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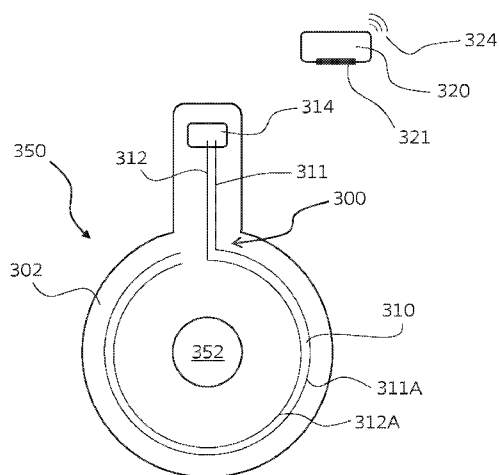


Fig. 11

(57) Abstract: An ostomy appliance including a system for differentiating sweat and stomal output in the ostomy appliance is disclosed. The ostomy appliance includes an adhesive layer configured to absorb liquid. The system includes a first electrode pair including a first and second Ag/AgCl electrode exposed to the adhesive layer; and an electronic device including one or more processors, a first interface 5 configured to connect to the first electrode pair, and a second interface. The processor is configured to obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair; determine one or more fitting parameters of an equivalent circuit model; determine the chloride concentration of the liquid; determine whether the liquid is sweat or stomal output; and output data indicative of the liquid 10 being sweat or stomal output via the second interface.



DIFFERENTIATION OF LIQUID IN OSTOMY APPLIANCE

The present disclosure relates to a system and a method for determining chloride concentration in a liquid, and for differentiating sweat and stomal output in an ostomy appliance. Further, the present disclosure relates to a medical device, such as an ostomy appliance, comprising the system.

5 **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
10 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 sensing system;

Fig. 2 illustrates an exemplary sensing system;

15 Fig. 3 illustrates a Randles circuit;

Fig. 4A illustrates an exemplary and schematic interface between Ag and AgCl;

Fig. 4B illustrates a modified Randles circuit;

Fig. 5 illustrates a method of determining chloride concentration in a liquid;

20 Fig. 6 illustrates a method of determining chloride concentration and total ion concentration in a liquid;

Fig. 7 illustrates a Nyquist plot;

Fig. 8A illustrates a Nyquist plot;

Fig. 8B illustrates a Bode plot;

25 Fig. 9A illustrates a fitting parameter obtained from an impedance spectrum as a function of the total salt concentration;

Fig. 9B illustrates a fitting parameter obtained from an impedance spectrum as a function of the total salt concentration;

Fig. 9C illustrates a fitting parameter obtained from an impedance spectrum as a function of the total salt concentration;

Fig. 9D illustrates a fitting parameter obtained from an impedance spectrum as a function of the total salt concentration;

Fig. 9E illustrates a fitting parameter obtained from an impedance spectrum as a function of the total salt concentration;

5 Fig. 10 illustrates an electronic device; and

Fig. 11 illustrates an ostomy appliance comprising a sensing system.

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
10 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
15 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 term “salt” is used to describe a chemical compound consisting of an ionic assembly of positively charged cations and negative charged anions, which results in a compound with no net electrical charge. The component ions in the salt compound can be either
20 inorganic, such as chloride (Cl^-), or organic, such as acetate (CH_3COO^-). Each ion can be either monatomic, such as fluoride (F^-), or polyatomic, such as sulfate (SO_4^{2-}) or nitrate (NO_3^-). The component ions may be denoted electrolytes when the salt is dissolved in a gel or liquid, e.g., in water. In some instances, where it simplifies the discussion, “salt” is used to denote the chemical compound irrespective of whether it is solid or dissolved in a gel or liquid (and thus dissociates to
25 form electrolytes). For this situation, the term “electrolyte solution” is also used, which thus refers to a liquid solution comprising electrolytes, i.e., salts dissolved in a liquid (e.g., water). In other words, by terms referring to a liquid comprising salts is meant that salt is dissolved in the liquid, whereby the salt is dissociated to form ions (e.g., positively charged sodium ions (Na^+) and negatively charged chloride (Cl^-), when the dissolved salt is NaCl), also denoted electrolytes. The terms may
30 be used interchangeably. Thus, it is to be understood that a salt, when (completely) dissolved in a liquid (e.g., water), is present by its component ions/electrolytes and the liquid may be referred to as an electrolyte solution.

One example of a salt is sodium chloride (NaCl), having positively charged sodium ions (Na⁺) and negatively charged chloride (Cl⁻). However, “salt” within the present disclosure relates to any salt falling within the definition above.

5 Throughout this disclosure, “chloride” is used to describe the chlorine anion, i.e., the negatively charged chlorine atom; Cl⁻. The term is used in singular, irrespective of the number of ions, unless otherwise specified. “Chloride ions” may be used where the physical ions are described with respect to, e.g., diffusion through a structure.

10 Throughout this disclosure, “nitrate” is used to describe the polyatomic nitrate ion, i.e., the negatively charged ion with the chemical formula NO₃⁻. The term is used in singular, irrespective of the number of ions, unless otherwise specified. “Nitrate ions” may be used where the physical ions are described with respect to, e.g., diffusion through a structure.

Throughout this disclosure, “liquid” may refer to liquid in its liquid phase or to liquid absorbed by a hydrogel. Further, “liquid” may refer to an electrolyte solution.

15 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
20 outcomes involving the characteristic provide the effect, but that exceptionally outcomes do not provide the effect.

The present disclosure provides a system for determining chloride concentration in a liquid and a method of determining chloride concentration in a liquid. Further, an ostomy appliance comprising a sensing system for differentiating/distinguishing sweat and stomal output in the ostomy appliance,
25 and a method, performed in an electronic device, for differentiating sweat and stomal output in an ostomy appliance, is disclosed.

In a first aspect of the invention, a system for determining chloride concentration in a liquid is disclosed. The system may also be denoted a sensing system. The system includes:

- a reservoir for containing the liquid;
- 30 - a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and the second Ag/AgCl electrode exposed to the reservoir; and

- an electronic device including one or more processors, a first interface configured to connect to the first electrode pair, and a second interface; wherein the one or more processors are configured to:
 - obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair;
 - determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
 - determine, based on at least the first fitting parameter, the chloride concentration of the liquid; and
 - output data indicative of the chloride concentration via the second interface.

In an alternative wording, the one or more processors are configured to:

- obtain, via the first interface, sensor data from the first electrode pair, the sensor data being representative of the impedance across the first electrode pair;
- determine one or more fitting parameters of an equivalent circuit model as a function of the sensor data, the one or more fitting parameters including a first fitting parameter;
- determine the chloride concentration of the liquid as a function of at least the first fitting parameter; and
- output data representative of the chloride concentration via the second interface.

Notably, the wording “based on” in the above context intends to describe a relationship between, e.g., the one or more fitting parameters and the sensor data. Namely, the one or more fitting parameters are determined as a function of the sensor data, such as determined using an algorithm, which will be explained in more detail below. In the following, the wording “based on” is used, but it is appreciated that it may be appropriately replaced by the wording “as a function of”.

In the following, to support discussions relating to the disclosed underlying theory of the disclosed embodiments, references are made to the figures. However, a more detailed description of the figures will follow.

Liquids comprising one or more salts dissolved therein are commonly used or measured in many industries, including, but not limited to, the chemical (manufacturing) industry, water treatment, agriculture (e.g., pesticide detection), food industry (e.g., food safety analysis), oil and gas industry, battery manufacturing, and the medical (device) industry (e.g., biomedical sensing). It may be advantageous to know which ions and/or the concentration of specific ions are dissolved in the liquids handled/treated. The present invention provides a system and a method for determining

chloride concentration in a liquid, whereby it may be determined whether chloride is present in the liquid, and if so, the concentration thereof.

In the medical industry, the liquids may be bioliquids originating from a living organism, such as a mammal, such as the human body. The bioliquid may be one or more of, but not limited to, sweat, stomal output (i.e., the solid and liquid wastes emanating from a stoma being a surgically created opening bypassing an organ, such as the intestines or urinary tract system of a person), wound exudate, blood, urine, and faeces. Such bioliquids commonly comprise one or more salts dissolved therein (ions), depending on the nature and/or source of the liquid. For example, sweat will typically comprise one or more salts dissolved in water, whereby the salt is dissociated and present as ions/electrolytes, such as Na^+ and Cl^- (forming NaCl). Other electrolytes commonly found in sweat include potassium (K^+), magnesium (Mg^{2+}), and calcium (Ca^{2+}), and phosphate (PO_4^{3-}) and bicarbonate (HCO_3^-). Similarly, other bioliquids may comprise other ions, or other bioliquids may comprise one or more of the same ions, but in different concentrations relative to each other. Thus, the bioliquids may be characterised by their ions and/or ion concentration.

Embodiments of the system and associated method as described herein allow for determining the chloride concentration in a liquid, such as the relative and/or absolute chloride concentration. For example, embodiments of the system and associated methods as described herein allow for determining the absolute chloride concentration and the total ion concentration in the liquid. The relative chloride concentration may be derived from the ratio between the absolute chloride concentration and the total ion concentration in the liquid.

In exemplary systems, the one or more processors are configured to obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair; determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters; determine, based on the one or more fitting parameters, the total ion concentration of the liquid; and output data indicative of the total ion concentration via the second interface. In the following, the discussion is related to determination of the chloride concentration based on a first fitting parameter, but it is appreciated that the one or more fitting parameters may include one or more fitting parameters indicative of the total ion concentration of the liquid, such that said total ion concentration of the liquid may be determined by means of the same system and actions of the one or more processors. For example, the relative chloride concentration of the liquid may be determined or derived by comparison to the total ion concentration of the liquid.

Knowledge of the chloride concentration in a liquid, such as the absolute chloride concentration or the relative chloride concentration (relative to the total ion concentration in the liquid), may support determining the nature of the liquid. In particular, where the likely liquids of a system are known

(e.g., a first and a second liquid), the method may be used to differentiate such two liquids by comparing the chloride concentration to the total ion concentration. Such relative measure may be indicative of the nature of the liquid.

The system and method as disclosed herein is based on electrochemical impedance spectroscopy (EIS) by using an appropriate equivalent circuit model to extract relevant fitting parameters.

Equivalent circuit modelling is a well-known technique used to represent the behaviour of a complex electrical or electronic system using a simplified circuit diagram/model. The purpose of an equivalent circuit model is to approximate the behaviour of the actual system under specific operating conditions, such as steady-state or transient conditions.

It is an object of the present invention to define an equivalent circuit model which appropriately describes the physical, electrochemical processes occurring at an Ag/AgCl interface of an Ag/AgCl electrode for the purpose of extracting information pertaining to the concentration of chloride in a liquid. In particular, it is an object of the present invention to define the equivalent circuit model such that it accurately describes the system while at the same time requires as little processing power as possible. This may be achieved by simplifying the model such that it may be fitted using as few fitting parameters as possible, but where at least one of these fitting parameters are exclusively indicative of the chloride concentration.

Thus, the systems and methods (e.g., performed by an electronic device of the system) according to the invention are associated with the use of a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, where the first Ag/AgCl electrode and second Ag/AgCl electrode are exposed to a reservoir for containing the liquid to be analysed. In other words, the Ag/AgCl electrodes are configured or arranged such that they may be exposed to liquid disposed in the reservoir.

Depending on the surrounding chloride concentration, either AgCl formation or dissociation can be promoted through the oxidation or reduction of Ag:



This principle is discussed in more detail in the following.

Ag/AgCl electrodes are well-known and employed in electrochemical measurements and may be fabricated by means of different techniques. Generally, an Ag/AgCl electrode comprises a silver (Ag) core and a porous thin film coating or layer of silver chloride (AgCl) on the silver core. Ag is electrically conductive, whereas AgCl is a dielectric. In other words, the AgCl layer is arranged/formed on the silver core. Throughout this disclosure, the term "Ag/AgCl electrode" is

used to denote such an electrode. Throughout this disclosure, the term "AgCl layer" is used to denote the layer of silver chloride covering the Ag core.

For example, the Ag/AgCl electrode may be fabricated by immersion of an Ag wire into a solution of FeCl_3 for a specified amount of time, whereby AgCl forms on the surface of the Ag wire. In

5 another technique, the electrode may be formed by (e.g., ink jet or screen) printing, such as by a one-step or two-step printing process. For example, Ag ink may be printed on a substrate and subsequently chlorinated to form the AgCl layer. It is appreciated that any Ag/AgCl electrode, irrespective of fabrication technique, may be used in a system as disclosed herein. However, in a preferred embodiment, the electrodes are printed/comprises cured ink. Thereby, the electrodes
10 may be quickly produced in a line-manufacturing process, and the electrodes may be immediately arranged on a substrate forming part of another device or appliance where chloride detection is desired.

The system according to the first aspect of the invention may comprise a reservoir for containing the liquid. The reservoir may be chosen in view of the liquid. For example, the reservoir may be a
15 container configured to hold/store liquid in its liquid phase. Alternatively, the reservoir may be a gel, such as a hydrogel, where the liquid is absorbed in said gel. In a preferred embodiment, the reservoir is a hydrogel configured to absorb (at least a portion of the) liquid. By a hydrogel may be meant a mixture of porous, permeable solids (e.g., hydrocolloids) configured to absorb at least 10 % by weight or volume of a liquid, such as water. The hydrogel may be prepared using a variety of
20 polymeric materials. In embodiments, the hydrogel comprises hydrocolloids, such as hydroxyethyl cellulose (HEC) and/or carboxymethyl cellulose (CMC).

The system according to the first aspect of the invention comprises a first electrode pair. The first electrode pair includes a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode. The first Ag/AgCl electrode and the second
25 Ag/AgCl electrode may be exposed to the reservoir, e.g., such that liquid disposed in the reservoir may contact the electrodes. The first conductor and the second conductor may in parts comprise a conductive material different from Ag/AgCl, such as one or more of metallic (e.g., silver, copper, gold, titanium, aluminium, stainless steel), ceramic (e.g., ITO), polymeric (e.g., PEDOT, PANI, PPy), and carbonaceous (e.g., carbon black, carbon nanotube, carbon fibre, graphene, graphite)
30 materials. In particular, for parts of the conductors outside the reservoir, any electrically conductive material commonly used in electronics may be used, as the purpose of the conductors outside the reservoir is merely to connect to the electronic device. In other words, the parts of the conductors outside the reservoir are not intended to take part in the electrochemical reaction described in more detail below. In further other words, the first conductor and the second conductor may be
35 formed such that for connections outside the reservoir, the material of the conductors is different

from Ag/AgCl, such as to reduce cost or to facilitate a certain (e.g., galvanic) connection to an interface of an electronic device. Most importantly, however, the Ag/AgCl electrode of the respective conductor is arranged such that liquid disposed in the reservoir may contact the Ag/AgCl electrode, thereby facilitating the electrochemical reaction between the liquid and the Ag/AgCl electrodes as discussed below.

Thus, the system may comprise a first Ag/AgCl electrode and a second Ag/AgCl electrode (i.e., forming a pair), both being arranged to be exposed to liquid in the reservoir. The Ag/AgCl electrodes may be connected to an interface of an electronic device via conductors of a different material (cf. the discussion above).

A first electrode pair is discussed throughout the present disclosure for simplicity, but the use of a plurality of electrode pairs is foreseen within the scope of the invention. For example, where the reservoir is a hydrogel, it may be advantageous to provide an electrode pair in each of a plurality of separate regions or zones of the hydrogel such that these separate regions/zones may be monitored separately (e.g., to determine a different chloride concentration in each region/zone). In embodiments, the system comprises two or more electrode pairs including a first conductor comprising a first Ag/AgCl electrode, a second conductor comprising a second Ag/AgCl electrode, and a third conductor comprising a third Ag/AgCl electrode, wherein the first Ag/AgCl electrode, the second Ag/AgCl electrode, and the third Ag/AgCl electrode are exposed to the reservoir, and wherein the first conductor and the second conductor form a first electrode pair and the second conductor and the third conductor forming a second electrode pair (i.e., the second conductor is shared between the first conductor and the third conductor). In an alternative embodiment, the two or more electrode pairs include a fourth conductor comprising a fourth Ag/AgCl electrode and the third conductor and the fourth conductor form the second electrode pair (i.e., no shared conductors). Each electrode pair may be considered or denoted a sensor, such as a chloride sensor, as such electrode pair facilitate detection of chloride concentration independently from other electrode pairs, such as when coupled to an electronic device as disclosed.

The system may include an electronic device including one or more processors, a first interface, and a second interface. The first interface may be configured to connect to the first electrode pair. For example, the electronic device may be connected to the first electrode pair, such as at least when being configured to obtain the sensor data. In embodiments, by connect is meant that the first interface is configured to connect to the first electrode pair electrically or wirelessly, such that sensor data may be obtained by the one or more processors via the first interface. Thus, the one or more processors may be connected to the first interface such that sensor data obtained via the first interface may be processed by the one or more processors. In a preferred embodiment, the first interface is configured to connect to the first electrode pair electrically. In a preferred embodiment,

the electronic device is, via the first interface, configured to measure the impedance across the first electrode pair, such as by means of applying a voltage at two or more (electrical) frequencies and measuring the associated current and thus derive the impedance, e.g., from knowledge of the circuit.

5 The first interface may include a first terminal element configured to connect at least electrically with a first connection part of the first conductor and a second terminal element configured to connect at least electrically with a second connection part of the second conductor. The first interface may comprise a plurality of terminal elements, such as more than two terminal elements, such as one terminal element for each conductor. In embodiments, where a plurality of electrode
10 pairs is provided, the first interface may be configured to connect to each conductor of each electrode pair. The system may comprise a multiplexer coupled to each of the conductors, so as to facilitate a connection between a plurality of conductors by means of fewer terminal elements of the first interface of the electronic device.

The first interface may further include mechanical coupling means, such that the first interface may
15 be configured to connect mechanically and electrically to the first electrode pair.

In embodiments, the electronic device comprises a second interface configured to output the data indicative of the chloride concentration. In embodiments, the second interface is configured to output data, such as processed data. The second interface may be configured to output the data by means of a wireless signal. In embodiments, the second interface is a transceiver. In
20 embodiments, the second interface is, or comprises, a (graphical) user interface. To output the data may comprise to transmit a wireless signal indicative of the data, such as to transmit the signal to an accessory device in wireless communication with the electronic device, such as according to a wireless data exchange protocol, such as via Bluetooth or the Internet. To output the data may comprise to display a representation of the data in the (graphical) user interface. To output the
25 data may comprise to store the data in a memory of the electronic device.

The one or more processors may be configured to perform one or more methods as disclosed herein. The one or more processors may be configured to perform steps of one or more methods as disclosed herein.

The electronic device may further comprise a memory coupled to the one or more processors
30 and/or a power unit, e.g., a battery, for powering electronics of the device. The electronic device may comprise a charging interface for charging the battery.

One or more auxiliary computing devices may form part of the system or be in communication with the electronic device. The one or more auxiliary computing devices may be an accessory device. An accessory 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 one or more computing devices may be a server device. The server device may be operated and/or controlled by a manufacturer and/or a service centre. The electronic device may be configured to establish a connection to any of the one or more computing devices, such as by a Bluetooth connection, by the Internet, or other wireless connection.

One or more actions of the electronic device, such as one or more actions of the one or more processors, may be shared with, or performed in, one or more auxiliary computing devices in communication with the electronic device without departing from the scope of the invention. For example, the electronic device may be configured to obtain the sensor data via its first interface and send (e.g., wirelessly) the sensor data to the auxiliary computing device, such as an accessory device or server device, which may thus be configured to determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter; determine, based on at least the first fitting parameter, the chloride concentration of the liquid; and output data indicative of the chloride concentration via an interface. However, for simplicity, for the remainder of this disclosure, the electronic device is described as being configured to perform the actions, but it is appreciated that this may be a disclosure of a shared functionality between an electronic device and an auxiliary computing device, such as for sharing or optimizing processing power.

The one or more processors of the electronic device are configured to:

- obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair;
- determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
- determine, based on at least the first fitting parameter, the chloride concentration of the liquid; and
- output data indicative of the chloride concentration via the second interface.

The one or more processors of the electronic device may be configured to perform the actions disclosed continuously, such as to continuously monitor the chloride concentration of liquid in the reservoir. For example, the one or more processors may monitor the chloride concentration by means of the disclosed actions at a rate between 0.01 Hz and 100 Hz, such as between 0.017 Hz and 10 Hz, such as 1 Hz.

In the following, to understand the above actions of the one or more processors, which may also be considered steps of a method performed by the one or more processors of the electronic device, including how to determine the chloride concentration of the liquid, electrochemical impedance

spectroscopy is discussed with examples from the present invention. Thus, whereas the discussion includes reference to known electrochemical impedance spectroscopy techniques, it is to be understood that the following disclosure also includes embodiments of the present invention. Subsequently, the above actions are discussed in greater detail in view of the introduced theory.

5 *Electrochemical impedance spectroscopy (EIS)*

Electrochemical impedance spectroscopy (EIS) is a technique widely used within materials science to, e.g., characterise corrosion processes, improve battery materials, and develop sensors for biomedical applications. It involves the application of a (e.g., sinusoidal) input stimulus, typically a voltage, at a range of different (electrical) frequencies to identify electrochemical processes
 10 occurring at different time scales. Importantly, the obtained impedance response is a function of the entire system under investigation, including the electrodes, any electrolyte solutions, and crucially, the interfaces between them. While electrons typically carry the charges in the electrodes, ions are the charge carriers in electrolyte solutions and therefore, an electrochemical reaction at the interface is necessary to convert these charges. In the absence of any reactions, the system
 15 does not allow for any direct current to flow, and the electrodes are polarised. Such non-faradaic systems are ideal candidates for electrochemical double-layer capacitors or simple biosensor designs. On the other hand, in order to detect specific analytes, non-polarisable electrodes are often used, which participate in well-defined electrochemical reactions.

One particular type of non-polarisable electrodes is the Ag/AgCl electrode. Depending on the
 20 surrounding chloride concentration, either AgCl formation or dissociation can be promoted through the oxidation or reduction of Ag:



Since the associated potential follows the Nernst equation, Ag/AgCl electrodes may be used to determine chloride concentrations potentiometrically. However, for potentiometric measurements
 25 of the chloride concentration, a stable reference electrode is needed such that the potential at the working electrode can be determined precisely. It can be difficult to fabricate such reference electrodes and incorporate them into devices (such as in adhesives or hydrogels as disclosed herein). Additionally, potentiometric measurements only provide chloride concentration. On the contrary, the impedance response, as disclosed herein, of such Ag/AgCl electrodes is less employed
 30 in methods and systems but allow for further parameters to be determined (such as the total ion concentration).

The inventors have found that valuable information pertaining to the electrochemical reactions occurring at Ag/AgCl interfaces may be extracted impedimetrically. In other words, by using impedance data, such as represented by an impedance spectrum, valuable information pertaining

to the electrochemical reactions occurring at Ag/AgCl interfaces may be extracted. As mentioned earlier, it is an object of the invention to define an equivalent circuit model which appropriately describes the physical, electrochemical processes occurring at an Ag/AgCl interface of an Ag/AgCl electrode, and in particular in regard to impedance measurements of the system as disclosed
 5 herein.

Generally, the AgCl layer of an Ag/AgCl electrode is considered to form a porous structure through which the chloride ions need to diffuse in order to reach the Ag/AgCl interface where the electrochemical reaction can proceed. Thus, the structure strongly affects the diffusion kinetics of the chloride ions as well as the effective electrode area.

10 In order to quantify the obtained impedance spectra, one can establish an equivalent circuit model where physical processes in a given system are assigned to some ideal circuit components. A balance must be found between describing the system accurately and minimising the number of fitting parameters in the model. Despite the complexity of the Ag/AgCl electrode, simple equivalent circuit models with a resistor and a constant phase element in parallel or Randles circuits (see Fig.
 15 3) are known and often employed to describe the electrochemical reaction. This so-called Randles circuit is among the most well-known circuit models to describe the impedance response of an electrochemical reaction on a flat surface. However, the inventors have found that further modification of the equivalent circuit model is needed in order to account for non-flat surfaces, including the porous structure of the AgCl of an Ag/AgCl electrode. This is explained in greater
 20 detail later. However, in order to understand a modified Randles circuit, it is beneficial to understand the Randles circuit.

In the simple model described by a Randles circuit (i.e., a flat surface), the resistance, R_e , of the electrolyte solution is in series with the impedance of the electrochemical reaction. When ions arrive at the electrode/electrolyte interface, a double-layer capacitance, C_{dl} , builds up. Simultaneously, the
 25 ions are consumed in the electrochemical reaction and hence a parallel arrangement of these contributions is used. In the electrochemical reaction, R_{ct} represents the charge transfer resistance, which is connected to the kinetics of the reaction. In case of fast reaction kinetics, the reaction is limited by the concentration of reacting species at the surface and hence diffusion becomes critical. Here, the Warburg impedance (also denoted Warburg diffusion element or Warburg element), Z_W , is
 30 introduced, which is associated with a Warburg coefficient, A_W :

$$Z_W = \frac{A_W}{\sqrt{\omega}} + \frac{A_W}{j\sqrt{\omega}}$$

where ω denotes the angular frequency and j is the imaginary unit. The Warburg coefficient is then related to the bulk concentration c_b and the diffusion coefficient D of the reacting species as follows:

$$A_w \propto \frac{1}{c_b \sqrt{D}}$$

It is an object of the present invention to use Ag/AgCl electrodes for chloride-specific impedimetric sensing applications. For this purpose, an equivalent circuit model is employed to quantify the obtained impedance spectra. However, the inventors have found that the Randles circuit is not sufficient, at least due to the non-flat surface of the AgCl layer on Ag.

Instead, the inventors have found that by applying appropriate assumptions, an equivalent circuit model of the system as disclosed may be reduced to a specific *modified* Randles circuit which is shown to be suitable for determining the chloride concentration (when used with Ag/AgCl electrodes as described), and which only requires a few fitting parameters. The latter may be particularly important as it reduces the needed processing power. Thereby, the method may be embodied in a large range of devices comprising one or more processors, or the battery life of the device may be extended by the reduced needed processing power.

As part of employing an equivalent circuit model, the one or more processors may be configured to obtain, via the first interface, sensor data from the first electrode pair, the sensor data being indicative of the impedance across the first electrode pair. The sensor data may be obtained by applying a voltage across the first electrode pair at one or more frequencies and measure the resulting current from which the impedance may be calculated. In other words, obtaining sensor data may comprise applying a voltage to an electrode pair including the first electrode pair and measure a resulting current through the respective electrode pair(s). The 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 an electrode pair (e.g., the first electrode pair) and measuring a resulting voltage 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.

In embodiments, to obtain sensor data from the first electrode pair may comprise applying a voltage across the first electrode pair at two or more frequencies and measuring the impedance of the circuit (i.e., between the first Ag/AgCl electrode and the second Ag/AgCl electrode).

Generally, the impedance Z comprises a real part Z' and an imaginary part Z'' :

$$Z = Z' + iZ''$$

In embodiments, the sensor data is representative of an impedance spectrum. The impedance spectrum may be plotted in a Nyquist plot representing the negative of the imaginary part ($-Z''$) versus the real part (Z') of the complex impedance (Z) (see Fig. 7 for an exemplary Nyquist plot). In

embodiments, the impedance across the first electrode pair is measured at two or more frequencies in the range from 0.1 Hz to 100 kHz. In embodiments, the impedance across the first electrode pair is measured at maximally 150 frequencies, or maximally 100 frequencies, or maximally 75 frequencies, or maximally 50 frequencies, or maximally 25 frequencies, or maximally 10 frequencies, in the range from 0.1 Hz to 100 kHz. Limiting the number of frequencies may provide a more power-efficient electronic device.

As part of employing an equivalent circuit model, the one or more processors may be configured to determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter. This is explained further in the following.

In order to quantify the obtained impedance spectra, the inventors have found that a certain equivalent circuit model related to the physical parameters of the system may be employed (see Fig. 4A). In other words, each of the processes of the system were considered in order to build an equivalent circuit model comprising corresponding circuit components:

- The first and second conductors may be accounted for by an inductance L .
- The electrolyte solution may be described by a resistance R_e .
- The interface between the electrolyte solution and the Ag/AgCl electrode, where the electrochemical reaction can occur, may be described by a Randles circuit:
 - o The electrolyte solution can only reach this interface through the pores in the AgCl layer and hence, a pore resistance, R_{po} , connected in series, may be introduced.
 - o Since the AgCl layer on top of the Ag is non-conductive and separates the electrolyte solution from the Ag, it represents a capacitor. Its contribution occurs in parallel with the penetration of electrolyte solution to the Ag/AgCl interface. However, it has been shown that the partial penetration of electrolyte solution into porous coatings can cause large variations in coating resistivity according to a power law, which in turn can cause constant phase element behaviour. Therefore, the capacitance of the AgCl layer may be represented by a constant phase element, CPE_{AgCl} .

The impedance of a constant phase element CPE is defined as $Z = 1 / (Q_0 (j\omega)^n)$, with the parameters Q_0 and n . It may be shown (e.g., derived from the linear relationship between $\log(|Z|)$ and $\log(\omega)$) that the value of n is thereby connected to the exponent of the power law relation as $1/(1-n)$. For $n=1$, the constant phase element behaves like a perfect capacitor and the associated Q_0 in fact describes the capacitance of the system. For $0 < n < 1$, however, some dispersion of relaxation times is accounted for and Q_0 does not have any direct physical meaning. Instead, it is related to the variation of resistivity within the AgCl layer.

Considering that the electrochemical reaction at the Ag/AgCl interface is known to occur rapidly, the inventors have found that it may be assumed that any ions arriving at the interface are consumed immediately. This implies that the contributions of both R_{ct} (charge transfer resistance) as well as C_{dl} (double layer capacitance) will be negligible. Consequently, the inventors have found that the equivalent circuit model, in the specific case considered, becomes mathematically equivalent to a *modified* Randles circuit (Fig. 4B). In this *modified* Randles circuit, the inventors have found that the R_{ct} may be exchanged with R_{po} (pore resistance of the AgCl), and C_{dl} may be exchanged with CPE_{AgCl} , as compared to the regular Randles circuit (Fig. 3).

The inductance L (introduced to account for the conductors at high frequencies) may be neglected, as it is neither associated with the electrodes nor the liquid.

Thus, the equivalent circuit model may, in words, describe the impedance response of an electrochemical reaction occurring between the liquid and an Ag/AgCl interface at each of the Ag/AgCl electrodes. The response of one of the Ag/AgCl electrodes is measured (i.e., at the working/sensing electrode), but since both electrodes are identical and a sinusoid signal around 0 V may be used, the signal would be the same at both electrodes.

Thus, in embodiments, the equivalent circuit model is a predefined equivalent circuit model, which may be the equivalent circuit model discussed above and shown in Fig. 4B. The predefined equivalent circuit model may comprise maximally five circuit components. In embodiments, the equivalent circuit model is a predefined equivalent circuit model comprising maximally five circuit components. The predefined equivalent circuit model may be considered or denoted a modified Randles circuit model due to its resemblance with a traditional Randles circuit. By using a predefined equivalent circuit model with thus likewise predefined circuit components, the fitting parameters of the model have a predetermined physical meaning in relation to the system and the electrochemical reaction.

In conclusion, the inventors have found that when considering impedimetric measurements of Ag/AgCl electrodes in contact with liquids, the equivalent circuit model may be represented by a modified Randles circuit where certain circuit components are to be substituted by circuit components representing the physical structure of the Ag/AgCl interface. Thereby, impedimetric measurements may be simplified and the number of fitting parameters needed to fit the impedance spectrum to the model is reduced, such as to five parameters, as will be explained in the following.

Detailed discussion relating to the number of circuit components of the predefined equivalent circuit model is provided below.

Having defined the equivalent circuit model, the sensor data being indicative of an impedance between the electrodes (e.g., an impedance spectrum) may be fitted to such model. This may be

done using a curve-fitting algorithm that varies the values of the fitting parameters and calculates the resulting behaviour of the circuit model. The curve-fitting algorithm seeks to find the values of the fitting parameters that provide the best match between the predicted behaviour of the circuit model and the sensor data. The goodness of fit is typically evaluated using statistical measures.

- 5 One such fitting algorithm may seek to minimise the amplitude-weighted fitting error. However, it is appreciated that equivalent circuit modelling and related data fitting techniques are well-known methods within electrochemical impedance spectroscopy, and as such, one may apply any suitable software and statistical measure configured for equivalent circuit modelling without departing from the scope of the invention.

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Based on the defined equivalent circuit model, e.g., the modified Randles circuit as described above, the number of fitting parameters is determined. In the above example of the modified Randles circuit, the following fitting parameters are used (and explained in more detail):

- R_e [Ω] (resistance of the electrolyte solution)
 - 15 - R_{po} [Ω] (pore resistance)
 - A_w [$\Omega \text{ s}^{-1/2}$] (Warburg coefficient associated with the Warburg diffusion element)
 - n [-] (parameter of the constant phase element)
 - Q_o [$\Omega^{-1} \text{ s}^n$] (parameter of the constant phase element)
 - L [$\Omega \text{ s}$] (inductance of conductors)
- 20 The inductance L may be neglected for reasons explained above. Thus, the modified Randles circuit may be fitted using maximally five fitting parameters. The five fitting parameters are associated with four circuit components of the modified Randles circuit (both n and Q_o are associated with the constant phase element).

- 25 Using the determined values of the respective fitting parameters, the inventors have found correlations between certain fitting parameters and the composition of the liquid (electrolyte solution) measured using the disclosed methods and systems.

In particular, the inventors have found that by determining one or more fitting parameters (e.g., all of the above five parameters) including a first fitting parameter, the chloride concentration in the liquid may be determined.

- 30 In a preferred embodiment, the first fitting parameter is the Warburg coefficient A_w . In an alternative embodiment, the first fitting parameter is n . In embodiments, two or more fitting parameters may be determined, including a first fitting parameter (e.g., the Warburg coefficient) and a second fitting parameters (e.g., n).

In particular, the inventors have found that the Warburg coefficient and n are exclusively indicative of the chloride concentration in the liquid measured, whereas the other parameters may depend on further features of the system, such as the level of hydration where the reservoir is a hydrogel and the liquid is absorbed therein. Due to being more strongly associated with a physical process, the Warburg coefficient is preferred. Thus, in the following, the discussion mainly relates to the Warburg coefficient.

The Warburg coefficient describes a diffusion process to the Ag/AgCl electrode, and in particular a diffusion process through the AgCl layer. As was previously shown, the Warburg coefficient is related to the bulk concentration c_b and the diffusion coefficient D (describing the mobility of the ions) of the reacting species as follows:

$$A_W \propto \frac{1}{c_b \sqrt{D}}$$

When considering a system comprising an AgCl/Ag electrode, the mobility is limited by the AgCl layer, meaning that the mobility of the ions in the AgCl layer is constant (in the above relation, D) irrespective of the mobility of the ions in the liquid (e.g., where the liquid is absorbed in a hydrogel, different hydration levels thereof provide different mobilities). However, the concentration of ions (in the above relation, c_b) affects the value of the Warburg coefficient, which is utilized according to embodiments of the present disclosure. Accordingly, since the Warburg coefficient is thus closely related to the system comprising an AgCl/Ag electrode, the first fitting parameter may be described as associated with a diffusion process of ions within the AgCl layer of the Ag/AgCl electrodes. In an alternative wording, the first fitting parameter is associated with diffusion of ions to the Ag/AgCl interface.

Since the Warburg coefficient is associated with the Warburg diffusion element, in embodiments, a circuit component of the equivalent circuit model is the Warburg diffusion element. For example, in embodiments, a circuit component of the maximally five circuit components (according to previous embodiments) is the Warburg diffusion element.

It is appreciated that by modelling the data differently while still using impedance spectroscopy as disclosed, it may be possible to find an alternative fitting parameter which is likewise exclusively indicative of the chloride concentration in the liquid measured. For example, a fitting parameter likewise predominantly related to ion mobility within the AgCl layer of the Ag/AgCl electrodes may be found. Thus, whereas the inventors have found that a specific circuit component (the Warburg element) of the equivalent circuit model is exclusively indicative of the chloride concentration, it is appreciated that other circuit components may be such exclusively indicative without departing from the scope of the invention.

Similarly, as briefly mentioned above, the inventors have found that the fitting parameter n is independent of a hydration level of the liquid/gel, but is affected by the chloride concentration, thus constituting an alternative first fitting parameter based on which the chloride concentration of the liquid may be determined.

- 5 Thus, in embodiments, it may be sufficient to determine only the first fitting parameter being either the Warburg coefficient or n , in order to determine the chloride concentration of the liquid.

In embodiments, the equivalent circuit model includes at least the Warburg diffusion element. In embodiments, the equivalent circuit model includes at least the constant phase element. For example, in embodiments, the equivalent circuit model includes one or more circuit components
10 including a first circuit component being the Warburg diffusion element. In embodiments, the equivalent circuit model includes maximally five, or maximally four, circuit components including a first circuit component being the Warburg diffusion element

In embodiments, the equivalent circuit model includes maximally five circuit components, including the Warburg diffusion element, and optionally an inductance associated with the conductors, a
15 resistance associated with the electrolyte solution, a resistance associated with a pore resistance of the Ag/AgCl layer, and/or a constant phase element.

In embodiments, the equivalent circuit model includes maximally five circuit components, including the Warburg diffusion element and the constant phase element, and optionally an inductance associated with the conductors, a resistance associated with the electrolyte solution, and/or a
20 resistance associated with a pore resistance of the Ag/AgCl layer.

In embodiments, the equivalent circuit model includes maximally four circuit components, including the Warburg diffusion element, and optionally a resistance associated with the electrolyte solution, a resistance associated with a pore resistance of the Ag/AgCl layer, and/or a constant phase element.

25 In embodiments, the equivalent circuit model consists of five circuit components, including the Warburg diffusion element, an inductance associated with the conductors, a resistance associated with the electrolyte solution, a resistance associated with a pore resistance of the Ag/AgCl layer, and a constant phase element.

In embodiments, the equivalent circuit model consists of four circuit components, including the
30 Warburg diffusion element, a resistance associated with the electrolyte solution, a resistance associated with a pore resistance of the Ag/AgCl layer, and a constant phase element.

The inductance of the conductors may be neglected under certain circumstances and assumptions, such that the equivalent circuit model may comprise maximally, or consist of, four circuit components. The inventors have found that neglecting the inductance yields satisfactory results.

In embodiments, the one or more fitting parameters include a third, a fourth, and/or a fifth fitting parameter indicative of the total ion concentration of the liquid. In particular, whereas the first fitting parameter may be exclusively indicative of the chloride concentration, the inventors have found that one or more of the one or more fitting parameters may be indicative of the total ion concentration of the liquid, and thus are not affected by the chloride concentration of the liquid. Thereby, the relative chloride concentration may be determined or derived by the ratio of the chloride concentration and the total ion concentration.

Whereas the equivalent circuit model may include a resistance associated with the electrolyte solution (liquid), it is appreciated that the electrolyte solution need not be part of the system as such, as the equivalent circuit model merely represents a theoretical build, employed by the one or more processors, of the system assuming the presence of the components.

Based on the above considerations, in embodiments, the one or more processors are configured to determine maximally five fitting parameters (e.g., when four circuit components are used (the constant phase element is associated with two fitting parameters (Q_0 and n)). In embodiments, the maximally five fitting parameters include a fitting parameter (A_w) associated with the Warburg diffusion element, a fitting parameter (R_e) associated with a resistance associated with the electrolyte solution, a fitting parameter (R_{po}) associated with a resistance associated with a pore resistance of the Ag/AgCl layer, and two fitting parameters (Q_0 and n) associated with a constant phase element

In embodiments, the one or more processors are configured to determine maximally six fitting parameters, including the above five fitting parameters and a sixth fitting parameter (L) associated with an inductance of the conductors.

Whereas the above discussion relates to a specific equivalent circuit model and associated fitting parameters, it is appreciated that the system as disclosed may be modelled according to a different equivalent circuit model, taking into account further, or different, contributions (and thus fitting parameters) from physical processes occurring in the electrolyte solution and/or at the Ag/AgCl interface, which affect the sensor data/impedance spectra. Thus, it is to be understood that the scope of the invention relates to the build of the system in combination with the study of impedance data (e.g., sensor data indicative of the impedance across the first electrode pair), and that the build of the system in such combination with the study of impedance data facilitates the determination of the chloride concentration of the liquid.

The one or more processors may be configured to determine, based on at least the first fitting parameter, the chloride concentration of the liquid. This is explained further in the following.

In embodiments, the one or more processors may be configured to determine, based on at least the first fitting parameter and a second fitting parameter, the chloride concentration of the liquid. Using two fitting parameters, the determination of the chloride concentration of the liquid may be strengthened. For example, the first fitting parameter may be the Warburg coefficient and the second fitting parameter may be n .

As discussed above, the inventors have found that at least a first fitting parameter of an equivalent circuit model exists, which is exclusively indicative of the chloride concentration in the liquid measured. For example, this first fitting parameter may be the Warburg coefficient or n . A second fitting parameter may be n if the first fitting parameter is the Warburg coefficient, and vice versa.

Based on this first fitting parameter, the chloride concentration of the liquid may be determined. In embodiments, the chloride concentration is found by means of inputting the first fitting parameter to a function, look-up table, a neural network, or a model, such as a machine-learning model. In other words, in embodiments, to determine, based on at least the first fitting parameter, the chloride concentration of the liquid comprises to input the first fitting parameter to a function, look-up table, a neural network, or a model, such as a machine-learning model. In embodiments, the function, look-up table, neural network, or model comprises one or more calibration curves including a first calibration curve indicative of the first fitting parameter as a function of chloride concentration of the liquid.

For example, the function, look-up table, neural network, or model, such as a machine-learning model, comprises reference values or reference curves for the first fitting parameter at different chloride concentrations. In other words, for a determined value or plurality of values (e.g., spectra or curves) of the first fitting parameter, the corresponding chloride concentration may be found by comparison of the value of the first fitting parameter to known values (e.g., spectra or curves) of the first fitting parameter at known chloride concentrations.

In embodiments, to determine, based on at least the first fitting parameter, the chloride concentration of the liquid may comprise to input the first fitting parameter to a function, look-up table, neural network, or model, such as a machine-learning model, where said function, look-up table, neural network, or model are configured to output the chloride concentration based on the input (the first fitting parameter). For example, the function, look-up table, neural network, or model, may be configured to compare the first fitting parameter to known calibration values or calibration curves, and based on such comparison, determine the chloride concentration of the

liquid. For example, the function, look-up table, neural network, or model comprise one or more calibration curves including a first calibration curve indicative of the first fitting parameter as a function of ion concentration of the liquid.

5 A function, look-up table, neural network, or model may be configured to output the chloride concentration based on the input by means of processing power of the one or more processors. In other words, the one or more processors may, by use of a function, look-up table, neural network, or model, be configured to output the chloride concentration based on the input.

The system described above may be considered a sensing system which can be incorporated into a medical device, such as an ostomy appliance, which is described in more detail later.

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In a second aspect of the invention, a method of determining chloride concentration in a liquid is disclosed. Preferably, the method is performed by/in an electronic device, such as by/in one or more processors of the electronic device.

The method comprises the steps of:

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- obtaining sensor data from a first electrode pair associated with a reservoir containing the liquid, the first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being indicative of the impedance across the first electrode pair;
 - determining, based on the sensor data, one or more fitting parameters of an equivalent

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 - circuit model, the one or more fitting parameters including a first fitting parameter;
 - determining, based on at least the first fitting parameter, the chloride concentration of the liquid; and
 - outputting data indicative of the chloride concentration.

In an alternative wording, the method comprises the steps of:

- 25
- obtaining sensor data from a first electrode pair associated with a reservoir containing the liquid, the first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being representative of the impedance across the first electrode pair;
 - determining one or more fitting parameters of an equivalent circuit model as a function

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 - of the sensor data, the one or more fitting parameters including a first fitting parameter;
 - determining the chloride concentration of the liquid as a function of at least the first fitting parameter; and
 - outputting data representative of the chloride concentration.

In embodiments, the electronic device comprises one or more processors, a first interface configured to connect to the first electrode pair, and a second interface, and wherein the sensor data is obtained via the first interface, and wherein data is outputted via the second interface.

It is appreciated that disclosed features, such as disclosed actions of the one or more processors, and associated technical effects, of the first aspect of the invention are considered applicable to the method according to the second aspect of the invention and vice versa. In particular, it is appreciated that theoretical discussions pertaining to electrochemical impedance spectroscopy, and the findings by the inventors, are applicable to the method according to the second aspect of the invention.

In embodiments, the step of obtaining sensor data from the first electrode pair may comprise applying a voltage across the first electrode pair at two or more frequencies and measuring the impedance of the circuit (i.e., between the first Ag/AgCl electrode and the second Ag/AgCl electrode). Thereby, for example, the sensor data may be represented by an impedance spectrum or in a Nyquist plot.

In embodiments, the step of determining, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter, may comprise fitting the sensor data to a predefined equivalent circuit model comprising maximally five, such as maximally four, circuit components. The predefined equivalent circuit model and the determination of one or more fitting parameters have been discussed extensively with respect to the first aspect of the invention, and it is appreciated that these discussions are likewise applicable to a method of determining chloride concentration.

In embodiments, the step of determining, based on at least the first fitting parameter, the chloride concentration of the liquid may comprise inputting the first fitting parameter to a function, look-up table, neural network, or model, such as a machine-learning model, where said function, look-up table, neural network, or model are configured to output the chloride concentration based on the input. For example, the function, look-up table, neural network, or model, may be configured to compare the first fitting parameter to known calibration values or calibration curves, and based on such comparison, determine the chloride concentration of the liquid. For example, the function, look-up table, neural network, or model comprise one or more calibration curves including a first calibration curve indicative of the first fitting parameter as a function of ion concentration of the liquid.

In embodiments, outputting data indicative of the chloride concentration may comprise transmitting, e.g., wirelessly, the data to an accessory device and/or displaying a visualization of the data on a graphical user interface or display of the electronic device.

In embodiments, the method according to the second aspect of the invention further comprises determining a second fitting parameter indicative of the total ion concentration of the liquid, determining, based on the second fitting parameter, the total ion concentration of the liquid, and outputting data indicative of the chloride concentration, the total ion concentration, and/or the relative chloride concentration (i.e., relative to the total ion concentration).

In a third aspect of the invention, a medical device comprising a system according to the first aspect of the invention is disclosed.

The system according to the first aspect of the invention may be incorporated into a medical device by means of adapting the reservoir to the desired use of the medical device. Thereby, the medical device may be provided with a sensing system according to the first aspect of the invention.

In embodiments, the medical device includes an adhesive layer for attachment of the medical device to the skin surface of a user, wherein the adhesive layer is the reservoir of the system.

In embodiments, the medical device is one of an ostomy appliance (e.g., a base plate of an ostomy appliance or a sensor patch for attachment to a base plate of an ostomy appliance), a wound dressing, a catheter, and a sweat sensor dressing. Such devices may all comprise a suitable reservoir according to the first aspect of the invention.

For example, in embodiments, the reservoir may be embodied as an adhesive layer such that the medical device may be adhered to a skin surface of a mammal, e.g., a human (user). Thereby, biofluids from the user may be absorbed by the adhesive layer (e.g., where the adhesive layer includes a hydrogel) and thus measured by the first Ag/AgCl electrode and second Ag/AgCl electrode of the first electrode pair exposed thereto. For example, where the system according to the first aspect of the invention is incorporated in a sweat sensor dressing, the system may be used to determine the chloride concentration of the sweat over time, such as to monitor hydration and/or nutrition.

In embodiments, the medical device may comprise a compartment (e.g., a lumen), wherein the compartment is the reservoir of the system. In embodiments, the medical device may be a catheter (e.g., a urinary catheter, such as an intermittent urinary catheter). For example, a lumen of the catheter is the reservoir of the system. The urinary catheter may form part of a urinary catheter system where the compartment is part of the urinary catheter system.

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 medical device/appliance (e.g., an ostomy appliance, a wound dressing, or a sweat sensor dressing).

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 medical device. In other words, the proximal side or surface is the side or surface closest to the user, when the device 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.

5 In the following, 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),” “liquids,” and “fluids” interchangeably. A
10 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.

15 The medical device may be an ostomy appliance.

The ostomy appliance may comprise a base plate and an ostomy pouch (also referred to as an ostomy bag). In embodiments, the ostomy appliance includes a base plate, such as a monolithic, one-piece base plate, e.g., integrated with a sensor assembly part, or a separate sensor assembly part, such as a sensor assembly part to be subsequently applied to a base plate. In other examples,
20 the sensor assembly part is a sensor patch for application to the base plate, such as the proximal surface of the base plate. Thereby, an arbitrary base plate, such as a conventional/generic base plate, can be monitored via the sensor patch. The sensing system according to the first aspect of the invention may form the majority of a base plate or sensor patch as such (i.e., electrodes and an adhesive (reservoir)). However, for the sake of discussing the sensing system in the context of an
25 ostomy appliance, said ostomy appliance is described as comprising such sensing system. Thus, it is appreciated that the sensing system may indeed be an integral part of the ostomy appliance.

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.,
30 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
35 as a peristomal skin area.

The reservoir of the first aspect of the invention may be an adhesive layer of a base plate provided for adhering the base plate to the skin surface, or the reservoir may be an adhesive layer of a sensor patch adapted to adhere to a generic base plate to provide the base plate with sensing capabilities.

- 5 The adhesive layer may be made of a first composition where components thereof provide a hydrogel as previously discussed, whereby the first composition may provide or constitute the reservoir according to the first aspect of the invention.

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
10 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
15 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
20 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
25 composition can comprise 20-60 % hydrocolloids. The first composition can optionally contain other components, such as fillers, tackifiers, plasticizers, and other additives.

In one or more examples, the hydrocolloid is hydroxyethyl cellulose (HEC). The adhesive layer may comprise hydroxyethyl cellulose (HEC). In one or more examples, the hydrocolloid is carboxymethyl cellulose (CMC). The adhesive layer may comprise carboxymethyl cellulose (CMC).

- 30 One major problem to users of ostomy appliances is the risk of leakage of stomal output from the ostomy appliance, in particular from the base plate. This situation may occur if the adhesive, securing the base plate to the peristomal skin, fails or deteriorates due to moisture absorption (e.g., due to sweating). Thereby, stomal output from the stoma may enter the interface between the skin surface and the base plate, where it may propagate and eventually escape the base plate and
35 reach the clothes, causing both skin issues and a major mental burden to the user. Thus, in the field

of ostomy appliances, it is an object to reduce the risk of leakage events and/or to eliminate the (mental) burden of leakage.

One way to eliminate the (mental) burden of leakage is to detect the presence of stomal output in the interface, before it reaches the clothes, and before it causes skin issues through prolonged exposure. Thus, it may be desired to provide a sensing system capable of detecting the presence of stomal output in the interface between the skin surface and the base plate. However, sweat may also appear in this interface, but this is of minor concern to the user, as it may more easily be absorbed by the adhesive (hydrogel) of the base plate and does not cause skin irritation to the same degree as stomal output. On the contrary, stomal output is not as readily absorbed, or the adhesive may lack capacity to absorb it, thus causing skin irritation. Thus, it is relevant to differentiate/distinguish sweat and stomal output in the interface. For example, a sensing system may be configured such that it is capable of determining whether a liquid in the interface is sweat or stomal output.

By using a system according to the first aspect of the invention (e.g., by incorporating it into a base plate or a sensor patch of an ostomy appliance) or employing a method according to the second aspect of the invention, it may be possible to determine the chloride concentration of the liquid. It is known that sweat has a higher relative chloride concentration than stomal output, and thus, by determining the concentration of chloride in the liquid, such as relative to the total ion concentration, it may be possible to determine whether the liquid is sweat or stomal output. Thus, embodiments of the present disclose provides a system and method for differentiating sweat and output in an ostomy appliance, such as in a base plate or sensor patch for attachment to a base plate, such as in the adhesive of the base plate or sensor patch, by means of impedimetric measurements as disclosed.

In particular, in an embodiment, an ostomy appliance comprising a sensing system for differentiating sweat and stomal output in the ostomy appliance is disclosed. The ostomy appliance comprises an adhesive layer (the adhesive layer is thus the reservoir discussed in the first aspect of the invention) for attachment of the ostomy appliance to the skin surface of a user, the adhesive layer being a hydrogel configured to absorb at least a portion of a liquid. The sensing system comprises:

- a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the adhesive layer; and
- an electronic device comprising one or more processors, a first interface configured to connect to the first electrode pair, and a second interface; wherein the one or more processors are configured to:

- obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair;
- determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
- determine, based on at least the first fitting parameter, the chloride concentration of the liquid;
- determine, based on the chloride concentration, whether the liquid is sweat or stomal output; and
- output data indicative of the liquid being sweat or stomal output via the second interface.

The ostomy appliance may be a base plate or a sensor patch for attachment to a base plate. Thus, the adhesive layer may be an adhesive layer of a base plate or a sensor patch and configured to adhere said base plate or sensor patch to the (peristomal) skin surface.

- Thus, the adhesive layer is configured to absorb a liquid, such as at least a portion of a liquid. At this point, the liquid may be any liquid, but given the environment/intended use of the ostomy appliance, it may be assumed that the liquid is either sweat or stomal output. In embodiments, this is a pre-defined condition/assumption/criterion included in the one or more processors. Thereby, based on this pre-defined criterion, the one or more processors may determine whether the liquid is sweat or stomal output when the chloride concentration has been determined.

- For example, the liquid may be determined to be either sweat or stomal output based on a comparison between the determined chloride concentration and a pre-defined threshold value (e.g., by inputting the chloride concentration in a function, the function being configured to at least compare the chloride concentration with the pre-defined threshold value). For example, the liquid may be determined to be sweat if the chloride concentration is above a first threshold value and stomal output if the chloride concentration is below the first threshold value. However, it is appreciated that more advanced models taking into account further parameters may be employed in the step of determining whether the liquid is sweat or stomal output based on the chloride concentration, and that the exemplary compliance with a threshold value is merely one possible embodiment that allows for determining whether the liquid is sweat or stomal output. For example, to determine whether the liquid is sweat or stomal output, based on the chloride concentration, may comprise to input the chloride concentration to a function, look-up table, neural network, or model, such as a machine-learning model, where said function, look-up table, neural network, or model are configured to determine whether the liquid is sweat or stomal output.

The hydrogel (adhesive layer) of the base plate or the sensor patch may thus function as the reservoir according to aspects of the present invention. In particular, the base plate or the sensor patch may be provided with a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to, such as embedded in or in contact with, the adhesive layer of said base plate or sensor patch.

Thus, disclosed is an ostomy appliance including a base plate or a sensor patch, the base plate or sensor patch comprising a system according to the first aspect of the invention.

For example, disclosed is an ostomy appliance including a base plate or a sensor patch, the base plate or sensor patch comprising an adhesive layer configured to absorb liquid, the adhesive layer optionally comprising a stomal opening with a center point configured to receive the stoma, and an electrode assembly, the electrode assembly comprising at least a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the adhesive layer. The electrode assembly may comprise an interface configured to connect to an electronic device. Thus, the electronic device may be configured to electrically and/or mechanically couple to the interface of the electrode assembly. The electronic device may be configured to perform any of the steps according to the second aspect of the invention.

Thereby is provided a base plate, or a sensor patch for attachment to the adhesive surface of a base plate, comprising a first and a second Ag/AgCl electrode, whereby it may be possible to determine the chloride concentration of liquid absorbed in the adhesive layer (hydrogel/reservoir) and thus determine whether the liquid is sweat or stomal output. Therefrom, the electronic device may provide or issue an alert informing the user that stomal output or sweat has been detected. To provide or issue an alert may include to send a wireless signal to an accessory device as previously discussed.

By providing the ostomy appliance (e.g., base plate or sensor patch) with a system according to the first aspect of the invention, the risk of a user experiencing a leakage may be reduced and/or the risk of skin damage due to leakage in the interface may be reduced. Further, the disclosed ostomy appliance may help in reducing leakage false positives due to the ability of distinguishing between different types of liquid (sweat and stomal output).

Thus, when used with an ostomy appliance as disclosed, a method according to the second aspect of the invention may comprise the intermediate step of determining whether the liquid is sweat or stomal output, based on the chloride concentration of the liquid, such as after determining, based on at least the first fitting parameter, the chloride concentration of the liquid. The method may thus

also comprise the step of outputting data indicative of the liquid being sweat or stomal output, such as in conjunction with, or instead of, outputting data indicative of the chloride concentration. These optional, intermediate steps may also be performed in an accessory device in communication with the electronic device.

- 5 In particular, in an embodiment, a method, performed in an electronic device, for differentiating sweat and stomal output in an ostomy appliance is disclosed, the ostomy appliance comprising an adhesive layer for attachment of the ostomy appliance to the skin surface of a user, the adhesive layer being a hydrogel configured to absorb at least a portion of a liquid. The method comprises the steps of:
- 10 - obtaining sensor data from a first electrode pair associated with the adhesive layer containing the liquid, the first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being indicative of the impedance across the first electrode pair;
 - determining, based on the sensor data, one or more fitting parameters of an equivalent
 - 15 circuit model, the one or more fitting parameters including a first fitting parameter;
 - determining, based on at least the first fitting parameter, the chloride concentration of the liquid;
 - determining, based on the chloride concentration, whether the liquid is sweat or stomal output ; and
 - 20 - outputting data indicative of the liquid being either sweat or stomal output.

The medical device may be a sweat sensor dressing, such as a wearable sweat sensor.

- For example, the sweat sensor dressing may comprise an adhesive adapted to absorb sweat expelled by a wearer/user (e.g., an adhesive comprising a first composition as disclosed above in
- 25 relation to an ostomy appliance), such that the reservoir of the system according to the first aspect of the invention may be the adhesive. For example, the first electrode pair of the system according to the first aspect of the invention may be arranged such that it is exposed to the adhesive. Thereby, when used with a system according to the first aspect of the invention, the sweat sensor dressing may be configured to monitor the chloride concentration of sweat expelled by the wearer.
- 30 Such information may be relevant to people prone to sweating, e.g., athletes: when engaging in physical activity, the body loses water and electrolytes due to thermoregulatory sweating. If the exercise is prolonged, high-intensity, or done in a hot environment, excessive sweating can lead to imbalances in water and electrolytes, which can negatively impact performance. For example, it is known that an increase in exercise load increases the chloride concentration in the sweat. By
- 35 continuously monitoring the chloride concentration by means of a sweat sensor dressing as

disclosed, one may plan the hydration and nutrition intake to counterbalance the loss of electrolytes.

Thus, for example, a sweat sensor dressing comprising a sensing system according to the first aspect of the invention is disclosed. The sweat sensor dressing comprises an adhesive layer (the adhesive layer is thus the reservoir discussed in the first aspect of the invention) for attachment of the sweat sensor dressing to the skin surface of a user, the adhesive layer being a hydrogel configured to absorb at least a portion of a liquid.

The medical device may be a wound dressing.

The wound dressing may comprise one or more of 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 a top layer on a distal side of the absorbent core layer. The first electrode pair of the system according to the first aspect of the invention may be arranged on a proximal side and/or distal side of the absorbent core layer, such as between the absorbent core layer and the adhesive layer and/or between the absorbent core layer and the top layer, respectively.

The absorbent core layer may be a uniform material, or it may be a composite, for example in the form of a layered construction comprising layers of different texture and properties. The absorbent core layer may comprise foam, cellulose, super absorbent particles, and/or fibres. The absorbent core layer may comprise a layer of foam facing the wound. The absorbent core layer may comprise a polyurethane foam. The absorbent core layer may comprise a super absorbing layer.

The first electrode pair of the system according to the first aspect of the invention may be arranged in contact with, such as embedded in, the adhesive layer of the wound dressing, such that the adhesive layer of the wound dressing may be the reservoir according to the first aspect of the invention. The first electrode pair of the system according to the first aspect of the invention may be arranged in contact with, such as embedded in, the absorbent core layer of the wound dressing, such that the absorbent core layer may be the reservoir according to the first aspect of the invention.

By providing the wound dressing with a system according to the first aspect of the invention, and thus facilitating the determination of the chloride concentration in any liquid absorbed by the wound dressing, an optimum or improved use of the wound dressing is enabled and facilitated. In particular, it is facilitated that a wound dressing is not changed too early (leading to increased costs and/or material waste) nor too late (leading to adhesive failure, leakage, and/or unsatisfactory wound healing conditions). Accordingly, the user or a health care professional is able to monitor and plan the use of the wound dressing. Further, determination of moisture or wetting pattern types and classification of operating states of the wound dressing is useful in helping to reduce the

risk of a user experiencing leakage from a wound dressing and/or in helping reduce the risk of unsatisfactory wound healing conditions. The present disclosure provides a simple, efficient, and easy-to-use wound dressing system with a high degree of comfort for a user.

Thus, for example, a wound dressing comprising a sensing system according to the first aspect of the invention is disclosed. The sweat sensor dressing comprises an adhesive layer and/or an
5 absorbent core layer (the adhesive layer and/or the absorbent core layer is thus the reservoir discussed in the first aspect of the invention).

Also disclosed is an ostomy appliance including a base plate or a sensor patch, and an electrode
10 assembly, the base plate or sensor patch comprising an adhesive layer configured to absorb liquid, the electrode assembly comprising at least a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the adhesive
15 layer; and an interface configured to connect to an electronic device. For example, the electrode assembly may be embedded in, or layered with, the adhesive layer of the ostomy appliance.

The ostomy appliance is thus suitable for use with the disclosed sensing system of the first aspect of the invention, or the ostomy appliance may be connected to an electronic device configured to perform the method according to the second aspect of the invention.

In particular, the ostomy appliance comprising the disclosed first electrode pair facilitates
20 determination of chloride concentration in the adhesive layer, which may yield further relevant information, such as determination of whether an absorbed liquid is sweat or stomal output.

Also disclosed is a medical appliance comprising a reservoir for containing liquid, such as an adhesive configured to absorb liquid, and an electrode assembly, the electrode assembly comprising at least a first electrode pair including a first conductor comprising a first Ag/AgCl
25 electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the reservoir; and an interface configured to connect to an electronic device.

The medical appliance is thus suitable for use with the disclosed sensing system of the first aspect of the invention, or the medical appliance may be connected to an electronic device configured to
30 perform the method according to the second aspect of the invention.

In particular, the medical appliance comprising the disclosed first electrode pair facilitates determination of chloride concentration in the reservoir, which may yield further relevant information, such as determination of the nature of the absorbed liquid.

Detailed description of the drawings

Fig. 1 illustrates an exemplary system 100. The system 100 comprises a reservoir 102 for containing a liquid 104, a first electrode pair 110 including a first conductor 111 comprising a first Ag/AgCl electrode 111A and a second conductor 112 comprising a second Ag/AgCl electrode 112A, the first Ag/AgCl electrode 111A and second Ag/AgCl electrode 111B exposed to the reservoir 102, and an electronic device 120 comprising one or more processors, a first interface 121 configured to connect to the first electrode pair 110, and a second interface 124.

The one or more processors of the electronic device 120 are configured to:

- obtain, via the first interface 121, sensor data from the first electrode pair 110, the sensor data indicative of the impedance across the first electrode pair 110;
- determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
- determine, based on at least the first fitting parameter, the chloride concentration of the liquid 104; and
- output data indicative of the chloride concentration via the second interface 124.

Whereas the second interface 124 is illustrated as a wireless interface (e.g., the electronic device 120 may comprise a wireless transceiver), it is appreciated that the second interface 124 may also, or additionally, be a graphical user interface, such as comprise a display, such that to output data indicative of the chloride concentration may comprise to display a visualization of the chloride concentration on the display.

The reservoir 102 of Fig. 1 is illustrated as a contained configured to hold the liquid 104 in a liquid phase. The reservoir 102 has walls 102' and a base 102'', but it is appreciated that the reservoir 102 may take any form suitable for the use situation.

Fig. 2 illustrates an exemplary system 200. Like reference numerals have been used for like features. The system 200 of Fig. 2 differs from the system 100 of Fig. 1 in that the reservoir 202 is embodied as a hydrogel gel configured to absorb at least a portion of a liquid 204. In other words, in Fig. 2, liquid 204 has been absorbed by the reservoir 202, and the electrode pair 110 is in contact with the liquid 204 by being embedded in the hydrogel. The hydrogel may be HEC.

Fig. 3 illustrates a Randles circuit, which is a commonly employed equivalent circuit model used to describe the impedance response of an electrochemical reaction on a flat surface.

In such a Randles circuit, the resistance, R_e , of the electrolyte solution is in series with the impedance of the electrochemical reaction. When ions arrive at the electrode/electrolyte interface, a double-layer capacitance, C_{dl} , builds up. Simultaneously, the ions are consumed in the electrochemical reaction and hence a parallel arrangement of these contributions is used. In the electrochemical reaction, R_{ct} represents the charge transfer resistance, which is connected to the kinetics of the reaction. In case of fast reaction kinetics, the reaction is limited by the concentration of reacting species at the surface and hence diffusion becomes critical. Here, the Warburg impedance (also denoted Warburg diffusion element or Warburg element), Z_w , is introduced, which is associated with a Warburg coefficient, A_w :

$$Z_w = \frac{A_w}{\sqrt{\omega}} + \frac{A_w}{j\sqrt{\omega}}$$

where ω denotes the angular frequency and j is the imaginary unit. The Warburg coefficient is then related to the bulk concentration c_b and the diffusion coefficient D of the reacting species as follows:

$$A_w \propto \frac{1}{c_b \sqrt{D}}$$

Fig. 4A illustrates an exemplary/schematic interface between the Ag and the porous AgCl layer of an Ag/AgCl electrode 111A of the system 100,200 shown in Figs. 1 and 2 when exposed to a liquid 104 (electrolyte solution).

Also shown/layered on top of the illustrated interface is an equivalent circuit model 50 found to accurately describe the impedance response of an electrochemical reaction in this (non-flat) interface (as opposed to the Randles circuit of Fig. 3, which is suitable for flat interfaces/surfaces).

In particular, the equivalent circuit model 50 is developed through knowledge of the system 100,200 of Figs. 1 and 2, and the underlying considerations are presented in the detailed description above.

Considering that the electrochemical reaction at the Ag/AgCl interface is known to occur rapidly, the inventors have found that it may be assumed that any ions arriving at the interface are consumed immediately. This implies that the contributions of R_{ct} (charge transfer resistance) is negligible and considerably smaller than the pore resistance R_{po} describing the diffusion of the electrolyte solution 104 through the pores in the AgCl layer, thus $R_{ct} \ll R_{po}$. Likewise, it implies that the C_{dl} (double layer capacitance) will be negligible: $C_{dl} \rightarrow 0$.

Consequently, the inventors have found that the equivalent circuit model 50 becomes mathematically equivalent to the *modified* Randles circuit 50' shown in Fig. 4B. In this *modified*

Randles circuit, the inventors have found that the R_{ct} may be exchanged with R_{po} (pore resistance of the AgCl), and C_{dl} may be exchanged with CPE_{AgCl} , as compared to the regular Randles circuit shown in Fig. 3.

Fig. 5 illustrates a method 1000 of determining chloride concentration in a liquid. Preferably, the method is performed in an electronic device as previously introduced. For example, the method may be performed in an electronic device 120 of the system 100,200 of Figs. 1 and 2.

The method 1000 comprises the steps of:

- obtaining 1002 sensor data from a first electrode pair associated with a reservoir containing the liquid, the first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being indicative of the impedance across the first electrode pair;
- determining 1004, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
- determining 1006, based on at least the first fitting parameter, the chloride concentration of the liquid; and
- outputting 1008 data indicative of the chloride concentration.

The steps of the method may comprise optional steps indicated by dashed boxes.

The step of obtaining 1002 sensor data may comprise the optional steps of applying 1002A a voltage across the first electrode pair at two or more frequencies and measuring 1002B the impedance of the circuit.

The step of determining 1004, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter, may comprise fitting 1004A the sensor data to a predefined equivalent circuit model comprising maximally five circuit components.

The step of determining 1006, based on at least the first fitting parameter, the chloride concentration of the liquid may comprise inputting 1006A the first fitting parameter to a function, look-up table, neural network, or model, such as a machine-learning model, where said function, look-up table, neural network, or model are configured to output the chloride concentration based on the input. For example, the function, look-up table, neural network, or model, may be configured to compare 1006B the first fitting parameter to known calibration values or calibration curves, and based on such comparison, determine 1006C the chloride concentration of the liquid. For example, the function, look-up table, neural network, or model comprise one or more calibration curves

including a first calibration curve indicative of the first fitting parameter as a function of ion concentration of the liquid.

The step of outputting 1008 data indicative of the chloride concentration may comprise transmitting 1008A, e.g., wirelessly, the data to an accessory device and/or displaying 1008B a visualization of the data on a graphical user interface or display of the electronic device.

Fig. 6 illustrates a method 2000 of determining chloride concentration and total ion concentration in a liquid. Preferably, the method is performed in an electronic device as previously introduced. For example, the method may be performed in an electronic device 120 of the system 100,200 of Figs. 1 and 2.

10 The method 2000 comprises the steps of:

- obtaining 2002 sensor data from a first electrode pair associated with a reservoir containing the liquid, the first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being indicative of the impedance across the first electrode pair;
- 15 - determining 2004, based on the sensor data, two or more fitting parameters of an equivalent circuit model, the two or more fitting parameters including a first fitting parameter and a second fitting parameter;
- determining 2006, based on at least the first fitting parameter, the chloride concentration of the liquid;
- 20 - determining 2007, based on at least the second fitting parameter, the total ion concentration of the liquid; and
- outputting 2008 data indicative of the chloride concentration, the total ion concentration, and/or the relative chloride concentration (i.e., relative to the total ion concentration).

The steps of the method 2000 may comprise optional steps indicated by dashed boxes.

25 The step of obtaining 2002 sensor data may comprise the optional steps of applying 2002A a voltage across the first electrode pair at two or more frequencies and measuring 2002B the impedance of the circuit.

The step of determining 2004, based on the sensor data, two or more fitting parameters of an equivalent circuit model, the two or more fitting parameters including a first fitting parameter and a second fitting parameter, may comprise fitting 2004A the sensor data to a predefined equivalent circuit model comprising maximally five circuit components.

The step of determining 2006, based on at least the first fitting parameter, the chloride concentration of the liquid may comprise inputting 2006A the first fitting parameter to a function,

look-up table, neural network, or model, such as a machine-learning model, where said function, look-up table, neural network, or model are configured to output the chloride concentration based on the input. For example, the function, look-up table, neural network, or model, may be configured to compare 2006B the first fitting parameter to known calibration values or calibration curves, and based on such comparison, determine 2006C the chloride concentration of the liquid. For example, the function, look-up table, neural network, or model comprise two or more calibration curves including a first calibration curve indicative of the first fitting parameter as a function of ion concentration of the liquid.

The step of determining 2007, based on at least the second fitting parameter, the total ion concentration of the liquid may comprise inputting 2007A the second fitting parameter to a function, look-up table, neural network, or model, such as a machine-learning model, where said function, look-up table, neural network, or model are configured to output the total ion concentration based on the input. For example, the function, look-up table, neural network, or model, may be configured to compare 2007B the second fitting parameter to known calibration values or calibration curves, and based on such comparison, determine 2007C the total ion concentration of the liquid. For example, the function, look-up table, neural network, or model comprise two or more calibration curves including a second calibration curve indicative of the second fitting parameter as a function of ion concentration of the liquid.

The step of outputting 2008 data indicative of the chloride concentration, the total ion concentration, and/or the relative chloride concentration (i.e., relative to the total ion concentration) may comprise transmitting 2008A, e.g., wirelessly, the data to an accessory device and/or displaying 2008B a visualization of the data on a graphical user interface or display of the electronic device.

Fig. 7 illustrates an experimentally obtained Nyquist plot of a hydrogel (reservoir) comprising HEC with a water volume fraction ϕ_{H_2O} of 0.84 (1.00 would correspond to a NaCl solution without HEC) and a concentration c_{NaCl} of NaCl of 10 mM obtained by mixing HEC with an aqueous NaCl solution.

The Nyquist plot was obtained by measuring the impedance from high (100 kHz) to low (0.1 Hz) frequencies and subsequently from low (0.1 Hz) to high (100 kHz) frequencies. The lines indicate the fit with a modified Randles circuit as described herein, e.g., in relation to Figs. 4A and 4B. The fit with the modified Randles circuit was performed in order to minimise the amplitude-weighted fitting error r^2_{ECM} also indicated.

Generally, the Nyquist plot is a representation of the negative of the imaginary part ($-Z''$) versus the real part (Z') of the complex impedance (Z):

$$Z = Z' + iZ''$$

The Nyquist plot may be considered an impedance spectrum and in embodiments of the present invention, the sensor data is representative of such an impedance spectrum.

Fig. 8A and Fig. 8B illustrates an experimentally obtained Nyquist plot (Fig. 8A) and Bode plot (Fig. 8B) of hydrogels with different NaNO_3 concentrations. The Bode plot represents the absolute value $|Z|$ of the impedance versus the frequency.

The experimental setup and studied cases are described in more detail below, and the data is visualized in the corresponding figures.

With the purpose of investigating the impedance response of Ag/AgCl electrodes, hydroxyethyl cellulose (HEC) gels containing different NaCl concentrations and different levels of hydration were studied. Since the level of hydration determines the mobility of the ions, the effect of the chloride concentration and mobility on the impedance response and the parameters of the modified Randles circuit may be systematically evaluated.

By substituting the chloride in the gel with nitrate, the equivalent circuit model is further scrutinised and demonstrate the specificity of the electrodes.

HEC was obtained from Ashland (USA), while NaCl and NaNO_3 were obtained from Sigma-Aldrich (Germany). In order to evaluate the effect of hydration of the gels on the impedance response, the NaCl concentration, c_{NaCl} , within the gel volume was kept constant. To do so, the density of the gel was assumed to be a linear combination of the densities of HEC (1.36 g/cm^3) and the respective NaCl solutions. Consequently, series of gels with water volume fractions, $\phi_{\text{H}_2\text{O}}$, of 0.67, 0.76, 0.84, and 0.92 were made by manually mixing HEC with aqueous NaCl solutions of different concentrations to yield the same overall NaCl concentration (see below table).

$\phi_{\text{H}_2\text{O}}$ (v/v)	NaCl in liquid (mM)				
0.67	15	75	224	447	745
0.76	13	66	197	395	658
0.84	12	59	178	355	592
0.92	11	54	162	325	541
1.00	10	50	150	300	500
c_{NaCl} (mM)	10	50	150	300	500

In order to evaluate the chloride specificity of the Ag/AgCl electrodes, as well as the parameters of the modified Randles circuit, chloride (Cl^-) was systematically substituted with nitrate (NO_3^-) within the gel in accordance with the table below. Here, the hydration level and NaCl concentration were kept constant at $\phi_{\text{H}_2\text{O}} = 0.84$ and $c_{\text{NaCl}} = 10 \text{ mM}$, respectively, while NaNO_3 was added to obtain total salt concentrations ($c_{\text{NaCl}} + c_{\text{NaNO}_3}$) of 50, 150, 300, and 500 mM. With reference to Figs. 8A and 8B, this corresponds to a concentration c_{NaNO_3} of NaNO_3 of 40 mM (squares), 140 mM

(triangles), 290 mM (stars), and 490 mM (crosses, x), respectively. Also indicated in Figs. 8A and 8B is the situation of 0 mM (circles) NaNO_3 , thus corresponding to the Nyquist plot of Fig. 7.

C_{salt} (mM)	Salt in liquid ($\phi_{\text{H}_2\text{O}} = 0.84$)
10	12 mM NaCl
50	12 mM NaCl + 47 mM NaNO_3
150	12 mM NaCl + 166 mM NaNO_3
300	12 mM NaCl + 343 mM NaNO_3
500	12 mM NaCl + 580 mM NaNO_3

With reference to Fig. 8A, the addition of increasing amounts of NaNO_3 is observed to cause a shift towards lower values of Z' , while the overall shape is maintained. Hence, differences in $|Z|$ were mainly observed at high frequencies but diminished at low frequencies, as illustrated by the Bode plot of Fig. 8B.

The lines and the amplitude-weighted fitting error r^2_{ECM} indicate the fit with a modified Randles circuit as described herein, e.g., in relation to Figs. 4A and 4B.

Figs. 9A-9E illustrate the previously defined fitting parameters as a function of the total salt concentration and derived from the fit with a modified Randles circuit to the data shown in Figs. 8A and 8B (triangles). Thus, the same experimental setup as disclosed in relation to Figs. 8A and 8B is used. For comparison, the fitting parameters of gels ($\phi_{\text{H}_2\text{O}} = 0.84$) at different NaCl concentrations (0, 50, 150, 300, and 500 mM) are also shown (circles), thus illustrating the chloride specificity of certain fitting parameters (e.g., see the Warburg coefficient in Fig. 9C, which is discussed in more detail below).

In particular, the following fitting parameters are plotted as a function of the total salt concentration:

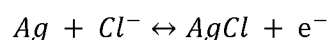
- Fig. 9A: R_e [Ω] (resistance of the electrolyte solution)
- Fig. 9B: R_{po} [Ω] (pore resistance)
- Fig. 9C: A_W [$\Omega \text{ s}^{-1/2}$] (Warburg coefficient associated with the Warburg diffusion element)
- Fig. 9D: n [-] (parameter of the constant phase element)
- Fig. 9E: Q_0 [$\Omega^{-1} \text{ s}^n$] (parameter of the constant phase element)

The differences of $|Z|$ at high frequencies as observed in Fig. 8B were caused by an increase in the conductivity of the gel as the salt concentration increased in general (i.e., representing contributions from both C_{NaCl} and C_{NaNO_3}). This is as expected: the impedance decreases as the salt concentration increases. This is also reflected in the fitting parameter R_e associated with the resistance of the electrolyte solution as illustrated in Fig. 9A. Since the mobilities of chloride and nitrate ions are similar in water, the same R_e was also obtained as a function of their concentrations in the gel.

All other fitting parameters, i.e., R_{po} , A_w , n , and Q_0 , remain substantially unaffected by an increase in the nitrate concentration (see Figs. 9B-9E).

On the contrary, it was found that the fitting parameters A_w (Fig. 9C) and n (Fig. 9D) exhibit a specificity for chloride: with increasing concentration of NaCl (circles), the fitting parameters differ from the corresponding fitting parameters of data associated with a constant concentration of NaCl (triangles). In particular, the parameters decreased compared to the situation of a like salt concentration where the salt concentration was mainly dominated by NaNO_3 and where the concentration of NaCl was constant (10 mM). The difference in the Warburg coefficient A_w is more pronounced and may more readily be attributed to the physical structure of the AgCl layer, as discussed previously. Thus, the data suggest that these parameters, A_w and n , are affected specifically by chloride in the gel (reservoir). A direct comparison of Q_0 , despite differing, is not possible due to the variations in n for an increase in NaCl concentration.

In conclusion, the data suggest, as was also expected by the theory, that the nitrate ions solely affect the conductivity of the gel and do not participate in, or interfere with, the electrochemical reaction:



In view of previously discussed embodiments of systems and methods for determining chloride concentration in a liquid, the Warburg coefficient (A_w) or n may be considered the first fitting parameter (or, in embodiments, one may be the first fitting parameter and the other may be a second fitting parameter), and the chloride concentration may thus be determined based on such first fitting parameter. For example, one or more calibration curves or reference values may be established based on the experiment described above. For example, a calibration curve may comprise data similar to the data presented in Fig. 9C.

Fig. 10 illustrates a schematic block diagram of an exemplary electronic device 120. The electronic device 120 comprises an electronic device housing 122, a processor 123, a first interface 121 and a second interface 124. The electronic device 120 may comprise a memory 125/125A. The memory 125/125A may be connected to the processor 123. The memory 125 may be embedded as flash memory 125A in the second interface 124.

The first interface 121 may be configured for electrically and/or mechanically connecting the electronic device 120 to the system 100,200 of Figs. 1 or 2. The first interface 121 may comprise a plurality of terminals for forming electrical connections with respective terminals/electrodes of the system, e.g., the first electrode pair 110 of Figs. 1 or 2. The first interface 121 may comprise at least two terminals, or between two and 10 terminals, such as between two and eight terminals, including a first terminal 121A and a second terminal 121B. The first interface 121 optionally

comprises a third terminal 121C, a fourth terminal 121D, a fifth terminal 121E, and/or a sixth terminal 121F. In one or more exemplary electronic devices, the first interface 121 comprises a number of terminals corresponding to the number of electrodes and/or conductors of the system to which it is to be coupled.

- 5 The first interface 121 of the electronic device 120 may comprise a coupling part 125 for forming a mechanical connection, such as a releasable coupling between the electronic device 120 and the system 100,200 of Figs. 1 or 2. The coupling part 125 and the terminals of the first interface 121 may form (at least part of) a first connector of the electronic device 120.

- 10 The second interface 124 of electronic device may be configured as an interface for connecting the electronic device 6 to an auxiliary computing device (not shown), such as an accessory device. The second interface 124 may comprise a wireless transceiver 124A also denoted a transceiver module, the wireless transceiver 124A being connected to the processor 123 and configured for wireless communication with an accessory device, e.g., via an antenna 124B.

- 15 Optionally, the second interface 124 may comprise a loudspeaker 126 and/or a haptic feedback element 127 for provision of respective audio signal and/or haptic feedback to the user.

The memory 125 may be an internal memory, such as flash memory 125A of the wireless transceiver 124A. Thereby, a separate memory module can be omitted which provides a simpler and lighter/smaller electronic device.

- 20 The second interface 124 may comprise a graphical user interface 128, such as a display, configured to display information, such as data determined by the processor 123.

- 25 The processor 123 is optionally configured to obtain, via the first interface 121, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair; determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter; determine, based on at least the first fitting parameter, the chloride concentration of the liquid; and data indicative of the chloride concentration via the second interface 124. To output the data via the second interface 124 may comprise to transmit a signal indicative of the data to an accessory device. To output the data via the second interface 124 may comprise to display a representation or visualization of the data in the graphical user interface 128 of the second interface 124.

- 30 The processor 101 may be optionally configured to perform any of the operations/actions disclosed in Figs. 5 and 6. The operations of the electronic device 120 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 123 or external memory, and are executed by the processor 123.

Furthermore, the operations of the electronic device 120 may be considered a method that the electronic device 120 is configured to carry out. Also, while the described functions and operations
5 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 125 and/or 125A 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 125 may include a non-volatile
10 memory for long term data storage and a volatile memory that functions as system memory for the processor 123. The memory 125, 125A may exchange data with the processor 123 over a data bus. Control lines and an address bus between the memory 125 and the processor 123 also may be present. The memory 125, 125A may be considered a non-transitory computer readable medium.

15 Fig. 11 illustrates a top view of an ostomy appliance 350 including a sensing system 300 for differentiating sweat and stomal output in the ostomy appliance. For example, the ostomy appliance and the sensing system may collectively be considered an ostomy system. The sensing system 300 may be the sensing system 200 discussed in relation to Fig. 2.

Whereas certain features, such as the first electrode pair 310 and the interface 314 thereof
20 (configured to connect to an electronic device 320, here shown de-coupled from the ostomy appliance), is described as being part of the sensing system 300, it is appreciated that the first electrode pair 310 and interface 314 may also be considered a part of the ostomy appliance as such, such as when the electrodes are arranged according to Fig. 11, in contact with an adhesive layer 302. However, for the purpose of describing the relationship between the first electrode pair
25 and the methods described herein (e.g., methods performed in the electronic device), the first electrode pair and the electronic device are referred to as part of the sensing system 300, which may then be embodied in an ostomy appliance 350, such as by including the first electrode pair in the ostomy appliance and allowing for the electronic device 320 to be coupled thereto.

The illustrated ostomy appliance 350 may be a sensor patch for attachment to the adhesive
30 surface of a base plate, thereby providing the base plate with the described functionalities of the sensor patch. The ostomy appliance 350 comprises the adhesive layer 302 for attachment of the ostomy appliance to the skin surface of a user. Thus, the adhesive layer may be considered both a part of the sensing system 300 and the ostomy appliance 350, and thus illustrates that the sensing system 300 may be adapted according to the intended use, such as by utilizing an existing reservoir

(adhesive layer of an ostomy appliance) and exposing the electrodes of the first electrode pair 310 to such adhesive layer 302. The figure may be considered a top view of the distal surface of a sensor patch, such that the adhesive layer 302 forms a proximal surface for attachment to the skin.

For example, the ostomy appliance 350 may be a base plate, or the ostomy appliance may be a sensor patch for attachment to a base plate, so as to provide a (generic) base plate with the functionalities described herein via the sensor patch. Irrespectively, the adhesive layer may be an adhesive layer of the base plate or the sensor patch. The adhesive layer may be a hydrogel configured to absorb at least a portion of a liquid, such as sweat and/or stomal output. In the figure, the adhesive layer 302 includes a stomal opening 352 configured to receive a stoma.

The sensing system 300 comprises a first electrode pair 310 including a first conductor 311 comprising a first Ag/AgCl electrode 311A and a second conductor 312 comprising a second Ag/AgCl electrode 312A, the first Ag/AgCl electrode 311A and second Ag/AgCl electrode 312A exposed to the adhesive layer 302. For example, the first Ag/AgCl electrode 311A and second Ag/AgCl electrode 312A are arranged on a distal side, such as on a distal surface, of the adhesive 302, or they may be arranged partly or fully embedded in the adhesive layer 302. For example, the adhesive layer 302 may form a sandwich structure on either side of the first Ag/AgCl electrode 311A and second Ag/AgCl electrode 312A.

For example, the Ag/AgCl electrodes 311A, 312A may, as illustrated, be arranged circularly around the stomal opening 352, so as to facilitate sensing in the entirety (or parts thereof) around the stoma. However, the layout of the electrodes is not limited to the illustrated embodiment and may take any layout/shape depending on the build of the ostomy appliance or desired sensing area/regions.

The conductors may extend radially away from the stomal opening, so as to connect the Ag/AgCl electrodes to the interface 314 configured to connect to the electronic device 320 of the sensing system. The conductors may be made from a conductive material different from the Ag/AgCl electrodes.

The sensing system 300 comprises an electronic device 320 comprising one or more processors, a first interface 321 configured to connect to the first electrode pair 310 (such as via the interface 314 of the first electrode pair 310), and a second interface 324; wherein the one or more processors are configured to:

- obtain, via the first interface 321, sensor data from the first electrode pair 310, the sensor data indicative of the impedance across the first electrode pair; 310
- determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;

- determine, based on at least the first fitting parameter, the chloride concentration of the liquid;
 - determine whether the liquid is sweat or stomal output, based on the chloride concentration, and
- 5 - output data indicative of the liquid being sweat or stomal output via the second interface 324.

Whereas the adhesive layer is configured to absorb at least a portion of a liquid, given the intended use of the ostomy appliance, the electronic device or the one or more processors thereof may be configured to assume that the liquid is either sweat or stomal output, as these are the liquids most
 10 commonly existing in the interface between the skin and the adhesive layer of the ostomy appliance. Thereby, based this pre-defined criteria/knowledge, the one or more processors may determine whether the liquid is sweat or stomal output when the chloride concentration has been determined, based on the knowledge that sweat has the highest concentration of chloride.

15 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
 20 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.

25 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
 30 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 may be appreciated that the term "based on", such as in the context of determining a second parameter based on a first parameter, is intended to mean that the second parameter is a function of the first parameter (e.g., the second parameter may be determined as a function of the first parameter). Further, the term "based on" may also be replaced by a wording explaining that the second parameter is indicative of, or representative of, the first parameter, since the second parameter is based on/is a function of/is derived from the first parameter. Such functionality may be employed by one or more processors.

It is to be noted that the words "comprising" and "including" do not necessarily exclude the presence of other elements or steps than those listed, and the words may be used interchangeably.

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

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.

It should further be noted that actions described as being performed by one or more processors (i.e., the one or more processors being configured to perform one or more actions) may be converted into steps of a method, such as a method performed in one or more processors. Further, it should be noted that one or more actions described as being performed by the one or more processors may be performed by two or more processors, wherein one processor forms part of an electronic device and another processor forms part of an auxiliary computing device.

Although particular 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.

Embodiments of the present disclosure are set out in the following items:

1. A system for determining chloride concentration in a liquid, the system comprising:
 - a reservoir for containing the liquid;
 - a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the reservoir; and
 - an electronic device comprising one or more processors, a first interface configured to connect to the first electrode pair, and a second interface; wherein the one or more processors are configured to:
 - obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair;
 - determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
 - determine, based on at least the first fitting parameter, the chloride concentration of the liquid; and
 - output data indicative of the chloride concentration via the second interface.
2. The system according to item 1, wherein the equivalent circuit model describes the impedance response of an electrochemical reaction occurring between the liquid and an Ag/AgCl interface at each of the Ag/AgCl electrodes.
3. The system according to any of items 1-2, wherein the equivalent circuit model is a predefined equivalent circuit model comprising maximally five circuit components.
4. The system according to any of items 1-3, wherein a circuit component of the equivalent circuit model is the Warburg diffusion element.
5. The system according to any of items 1-4, wherein the first fitting parameter is associated with a diffusion process of ions within the AgCl layer of the Ag/AgCl electrodes.

6. The system according to any of items 1-5, wherein the one or more processors are configured to determine maximally five fitting parameters.
- 5 7. The system according to any of items 1-6, wherein the reservoir is a hydrogel configured to absorb at least a portion of the liquid.
8. The system according to item 7, wherein the hydrogel comprises hydroxyethyl cellulose (HEC).
- 10 9. The system according to any of items 1-8, wherein to determine, based on at least the first fitting parameter, the chloride concentration of the liquid comprises to input the first fitting parameter to a function, look-up table, neural network, or model, such as a machine-learning model.
- 15 10. The system according to item 9, wherein the function, look-up table, neural network, or model comprises one or more calibration curves including a first calibration curve indicative of the first fitting parameter as a function of chloride concentration of the liquid.
- 20 11. The system according to any of items 1-10, wherein the sensor data is representative of an impedance spectrum.
12. The system according to any of items 1-11, wherein the impedance across the first electrode pair is measured at two or more frequencies in the range from 0.1 Hz to 100 kHz.
- 25 13. A method, performed in an electronic device, of determining chloride concentration in a liquid, the method comprising the steps of:
- obtaining sensor data from a first electrode pair associated with a reservoir containing the liquid, the first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being indicative of the impedance across the first electrode pair;
 - 30 - determining, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
 - determining, based on at least the first fitting parameter, the chloride concentration of the liquid; and
 - 35 - outputting data indicative of the chloride concentration.

14. The method according to item 13, wherein the electronic device comprises one or more processors, a first interface configured to connect to the first electrode pair, and a second interface, and wherein the sensor data is obtained via the first interface, and wherein data is outputted via the second interface.

15. A medical device comprising a system according to any of items 1-12.

16. The medical device according to item 15, wherein the medical device comprises an adhesive layer for attachment of the medical device to the skin surface of a user, and wherein the adhesive layer is the reservoir of the system.

17. The medical device according to any of items 15-16, wherein the medical device is one of an ostomy appliance, a wound dressing, a catheter, and a sweat sensor dressing.

18. An ostomy system for differentiating sweat and stomal output, the ostomy system comprising an ostomy appliance and an electronic device configured to electrically and/or mechanically couple to the ostomy appliance, the ostomy appliance comprising an adhesive layer for attachment of the ostomy appliance to the skin surface of a user and an electrode assembly, the adhesive layer being a hydrogel configured to absorb at least a portion of a liquid, and the electrode assembly comprising:

- a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the adhesive layer; and
- an interface configured to electrically and/or mechanically couple the electrode assembly to the electronic device;

the electronic device comprising one or more processors, a first interface configured to electrically and/or mechanically couple to the interface of the electrode assembly, and a second interface; wherein the one or more processors are configured to:

- obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair;
- determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
- determine, based on at least the first fitting parameter, the chloride concentration of the liquid;

- determine, based on the chloride concentration, whether the liquid is sweat or stomal output; and
- output data indicative of the liquid being sweat or stomal output via the second interface.

5

List of references

	50	Equivalent circuit model
	50'	Modified Randles circuit
	100	System
10	102	Reservoir
	102'	Walls of reservoir
	102''	Base of reservoir
	104	Liquid/electrolyte solution
	110	First electrode pair
15	111	First conductor
	111A	First Ag/AgCl electrode
	112	Second conductor
	112A	Second Ag/AgCl electrode
	120	Electronic device
20	121	First interface
	121A, ..., 121F	Terminals of first interface
	122	Electronic device housing
	123	Processor
	124	Second interface
25	124A	Wireless transceiver
	124B	Antenna
	125	Memory
	125A	Memory
	126	Loudspeaker
30	127	Haptic feedback element
	128	Graphical user interface
	200	System
	202	Reservoir
	204	Liquid
35	300	Sensing system

	302	Adhesive layer
	310	First electrode pair
	311	First conductor
	311A	First Ag/AgCl electrode
5	312	Second conductor
	312A	Second Ag/AgCl electrode
	314	Interface of first electrode pair 310
	320	Electronic device
	321	First interface
10	324	Second interface
	350	Ostomy appliance
	352	Stomal opening
	1000	Method of determining chloride concentration in a liquid
	1002	Obtaining sensor data
15	1002A	Applying a voltage across the first electrode pair
	1002B	Measuring the impedance of the circuit
	1004	Determining, based on the sensor data, one or more fitting parameters
	1004A	Fitting the sensor data to a predefined equivalent circuit model
	1006	Determining the chloride concentration of the liquid
20	1006A	Inputting the first fitting parameter to a function (...)
	1006B	Compare the first fitting parameter to known calibration values or calibration curves
	1006C	Determine the chloride concentration of the liquid
	1008	Outputting data indicative of the chloride concentration
	1008A	Transmitting the data to an accessory device
25	1008B	Displaying a visualization of the data
	2000	Method of determining chloride concentration and total ion concentration in a liquid
	2002	Obtaining sensor data
	2002A	Applying a voltage across the first electrode pair
	2002B	Measuring the impedance of the circuit
30	2004	Determining, based on the sensor data, two or more fitting parameters
	2004A	Fitting the sensor data to a predefined equivalent circuit model
	2006	Determining the chloride concentration of the liquid
	2006A	Inputting the first fitting parameter to a function (...)
	2006B	Compare the first fitting parameter to known calibration values or calibration curves
35	2006C	Determine the chloride concentration of the liquid
	2007	Determining the total ion concentration of the liquid

- 2007A Inputting second fitting parameter to a function (...)
- 2007B Compare second fitting parameter to known calibration values or calibration curves
- 2007C Determine the total ion concentration of the liquid
- 2008 Outputting data indicative of the chloride- and total ion concentration
- 5 2008A Transmitting the data to an accessory device
- 2008B Displaying a visualization of the data

Claims

1. An ostomy appliance comprising a sensing system for differentiating sweat and stomal output in the ostomy appliance, the ostomy appliance comprising an adhesive layer for attachment of the ostomy appliance to the skin surface of a user, the adhesive layer being
5 a hydrogel configured to absorb at least a portion of a liquid;
the sensing system comprising:
 - a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the adhesive layer; and
 - 10 - an electronic device comprising one or more processors, a first interface configured to connect to the first electrode pair, and a second interface; wherein the one or more processors are configured to:
 - obtain, via the first interface, sensor data from the first electrode pair, the sensor data indicative of the impedance across the first electrode pair;
 - 15 - determine, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
 - determine, based on at least the first fitting parameter, the chloride concentration of the liquid;
 - 20 - determine, based on the chloride concentration, whether the liquid is sweat or stomal output; and
 - output data indicative of the liquid being sweat or stomal output via the second interface.
- 25 2. The ostomy appliance according to claim 1, wherein the equivalent circuit model describes the impedance response of an electrochemical reaction occurring between the liquid and an Ag/AgCl interface at each of the Ag/AgCl electrodes.
3. The ostomy appliance according to any of claims 1-2, wherein the equivalent circuit model
30 is a predefined equivalent circuit model comprising maximally five circuit components.
4. The ostomy appliance according to any of claims 1-3, wherein a circuit component of the equivalent circuit model is the Warburg diffusion element.
- 35 5. The ostomy appliance according to any of claims 1-4, wherein the first fitting parameter is associated with a diffusion process of ions within the AgCl layer of the Ag/AgCl electrodes.

6. The ostomy appliance according to any of claims 1-5, wherein the one or more processors are configured to determine maximally five fitting parameters.
- 5 7. The ostomy appliance according to any of claims 1-6, wherein the adhesive layer comprises hydroxyethyl cellulose (HEC).
8. The ostomy appliance according to any of claims 1-7, wherein to determine, based on at least the first fitting parameter, the chloride concentration of the liquid comprises to input
10 the first fitting parameter to a function, look-up table, neural network, or model, such as a machine-learning model.
9. The ostomy appliance according to claim 8, wherein the function, look-up table, neural network, or model comprises one or more calibration curves including a first calibration
15 curve indicative of the first fitting parameter as a function of chloride concentration of the liquid.
10. The ostomy appliance according to any of claims 1-9, wherein the sensor data is representative of an impedance spectrum.
20
11. The ostomy appliance according to any of claims 1-10, wherein the impedance across the first electrode pair is measured at two or more frequencies in the range from 0.1 Hz to 100 kHz.
- 25 12. The ostomy appliance according to any of claims 1-11, wherein to determine, based on the chloride concentration, whether the liquid is sweat or stomal output, comprises to input the chloride concentration to a function, look-up table, neural network, or model, such as a machine-learning model, configured to determine whether the liquid is sweat or stomal output.
- 30
13. A method, performed in an electronic device, for differentiating sweat and stomal output in an ostomy appliance comprising an adhesive layer for attachment of the ostomy appliance to the skin surface of a user, the adhesive layer being a hydrogel configured to absorb at least a portion of a liquid, the method comprising the steps of:
- 35 - obtaining sensor data from a first electrode pair associated with the adhesive layer containing the liquid, the first electrode pair including a first conductor comprising a first

Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the sensor data being indicative of the impedance across the first electrode pair;

- determining, based on the sensor data, one or more fitting parameters of an equivalent circuit model, the one or more fitting parameters including a first fitting parameter;
- determining, based on at least the first fitting parameter, the chloride concentration of the liquid;
- determining, based on the chloride concentration, whether the liquid is sweat or stomal output; and
- outputting data indicative of the liquid being either sweat or stomal output.

14. The method according to claim 13, wherein the electronic device comprises one or more processors, a first interface configured to connect to the first electrode pair, and a second interface, and wherein the sensor data is obtained via the first interface, and wherein data is outputted via the second interface.

15. An ostomy appliance including a base plate or a sensor patch and an electrode assembly, the base plate or sensor patch comprising an adhesive layer configured to absorb liquid, the electrode assembly comprising:

- at least a first electrode pair including a first conductor comprising a first Ag/AgCl electrode and a second conductor comprising a second Ag/AgCl electrode, the first Ag/AgCl electrode and second Ag/AgCl electrode exposed to the adhesive layer; and
- an interface configured to connect to an electronic device.

1/11

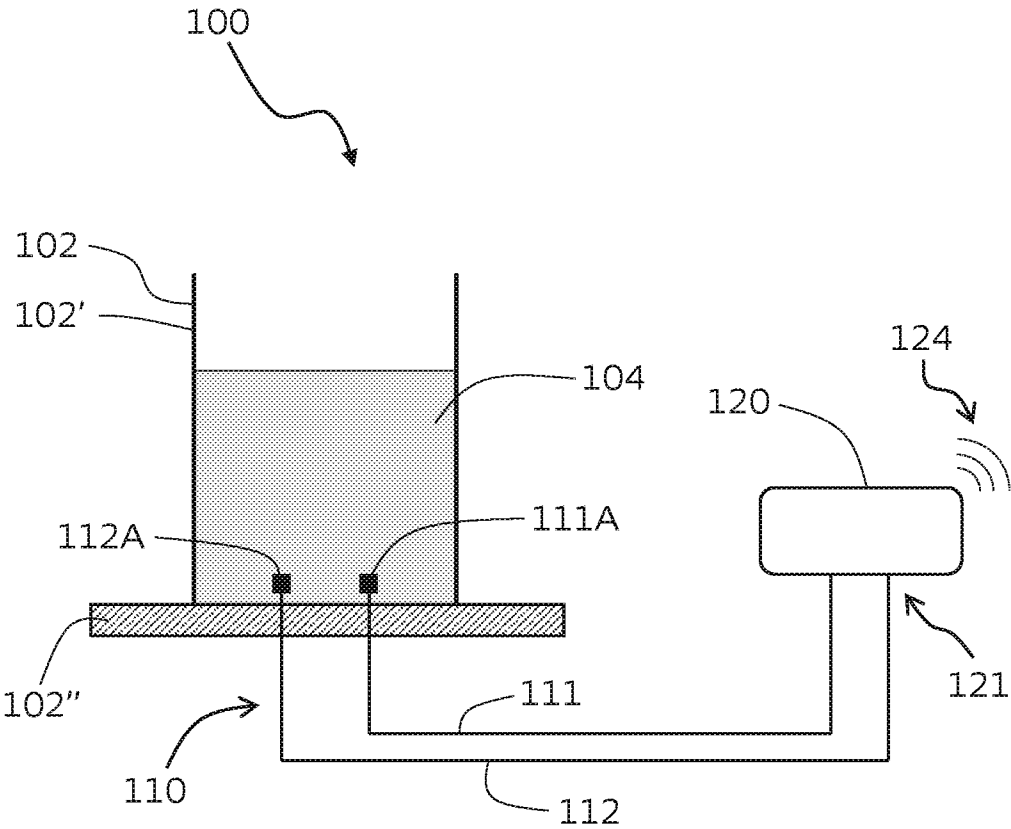


Fig. 1

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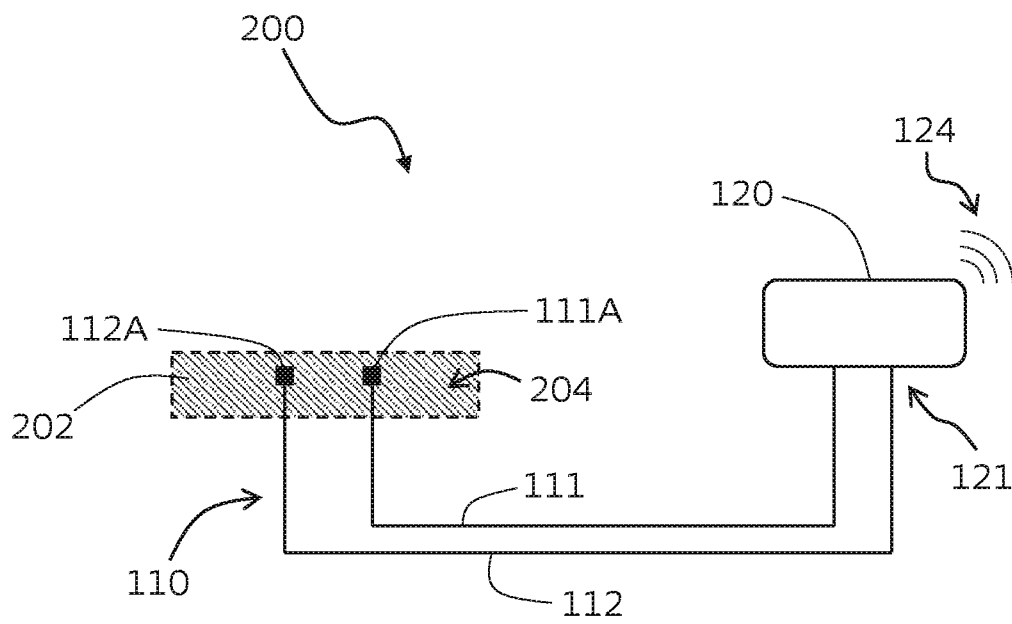


Fig. 2

3/11

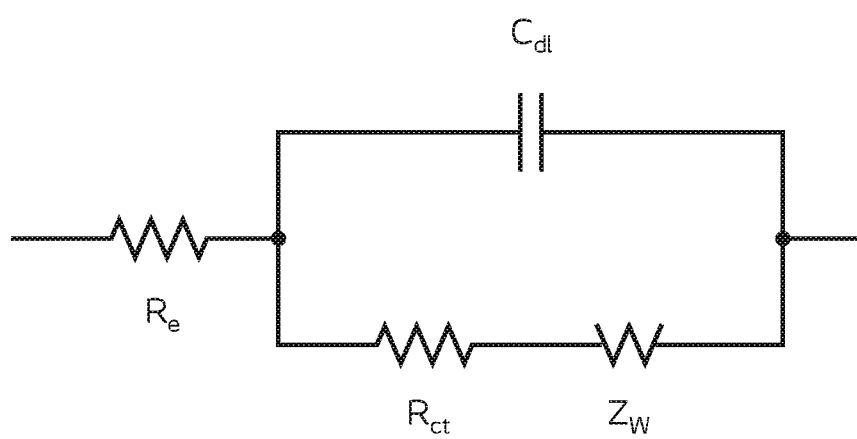


Fig. 3

4/11

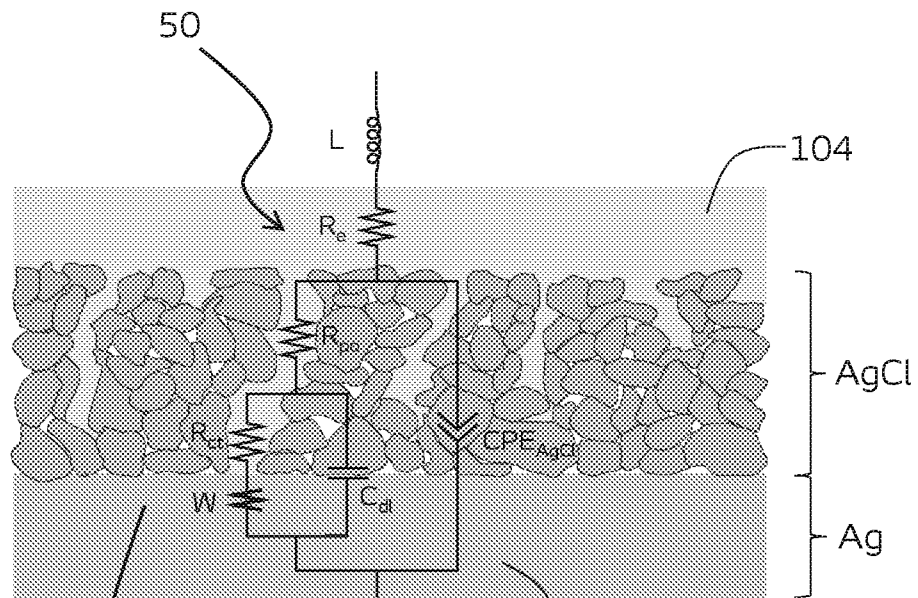


Fig. 4A

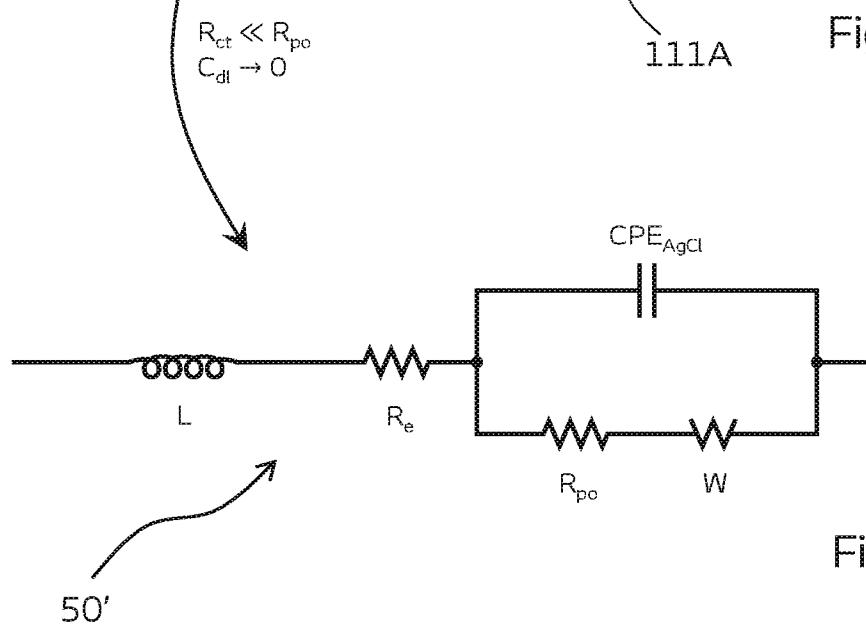


Fig. 4B

5/11

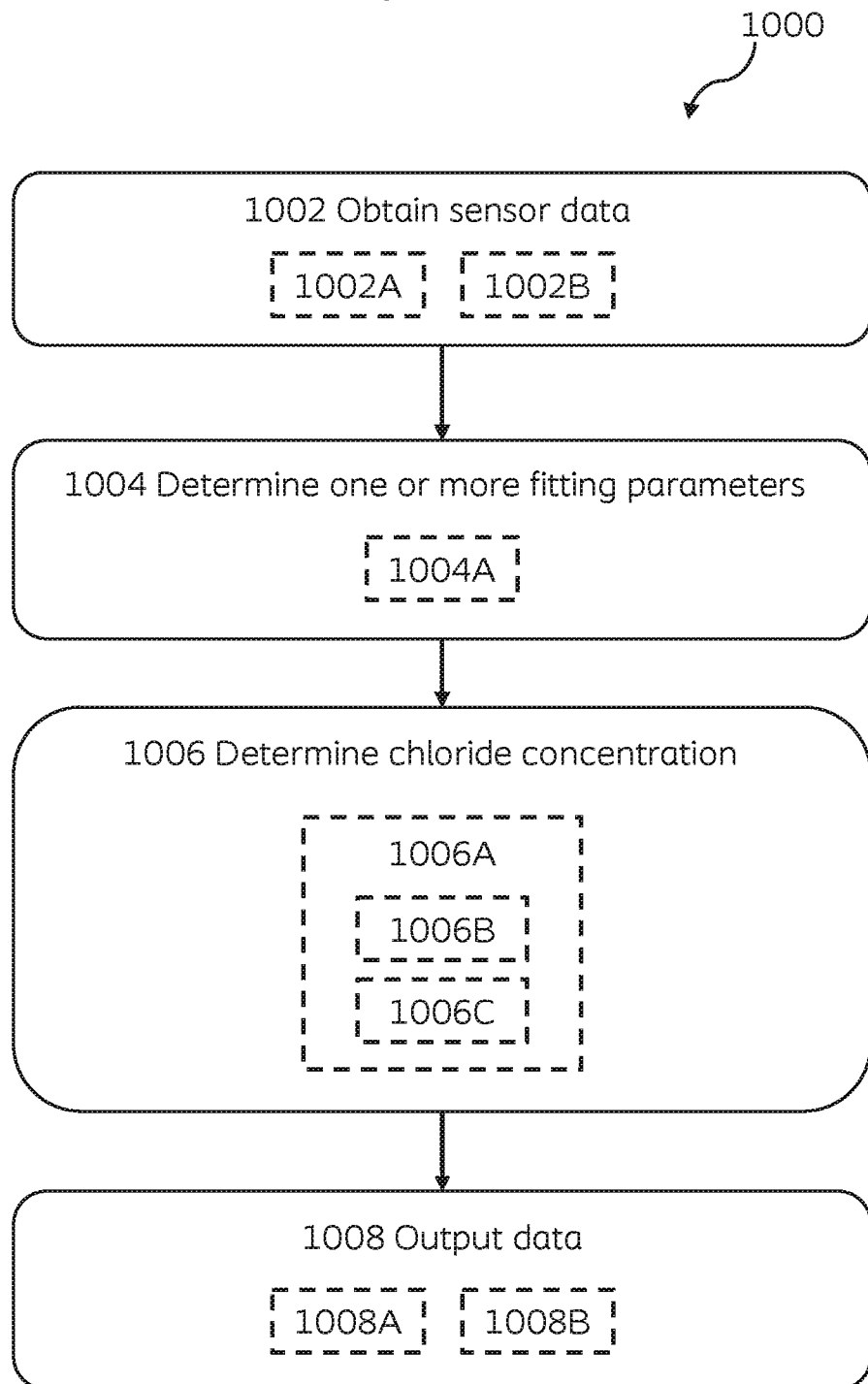


Fig. 5

6/11

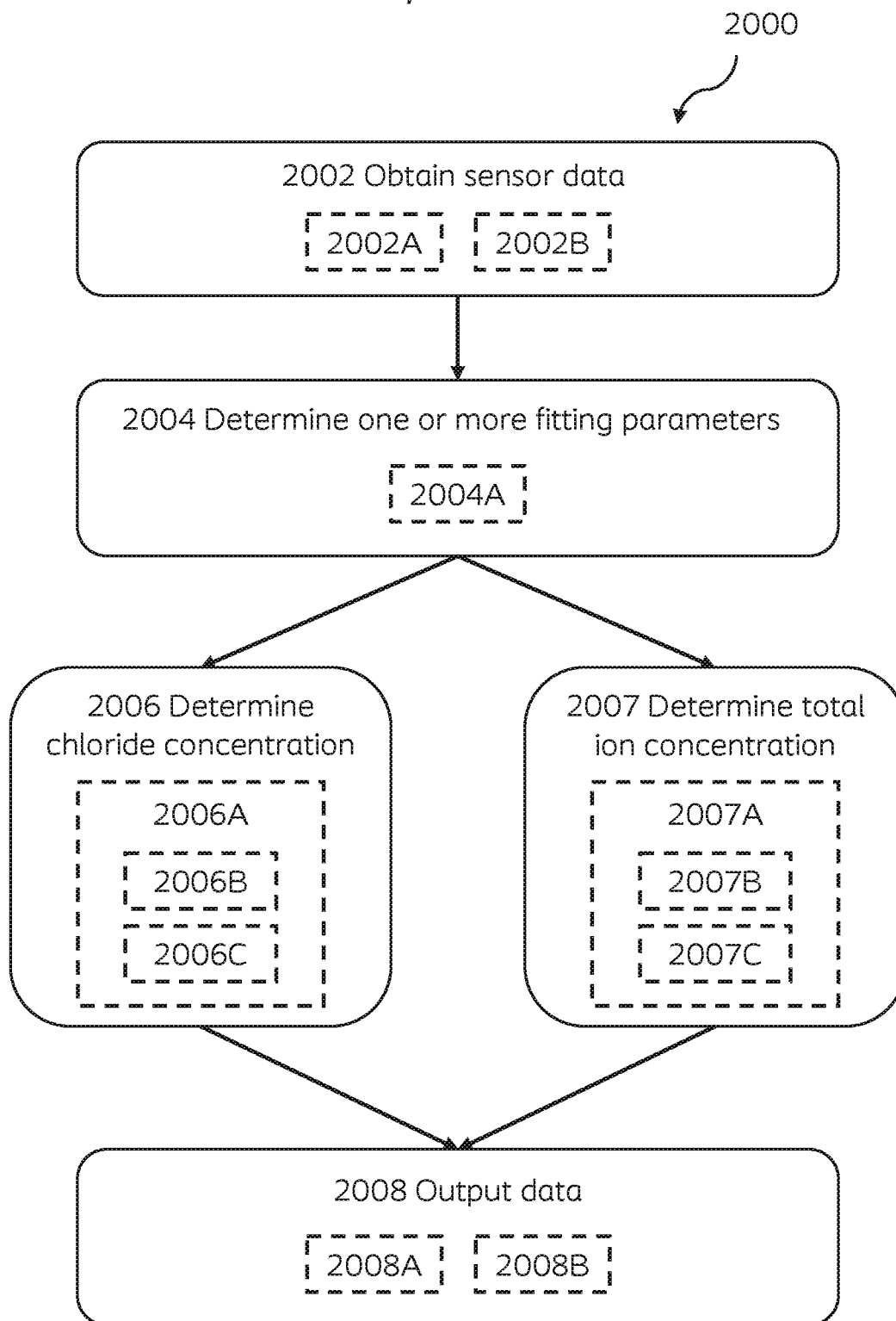


Fig. 6

7/11

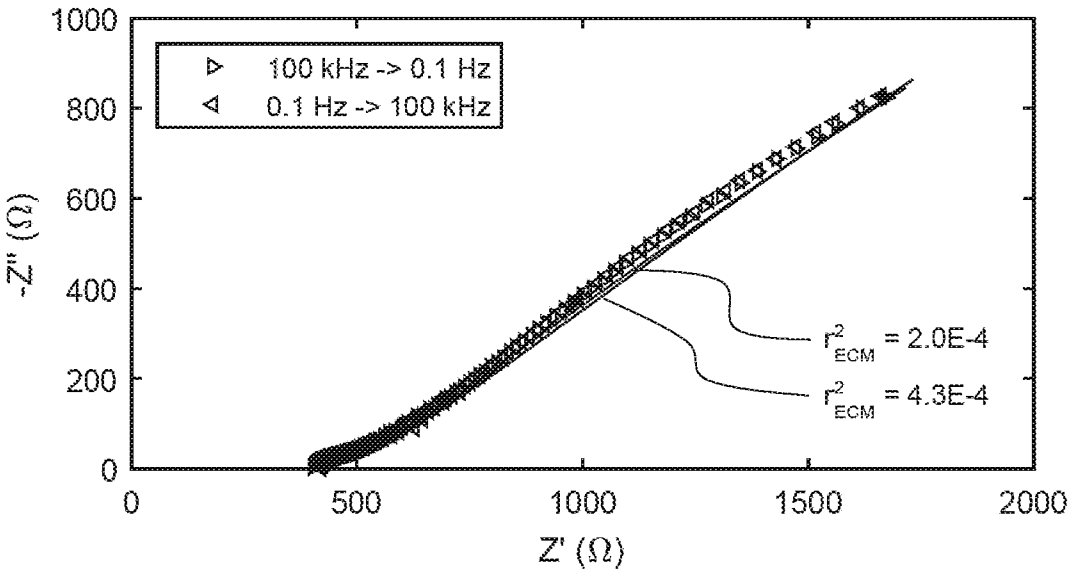


Fig. 7

8/11

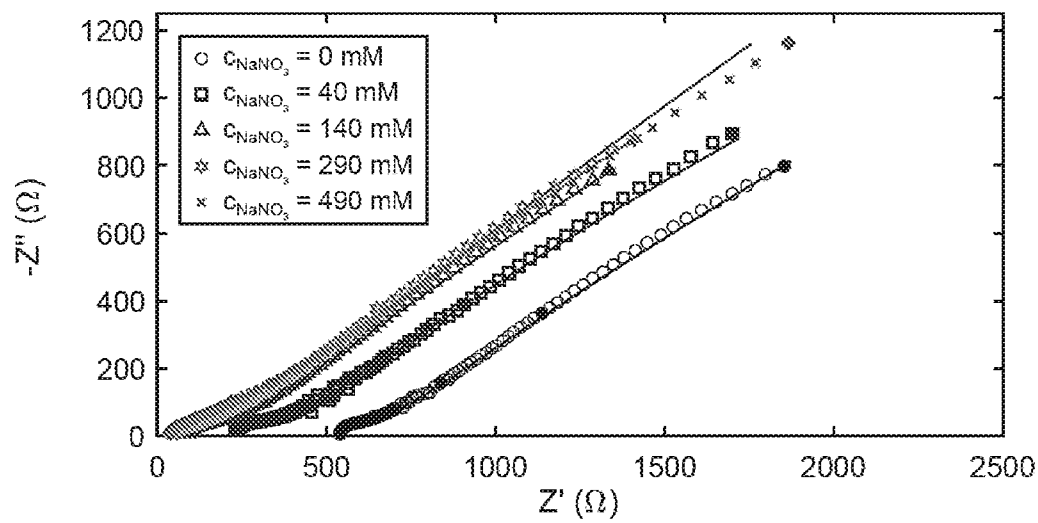


Fig. 8A

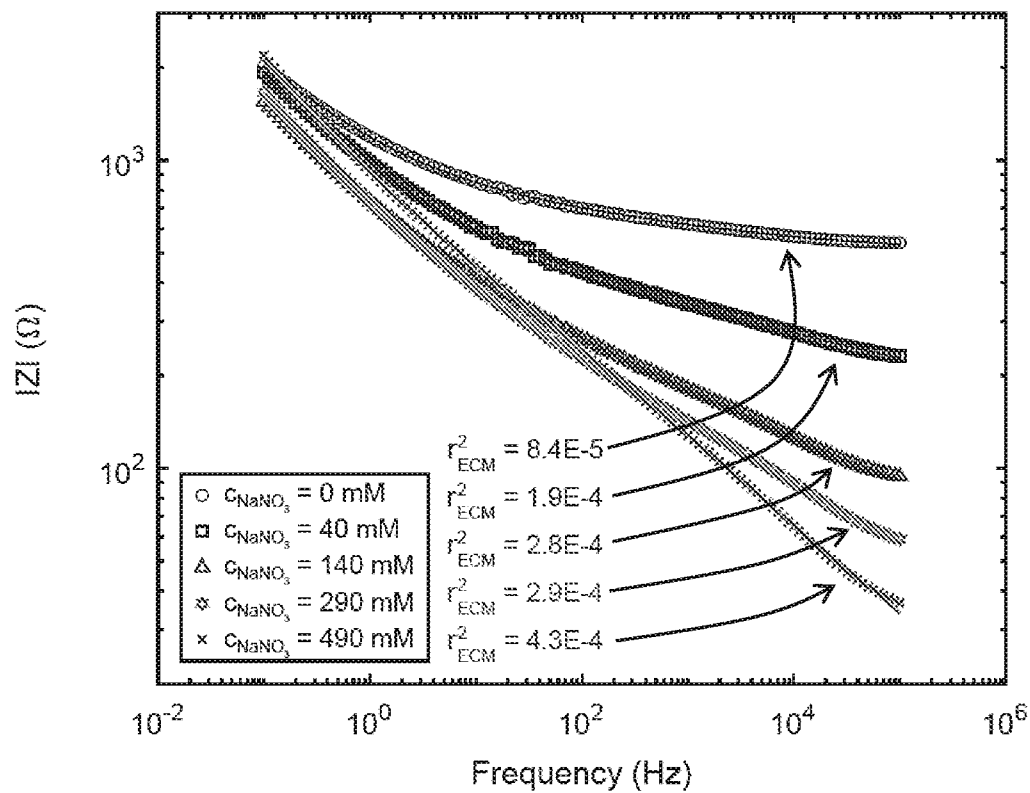


Fig. 8B

9/11

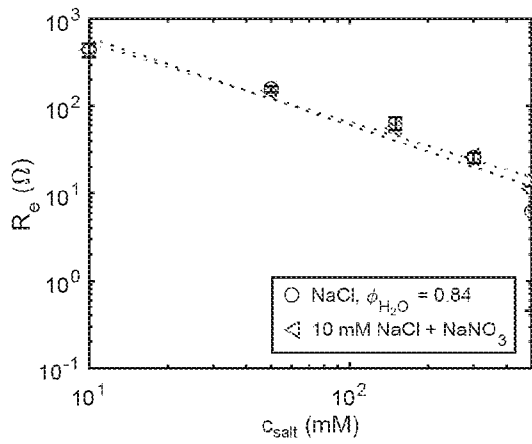


Fig. 9A

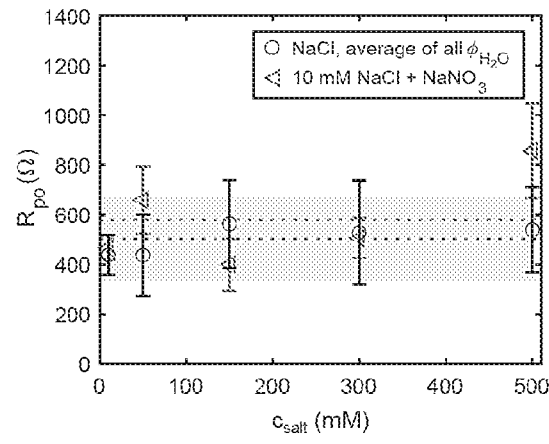


Fig. 9B

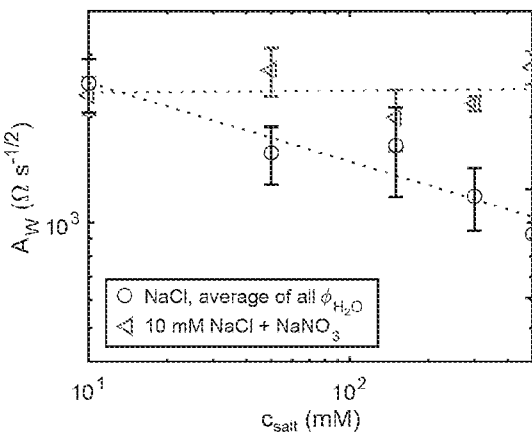


Fig. 9C

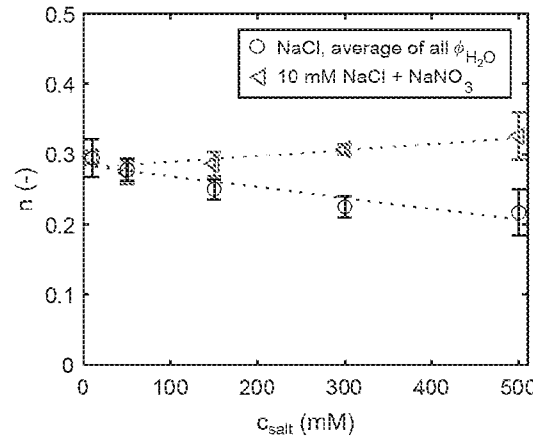


Fig. 9D

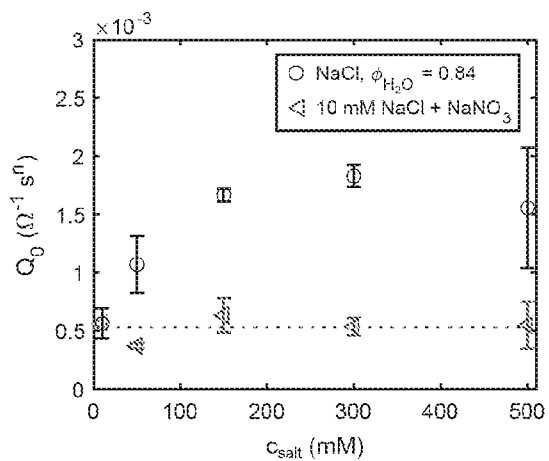


Fig. 9E

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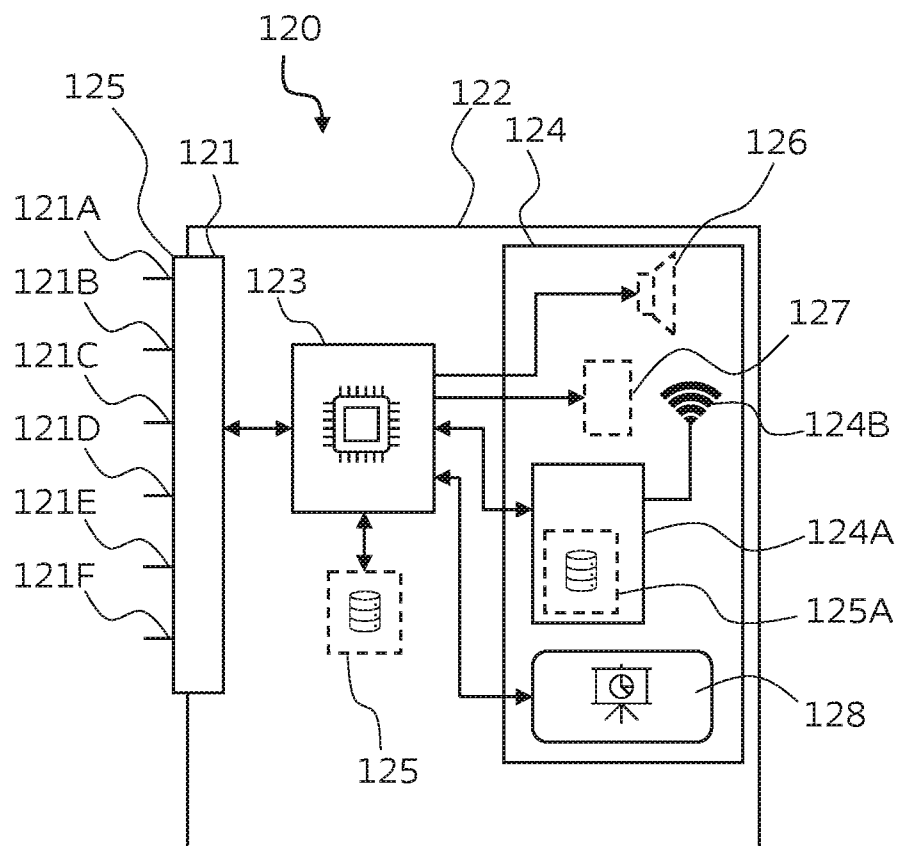


Fig. 10

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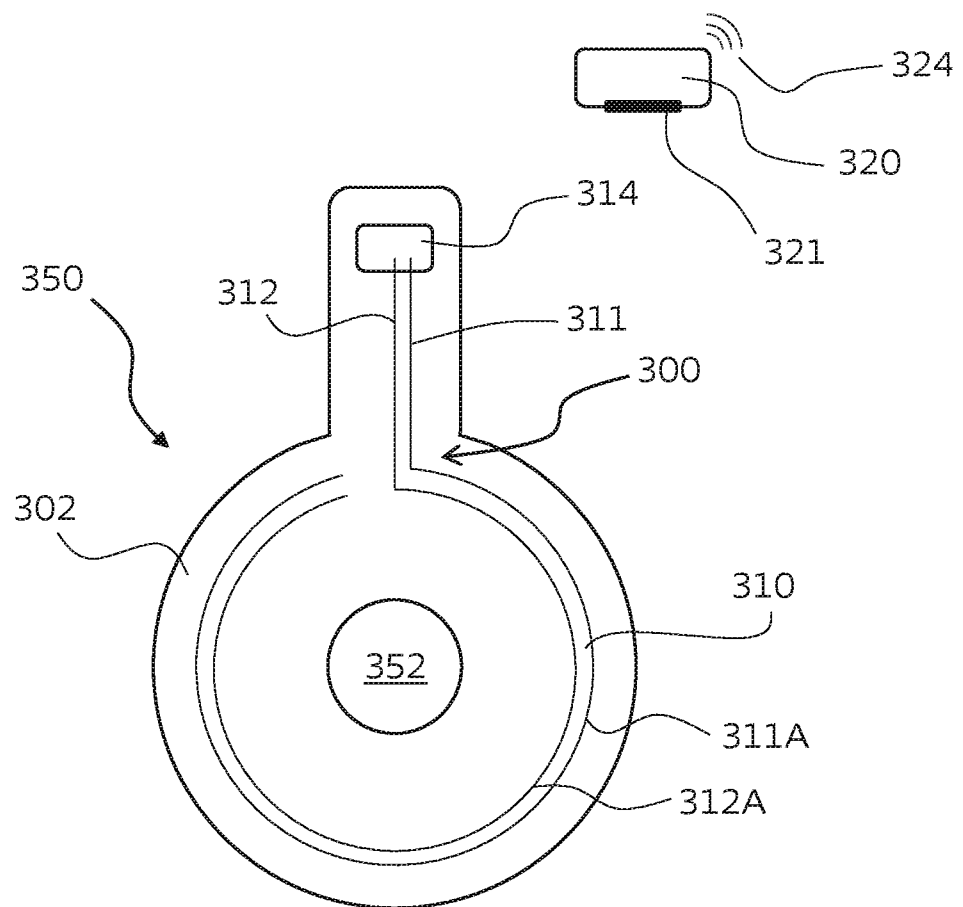


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2024/050139

A. CLASSIFICATION OF SUBJECT MATTER		
INV.	G01N27/02	A61B5/145
	G01N33/487	A61B5/00
	A61F5/443	
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 A61B A61F		
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.
A	JP 2015 224904 A (UNIV OKAYAMA) 14 December 2015 (2015-12-14) paragraphs [0009], [0018], [0022], [0023], [0029] - [0031] figures 1,2,5,6,7 ----- -/-	1 - 15
☒ Further documents are listed in the continuation of Box C.		
☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
29 August 2024		06/09/2024
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Kratz, Dorothee

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International application No

PCT/DK2024/050139

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