable hydrocolloids for incorporation in the first composition are selected from naturally occurring hydrocolloids, semisynthetic hydrocolloids and synthetic hydrocolloids. In embodiments, the first composition can comprise 20-60 % hydrocolloids. The first composition can optionally contain other components, such as fillers, tackifiers, plasticizers, and other additives.

The adhesive layer can have a substantially uniform thickness. The adhesive layer can have a thickness in the range from 0.1 mm to 1.5 mm, e.g., in the range from 0.2 mm to 1.2 mm, such as 0.8 mm or 1.0 mm. The adhesive layer can have a primary thickness in a primary part of the adhesive layer, e.g., in a primary region within a primary radial distance or in a primary radial distance range from a centre point of a stomal opening provided in the base plate, where the personal care appliance is an ostomy appliance comprising a base plate. The primary thickness can be in the range from 0.2 mm to 1.5 mm, such as about 1.0 mm. The primary radial distance can be in the range from 20 mm to 50 mm, such as in the range from 25 mm to 35 mm, e.g., 30 mm. The adhesive layer can have a secondary thickness in a secondary part of the adhesive layer, e.g., in a secondary region outside a secondary radial distance or in a secondary radial distance range from the centre point of the stomal opening, where the personal care appliance is an ostomy appliance comprising a base plate. The secondary thickness can be in the range from 0.2 mm to 1.0 mm, such as about 0.5 mm. The secondary radial distance can be in the range from 20 mm to 50 mm, such as in the range from 25 mm to 35 mm, e.g., 30 mm.

In embodiments, the personal care appliance comprises a second layer. In embodiments, the second layer is an adhesive layer, such as a second adhesive layer. In embodiments, the second layer is arranged on a distal side of the adhesive layer referred to above, which may also be denoted the first adhesive layer. In embodiments, the second layer comprises a proximal surface and a distal surface. In embodiments, the proximal surface is adhered or in contact with the distal surface of the first adhesive layer. In embodiments, the second layer has a second radial extension that is larger than a first radial extension of the first adhesive layer at least in a first angular range of the base plate, where the

personal care appliance is an ostomy appliance comprising a base plate. Accordingly, a part of a proximal surface of the second layer can be configured for attachment to the skin surface of a user. The part of a proximal surface of the second layer configured for attachment to the skin surface of a user is also denoted the skin attachment surface of the second adhesive layer. The second layer can have a stomal opening, such as a second layer stomal opening and/or a second adhesive stomal opening, with a centre point, where the personal care appliance is an ostomy appliance comprising a base plate.

In embodiments, the second adhesive layer is made of a second composition. In embodiments, the second composition comprises one or more polyisobutenes and/or styrene-isoprene-styrene. In embodiments, the second composition comprises one or more hydrocolloids. In embodiments, the second composition comprises one or more water soluble or water swellable hydrocolloids. In embodiments, the second composition is a pressure sensitive adhesive composition suitable for medical purposes comprising a rubbery elastomeric base and one or more water soluble or water swellable hydrocolloids. In embodiments, the second composition comprises one or more polybutenes, one or more styrene copolymers, one or more hydrocolloids, or any combination thereof. The combination of the adhesive properties of the polybutenes and the absorbing properties of the hydrocolloids renders the second composition suitable for use in personal care appliances, including ostomy appliances. For example, the styrene copolymer can be a styrene-butadiene-styrene block copolymer or a styrene-isoprene-styrene block copolymer. Preferably, one or more styrene-isoprene-styrene (SIS) block type copolymers are employed. The amount of styrene block-copolymer can be from 5% to 20% of the total adhesive composition. The butene component is suitably a conjugated butadiene polymer selected from polybutadiene, polyisoprene. The polybutenes are preferably present in an amount of from 35 - 50% of the total adhesive composition. Preferably, the polybutene is polyisobutylene (PIB). Suitable hydrocolloids for incorporation in the second composition are selected from naturally occurring hydrocolloids, semisynthetic hydrocolloids, and synthetic hydrocolloids. The second composition can comprise 20-60% hydrocolloids. Optionally, the second composition can contain other components, such as fillers, tackifiers, plasticizers, and/or other additives.

Different ratio of contents can change properties of the first and/or second adhesive layers. In embodiments, the second adhesive layer and the first adhesive layer have different properties. In embodiments, the second adhesive layer (second composition) and the first adhesive layer (first composition) have different ratios of polyisobutenes, styrene-isoprene-styrene, and/or hydrocolloids. For example, the second adhesive layer can

provide a stronger attachment to the skin compared to attachment to the skin provided by the first adhesive layer. Alternatively, or additionally, the second adhesive layer can be thinner than the first adhesive layer. Alternatively, or additionally, the second adhesive layer can be less water and/or sweat absorbing than the first adhesive layer. Alternatively, or additionally, the second adhesive layer can be less moldable than the first adhesive layer. In embodiments, the second adhesive layer provides a second barrier against leakage.

The second layer can have a substantially uniform thickness. The second layer can have a thickness in the range from 0.1 mm to 1.5 mm, e.g., in the range from 0.2 mm to 1.0 mm, such as 0.5 mm, 0.6 mm, or 0.7 mm.

In one or more examples, the hydrocolloid is hydroxyethyl cellulose (HEC). In other words, the adhesive layer may comprise hydroxyethyl cellulose (HEC). In an embodiment, the HEC is the only type of hydrocolloid of the adhesive layer.

In one or more examples, the hydrocolloid is carboxymethyl cellulose (CMC). In other words, the adhesive layer may comprise carboxymethyl cellulose (CMC). In an embodiment, the CMC is the only type of hydrocolloid of the adhesive layer.

Methods of monitoring an adhesive layer, e.g., of a personal care appliance, are disclosed. The methods may be a method of monitoring an adhesive layer in an ostomy appliance, a wound dressing, or a sensor patch. The method may be a method of monitoring an adhesive layer in a body worn appliance. The method comprises obtaining sensor data; determining, based on the sensor data, one or more parameters indicative of respective electrical properties of the adhesive layer; determining, based on the one or more parameters, an operating state of the adhesive layer; and outputting the operating state via an interface. The methods as disclosed herein may be performed in a monitor device, such as a monitor device mechanically and electrically coupled to the personal care appliance, such as coupled to sensors of the personal care appliance. The methods as disclosed herein may be performed in an accessory device of the personal care system, wherein the obtaining of sensor data may comprise obtaining the sensor data from a monitor device coupled to the personal care appliance, such as coupled to sensors of the personal care appliance. The methods as disclosed herein may be performed by a server device. The methods as disclosed herein and different parts thereof may be shared between respective processing power of a monitor device, an accessory device and/or a

server device. In other words, the methods as disclosed herein may be distributed between and performed by a monitor device, an accessory device and/or a server device.

When exposed to liquid, the adhesive layer (and in particular the hydrocolloids thereof) is hydrated (e.g., the hydrocolloids absorb liquid/moisture) and the electrical properties of the adhesive layer change. The changes in the electrical properties depend on the nature and/or the volume of the liquid hydrating the adhesive layer. In other words, the changes in the electrical properties are associated with the nature (contents, type) of the liquid causing the changes. In further other words, methods as described herein allow for determining what liquid is causing the hydration of the adhesive layer. The liquid may be a bioliquid originating from a human or animal. Thus, methods as described herein allow for distinguishing liquids in the adhesive layer by means of the measuring principles forming part of the method as disclosed. Thereby, the personal care appliance comprising an adhesive layer may be provided in an optimal shape or integrality adapted for the intended use while preserving the ability to inform the user of the operating state of the appliance, and in particular to inform the user of what liquids are present in or near (e.g., in an interface between the skin surface and an adhesive surface of the adhesive layer) the adhesive layer of the appliance. For example, in the case of the personal care appliance being a base plate or sensor patch of an ostomy appliance, said base plate or sensor patch may be optimized in terms of shape and functionality, while preserving the ability to distinguish sweat and stomal output, which are commonly expected liquids associated with an ostomy appliance, but causing different levels of concern for the user. Methods as disclosed herein allow for communicating to the user, via an appropriately determined operating state, whether it is sweat or output being absorbed in the adhesive layer. Thereby, the user may take appropriate action.

The sensor data may comprise first sensor data from a first electrode pair associated with, such as integrated in and/or in contact with, the adhesive layer. In other words, the method may comprise obtaining first sensor data from a first electrode pair associated with the adhesive layer. The first sensor data may be indicative of impedance between electrodes of the first electrode pair. The sensor data, such as the first sensor data, may be obtained by applying a voltage at one or more frequencies and measure the resulting current. In other words, obtaining sensor data may comprise applying a voltage to one or more electrode pairs including a first electrode pair and measure a resulting current through the respective electrode pair(s). The sensor data, such as the first sensor data, may be obtained by applying a current at one or more frequencies and measure the resulting voltage. In other words, obtaining sensor data may comprise applying a current

to one or more electrode pairs including a first electrode pair and measuring a resulting current through the respective electrode pair(s). The first sensor data may be indicative of impedance at one or a plurality of frequencies, e.g., at a primary frequency and/or a secondary frequency. The first electrode pair may comprise a first electrode and a second electrode associated with the adhesive layer such that current may propagate through the adhesive from the first electrode to the second electrode (or vice versa).

The impedance Z of the adhesive layer comprises a real part Z' that has been shown to depend on both hydration level and ion concentration of/in the adhesive layer. Further, the impedance Z of the adhesive layer comprises an imaginary part Z'' that has been shown to depend mainly on the hydration level of the adhesive layer:

$$Z = Z' + iZ'' = R_{el} + \frac{1}{Q_0(i\omega)^n}$$

where R_{el} is the resistance of the adhesive layer (indicative of mobile electrolytes/ions absorbed therein), and Q_0 is a constant phase constant and is a measure of the hydration level of the adhesive layer and may be representative of the double layer capacitance formed in the system. R_{el} relates to conductance G in that G = 1/ R_{el}, which may be normalized by electrode area A and distance d to determine conductivity σ by σ = G*d/A=d/(A*R_{el}). The impedance Z is dominated by Q_0 at low frequencies and by R_{el} (i.e., the conductivity σ) at high frequencies.

The present invention allows for a decoupling of hydration level and ion concentration effects in the adhesive layer which is then used for classifying/determining an operating state of the adhesive layer, where the operating state may be indicative of the hydration level and/or ion concentration, or the operating state may be indicative of the hydration level and/or the type of liquid in the adhesive layer, the type/nature of liquid being determined/derived from the ion concentration of the liquid, which in turn is determined/derived from the ion concentration in the adhesive layer. In particular, the method may be suitable for systems wherein two known liquids are expected, such that their relative ion concentration may be used in determining their nature/origin (e.g., a determined ion concentration may be input in a function, look-up table, a neural network, or a model, such as a machine-learning model, in order to determine its nature/origin). For example, stomal output will typically exhibit a higher ion concentration relative to sweat, and the methods as disclosed herein provide for determining such ion concentration and

communicating to the user the type of liquid via an appropriate operating state indicative of the nature of the liquid.

In one or more example methods, determining, based on the sensor data, such as the first sensor data, one or more parameters indicative of respective electrical properties of the adhesive layer may comprise determining, based on the sensor data, such as the first sensor data and/or second sensor data, a first parameter indicative of a first electrical property of the adhesive layer. In one or more examples, the first parameter is electrical conductivity or conductance. The electrical conductivity, also denoted σ, may be representative of the real part of the impedance. In other words, the first parameter may be a conductance or conductivity parameter. The first parameter may be indicative of a conductance.

The first parameter may be resistivity. In other words, the first parameter may be a resistance or resistivity parameter. The first parameter may be indicative of a resistance.

In one or more example methods, determining, based on the sensor data, such as the first sensor data, one or more parameters indicative of respective electrical properties of the adhesive layer may comprise determining, based on the sensor data, such as the first sensor data and/or second sensor data, a second parameter indicative of a second electrical property of the adhesive layer. The second electrical property may be different from the first electrical property. The second parameter may be different from the first parameter. In one or more examples, the second parameter is capacitance or capacity. The capacitance, also denoted C, may be representative of the imaginary part of the impedance. In other words, the second parameter may be a capacitance or capacity parameter. The second parameter may be indicative of a capacitance.

The second parameter may be a constant phase parameter or double layer capacitance, also denoted Q_0, which may be derived from the imaginary part of the impedance. In other words, the second parameter may be indicative of a constant phase impedance of a constant phase element.

In one or more examples, the second parameter may be indicative of a capacity and/or a change in capacitance of the adhesive layer. Thus, in one or more examples, the second parameter being capacitance is measured or determined at high frequencies, such as larger than 200 kHz or even larger than 1 MHz and the above equation would extend to:

$$Z = \frac{1}{R} + i\omega C + \frac{1}{Q_0 (i\omega)^n}$$

In one or more examples, the second parameter may be indicative of an effective capacitance of the adhesive layer.

In one or more example methods, determining, based on the one or more parameters, an operating state of the adhesive layer may comprise determining, based on the first parameter and the second parameter, an operating state of the adhesive layer, e.g., by mapping the first parameter and the second parameter to the operating state. Determining an operating state may comprise inputting the first parameter and/or the second parameter to a function, look-up table, a neural network, or a model, such as a machine-learning model. In other words, determining the operating state may be based on a function, look-up table, a neural network, or a model, such as a machine-learning model. In one or more examples, the operating state of the adhesive layer may be based on a relationship, such as a ratio and/or a difference between the first parameter and the second parameter.

The operating state of the adhesive layer may be indicative of one or more of an ion concentration and/or hydration level in the adhesive layer. The operating state of the adhesive layer may be selected from a plurality of, such as 2 or in the range from 3 to 20, operating states. For example, a first set of operating states may be associated with the determination of the liquid being stomal output, and the respective operating states of the first set may be indicative of an amount of stomal output (hydration level) absorbed in the adhesive layer. For example, three operating states may be indicative of various amounts of stomal output absorbed in the adhesive layer, such as indicative of “low”, “medium”, and “high” amounts. Likewise, a second set of operating states may be associated with the determination of the liquid being sweat, and the respective operating states of the second set may be indicative of an amount of sweat (hydration level) absorbed in the adhesive layer. For example, three operating states may be indicative of various amounts of sweat absorbed in the adhesive layer, such as indicative of “low”, “medium”, and “high” amounts.

The method comprises outputting the operating state via an interface. Outputting the operating state may comprise transmitting an operating state identifier indicative of the operating state and/or displaying (e.g., the interface may be a graphical user interface of the accessory device) an operating state representation indicative of the operating state.

In one or more examples, determining an operating state of the adhesive layer comprises determining an ion concentration in the adhesive layer based on the first parameter and/or the second parameter and determining the operating state based on the ion concentration, e.g., by mapping the ion concentration to the operating state. In other words, determining an operating state of the adhesive layer may comprise determining an ion concentration in the adhesive layer based on the first parameter and/or the second parameter and mapping the ion concentration to the operating state.

Determining an ion concentration may comprise one or more of inputting the first parameter and/or the second parameter to a function, look-up table, a neural network, or a model, such as a machine-learning model. In other words, determining the ion concentration may be based on a function, look-up table, a neural network, or a model, such as a machine-learning model.

In one or more examples, determining an operating state of the adhesive layer comprises determining a hydration level and/or an ion mobility in the adhesive layer based on the first parameter and/or the second parameter and determining the operating state based on the hydration level, e.g., by mapping the hydration level and/or ion mobility to the operating state. In other words, determining an operating state of the adhesive layer comprises determining a hydration level and/or an ion mobility in the adhesive layer based on the first parameter and/or the second parameter and mapping the hydration level to the operating state.

In one or more example methods, determining an operating state of the adhesive layer comprises determining the operating state based on the ion concentration and/or the hydration level of the adhesive layer.

Determining a hydration level may comprise one or more of inputting the first parameter and/or the second parameter to a function, look-up table, a neural network, or a model, such as a machine-learning model. In other words, determining the hydration level may be based on a function, look-up table, a neural network, or a model, such as a machine-learning model.

In one or more examples, determining an operating state of the adhesive layer comprises determining whether the adhesive layer is in a first operating state indicative of the adhesive layer being wetted with a first liquid. The first liquid may be sweat. The first liquid

may be a bioliquid. The bioliquid may be one of sweat, stomal output, wound exudate, blood, urine, and faeces. The first liquid may be water.

In one or more examples, determining an operating state of the adhesive layer comprises determining whether the adhesive layer is in a second operating state indicative of the adhesive layer being wetted with a second liquid. The second liquid may be stomal output. The second liquid may be blood. Preferably, the second liquid is different from the first liquid, such as different in contents, type, nature, and/or concentration of contents, such as ions. The second liquid may be a bioliquid different from the first liquid and may be one of sweat, stomal output, wound exudate, blood, urine, and faeces. The second liquid may be water.

In one or more examples, determining a first parameter comprises determining the first parameter at one or more (electrical) frequencies, e.g., including a first primary frequency and/or a first secondary frequency. Thus, determining a first parameter optionally comprises determining the first parameter at a first primary frequency and/or at a first secondary frequency.

The first primary frequency may be in a primary frequency range, such as from 10 Hz to 500 Hz or from 500 Hz to 100 kHz. In one or more examples, first primary frequency is less than 200 kHz, such as 100 Hz or 64 kHz. A first primary frequency from 500 Hz to 100 kHz may allow power efficient sensing. The primary frequency, such as the first primary frequency and/or the second primary frequency may be less than 200 kHz, such as about 47 kHz, 62.5 kHz, 93.75 kHz, 100 kHz, 125 kHz, or 187.5 kHz. The primary frequency, such as the first primary frequency and/or the second primary frequency may be less than 10 Hz.

Determining an operating state of the adhesive layer is optionally based on the first parameter at the first primary frequency. The first parameter at the first primary frequency is also denoted the first primary parameter.

In one or more examples, the first secondary frequency is in a secondary frequency range, such as from 10 kHz to 200 kHz or from 200 kHz to 15 MHz. Determining an operating state of the adhesive layer may be based on the first parameter at the first secondary frequency. The first parameter at the first secondary frequency is also denoted the first secondary parameter. In one or more examples, the first secondary frequency is 100 kHz or 64 kHz. A first secondary frequency from 500 Hz to 100 kHz may allow power

efficient sensing. The secondary frequency, such as the first secondary frequency and/or the second secondary frequency may be larger than 200 kHz, such as larger than 500 kHz or even larger than 1 MHz. In one or more examples, the secondary frequency, such as the first secondary frequency and/or the second secondary frequency, is 250 kHz, 375 kHz, 750 kHz, 1 MHz, 1.5 MHz, 2 MHz, 3 MHz, 4 MHz, 6 MHz, 8 MHz, or 12 MHz.

In one or more examples, determining the second parameter comprises determining the second parameter at one or more (electrical) frequencies, e.g., including a second primary frequency and/or a second secondary frequency. Thus, determining a second parameter optionally comprises determining the second parameter at a second primary frequency and/or at a second secondary frequency.

The second primary frequency may be in a primary frequency range from 10 Hz to 500 Hz or from 500 Hz to 100 kHz. In one or more examples, the second primary frequency is less than 200 kHz, such as 100 Hz or 64 kHz. A second primary frequency from 500 Hz to 100 kHz may allow power efficient sensing. Determining an operating state of the adhesive layer is optionally based on the second parameter at the second primary frequency. The second parameter at the second primary frequency is also denoted the second primary parameter. The second primary frequency may be the same as the first primary frequency and then commonly denoted the primary frequency.

In one or more examples, the second secondary frequency is in a secondary frequency range, such as from 10 kHz to 200 kHz. Determining an operating state of the adhesive layer may be based on the second parameter at the second secondary frequency. The second parameter at the second secondary frequency is also denoted the second secondary parameter. The second secondary frequency may be the same as the first secondary frequency and then commonly denoted the secondary frequency.

In one or more examples, the second secondary frequency may be larger than 200 kHz, such as larger than 500 kHz or even larger than 1 MHz. In one or more examples, the second secondary frequency is 250 kHz, 375 kHz, 750 kHz, 1 MHz, 1.5 MHz, 2 MHz, 3 MHz, 4 MHz, 6 MHz, 8 MHz, or 12 MHz. In other words, the second parameter may be determined at a frequency larger than 500 kHz or even larger than 1 MHz.

In one or more examples, the secondary frequency range may be different from, such as non-overlapping, the primary frequency range. The secondary frequency range may overlap the primary frequency range, either in parts (e.g., one end-point of the secondary

frequency range may be within the primary frequency range and one end-point of the secondary frequency range may be outside the primary frequency range) or in totality (i.e., from end-point to end-point).

It is to be understood that the first parameter and the second parameter may be determined at respective primary frequency and/or secondary frequency.

In one or more examples, obtaining sensor data comprises obtaining second sensor data from a second electrode pair associated with the adhesive layer. The second electrode pair may comprise the second electrode (i.e., shared with the first electrode pair) and a third electrode. The second electrode pair may comprise a third electrode and a fourth electrode. The second electrode pair may be arranged similar to the first electrode pair, such that current may flow through the adhesive from one of the electrodes of the second electrode pair to the other of the electrodes of the second electrode pair. One or both of determining a first parameter and determining a second parameter may be based on the second sensor data.

An electronic device, such as a monitor device and/or an accessory device, is disclosed, the electronic device comprising an interface and one or more processors, wherein the one or more processors are configured to perform a method as disclosed herein.

In one or more examples, the interface comprises a first interface configured to couple to at least the first electrode pair of the adhesive layer. The interface may comprise a second interface configured to output the operating state. The second interface is optionally configured to output the operating state by means of a wireless signal. The second interface may be a transceiver, or the second interface may be a graphical user interface. To output the operating state may comprise to display a representation of the operating state in the graphical user interface.

An electronic device, such as a monitor device and/or an accessory device, is disclosed, the electronic device comprising a first interface and a second interface and one or more processors, wherein the one or more processors are configured to obtain, via the first interface, sensor data comprising first sensor data from a first electrode pair associated with an adhesive layer of a personal care appliance; determine, based on the sensor data, a first parameter indicative of a first electrical property of the adhesive layer; determine, based on the sensor data, a second parameter indicative of a second electrical property of the adhesive layer; determine, based on the first parameter and the second parameter, an

operating state of the adhesive layer; and outputting the operating state via the second interface.

The first interface and the second interface may be identical or connected. The first interface may be an interface adapted to obtain or collect sensor data, e.g., via an electrical or wireless connection. The second interface may be an interface adapted to communicate the operating state, e.g., wirelessly or the second interface may comprise a graphical user interface configured to communicate the operating state by means of displaying a representation of the operating state.

The personal care system may be an ostomy system. Thus, the personal care appliance may be an ostomy appliance. The ostomy appliance may comprise at least a base plate. The ostomy appliance may comprise at least a sensor patch configured to be attached to the adhesive surface of a base plate of the ostomy appliance.

The personal care system may be a wound dressing system. Thus, the personal care appliance may be a wound dressing appliance also denoted wound dressing. A wound dressing system and devices thereof are provided, such as a wound dressing, a monitor device, and optionally one or more accessory devices which either alone or together facilitate reliable monitoring of the wound dressing and operating state thereof. Accordingly, the wound dressing system and devices thereof enable providing information to the user about the operating state of the wound dressing, and in turn optionally enable providing an indication to the user or a caretaker of the remaining time frame for replacing the wound dressing without experiencing leakage and/or to provide optimum wound healing conditions.

The personal care system may be a medical device system comprising a medical appliance comprising an adhesive layer for attachment of the medical appliance to the skin surface of a user/patient, the adhesive layer being the adhesive layer as discussed above. In particular, the medical appliance may be a medical appliance applied in relation to a stoma, wound, or similar, from which a (bio-)liquid may be expelled.

The personal care system comprises one or more of a personal care appliance, a monitor device, and an accessory device as described herein.

Depending on the nature, type or the pattern of moisture propagation in the personal care appliance, the personal care system and devices thereof enable providing information to

the user about the operating state, such as status and/or a type of liquid contacting/wetting the adhesive layer, and in turn enable providing an indication to the user of the severity and thus the remaining time frame for replacing the personal care appliance without experiencing severe leakage and/or skin damage and/or to improve wound healing.

The ostomy appliance comprises a base plate and an ostomy pouch (also referred to as an ostomy bag). The ostomy appliance may be a colostomy appliance, an ileostomy appliance or a urostomy appliance. The ostomy appliance may be a two-part ostomy appliance, i.e., the base plate and the ostomy pouch may be releasably coupled e.g., with a mechanical and/or an adhesive coupling, e.g., to allow that a plurality of ostomy pouches can be utilized (exchanged) with one base plate. Further, a two-part ostomy appliance may facilitate correct application of the base plate to skin, e.g., to an improved user sight of the stomal region. The ostomy appliance may be a one-part ostomy appliance, i.e., the base plate and the ostomy pouch may be fixedly attached to each other. The base plate is configured for coupling to a user's stoma and/or skin surrounding the stoma, such as a peristomal skin area.

The ostomy appliance may comprise an electrode assembly or the ostomy system optionally comprises an electrode assembly mountable on a proximal side of the base plate of the ostomy appliance (e.g., the electrode assembly may be provided in a sensor patch for attachment to the proximal side, such as the proximal adhesive surface, of the base plate of the ostomy appliance). The electrode assembly comprises a first electrode pair (first sensor) optionally arranged on a distal side of an adhesive layer of a base plate of an ostomy appliance or on a distal side of an adhesive layer of a sensor patch, the first electrode pair forming a first sensor. The electrode assembly may comprise a plurality of electrode pairs including a second electrode pair (second sensor). The first electrode pair and the second electrode pair may share a common electrode. The ostomy appliance/electrode assembly may comprise a monitor interface for connecting electrodes of the electrode assembly to terminals of the first interface of the monitor device.

The wound dressing appliance comprises a top layer, an adhesive layer with a proximal surface configured for attachment of the wound dressing to the skin surface of a user; an absorbent core layer; and an electrode assembly comprising one or a plurality of electrode pairs forming respective one or more sensors. The top layer is optionally on a distal side of the electrode assembly. The wound dressing may comprise a monitor interface for

connecting electrodes of the electrode assembly to terminals of the first interface of the monitor device.

A monitor device for a personal care system is disclosed, the monitor device comprising an interface and one or more processors, and optionally a memory. The interface of the monitor device comprises a first interface connected to one or more of the processor(s), the first interface configured for connecting the monitor device to the personal care appliance, such as to an electrode assembly thereof; and a second interface comprising a transceiver module connected to one or more of the processor(s) and configured for connecting the monitor device to one or more accessory devices.

Also disclosed is a computer readable storage medium storing one or more programs, the one or more programs comprising instructions, which when executed by an electronic device with an interface and one or more processors cause the electronic device to be configured to operate in accordance with methods as described herein.

It is to be noted that descriptions of the electronic device, such as monitor device and/or accessory device, being configured to perform acts also apply to the corresponding acts in the methods and vice versa.

The present disclosure provides a reliable and secure monitoring of the personal care appliance and operating state thereof. Thus, the present disclosure helps reducing the risk of a user experiencing a leakage, such as a stomal output leakage between a user's skin and the base plate of an ostomy appliance, from an ostomy appliance or helps reducing the risk of a user experiencing a wet wound due to saturated liquid in an absorbent core layer of a wound dressing appliance. Further, the present disclosure may help in reducing leakage false positives due to the ability of distinguishing between different types of liquid. In particular, determination and/or communication of the operating state of the adhesive layer is performed based on sensor data indicative of a condition of the personal care appliance which may not be visible to and/or detectable by the user, e.g., during use of the personal care appliance. Further, the present disclosure allows differentiating between different types of liquid, such as output and sweat, and the degree of the hydration allowing to further differentiate between different operating states.

It is an advantage of the present disclosure that a user of a personal care appliance or a health care professional is able to monitor and plan the use of the personal care appliance

with daily life. Further, the present disclosure allows for distinguishing between different types of liquid wetting an adhesive layer.

It is further an advantage that the personal care appliance comprising an adhesive layer may be provided in an optimal shape or integrality adapted for the intended use while preserving the ability to inform the user of the operating state of the appliance, and in particular to inform the user of what liquids are present in or near (e.g., in an interface between the skin surface and an adhesive surface of the adhesive layer) the adhesive layer of the appliance. For example, in the case of the personal care appliance being a base plate or sensor patch of an ostomy appliance, said base plate or sensor patch may be optimized in terms of shape and functionality, while preserving the ability to distinguish sweat and stomal output, which are commonly expected liquids associated with an ostomy appliance, but causing different levels of concern for the user.

Detailed description of the drawings

Fig. 1 illustrates an exemplary personal care system 1 embodied as an ostomy system 1A. The personal care system 1 (ostomy system 1A) comprises a personal care appliance 2 embodied as an ostomy appliance 2A including a base plate 4 and an ostomy pouch (not shown). Further, the personal care system 1 comprises a monitor device 6, a primary accessory device 8 (mobile telephone, tablet, or smartphone). The monitor device 6 is connectable to the personal care appliance 2, such as to base plate 4 and/or to an electrode assembly of or mounted to the personal care appliance 2, via respective first connectors of the monitor device 6 and base plate 4/electrode assembly. The monitor device 6 is configured for wireless communication via connection 9 with the accessory device 8. Optionally, the accessory device 8 is configured to communicate with a server device 10 of the personal care system 1, e.g., via network 12. The server device 10 may be operated and/or controlled by the ostomy appliance manufacturer and/or a service centre. Sensor data are obtained from electrode pairs/sensors of electrode assembly embedded in or in contact with adhesive layer of the personal care appliance 2 with the monitor device 6. The monitor device 6 processes and/or transmits to the accessory device the sensor data appliance data. In the illustrated personal care system, the accessory device 8 is a mobile phone, however the accessory device 8 may be embodied as another handheld device, such as a tablet device, or a wearable, such as a watch or other wrist-worn electronic device. The base plate 4 comprises a coupling member 14 in the form of a coupling ring 16 for coupling an ostomy pouch (not shown) to the base plate (two-part ostomy appliance). The base plate 4 has a stomal opening 18 with a centre point

19. The size and/or shape of the stomal opening 18 is typically adjusted by the user or nurse before application of the ostomy appliance to accommodate the user's stoma.

The personal care system 1 optionally comprises a docking station 20 forming an accessory device of the personal care system 1. The docking station 20 comprises a docking monitor interface including a first connector 22 configured for electrically and/or mechanically connecting the monitor device 6 to the docking station 20. The docking monitor interface may be configured for wirelessly connecting the monitor device 6 to the docking station 20. The docking station 20 comprises a user interface 24 for receiving user input and/or providing feedback to the user on the operational state of the docking station 20. The user interface 24 may comprise a touchscreen. The user interface 24 may comprise one or more physical buttons and/or one or more visual indicators, such as light emitting diodes.

Fig. 2 illustrates an exemplary personal care system 1 embodied as a wound dressing system 1B. The personal care system 1 (wound dressing system 1B) comprises a personal care appliance 2 embodied as a wound dressing appliance 2B. The wound dressing appliance comprises an adhesive layer, such as an adhesive layer, having one or more sensor pairs embedded therein or in contact therewith.

Fig. 3 is a schematic block diagram of an exemplary electronic device, such as a monitor device. The monitor device 6 comprises a monitor device housing 100, a processor 101, and an interface, the interface including a first interface 102 (appliance interface) and a second interface 104 (accessory interface). The monitor device 6 comprises a memory 106/106A. The memory 106/106A is optionally connected to the processor 101. The memory 106 is embedded optionally as flash memory in the second interface 104.

The first interface 102 is configured as an appliance interface for electrically and/or mechanically connecting the monitor device 6 to the personal care appliance, e.g., ostomy appliance 2A or wound dressing appliance 2B. The first interface 102 comprises a plurality of terminals for forming electrical connections with respective terminals/electrode pairs of the personal care appliance 2 (electrode assembly). The first interface 102 optionally comprises between four and 20 terminals, such as between six and twelve terminals, including a ground terminal 108, a first terminal 110, a second terminal 112 and a third terminal 114. The first interface 102 optionally comprises a fourth terminal 116 and a fifth terminal 118. In one or more exemplary monitor devices, the first interface 102 optionally comprises a sixth terminal and/or a seventh terminal. The first interface 102 of the monitor

device 6 comprises a coupling part 120 for forming a mechanical connection, such as a releasable coupling between the monitor device and the personal care appliance, e.g., with a base plate of an ostomy appliance, a sensor patch and/or an electrode assembly of ostomy system/wound dressing system. The coupling part 120 and the terminals 108, 110, 112, 114, 116, and 118 of the first interface 102 form (at least part of) a first connector of the monitor device 6.

The second interface 104 of monitor device is configured as an accessory interface for connecting the monitor device 6 to accessory device 8. The second interface 104 comprises an antenna 122 and a wireless transceiver 124 also denoted transceiver module, the wireless transceiver 124 connected to the processor 101 and configured for wireless communication with accessory device(s), such as configured for connecting the monitor device to the accessory device 8 of the personal care system. Optionally, the second interface 104 comprises a loudspeaker 126 and/or a haptic feedback element 128 for provision of respective audio signal and/or haptic feedback to the user. The memory 106 may be an internal memory, such as flash memory of the wireless transceiver 124. Thereby, a separate memory module can be omitted which provides a simpler and lighter/smaller monitor device.

The processor 101 is optionally configured to obtain, via the first interface 102, sensor data comprising first sensor data from a first electrode pair associated with an adhesive layer of a personal care appliance; determine, based on the sensor data, a first parameter indicative of a first electrical property of the adhesive layer; determine, based on the sensor data, a second parameter indicative of a second electrical property of the adhesive layer; determine, based on the first parameter and the second parameter, an operating state of the adhesive layer; and outputting the operating state via the interface, such as the second interface 104. Outputting the operating state via the interface may comprise to transmit a signal indicative of the operating state to an accessory device. Outputting the operating state via the interface may comprise to display a representation of the operating state in a graphical user interface of the second interface.

The processor 101 may be optionally configured to perform any of the operations disclosed in Fig. 4 (such as any one or more of S202, S204, S206, S208). The operations of the monitor device 6 may be embodied in the form of executable logic routines (such as, lines of code, software programs, etc.) that are stored on a non-transitory computer readable medium, such as internal memory in the processor 101 or external memory, and are executed by the processor 101.

Furthermore, the operations of the monitor device 6 may be considered a method that the monitor device 6 is configured to carry out. Also, while the described functions and operations may be implemented in software, such functionality may as well be carried out via dedicated hardware or firmware, or some combination of hardware, firmware and/or software.

The memory 106 and/or 106A may be one or more of a buffer, a flash memory, a hard drive, a removable media, a volatile memory, a non-volatile memory, a random access memory (RAM), or other suitable device. In a typical arrangement, the memory 106 may include a non-volatile memory for long term data storage and a volatile memory that functions as system memory for the processor 106. The memory 106, 106A may exchange data with the processor 101 over a data bus. Control lines and an address bus between the memory 106 and the processor 101 also may be present (not shown in Figs. 1 and 2). The memory 106, 106A is considered a non-transitory computer readable medium.

Fig. 4 shows a flow diagram of an example method 200 of monitoring an adhesive layer, e.g., with an electronic device, such as a monitor device 6 and/or an accessory device 8, as disclosed herein. The method 200 comprises obtaining S202 sensor data comprising first sensor data from a first electrode pair associated with the adhesive layer; determining S204, based on the sensor data, one or more parameters including determining S204A a first parameter indicative of a first electrical property, such as electrical conductivity, of the adhesive layer and determining S204B, based on the sensor data, a second parameter indicative of a second electrical property, such as capacitance, of the adhesive layer; determining S206, based on the first parameter and the second parameter, an operating state of the adhesive layer; and outputting S208 the operating state via an interface.

In the method 200, determining S206 an operating state of the adhesive layer comprises determining S206A an ion concentration in the adhesive layer based on the first parameter and/or the second parameter and mapping S206B the ion concentration to the operating state.

In the method 200, determining S206 an operating state of the adhesive layer comprises determining S206C a hydration level in the adhesive layer based on the first parameter and/or the second parameter and mapping S206D the hydration level to the operating state.

In the method 200, determining S206 an operating state of the adhesive layer comprises determining S206E whether the adhesive layer is in a first operating state indicative of the adhesive layer being wetted with a first liquid being sweat.

In the method 200, determining S206 an operating state of the adhesive layer comprises determining S206F whether the adhesive layer is in a second operating state indicative of the adhesive layer being wetted with a second liquid being stomal output.

In the method 200, determining S204A a first parameter comprises determining S204C the first parameter at one or more frequencies including a first primary frequency, wherein the first primary frequency is in a primary frequency range from 10 Hz to 500 Hz or less than 200 kHz, and wherein determining S206 an operating state of the adhesive layer is based on the first parameter at the first primary frequency.

In the method 200, determining S204A a first parameter optionally comprises determining S204D the first parameter at a first secondary frequency, wherein the first secondary frequency is in a secondary frequency range, e.g., from 10 kHz to 200 kHz, and wherein determining S206 an operating state of the adhesive layer is based on the first parameter at the first secondary frequency.

In the method 200, determining S204B a second parameter comprises determining S204E the second parameter at one or more electrical frequencies e.g., including a second primary frequency, wherein the second primary frequency is in a primary frequency range from 10 Hz to 500 Hz, and wherein determining an operating state of the adhesive layer is based on the second parameter, e.g., at the second primary frequency.

In the method 200, determining S204B a second parameter optionally comprises determining S204F the second parameter at a second secondary frequency, wherein the second secondary frequency, e.g., is in a secondary frequency range from 10 kHz to 200 kHz or larger than 200 kHz, and wherein determining an operating state of the adhesive layer is based on the second parameter at the second secondary frequency.

In the method 200, obtaining S202 sensor data comprises obtaining S202A first sensor data from the first electrode pair associated with the adhesive layer and obtaining S202B second sensor data from a second electrode pair associated with the adhesive layer; and wherein one or both of determining a first parameter and determining a second parameter is based on the second sensor data.

Fig. 5 shows graphs of measurements with an adhesive layer comprising CMC hydrocolloids only and exposed to various aqueous solutions: 1000mM NaCl (ref 502), 150 mM NaCl (ref 504), 50 mM NaCl (ref 506) and artificial sweat (ref 508), at skin temperature (32 °C). The measurements are made using a first electrode pair associated with, such as embedded in or contacting, the adhesive layer, and measured during constant exposure to the solutions with different NaCl content as well as artificial sweat.

In Fig. 5A, the complex impedance $|Z|$ is measured as a function of time. The conductivity σ and the constant phase parameter Q_0 may be derived from this measurement, see Fig. 5C and Fig. 5B, respectively.

The electrical conductivity σ, see Fig. 5C, as a first parameter is representative of number and mobility of ions in the adhesive and increases with the number of ions in the liquid, the amount of liquid in the adhesive, and the number of ions in the hydrocolloid. As time increases, the adhesive layer absorbs more and more liquid, and as such, the number of ions in the liquid, the amount of liquid in the adhesive, and the number of ions in the particles increases.

The constant phase parameter Q_0, see Fig. 5B, as a second parameter is representative of the hydration level or amount of liquid in the adhesive layer.

Fig. 5D shows electrical conductivity σ as a function of constant phase parameter Q_0 and indicates that artificial sweat ranges somewhere between the 50 mM and the 150 mM NaCl solution. Fig. 5D clearly shows the benefits of the combination of using a first parameter and a second parameter for the classification of the operating state of the adhesive layer.

Figs. 6A, 6B, 6C, and 6D shows graphs of a measurement similar to the measurements discussed in relation to Figs. 5A-5D. The data shown in Figs. 6A-6D is represented by means of a dotted (1000 mM NaCl solution), small-dashed (150 mM NaCl solution), large-dashed (50 mM NaCl solution), and solid line (artificial sweat), corresponding to refs 502, 504, 506, and 508 of Figs. 5A-5D, respectively.

The data of Figs. 6A-6D exhibits the same behaviour as discussed in relation to Figs. 5A-5D, respectively.

Figs. 7A-7D shows graphs of measurements with an adhesive layer comprising HEC hydrocolloids and exposed to two types of stomal output, namely thick output (dashed line), regular output (solid line), and a 150 mM NaCl aqueous solution (dotted line), at skin temperature (32 °C). The measurements are made using a first electrode pair associated with, such as embedded in or contacting, the adhesive layers, and measured during constant exposure to the described liquids.

In Fig. 7A, the complex impedance $|Z|$ is measured as a function of time. The conductivity σ and the constant phase parameter Q_0 may be derived from this measurement (see Fig. 7C and 7B, respectively).

The electrical conductivity σ, see Fig. 7C, as a first parameter is representative of ions in the adhesive and increases with the number of ions in the liquid, the amount of liquid in the adhesive, and the number of ions in the adhesive. As time increases, the adhesive layer absorbs more and more liquid, and as such, the number of ions in the liquid, the amount of liquid in the adhesive, and the number of ions in the particles increases.

The constant phase parameter Q_0, see Fig. 7B, as a second parameter is representative of the hydration level or amount of liquid in the adhesive layer.

Fig. 7D shows electrical conductivity σ as a function of constant phase parameter Q_0 and indicates that output is similar to or above the 150 mM NaCl solution. This is to be compared to the results using artificial sweat as discussed in relation to Fig. 5, indicating that sweat ranges somewhere near the 50 mM NaCl solution, while output ranges somewhere near or even above the 150 mM NaCl solution.

Figs. 8A-8D shows graphs of measurements with adhesive layer comprising CMC hydrocolloids and exposed to two types of stomal output, namely thick output (dashed line), regular output (solid line), and a 150 mM NaCl aqueous solution (dotted line) at skin temperature (32 °C). The measurements are made using a first electrode pair associated with, such as embedded in or contacting, the adhesive layers, and measured during constant exposure to the described liquids.

In Fig. 8A, the complex impedance $|Z|$ is measured as a function of time. The conductivity σ and the constant phase parameter Q_0 may be derived from this measurement (see Fig. 8C and 8B, respectively).

The electrical conductivity σ, see Fig. 8C, as a first parameter is representative of ions in the adhesive and increases with the number of ions in the liquid, the amount of liquid in the adhesive, and the number of ions in the adhesive. As time increases, the adhesive layer absorbs more and more liquid, and as such, the number of ions in the liquid, the amount of liquid in the adhesive, and the number of ions in the particles increases.

The constant phase parameter Q_0, see Fig. 8B as a second parameter is representative of the hydration level or amount of liquid in the adhesive layer.

Fig. 8D shows electrical conductivity σ as a function of constant phase parameter Q_0 and indicates that output is similar to or above the 150 mM NaCl solution. This is to be compared to the results using artificial sweat as discussed in relation to Fig. 5, indicating that sweat ranges somewhere near the 50 mM NaCl solution, while output ranges somewhere near or even above the 150 mM NaCl solution.

The difference in behaviour of (artificial) sweat and output allows to differentiate between the two liquids and assign different operating states to the adhesive being wetted with sweat and output. In other words, the presence of sweat can be detected and communicated, e.g., as a first operating state of the adhesive layer, and a presence of output can be detected and communicated, e.g., as a second operating state of the adhesive layer. Further, a high level of hydration and a low level of hydration of the same liquid can be detected and communicated, e.g., as separate operating states of the adhesive layer.

As seen from Figs. 5D, 6D, 7D, and 8D, the use of first parameter and second parameter allows a fast detection and classification of the type and content of liquid wetting the adhesive layer.

The use of the terms “first”, “second”, “third” and “fourth”, “primary”, “secondary”, “tertiary” etc. does not imply any particular order, but are included to identify individual elements. Moreover, the use of the terms “first”, “second”, “third” and “fourth”, “primary”, “secondary”, “tertiary” etc. does not denote any order or importance, but rather the terms “first”, “second”, “third” and “fourth”, “primary”, “secondary”, “tertiary” etc. are used to distinguish one element from another. Note that the words “first”, “second”, “third” and “fourth”, “primary”, “secondary”, “tertiary” etc. are used here and elsewhere for labelling purposes only and are not intended to denote any specific spatial or temporal ordering.

Furthermore, the labelling of a first element does not imply the presence of a second element and vice versa.

It may be appreciated that the figures comprise some modules or operations which are illustrated with a solid line and some modules or operations which are illustrated with a dashed line. The modules or operations which are comprised in a solid line are modules or operations which are comprised in the broadest example embodiment. The modules or operations which are comprised in a dashed line are example embodiments which may be comprised in, or a part of, or are further modules or operations which may be taken in addition to the modules or operations of the solid line example embodiments. It should be appreciated that these operations need not be performed in order presented. Furthermore, it should be appreciated that not all of the operations need to be performed. The exemplary operations may be performed in any order and in any combination.

It is to be noted that the word "comprising" does not necessarily exclude the presence of other elements or steps than those listed.

It is to be noted that the words "a" or "an" preceding an element do not exclude the presence of a plurality of such elements.

It should further be noted that any reference signs do not limit the scope of the claims, that the exemplary embodiments may be implemented at least in part by means of both hardware and software, and that several "means", "units" or "devices" may be represented by the same item of hardware.

The various exemplary methods, devices, and systems described herein are described in the general context of method steps processes, which may be implemented in one aspect by a computer program product, embodied in a computer-readable medium, including computer-executable instructions, such as program code, executed by computers in networked environments. A computer-readable medium may include removable and non-removable storage devices including, but not limited to, Read Only Memory (ROM), Random Access Memory (RAM), compact discs (CDs), digital versatile discs (DVD), etc. Generally, program modules may include routines, programs, objects, components, data structures, etc. that perform specified tasks or implement specific abstract data types. Computer-executable instructions, associated data structures, and program modules represent examples of program code for executing steps of the methods disclosed herein. The particular sequence of such executable instructions or associated data structures

represents examples of corresponding acts for implementing the functions described in such steps or processes.

Although features have been shown and described, it will be understood that they are not intended to limit the claimed invention, and it will be made obvious to those skilled in the art that various changes and modifications may be made without departing from the spirit and scope of the claimed invention. The specification and drawings are, accordingly to be regarded in an illustrative rather than restrictive sense. The claimed invention is intended to cover all alternatives, modifications, and equivalents.

List of references

1 personal care system
1A ostomy system
1B wound dressing system
2 personal care appliance
2A ostomy appliance
2B wound dressing appliance
4 base plate
6 monitor device
8 accessory device, smartphone
9 connection between the monitor device and the accessory device
10 server device
12 network
14 coupling member
16 coupling ring
18 stoma-receiving opening
19 center of the opening
20 docking station
22 first connector
24 user interface
100 monitor device housing
101 processor
102 first interface
104 second interface
106, 106A memory
108 ground terminal of monitor device
110 first terminal of monitor device
112 second terminal of monitor device
114 third terminal of monitor device
116 fourth terminal of monitor device
118 fifth terminal of monitor device
120 coupling part
122 antenna
124 wireless transceiver, transceiver module
126 loudspeaker
128 haptic feedback element

200 method of monitoring an adhesive layer

S202 obtaining sensor data

S202A obtaining first sensor data from a first electrode pair associated with the adhesive layer

S202B obtaining second sensor data from a second electrode pair associated with the (skin) adhesive layer

S204 determining one or more parameters

S204A determining, based on the sensor data, a first parameter

S204B determining, based on the sensor data, a second parameter

S206 determining an operating state of the adhesive layer

S206A determining an ion concentration in the adhesive layer

S206B mapping the ion concentration to the operating state

S206C determining a hydration level in the adhesive layer

S206D mapping the hydration level to the operating state

S206E determining whether the adhesive layer is in a first operating state

S206F determining whether the adhesive layer is in a second operating state

S208 outputting the operating state via an interface.

Claims

1. A method of monitoring an adhesive layer, the method comprising:

obtaining sensor data comprising first sensor data from a first electrode pair associated with the adhesive layer;

determining, based on the sensor data, a first parameter indicative of a first electrical property of the adhesive layer;

determining, based on the sensor data, a second parameter indicative of a second electrical property of the adhesive layer;

determining, based on the first parameter and the second parameter, an operating state of the adhesive layer; and

outputting the operating state via an interface.

2. Method according to claim 1, wherein the first parameter is electrical conductivity.

3. Method according to any of claims 1-2, wherein the second parameter is capacitance or impedance of a constant phase element.

4. Method according to any of claims 1-3, wherein determining an operating state of the adhesive layer comprises determining an ion concentration in the adhesive layer based on the first parameter and/or the second parameter and mapping the ion concentration to the operating state.

5. Method according to any of claims 1-4, wherein determining an operating state of the adhesive layer comprises determining a hydration level in the adhesive layer based on the first parameter and/or the second parameter and mapping the hydration level to the operating state.

6. Method according to any of claims 1-5, wherein determining an operating state of the adhesive layer comprises determining whether the adhesive layer is in a first operating state indicative of the adhesive layer being wetted with a first liquid being sweat.

7. Method according to any of claims 1-6, wherein determining an operating state of the adhesive layer comprises determining whether the adhesive layer is in a second operating state indicative of the adhesive layer being wetted with a second liquid being stomal output.

8. Method according to any of claims 1-7, wherein determining a first parameter comprises determining the first parameter at one or more frequencies including a first primary frequency, wherein the first primary frequency is in a primary frequency range from 10 Hz to 500 Hz, and wherein determining an operating state of the adhesive layer is based on the first parameter at the first primary frequency.

9. Method according to any of claims 1-8, wherein determining a first parameter comprises determining the first parameter at a first secondary frequency, wherein the first secondary frequency is in a secondary frequency range from 10 kHz to 200 kHz, and wherein determining an operating state of the adhesive layer is based on the first parameter at the first secondary frequency.

10. Method according to any of claims 1-9, wherein determining a second parameter comprises determining the second parameter at one or more electrical frequencies including a second primary frequency, wherein the second primary frequency is in a primary frequency range from 10 Hz to 500 Hz, and wherein determining an operating state of the adhesive layer is based on the second parameter at the second primary frequency.

11. Method according to any of claims 1-10, wherein determining a second parameter comprises determining the second parameter at a second secondary frequency, wherein the second secondary frequency is in a secondary frequency range from 10 kHz to 200 kHz, and wherein determining an operating state of the adhesive layer is based on the second parameter at the second secondary frequency.

12. Method according to any of claims 1-11, wherein obtaining sensor data comprises obtaining second sensor data from a second electrode pair associated with the adhesive layer; and wherein one or both of determining a first parameter and determining a second parameter is based on the second sensor data.

13. An electronic device comprising an interface and one or more processors, wherein the one or more processors are configured to perform a method according to any of claims 1-12.

14. Electronic device according to claim 13, wherein the interface comprises a first interface configured to couple to at least the first electrode pair of the adhesive layer and a second interface configured to output the operating state.

15. An electronic device comprising a first interface and second interface and one or more processors, wherein the one or more processors are configured to:

obtain, via the first interface, sensor data comprising first sensor data from a first electrode pair associated with an adhesive layer of a personal care appliance;

determine, based on the sensor data, a first parameter indicative of a first electrical property of the adhesive layer;

determine, based on the sensor data, a second parameter indicative of a second electrical property of the adhesive layer;

determine, based on the first parameter and the second parameter, an operating state of the adhesive layer; and

outputting the operating state via a second interface.

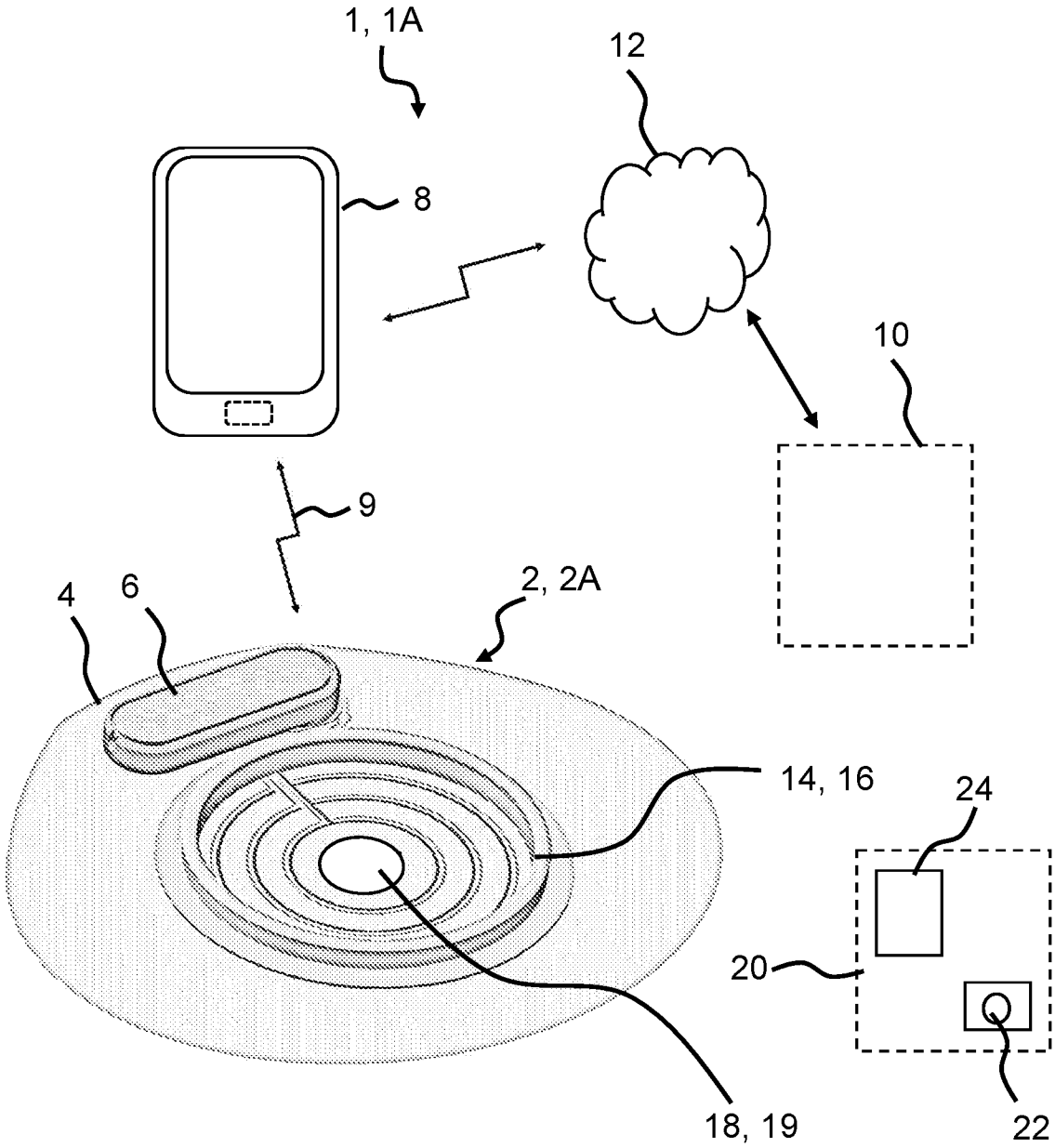

Fig. 1

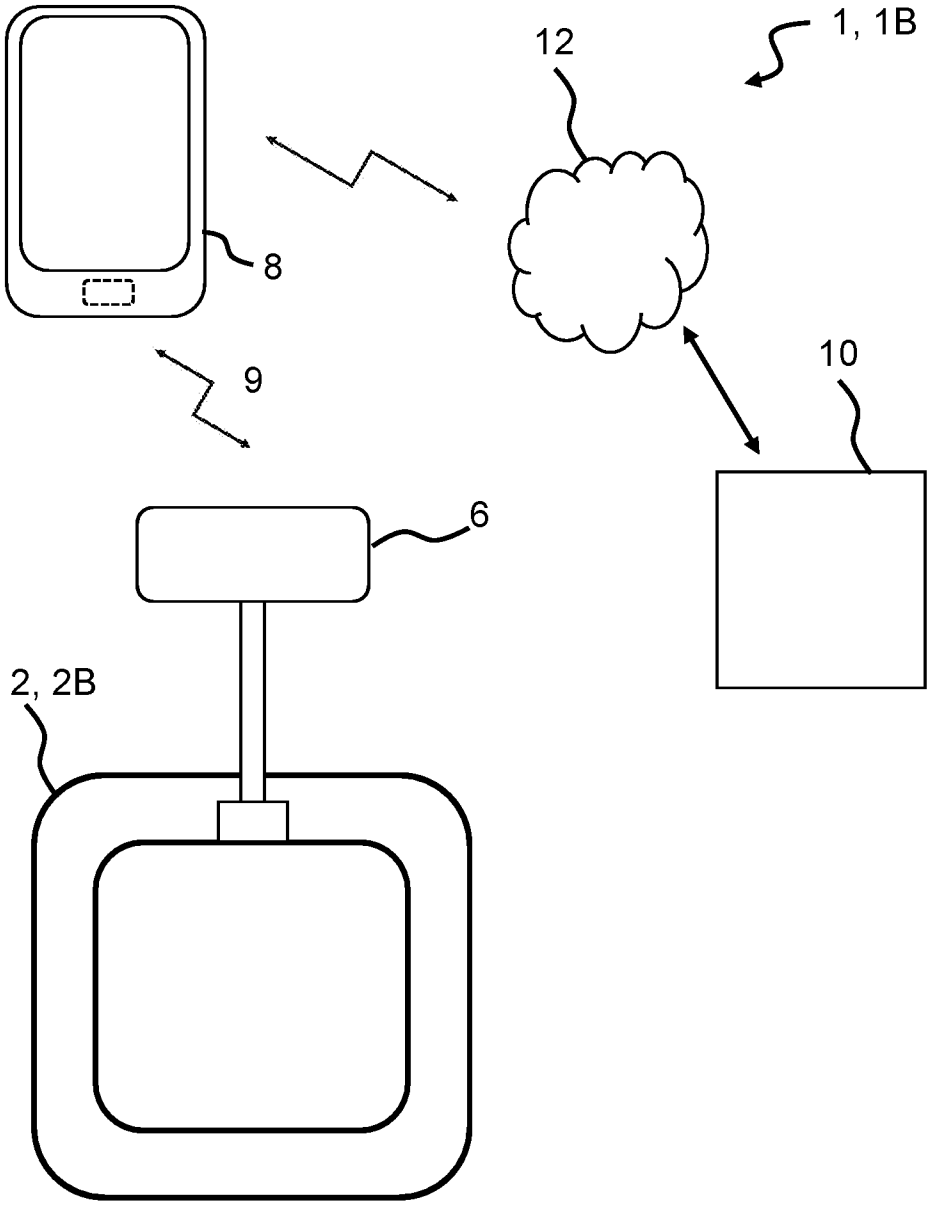

Fig. 2

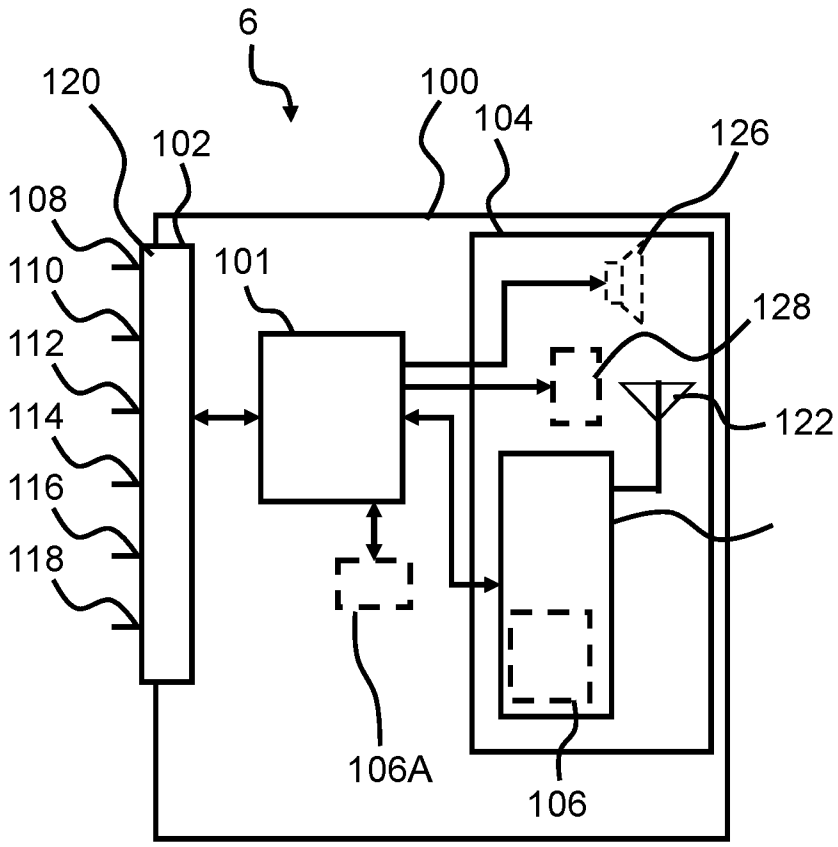
6
120
100
104
102
126
108
110
101
128
112
114
122
116
118
106A
106

Fig. 3


200
S202 Obtain sensor data
S202A
S202B
S204 Determine parameters
S204A
S204C
S204D
S204B
S204E
S204F
S206 Determine operating state
S206A
S206B
S206C
S206D
S206E
S206F
S208 Output operating state

Fig. 4

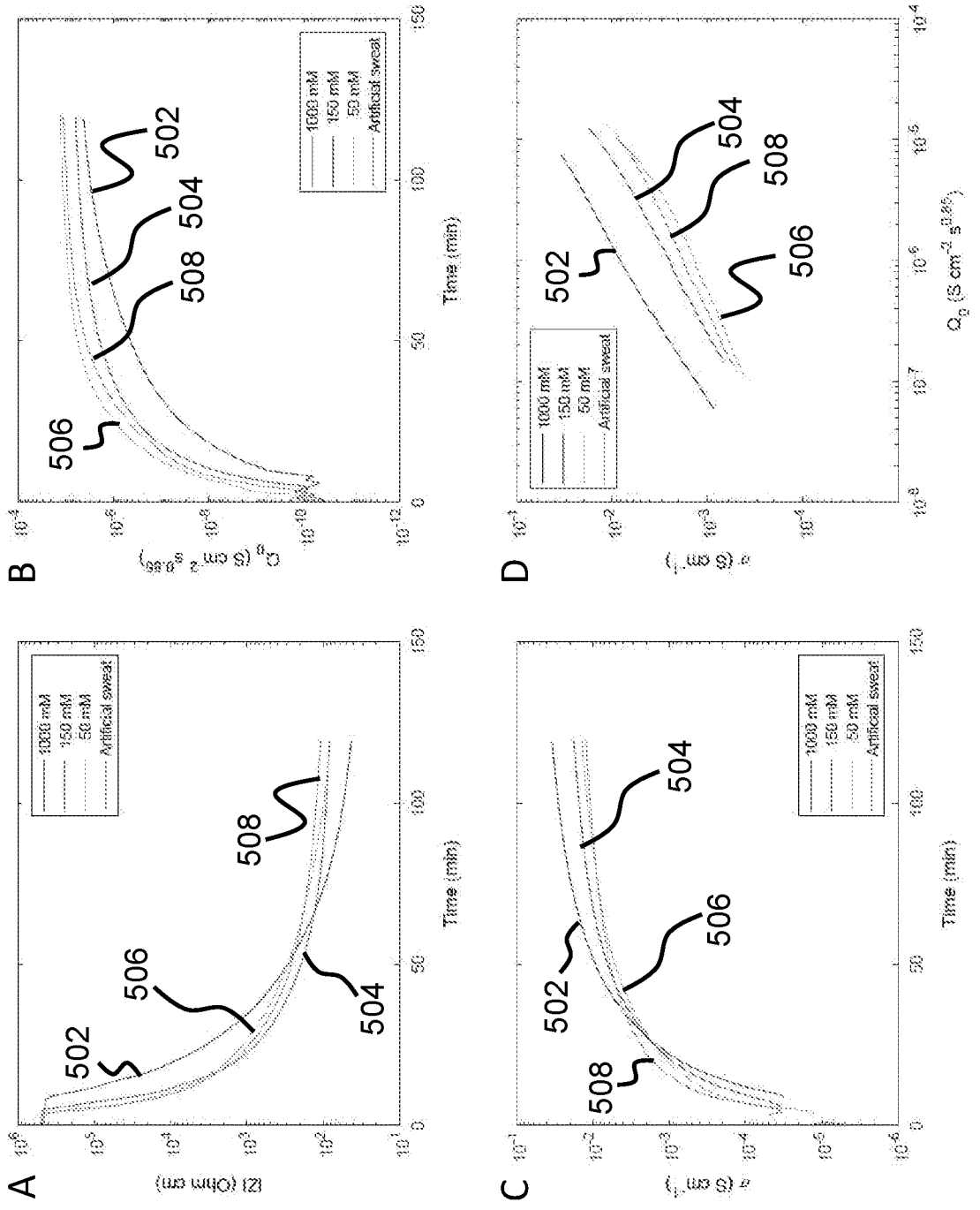
A
B
C
D
Time (min)
1000 mM
150 mM
50 mM
Artificial sweat
502
504
506
508

Fig. 5

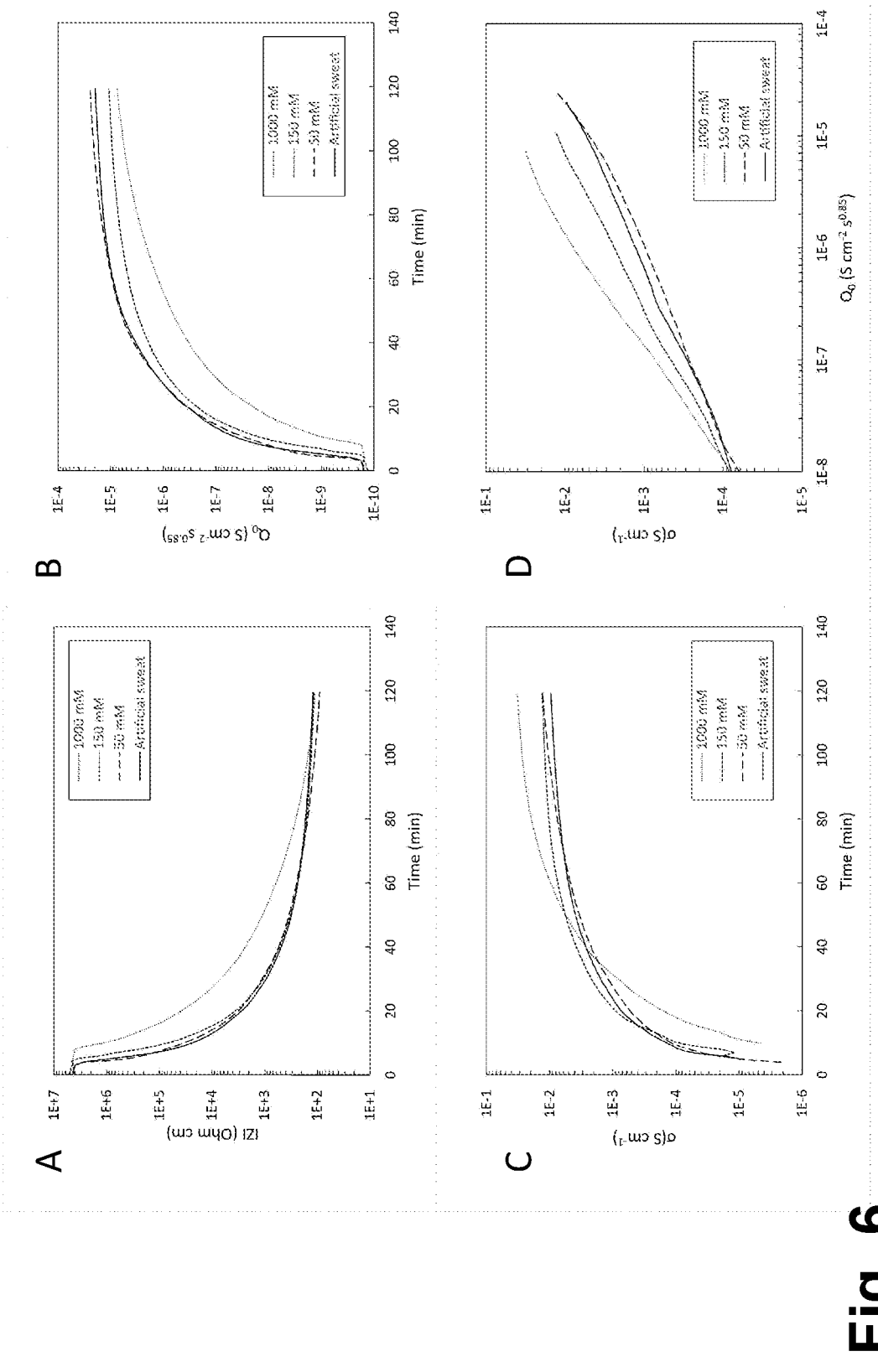
A
B
C
D
1000 mM
150 mM
50 mM
Artificial sweat
Time (min)
|Z| (Ohm cm)
Q_0 (S cm^{-2} s$^{0.85}$)
σ(S cm^{-1})

Fig. 6

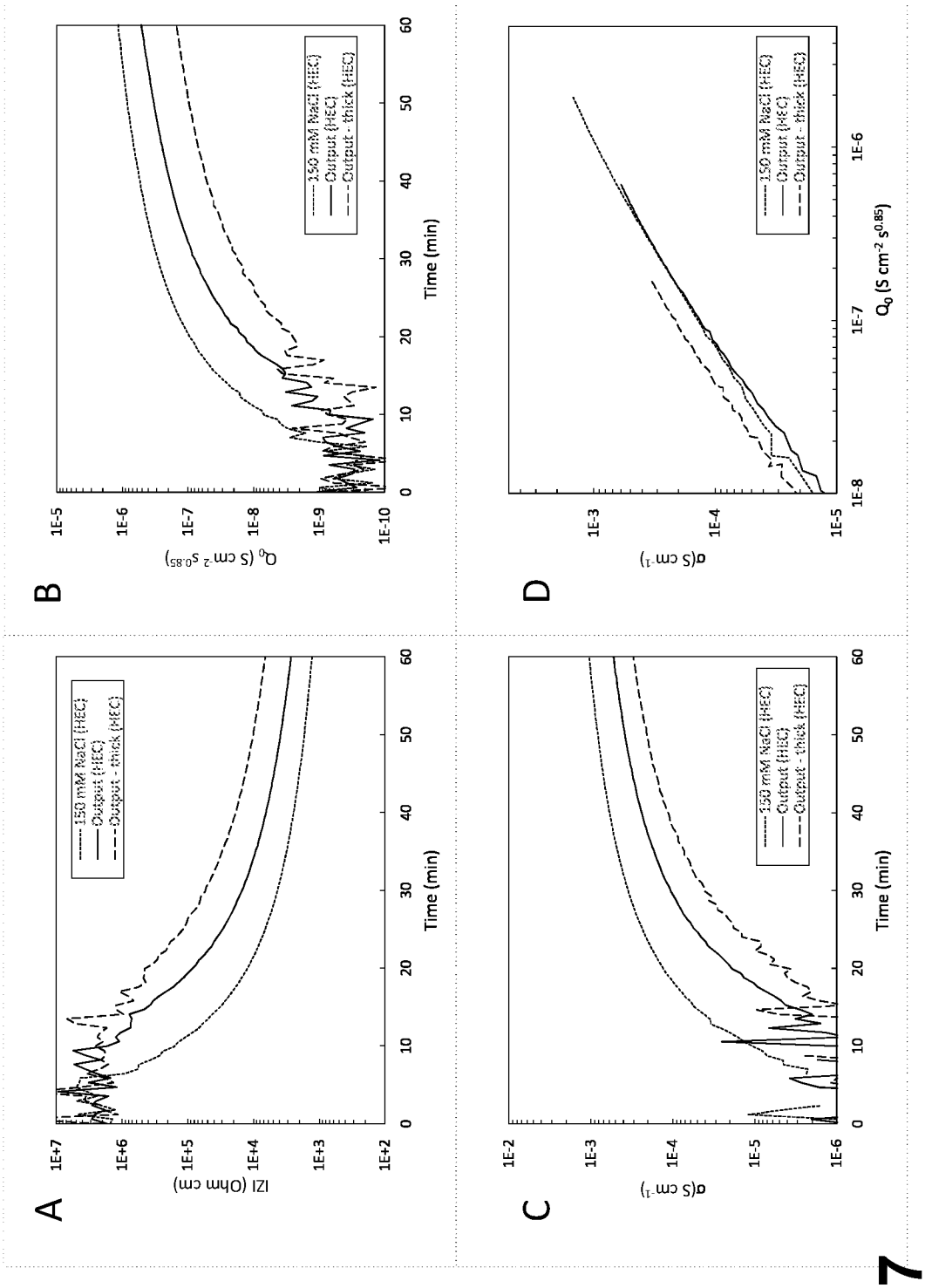
A
|Z| (Ohm cm)
Time (min)
150 mM NaCl (HEC)
Output (HEC)
Output - thick (HEC)
B
Q_0 (S cm^{-2} s$^{0.85}$)
Time (min)
C
σ(S cm^{-1})
Time (min)
D
σ(S cm^{-1})
Q_0 (S cm^{-2} s$^{0.85}$)

Fig. 7

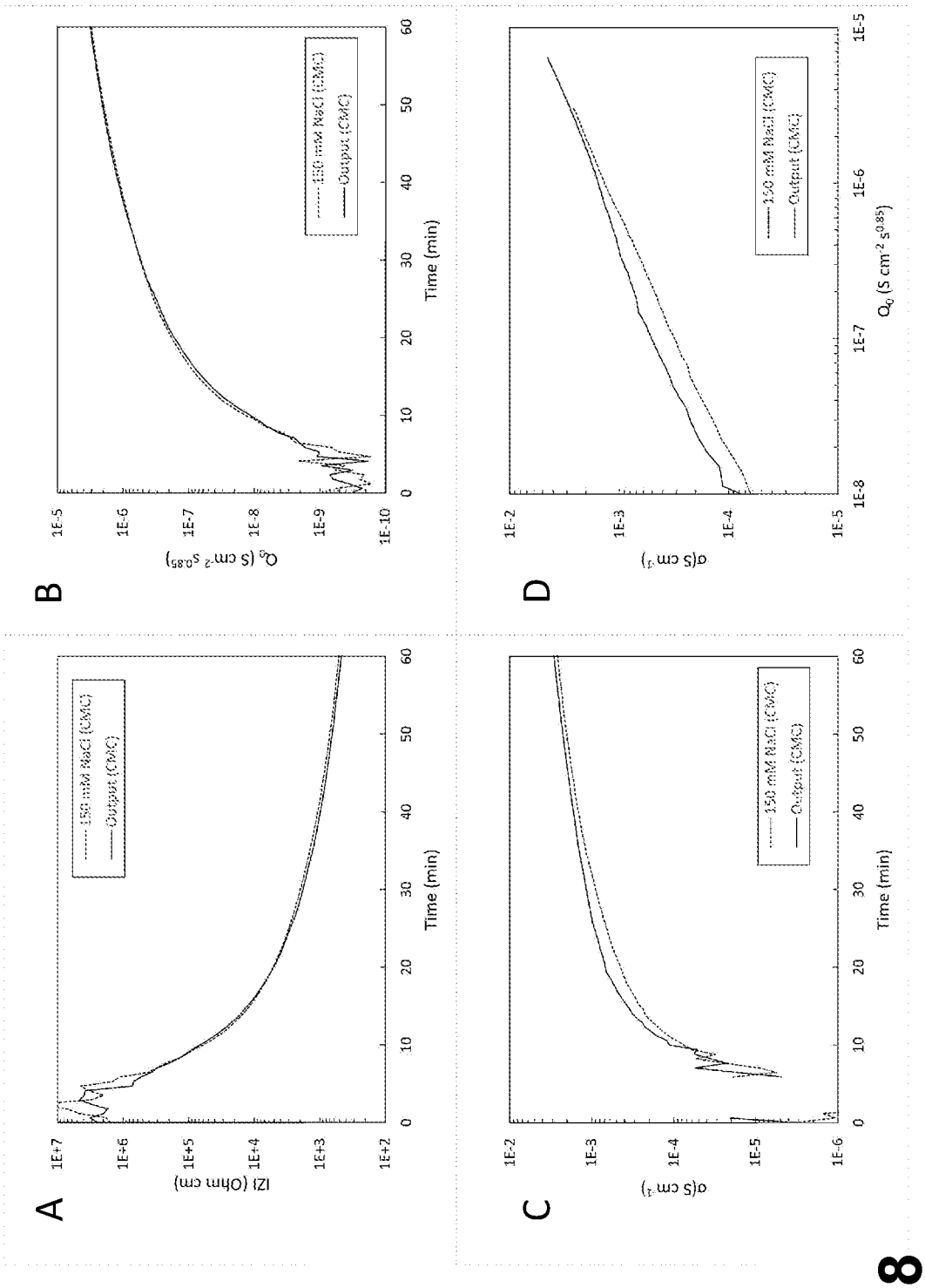
A
B
C
D
|Z| (Ohm cm)
Q_0 (S cm^{-2} s$^{0.85}$)
α(S cm^{-1})
α(S cm^{-1})
Time (min)
Time (min)
Q_0 (S cm^{-2} s$^{0.85}$)
150 mM NaCl (CMC)
Output (CMC)
150 mM NaCl (CMC)
Output (CMC)
150 mM NaCl (CMC)
Output (CMC)
150 mM NaCl (CMC)
Output (CMC)

Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2023/050325

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N27/04 A61B5/00 A61F5/445
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)
G01N A61F 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.
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[x] Further documents are listed in the continuation of Box C.

[x] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 March 2024	05/04/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Kratz, Dorothee

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INTERNATIONAL SEARCH REPORT

International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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International application No
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