

- (51) International Patent Classification:  
A61F 5/445 (2006.01) A61F 5/44 (2006.01)

(21) International Application Number:  
PCT/US2024/036006

(22) International Filing Date:  
28 June 2024 (28.06.2024)

(25) Filing Language:  
English

(26) Publication Language:  
English

(30) Priority Data:  
63/510,653 28 June 2023 (28.06.2023) US

(71) Applicant: **HOLLISTER INCORPORATED** [US/US];  
2000 Hollister Drive, Libertyville, Illinois 60048 (US).

(72) Inventors: **LATTANZI, Lauren M.**; 2000 Hollister Drive,  
Libertyville, Illinois 60048 (US). **LIDDLE, Scott E.**; 2000  
Hollister Drive, Libertyville, Illinois 60048 (US).
- (74) Agent: **ASARIA, Riyazhassan M.**; 2045 W. Grand Ave Ste  
B, PMB 84396, Chicago, Illinois 60612-1577 (US).

(81) Designated States (unless otherwise indicated, for every  
kind of national protection available): AE, AG, AL, AM,  
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,  
CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM,  
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,  
HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG,  
KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY,  
MA, MD, MG, MK, MN, MU, MW, MX, MY, MZ, NA,  
NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO,  
RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH,  
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,  
ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every  
kind of regional protection available): ARIPO (BW, CV,  
GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, SD, SL, ST,  
SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ,  
RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ,  
DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT,

(54) Title: SYSTEM AND METHODS FOR DETECTING MOISTURE AND LEAKAGE

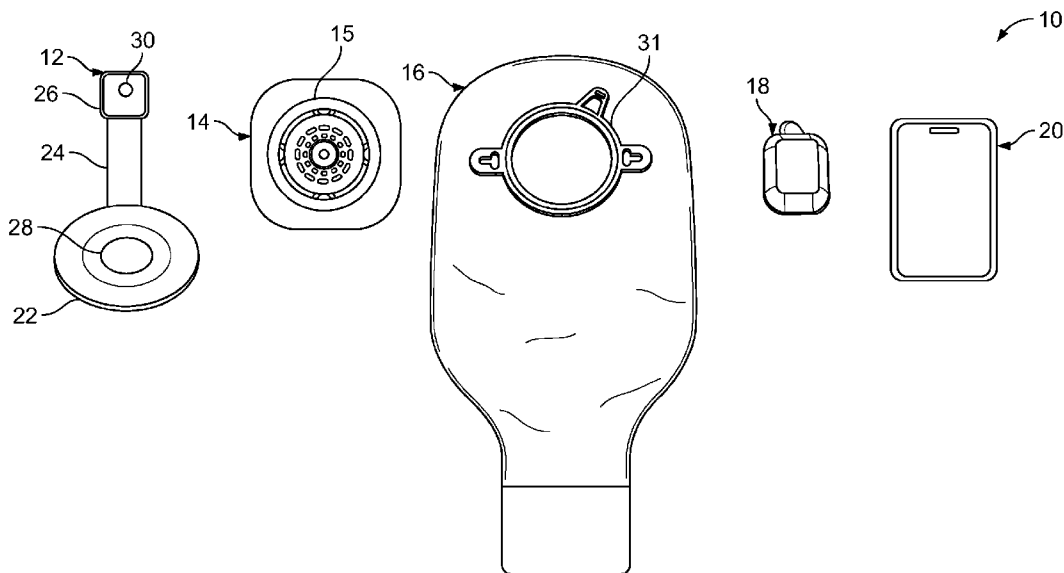


FIG. 1

(57) Abstract: A method for determining ostomy fluid leak is detected. The method can include a wearable device obtaining channel data of at least one channel. The wearable device may determine that the channel data is a leak value. The wearable device may determine that the at least one channel is in an activating state based on a previously recorded state and the leak value. The wearable device may determine that the at least one channel is in an active state based on the activating state and a time threshold value. The active state may include an active leak state, an active moisture state, and a prompt state. The wearable device may output the active state.

LU, LV, MC, ME, MK, MT, NL, NO, PL, PT, RO, RS, SE,  
SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN,  
GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published:**

— *with international search report (Art. 21(3))*

## SYSTEM AND METHODS FOR DETECTING MOISTURE AND LEAKAGE

### BACKGROUND

[0001] This disclosure is related to an ostomy leakage detection system. More particularly, the present disclosure pertains to systems and methods for detecting moisture and leakage in an ostomy system.

[0002] An ostomy pouch system typically includes a pouch formed from opposing sidewalls defining an internal collection area, an inlet opening for receiving a stoma, and an ostomy appliance for attaching the pouch to a user. The ostomy appliance may include, for example, an ostomy barrier of a one-piece pouch system, which is attached to one of the pouch sidewalls proximate an inlet opening, or a faceplate for a two-piece pouch system configured to releasably engage a pouch, and a barrier ring. The ostomy appliance may include a skin barrier material for adhering to and sealing against a user's peristomal skin surrounding the stoma.

[0003] The ostomy appliance may be susceptible to ostomy effluent leakage, and the seal formed between the skin barrier material and the user may weaken. Oftentimes, the user may be unaware of, or cannot easily assess, an extent of weakening in the seal. Thus, the user may not become aware of a weakened seal, and consequently, the ostomy effluent may leak through to an exterior of the ostomy appliance.

[0004] Leakage detection methods may be used to determine leakage in ostomy appliances. However, these methods may provide false detection of moisture when a user is in wet environments rather than when there is a leak. For example, false detection may occur when a user is showering and moisture penetrates internal sensors.

[0005] Accordingly, it is desirable to provide an improved leakage detection system.

**BRIEF SUMMARY**

**[0006]** A system and method for detecting moisture and leakage in an ostomy system is provided according to various embodiments.

**[0007]** In one aspect, a method for determining ostomy fluid leak is detected is provided. The method may include a wearable device obtaining channel data of at least one channel. The wearable device may determine that the channel data is a leak value. The wearable device may also determine that the at least one channel is in an activating state based on a previously recorded state and the leak value. The wearable device may further determine that the at least one channel is in an active state based on the activating state and a time threshold value. The active state may include an active leak state, an active moisture state, and a prompt state. The wearable device may also output the active state.

**[0008]** In an embodiment, the wearable device may determine that the channel data has a value greater than a low threshold value. The wearable device may also determine that the channel data has a value less than a resistance threshold value.

**[0009]** In an embodiment, the wearable device may determine at least one channel is an active state by determining a first and a second channel are in active leak states and the first and second channels are adjacent channels.

**[0010]** In an embodiment, the resistance threshold value may be associated with a resistance of 1M ohms.

**[0011]** In an embodiment, the low threshold value may be associated with a resistance of 30k ohms.

**[0012]** In an embodiment, the wearable device may obtain a previously recorded state. The

wearable device may also determine that the previously recorded state is a normal state. The wearable device may further determine that the leak value was detected for a time greater than or equal to a leak time threshold.

**[0013]** In an embodiment, the leak time threshold may include 15 minutes.

**[0014]** In an embodiment, the wearable device may obtain a leak scan delay timer. The leak scan delay timer may be started at when the at least one channel is in the activating state. The wearable device may also determine that the leak scan delay timer is greater than or equal to the time threshold value. The wearable device may further determine that the active state is the active leak state, wherein the active leak state may include an ostomy fluid leak.

**[0015]** In an embodiment, the time threshold value may be 1 hour.

**[0016]** In an embodiment, the channel is associated with a sensor associated with a barrier appliance and the wearable device may determine the barrier appliance has been replaced.

**[0017]** In an embodiment, the wearable device may obtain a leak scan delay timer. The leak scan delay timer may be started at when the at least one channel is in the activating state. The wearable device may also determine that the leak scan delay timer stops in a time less than the time threshold value. The wearable device may further determine that the active state is the active moisture state, wherein the active moisture state may include moisture detected in an ostomy.

**[0018]** In an embodiment, the time threshold value may be 30 minutes.

**[0019]** In an embodiment, the wearable device may obtain a leak scan delay timer. The leak scan delay timer may be started at when the at least one channel is in the activating state. The wearable device may also determine that the leak scan delay timer stops in a time between a first and second time threshold value. The wearable device may further determine that the active state is a prompt state. The prompt state may include outputting a sensor state reevaluation. In an

embodiment, the first time threshold value may include 30 minutes and the second time threshold value is 1 hour.

**[0020]** In an embodiment, the wearable device may obtain an overall sensor level. The wearable device may also determine that the overall sensor level is greater than or equal to the channel data. The wearable device may further that the at least one channel is in the active leak state.

**[0021]** In an embodiment, the wearable device may filter channel data of at least one channel. The filtering may include a median filter that filters out noise and prevent false leakage detection. The wearable device may also determine that the channel data is a leak value.

**[0022]** In an embodiment, the wearable device may determine that the channel data is a leak value.

**[0023]** In a second aspect, a computing device for displaying leakage information for an ostomy leakage detection system is provided. The computing device may include one or more processors, a non-transitory computer-readable memory storing instructions executable by the one or more processors. The one or more processors may be configured to obtain channel data of at least one channel. The one or more processors may further be configured to determine that the channel data is a leak value. The one or more processors may further be configured to determine that the at least one channel is in an activating state based on a previously recorded state and the leak value. The one or more processors may further be configured to determine that the at least one channel is in an active state based on the activating state and a time threshold value. The active state may include an active leak state, an active moisture state, and a prompt state. The one or more processors may further be configured to output the active state.

**[0024]** In an embodiment, the one or more processors may further be configured to determine

that the channel data has a value greater than a low threshold value. The one or more processors may also determine that the channel data has a value less than a resistance threshold value.

**[0025]** In an embodiment, the resistance threshold value may be 1M ohms and the low threshold value is 30k ohms.

**[0026]** In an embodiment, the one or more processors may further be configured to obtain a previously recorded state. The one or more processors may also determine that the previously recorded state is a normal state. The one or more processors may also determine that the leak value was detected for a time greater than or equal to a leak time threshold.

**[0027]** In a third aspect, a non-transitory computer-readable storage medium storing a plurality of programs for execution by a computing device having one or more processors is provided. When the plurality of programs, when executed by the one or more processors, cause the computing device to perform obtaining channel data of at least one channel. The plurality of programs may additionally further cause the computing device to perform determining that the channel data is a leak value. The plurality of programs may additionally further cause the computing device to perform determining that the at least one channel is in an activating state based on a previously recorded state and the leak value. The plurality of programs may additionally further cause the computing device to perform determining that the at least one channel is in an active state based on the activating state and a time threshold value. The active state may include an active leak state, an active moisture state, and a prompt state. The plurality of programs may additionally further cause the computing device to perform outputting the active state.

**[0028]** In an embodiment, the plurality of programs may additionally further cause the computing device to perform determining that the channel data has a value greater than a low threshold value. The plurality of programs may additionally further cause the computing device to

perform determining that the channel data has a value less than a resistance threshold value.

[0029] In an embodiment, the plurality of programs may additionally further cause the computing device to perform obtaining a previously recorded state. The plurality of programs may additionally further cause the computing device determining that the previously recorded state is a normal state. The plurality of programs may additionally further cause the computing device determining that the leak value was detected for a time greater than or equal to a leak time threshold.

[0030] The foregoing general description and the following detailed description are examples only and are not restrictive of the present disclosure.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0031] The benefits and advantages of the present embodiments will become more readily apparent to those of ordinary skill in the relevant art after reviewing the following detailed description and accompanying drawings, wherein:

[0032] FIG. 1 is a schematic view of an ostomy system, according to an embodiment.

[0033] FIG. 2 is a front view of an ostomy system attached to a user, according to an embodiment.

[0034] FIG. 3A is a body-side elevation view of a sensor circuit, according to an embodiment.

[0035] FIG. 3B is an enlarged partial body-side elevation view of a sensor circuit, according to an embodiment.

[0036] FIG. 4 is a flow diagram illustrating an algorithm for detecting an ostomy fluid leak, according to an embodiment.

[0037] FIG. 5 is a flow diagram illustrating a check system flags process for detecting an

ostomy fluid leak.

**[0038]** FIG. 6A is a flow diagram illustrating a check system timers process for detecting an ostomy fluid leak.

**[0039]** FIG. 6B is a continuation of the flow diagram in FIG. 6A.

**[0040]** FIG. 7A is a flow diagram illustrating a channel preprocessing process for detecting an ostomy fluid leak.

**[0041]** FIG. 7B is a continuation of the flow diagram in FIG. 7A.

**[0042]** FIG. 8 is a flow diagram illustrating an error/low maintenance process for detecting an ostomy fluid leak.

**[0043]** FIG. 9 is a flow diagram illustrating a normal process for detecting an ostomy fluid leak.

**[0044]** FIG. 10 is a flow diagram illustrating an activating process for detecting an ostomy fluid leak.

**[0045]** FIG. 11A is a flow diagram illustrating an activating process for detecting an ostomy fluid leak.

**[0046]** FIG. 11B is a continuation of the flow diagram in FIG. 11A.

**[0047]** FIG. 12 is a flow diagram illustrating a leak state process for detecting an ostomy fluid leak.

**[0048]** FIG. 13 is a flow diagram illustrating a moisture active process for detecting an ostomy fluid leak.

**[0049]** FIG. 14 is a flow diagram illustrating an error/low check process for detecting an ostomy fluid leak.

**[0050]** FIG. 15 is a diagram illustrating a channel check process for detecting an ostomy fluid

leak.

**[0051]** FIG. 16 is a flow diagram illustrating a leak scan process for detecting an ostomy fluid leak.

**[0052]** FIG. 17 is a flow diagram illustrating a timeout scan process for detecting an ostomy fluid leak.

**[0053]** FIG. 18 is a flow diagram illustrating a method for determining ostomy fluid leak, according to an embodiment.

**[0054]** FIG. 19 is a flow diagram illustrating a method for determining ostomy fluid leak, according to another embodiment.

**[0055]** FIG. 20 is a schematic diagram of a sensing region of a sensing accessory of the ostomy system.

**[0056]** FIG. 21 is flow diagram of steps undertaken to determine the presence of leakage at various sensor channels of the ostomy system.

**[0057]** FIGS. 22 and 22A are flow diagrams of steps undertaken by the ostomy system to determine if a barrier of the ostomy system may have been changed.

**[0058]** FIG. 23 is a schematic block illustration of a computing environment, according to an embodiment.

## **DETAILED DESCRIPTION**

**[0059]** While the present disclosure is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described presently preferred embodiments with the understanding that the present disclosure is to be considered an exemplification and is not intended to limit the disclosure to the specific embodiments illustrated. The words “a” or “an” are to be

taken to include both the singular and the plural. Conversely, any reference to plural items shall, where appropriate, include the singular. The words “first,” “second,” “third,” and the like may be used in the present disclosure to describe various information, such information should not be limited to these words. These words are only used to distinguish one category of information from another. The directional words “top,” “bottom,” “up,” “down,” “front,” “back,” and the like are used for purposes of illustration and as such, are not limiting. Depending on the context, the word “if” as used herein may be interpreted as “when” or “upon” or “in response to determining.”

**[0060]** The present disclosure provides a system and method for detecting moisture and leakage in an ostomy system. The method can be applied to a computing device such as a wearable device. The ostomy leakage detection system can be configured to detect ostomy effluent leakage and moisture under a skin barrier and to alert a user. The ostomy leakage detection system can provide multiple benefits to the user. For example, the system can allow the user to intervene and change a skin barrier and/or ostomy pouch system before a leak progresses which can cause inconvenience to the user. Further, the ostomy leakage detection system can assist in maintaining a user’s skin health by detecting a leakage in its early stage to prevent prolonged skin exposure to ostomy effluent, which can lead to skin health complications. The ostomy leakage detection system can also support a user’s emotional well-being by reducing anxiety associated with a risk of leakage. The ostomy leakage detection system may be applied to an ostomy barrier of a one-piece pouch system or a faceplate for a two-piece pouch system.

**[0061]** FIG. 1 illustrates an ostomy two-piece pouch system 10. According to example embodiments shown schematically in FIG. 1, the ostomy system 10 can generally include a sensing accessory 12, an ostomy barrier appliance 14, an ostomy pouch 16, a wearable device 18, and a mobile device 20. The sensing accessory 12 can include a sensing region 22, a tail region 24, and

a connection region 26. The ostomy barrier appliance 14 can include an ostomy barrier coupling member 15. The ostomy pouch 16 can receive and hold bodily waste and can include a pouch coupling member 31 for coupling with the ostomy barrier coupling member 15. The sensing region 22 can include an inlet opening 28 configured to surround a stoma (not shown). The tail region 24 can include a connector opening 30 configured to electrically and mechanically connect with the wearable device 18. The sensing region 22 can be mounted around a stoma between the user's abdomen and the ostomy barrier appliance 14. The sensing accessory 12 can include printed circuitry for detecting moisture and leakage. The sensing accessory 12 can include a hydrocolloid for mounting to a user.

**[0062]** FIG. 2 illustrates the ostomy pouch system 10 mounted to a user. According to example embodiments shown in FIG. 2, the sensing accessory 12 can be mounted to a user using an adhesive and the inlet opening 28 can surround the stoma. The ostomy barrier appliance 14 can be mounted over the sensing region 22 with an adhesive and can surround the stoma. The ostomy pouch 16 can be mounted on the ostomy barrier appliance 14 using the pouch coupling member 31 and the ostomy barrier coupling member 15. The wearable device 18 can be attached to the sensing accessory 12 using the connector opening 30. The wearable device 18 can be mounted on a user using a patch or an adhesive.

**[0063]** According to example embodiments, the ostomy leakage detection system may comprise three subsystems – the sensing accessory 12, the wearable device 18, and a mobile application on the mobile device 20. The sensing accessory 12 may be provided as an accessory for an ostomy pouch system. The sensing accessory 12 may include sensors for detecting the presence of ostomy effluent. The sensing accessory 12 may be configured to communicate leakage detection signals to the wearable device 18.

**[0064]** The wearable subsystem 18 may be a wearable device configured to perform at least some processing of leakage detection signals and to alert a user of a leakage event. The wearable subsystem 18 may be configured to communicate electronically through a wired or wireless communication system with a mobile software application. Such electronic communications may include raw data as acquired from the sensing accessory 12 or a leak status notification/alert of the sensing accessory 12. The mobile application may be a digital software subsystem installed on the mobile device 20. The mobile application may be configured to further process leak detection data and provide an alert or other information about an ostomy appliance to a user.

**[0065]** The mobile application can display on the mobile device 20 a GUI with a leakage status, a leakage level, and a status summary for alerting a user of the ostomy leakage detection system to the presence of ostomy effluent (leakage or moisture) under the sensing accessory 12 (or hydrocolloid barrier). The status summary can include an indication description of the general state of the sensing accessory 12 and any recommendations for maintaining the sensing accessory 12. The mobile application can further display a current wear time and interactive screens for setting the orientation of the sensing accessory 12, setting alerts for leakage detected, and acquiring and displaying a history of leakage detected.

**[0066]** The sensing accessory 12 can acquire data related to leakage and moisture conditions detected at certain locations along the accessory including on annular rings or levels around the central opening 28 and/or other sections thereof such as quadrants of the levels. The acquired data can be leakage data and/or moisture data. The wearable device 18 can determine that leakage or moisture has been detected based on the leakage data and moisture data. The mobile application on the mobile device 20 can receive the leakage data, moisture data, leakage detected information, and moisture detected information and display a GUI for indicating the identification of a leak,

moisture or dry state to a user. The GUI can include a leakage level and status summary that can visually indicate to the user critical information that the user can use to make their ostomy experience easier. The GUI can display on the mobile device 20 such information in both graphic and textual form. Embodiments providing such capabilities represent an improvement over conventional leakage detection systems. For example, the leakage level can be displayed as “Normal” and the status summary indicator in the GUI can display an indication such as “No moisture detected.” The presentation of such information in the GUI can enable a user to quickly understand that their ostomy appliance is working properly. In another example, the GUI can display indications corresponding to detected leakage conditions of the ostomy appliance. According to embodiments presented herein, such conditions and corresponding indications can be tiered based on the severity of the detected leakage (e.g. a first condition representative of a minor leak, a second condition representative of a moderate leak, and a third condition representative of a critical leak). It will be understood that any number of levels or tiers may be used without departing from the scope of the subject invention, and that any number of predetermined thresholds can be used to differentiate the designated tiers without limitation. In one example, the GUI can display information indicating that the detected leakage is associated with conditions representative of a more severe leak and can display an indication of same (e.g. “Level 3.”) The status summary indicator can concurrently display additional information or recommendations such as “Barrier change recommended” to enable the user to quickly understand that they should change their sensing accessory 12 without having to determine that there is a problem and what the problem entails.

[0067] FIG. 3A shows a body-side view of a sensor circuit 34. According to example embodiments shown schematically in FIG. 3A, the sensor circuit 34 can generally include a

conductive sensor 36, a conductive trace 38, and a connection point 40. The sensor circuit 34 can be located on the sensing region 22, the tail region 24, and the connection region 26 of sensing accessory 12. The conductive sensor 36 can be configured to detect a leak around a stoma. The conductive trace 38 can be located on the tail region 24 and may be configured to connect the conductive sensor 36 to the connection point 40. The connection point 40 can be located on the connection region 26 and may be configured to connect to a connection pad on the wearable device 18. The sensing region 22 can be broken into four quadrants (e.g., NE, SE, NW, SW).

**[0068]** According to example embodiments, the conductive sensor 36 can include multiple pairs of conductive traces that can be arranged in radial sensing levels (or rings) with levels broken into the four quadrants (e.g., NE, SE, NW, SW) of sensor pairs for detecting the direction of fluid and moisture progression. The radial sensing levels can include a first radial sensing level (or first ring) located nearest the inlet opening 28, a second outermost radial sensing level (or second ring) located near the outer edge of the sensing region 22, and one or more radial sensing levels (or rings) located between the first and second radial sensing levels. The conductive traces can be adjacent to ground traces so that resistance may be measured between the two for detecting fluid and moisture. In another embodiment, the conductive traces can detect fluid and moisture based on resistance, resonance frequency or the like.

**[0069]** The conductive sensor 36 may be arranged in a predetermined pattern in the sensor region 22. For example, the sensor circuit 34 may be generally arranged in a circular or semi-circular pattern. Other suitable patterns can be provided, such as an oval or oblong pattern, or other closed or substantially closed loop patterns without limitation. The sensor circuit 34 in the sensor region 22 may be arranged at one or more radial distances from the inlet opening 28. For example, the sensor circuit 34 may include a plurality of electrically conductive traces arranged at a plurality

of different radial distances from the inlet opening 28. The sensor circuit 34 may include conductive traces and conductive pads or points that may be formed by printing on a circuit substrate using a conductive ink via a conventional printing process, for example, screen printing.

**[0070]** FIG. 3B shows a body-side view of a sensor circuit 34'. According to example embodiments shown schematically in FIG. 3B, the sensor circuit 34' can include a conductive sensor 36'. The conductive sensor 36' can include a first radial sensing level 44 (or first ring) located near the inlet opening 28, a second radial sensing level 46 (or second ring) located between the first radial sensing level and a third radial sensing level, and the third radial sensing levels 48 (or third ring) located near the outer edge of the sensing region 22.

**[0071] Wearable Device**

**[0072]** In an embodiment, the wearable device 18 can input electrical signals from the conductive sensor 36 through the connection points 40. The electrical signals can be used to measure, for example, a resistance value within the radial sensing levels. The radial sensing levels may also be referred to as channels. In an example embodiment, the radial sensing levels can include eight channels.

**[0073]** In an embodiment, the wearable device 18 can determine a leakage or moisture using the one or more algorithms. The one or more algorithms can receive inputs including resistance values, a sensor connection event flag, and a time-elapsed-between-samples value. The resistance values can include resistance values for each channel of the sensor circuit that may be sampled at a specific time interval. The resistance values can be sampled at the specific time interval. The specific time interval can be a sample time between 30 seconds to five minutes for detecting moisture or leakage. For example, the resistance values can be sampled every 45 seconds. The sensor connection event flag can indicate that the sensing accessory 12 is connected to the wearable

device 18 to enable detection to be performed. For example, the sensor connection event flag can receive a “Sensor Connect” flag when the sensing accessory 12 is connected to the wearable device 18. The time elapsed between samples value can be a representation of, and correspond to, a time period, counted in seconds, between consecutive sample events. For example, the time elapsed can be equal to the delta\_t timer and the timer can be reset to 0 upon each sensor connection event or sample event.

**[0074]** The one or more algorithms may also receive inputs from the wearable device 18 and/or the mobile application on the mobile device 20. The inputs can include, for example, a “force sensor reset” and/or “cancel reset” input. These inputs can be part of the “System Flag In” input. For example, where the mobile application receives input that a barrier was changed, the “force sensor reset” prompt can be generated. The cancel reset prompt can also be generated to provide indication that input to override a reset can be entered. For example, the mobile application can display the cancel reset prompt and be configured to receive one of a YES or NO input – the receipt of a NO input can enable the reset to proceed which would usually correspond to a situation where the barrier had in fact been manually changed.

**[0075]** In an embodiment, the one or more algorithms can have outputs including an alert or a notification on the wearable device 18 and/or the mobile application on the mobile device 20. The outputs can include the overall leak state of the sensor, moisture active state of individual channels, channel error/low, clearing of a moisture active state, sensor reset, and prompt user (barrier change). Each of these outputs can be listed as oval shaped nodes in the following figures.

**[0076] Detecting Ostomy Fluid Leak**

**[0077]** FIG. 4 shows a process 100 for detecting the presence of leakage and moisture on the ostomy pouch system 10. The process 100 can be part of one or more algorithms and may operate

on a computing device such as a wearable device, mobile device, personal computer or server, and the like.

**[0078]** In step 110, the wearable device can start the process 100. The start step 110 can include receiving input data, timer information, and system flags information. The inputs can include Channel Data information, a delta\_t time elapsed timer, and System Flags In information. The Channel Data input can include a number of data channels, each can be tied to the sensing levels on the conductive sensor 36. For example, an eight-channel data input from the eight sensing levels on the conductive sensor 36. The System Flags In input can include a Sensor Connection, Cancel Reset, and Force Rest (Barrier Change Button Press) information. The start leak algorithm step 110 can further include resetting the delta\_t timer upon every sensor connection to restart sampling the sensor. The resetting of the delta\_t timer can restart the timer for sampling if there is a leak detected on the sensor. In an embodiment, the start step 110 can be executed after the wearable device 18 is powered on, restarted or when the process 100 is reset, for example, at step 120. The force reset input can be based on a barrier change button press.

**[0079]** In step 120, the wearable device can perform a systems check of the conductive sensor 36 by checking the system flags (FIG. 5) and the system timers (FIG. 6). The system check can include an asynchronous check and resolution of system input flags and can also increment system wide timers.

**[0080]** In step 130, the wearable device can initialize sensor and channel properties. For example, initialization of sensor and channel properties can occur on the startup or boot up of the wearable device and upon sensor reset.

**[0081]** In an embodiment, the sensor properties can include default values. For example, the sensor properties can include a sensor state equal to level 0, barrier change timer equal to zero,

barrier prompt timer equal to zero, system flag in equal to none, system flag out equal to none, sensing lockout equal to true, and sensing lockout timer equal to zero. The sensor properties can include constants which can include an open value equal to 32767, a number of channels equal to eight, a barrier change equal to 15 minutes, a barrier prompt equal to 30 seconds, and a lockout equal to 6 hours.

**[0082]** In an embodiment, the sensor state can store the state the sensor is operating in (normal state or leak state). The barrier change timer can be a timer that stores when the barrier was last changed. The barrier prompt timer can be a timer that initiates a prompt when a barrier is changed. The system flag in can be used to signal the occurrence or state of an event or condition. The system flag out can be an indicator or flag being output by a system to signify a certain condition or event. The sensing lockout can prevent the sensor from detecting a leak. The sensing lockout timer can be a timer that prevents the sensor from detecting a leak.

**[0083]** In an embodiment, the channel can include eight channels. The channel properties can include variables with default values. For example, the variables can include a ring buffer having a plurality of elements and a value of each element is set equal to 32767, a median value (or a filtered value) set equal to 32767, a current channel data equal to normal, a channel state equal to normal, a previous state equal to normal, an error timer equal to zero, a low value timer equal to zero, a normal timer equal to zero, a leak timer equal to zero, a leak scan delay timer equal to zero, a moisture clear timer equal to zero, a moisture active timer equal to zero, a consider leak equal to false, a channel flag equal to normal, a leak severity equal to channel leak level, a run leak scan equal to false, and a run timeout scan equal to false. The channel constant values can include an open value equal to 32767 (i.e., a value associated with a resistance higher than that which the channel can measure), a threshold high equal to 1M ohms, a threshold low equal to 30k ohms, a

moisture time equal to 15 minutes, a leak time equal to 30 minutes, a leak scan delay equal to one hour, a moisture clear equal to 15 minutes, a low value time equal to five minutes, an error time equal to five minutes, a normal time equal to five minutes, a threshold upper equal to 2M ohms, and a moisture active timeout equal to ten hours. In an embodiment, the ring buffer can be used to store new values obtained from the sensor and passed through a median filter to determine a leak. It should be apparent that other types of filters, for example, a low pass filter may be used instead of a median filter. For example, in one embodiment, the ring buffer has 47 values and a 47 tap low pass filter may be used. It should be apparent to one has ordinary skill in the art that in other embodiments, values of one or more variables noted above may be set to different default values.

**[0084]** In step 140, the wearable device can reset the sensor and channels. For example, the reset of sensor and channels can include resetting properties and constants to an initial state. This can occur when a System Flag In flag includes a Force Reset from the mobile device 20 or when a barrier change has been assumed by the process during a sensor check.

**[0085]** In an embodiment, the reset sensor values can include setting a sensor state equal to level 0, setting one or more cancel barrier change timers, setting a system flag in equal to none, and setting a sensing lockout equal to true.

**[0086]** In an embodiment, the channel reset values include setting a reset all counters and timers, values of elements of the ring buffer and median values set equal to open, a channel state set equal to normal, and a channel flag set equal to normal.

**[0087]** In step 150, the wearable device can preprocess channels (FIGS. 7-13). The preprocess channels process can include a channel state machine, an error/low maintenance process, a normal process, an activating process, and an active switch process. For example, preprocessing can include each individual channel when a new resistance value is collected then passed into a channel

state machine.

**[0088]** In an embodiment, the actions are taken according to the current state of the respective channel within the state machine (Error/Low maintain, Normal, Activating, Active Switch, Moisture Active, and Leak). In an embodiment, the current state can be reevaluated based on the new data point, current overall sensor state, and existing timers.

**[0089]** In step 160, the wearable device can include sensor processing steps (FIGS. 14-17). The sensor processing steps can include error and low level check, a channel processing, a leak scan, and a timeout scan.

**[0090]** In an embodiment, the current state of all channels, accessed by sensor as “channel flags”, in conjunction with existing timers are assessed as a whole to determine if the overall sensor state must be reevaluated and if a user is to be notified of a new error or leak state.

**[0091] Check Sensor**

**[0092]** In an embodiment, the check sensor can include a check system flags process and a check system timers process.

**[0093]** FIG. 5 is a flow chart illustrating the check system flags 200 process. The check system flags 200 process can include checking the System Flag In for a force reset, cancel reset, and sensor connect. The force reset can be set when the system has received a force reset command. The cancel reset can cancel a force reset or other form of system reset when the system has received a cancel reset command. The sensor connect can be set when a new sensor is detected or when there has been a connection change in the sensor. In step 210, the System Flag In can be determined to be equal to Force Reset. In step 212, the System Flag Out can be determined to be equal to Reset Sensor. In step 214, the Run Sensor can be Reset and the process can continue to step 140 (FIG. 4). In Step 216, the System Flag In can be determined to be equal to Cancel Reset. In Step 218,

the Cancel Barrier Change Timer can be set and processing proceeds to step 228. In step 220, the System Flag In can be determined to be equal to Sensor Connect. In step 222, a determination can be made as to whether the Barrier Change Timer is Running? If yes, step 228 can be taken, if No then Step 224 can be taken. In step 224, a determination can be made as to whether the Sensor in leak state and Channel Data (x8) are open. If yes, then step 226 can be taken, and if no, then step 228 can be taken. In step 226, Start Barrier Change Timer and Start Barrier Prompt Timer can be started. In step 228, System Flag In can be set to None and the process can continue to step 310 (FIG. 6).

**[0094]** In an embodiment, if a “Force Reset” flag is received from the mobile device 20, the sensor and channels can be reset and the process can continue to step 140 (FIG. 4). In an embodiment, the system can display a prompt on the mobile device 20 asking for input as to whether the barrier was changed. The system can receive a “No” input and a “Cancel Reset” flag can be set, and the barrier change timer can be reset so that a barrier change is not assumed and a sensor/channel reset does not occur.

**[0095]** In an embodiment, if the sensor circuit 34 is connected to a wearable device 18, a “Sensor Connect” flag can be received by the algorithm. In an embodiment, if a barrier change timer is not currently running, the sensor can be in a leak state, and resistance values of all channels of the first sample immediately following the connection are open values, then the barrier change timer and barrier prompt timers can be started.

**[0096]** FIGS. 6A and 6B are flow charts illustrating a check system timers process shown as process 300A and 300B. The check system timers 300A and 300B process can check the system timers. In step 310 of FIG. 6A, a determination can be made to identify whether the Sensing Lockout flag is true. If yes, then step 336 can be taken, and if no, then step 312 can be taken. In

step 312, a determination can be made to identify whether the barrier change timer is running and step 314 can be taken. In step 314, a determination can be made to identify whether the channel data is open. If yes, step 318 is taken, and if no, then step 316 is taken. In step 316, the barrier change can be canceled, and Timers can be prompted. After step 316 the check sensor process is complete and processing proceeds to step 150 (FIG. 4). In step 318, the barrier change timer can be increased by the delta\_t timer. Step 318 continues to step 320 (FIG. 6B). In step 320 of FIG. 6B, a determination can be made to identify if barrier prompt timer is running. If yes, then step 328 is taken, if no, then step 322 is taken. In step 322, barrier change timer can be determined to be greater than a predetermined threshold, for example 15 minutes. In step 324, System Flag Out can be equal to reset sensor. In step 326, sensor rest can be run, and the process can continue to step 140 (FIG. 4). In step 328, a determination can be made to identify if the barrier prompt timer is greater than a predetermined threshold, for example 30 seconds. If yes, then step 330 can be taken, if no, then step 334 can be taken. In step 330, system flag out can be equal to a user input, for example, the system can prompt the user with a message “did you change barrier?” The user input value can be based on a user prompt output that asks the user if a barrier has been changed. In step 332, the barrier prompt timer can be canceled and the process can continue to (FIG. 7A). In step 334, the barrier prompt timer can be added by delta\_t time. After step 334, the check sensor process is completed and processing proceeds to block 150 (FIG. 4)

[0097] Referring once again to FIG. 6A, if the sensing lockout is determined to be true in step 310, then in step 336, the sensing lockout timer can be increased by delta\_t time. In step 338, a determination can be made whether the sensing lockout timer is greater than equal to a predetermined threshold, for example 6 hours. If yes, then step 340 can be taken, if no, then step 342 can be taken. In step 340, the sensing lockout can be set to false and the sensing lockout timer

can be set to 0. After step 340, processing proceeds to step 150, FIG. 4. In step 342, the process can be restarted and the process can continue to step 110 (FIG. 4).

**[0098]** In an embodiment, if the sensing lockout is true (set, for example, upon initialization and sensor reset), the lockout timer can be incremented by  $\Delta t$ . In an embodiment, if the lockout timer has not reached a predetermined threshold, for example 6 hours, then processing can be concluded and a new data sample can be processed. The predetermined threshold can be configured to detect a true leakage event of effluent spreading from the stoma. For example, a true leakage event may be unlikely to occur within the first 6 hours of wear, however prior to application of the sensing device it can be likely for moisture on the skin to trigger false alerts. The lockout feature can prevent these false early alerts. Once the lockout timer reaches 6 hours, the lockout can be set to false and further processing may resume.

**[0099]** In an embodiment, while the sensing lockout is false, the barrier change timer can be checked. If the barrier change timer is running and the current resistance data of all channels are open values, the barrier change timer can be incremented by  $\Delta t$ . An open value is associated with a channel if a lack of moisture is detected on the channel. If any of the resistance data is not open, the barrier change and prompt timers can be cancelled. If the prompt timer has reached a predetermined threshold, for example 30 seconds, a prompt can be sent to the mobile device 20 that asks the user if the barrier has been changed and the prompt timer can be reset. If the barrier change timer has reached a predetermined threshold, for example 15 minutes, a flag can be sent to the mobile device 20 to indicate that the sensor has been reset and the sensor and channel resets can be executed (step 140 in FIG. 4).

**[00100] Channel Preprocessing**

**[00101]** In an embodiment, the channel preprocessing can include preprocessing, channel state

machine, error/low maintain, normal, activating, active switch, leak, and a moisture active step.

**[00102]** FIGS. 7A and 7B are flow diagrams that representatively illustrate preprocessing processes shown as process 400A and 400B. In step 410 of FIG. 7A, a new value can be added to the ring buffer. In step 412, a median filter can be used to reduce noise and prevent the system from detecting a false leakage or moisture event. In step 414, it can be determined if the median value is less than a predetermined error threshold. In some embodiments, a median value less than the predetermined error threshold indicates an error in the channel data and may be, for example, zero, or another predetermined value the median value should exceed for the channel data to be considered valid. If the median value is not less than the predetermined error value, then step 416 can be taken, otherwise, step 426 can be taken. The median of the values in the ring buffer is determined and such median is checked in 414, 416, 420 and that a noise removal, low pass, or smoothing filter may be applied to the values in the ring buffer before such median is calculated, or a weighted sum of the values in the ring buffer that reduces noise may be used instead of a median of such values. In step 416, a determination can be made to identify if the median value is less than the low threshold. If no, then step 418 can be taken, if yes, then step 438 can be taken. In step 418, error timer can be set to 0 and low timer can be set to 0. In step 420, a determination can be made to identify if the median value is less than a predetermined threshold that indicates a leak or presence of moisture. If no, then step 424 can be taken, if yes, then step 421 can be taken. In step 424, channel data can be set to normal. In step 421, channel data can be set to “leak” and processing proceeds to step 910 (FIG. 12). In step 424, the channel data is set to “normal” and processing proceeds to step 610 (FIG. 9) In step 426, channel data can be set to “error.” In step 428, error timer can be increased by the delta\_t timer and low timer can be set to 0. After step 428, processing can continue to step 430 (FIG. 7B). In step 430 of FIG. 7B, a determination can be

made to identify if the channel flag is equal to an error. If no, step 432 is taken, otherwise processing proceeds to step 512 (FIG. 8). In step 432, a determination can be made to identify if the error timer is greater than equal to a predetermined threshold, for example 5 minutes. If yes, step 434 is taken, otherwise processing process to step 512 (FIG. 8). In step 434, a determination can be made to identify if channel flag is equal to low. If no, then step 436 is taken, and if yes, then step 454 is taken. In step 436, the previous state can be set to equal a channel flag. In step 454, timer values can be set. In step 456, the channel flag can be equal to error and processing proceeds to step 512 (FIG. 8). In step 438 (FIG. 7A), the channel data is set to low. In step 440, the low timer can be set equal to  $\Delta t$  and the error timer can be set equal to 0. Thereafter, in step 442 (FIG. 7B), a determination can be made to identify if the channel flag is low. If no, processing continues to step 444, otherwise processing proceeds to step 512 (FIG. 8). In step 444, a determination can be made to identify if the low timer is greater than or equal to a predetermined threshold, for example 5 minutes. If yes, then step 446 is taken, otherwise processing proceeds to step 512 (FIG. 8). In step 446, a determination can be made to identify if the channel flag is equal to an error. If yes, then step 450 is taken, and if no, then step 448 is taken. In step 448, the previous state can be set equal to channel flag and processing continues to step 450. In step 450, the timer values can be set. In step 452, the channel flag can be set to low and the processing can continue to step 512 of FIG. 8.

**[00103]** In an embodiment, the channel preprocessing can occur for each individual channel upon each new data sample that is collected by the device when the lockout is not active. The new value is added to a ring buffer of 101 values which can be subsequently passed through a median filter. It should be apparent that the ring buffer may have more or fewer entries than 101 described herein. If the median value is less than zero, an error timer can be incremented. If the error timer

reaches a predetermined threshold, for example 5 minutes, the current channel state (channel flag) can be stored as “previous state” as long as the state is not “Low”, all channel timers can be reset and the channel can enter an error maintain state (FIG. 8). If the median value is less than the low threshold, for example a predetermined threshold that represents a resistance of  $30\text{k}\Omega$ , the same process can be followed but for the respective Low variables and the previous state can be stored if the current state is not error. The previous states can be stored prior to entering low or error maintain states so that a channel can return to its prior state when it clears from either state.

**[00104]** In an embodiment, if the median value is not error or low, but below a predetermined threshold, for example a value that represents a resistance of  $1\text{M}\Omega$ , it can be identified as corresponding to a leak value. However, if it is above the predetermined threshold, the median value can be considered normal.

**[00105]** In an embodiment, an error/low value state can be two separate states but can be shown as one in FIG. 8. The state processes can be identical with the exception of error() node being ‘Channel Data – Error?’ for Error State and ‘Channel Data = Low?’ for the low value state. For example, a resistance value can be detected that may signify a short circuit and therefore the channel data can be set to error.

**[00106]** FIG. 8 is an error/low value maintain process 500. The process 500 can be part of a Channel State Machine. A channel state machine can be used to represent a behavior of a communication channel and can describe the different states that a communication channel can be in. In step 512, a determination can be made to identify if the channel data is equal to an error or low. If yes, then step 528 is taken, and if no, then step 514 is taken. In step 514, the normal timer can be increased by  $\text{delta\_t}$  time. In step 528, the normal timer is set to zero and processing proceeds to step 530. In step 516, a determination can be made to identify if the normal timer is

greater than equal to a predetermined threshold, for example 5 minutes. If yes, then step 518 is taken, and if no, then step 530 is taken. In step 530, a maintain state (FIG. 12) can be taken. In step 518, the normal timer can be set equal to 0. In step 520, a determination can be made to identify if the previous state is equal to normal. If yes, then step 532 is taken, and if no, then step 522 is taken. In step 522, a determination can be made to identify if the previous state is equal to leak. If yes, then step 540 is taken, and if no, then step 524 is taken. In step 540, the channel flag can be set equal to leak, the channel state can be set equal to leak, and the process can continue to FIG. 12. In step 524, a determination can be made to identify if the previous state is equal to moisture active. If yes, then step 526 is taken. In step 526, the channel flag can be set equal to moisture active and the channel state can be set equal to moisture active. Step 526 marks the end of processing one channel. If any channels remain to be processed, processing returns to 410 (FIG. 7A) to process an unprocessed channel. Otherwise, processing proceeds to step 1110 (FIG. 14) if no channels remain to be processed. In step 532, the channel flag can be set equal to normal. In step 534, a determination can be made to identify if the channel data is equal to normal. If yes, then step 536 is taken, and if no, then step 538 is taken. In step 536, the channel state is equal to normal and the process can continue to FIG. 9. In step 538, the channel state is set equal to activating and the process can continue to FIG. 10.

**[00107]** In an embodiment, if the current channel data is not error or low, then a normal timer can be incremented by  $\Delta t$ . The normal timer can be reset if the channel data is error or low. If the normal timer reaches a predetermined threshold, for example 5 consecutive minutes, then the channel can enter the stored previous state. However, if the previous state was normal and the current channel data corresponds to leak then the channel can enter an activating state.

**[00108]** FIG. 9 is a normal channel state process 600. In step 610, a determination can be made

to evaluate if the channel data parameter is equal to leak. If the outcome of such evaluation is yes, then step 614 can be taken, and if no, then step 612 can be taken. In step 614, the activating process can be taken (step 710 in FIG. 10). In step 612, the maintain state can be processed (Step 910 in FIG. 12) to determine if a channel data includes a leak. If there is a leak then the process can continue to FIG. 10. Otherwise, the process can continue to the maintain state (FIG. 12).

**[00109]** FIG. 10 is an activating process 700. In step 710, a determination can be made to evaluate if the channel data is equal to leak. If the outcome of such evaluation is yes, then step 716 can be taken, and if no, then step 712 can be taken. In step 712, the leak timer can be set to a predetermined value such as to 0. In step 714, a determination can be made to evaluate if the channel data parameter is equal to normal and, if so, the process can continue to FIG. 9. If channel data is not determined to be normal in step 714, processing of the current channel is complete. Thereafter, if any channels remain to be processed, processing proceeds to step 410 (FIG. 7A) to process another channel. Otherwise, processing proceeds to step 1110 (FIG. 14) if all of the channels have been processed. In step 716, the leak timer can be increased by the  $\Delta t$  time. In step 718, a determination can be made to evaluate if the leak timer is greater than equal to a predetermined threshold, for example 15 minutes. If the outcome of such evaluation is yes, then step 722 can be taken, and if no, then step 720 can be taken. In step 722, the leak scan delay timer can be increased by the  $\Delta t$  time and the process can continue to FIG. 11A (step 810). In step 720, the maintain state (FIG. 12) can be undertaken.

**[00110]** In an example embodiment, the activating step can include a channel entering an activating state from normal state if the median value is considered a leak value. If the data corresponds to a leak for a predetermined threshold, for example 15 consecutive minutes (Leak Timer), then the leak scan delay timer can be started and the channel can enter an active switch

state. If the data is normal, then the leak timer can be reset and the channel can enter a normal state.

[00111] FIGS. 11A and 11B illustrate steps for an active switch process shown as process 880A and 800B. In step 810 of FIG. 11A, a determination can be made to evaluate if the leak scan delay timer is greater than a predetermined value such as, for example, 0. If the result of such determination is yes, then step 812 can be taken, and if no, then step 836 can be taken. In step 812, a determination can be made to evaluate whether the channel data corresponds to a leak and if the consider leak is equal to false. If yes, then step 814 can be taken, and if no, then step 822 can be taken. In step 814, the leak timer can be increased by the delta\_t time. In step 816, a determination can be made to evaluate if the leak timer is greater than a predetermined threshold, for example 30 minutes. If the outcome of such determination is yes, then step 818 can be taken, and if no, then step 820 can be taken. In step 818, the consider leak parameter can be set equal to true and the leak timer can be set equal to a predetermined value such as 0. In step 820, the leak scan delay timer can be increased by the delta\_t time. Step 820 can continue to step 824 (FIG. 11B). In step 824 of FIG. 11B, a determination can be made to evaluate if the leak scan delay timer is greater than equal to a predetermined threshold, for example 1 hour. If the outcome of such evaluation is yes, then step 828 can be taken, if no, then step 826 can be taken. In step 826, the maintain state can be processed (FIG. 12). In step 828, a determination can be made to evaluate if the consider leak parameter is equal to true. If yes, then step 830 can be taken, if no, then step 832 can be taken. In step 832, the leak scan delay timer can be set equal to a predetermined value such as 0. In step 830, the run leak scan parameter can be set equal to true and the consider leak parameter can be set equal to false. In step 832, the leak scan delay timer can be set equal to 0. In step 834, the channel flag can be set equal to a moisture active condition and the process can continue to FIG. 13. Step

830 marks the end of preprocessing the current channel, If there are any channels remaining that have not been preprocessed, processing proceeds to step 810 (FIG. 11A) to preprocess another channel. Otherwise, processing proceeds to step 1110 (FIG. 14). In step 836 (FIG. 11A), a determination can be made if the sensor level is greater than or equal to the channel level. If the outcome of such determination is yes, then step 840 can be taken, and if no, then step 838 can be taken. In step 840, the channel flag can be set equal to a leak condition and the process can continue to FIG. 12. In step 838, the channel flag can be set equal to the moisture active condition and the process can continue to FIG. 13.

**[00112]** According to example embodiments presented herein, while the system is in an active switch state, the leak scan delay timer can continue to increment by  $\Delta t$  until it reaches a predetermined threshold, for example 1 hour. The leak timer can continue to increment if the channel data continues to correspond to a leak condition and can be reset to zero otherwise. Once the leak scan delay timer has reached the predetermined threshold, for example the 1 hour, the channel state can be set to a leak or moisture active condition. If the leak timer has reached a predetermined threshold, for example 30 minutes prior to the expiration of the leak scan delay timer, the “Consider Leak” and “Run Leak Scan” parameters can be set to a condition (e.g., True) which can prompt a sensor state reevaluation within the sensor state machine. However, if the leak timer does not reach the predetermined threshold at any point during an active switch, the channel can enter a moisture active condition upon the expiration of the leak scan delay timer and the output can be sent to the mobile device 20. If the overall sensor level is greater than or equal to the level of the channel in an active switch at any point, then the channel can immediately enter a leak state. If the leak scan is run in the sensor state machine and the sensor level remains less than the channel level in active switch whose leak scan delay timer has expired, then the channel can enter

a moisture active state.

**[00113]** FIG. 12 illustrates a maintain state process 900 according to example embodiments presented herein. In step 910, the maintain state can be instituted. A channel can remain in a leak state unless a sensor reset occurs either through a barrier change or a force reset by the user from the mobile device 20. Whenever the sensor detects a sensor reset or force reset, processing begins again at step 110 of FIG. 4.

**[00114]** FIG. 13 illustrates a moisture active process 1000 according to example embodiments presented herein. As shown schematically in FIG. 13, the process 1000 can comprise a determination step 1010 to evaluate if the sensor level is greater than equal to the channel level. If the outcome of such determination is yes, the process can advance to step 1024, and if no, the process can advance to step 1012. In step 1012, a determination can be made if the moisture active timer is greater than equal to a predetermined moisture timeout and the timeout scan is equal to a predetermined condition (e.g., False). If the outcome of such determination is yes, the process can advance to step 1026, and if no, the process can advance to step 1014. In step 1014, a determination can be made if the median value of the resistance values sampled (for example, the value with associated with resistance detected on the sensor) is greater than equal to a predetermined upper threshold. If the outcome of such determination is yes, the process can advance to step 1016, and if no, the process can advance to step 1028. In step 1016, the moisture clear timer can be increased by  $\Delta t$  time. In step 1018, a determination can be made to evaluate if the moisture clear timer is greater than equal to moisture clear time. The moisture clear timer can be a timer that keeps track of how long moisture has been detected. The moisture clear time can be a threshold that can signify when the system can be at a normal state or leak state. For example, moisture can be detected, but it may be sweat and not a leak. The system can wait a certain amount of time, for

example based on a predetermined threshold, and determine if the moisture, in this case sweat, has cleared up. If the outcome of such determination is yes, the process can advance to step 1020, and if no, the process can advance to step 1030. In step 1020, the channel flag can be set to normal. In step 1022, the moisture clear timer can be set to a predetermined value such as 0 and the timeout scan can be set to a predetermined condition (e.g., False) and the process can continue to FIG. 9. In step 1024, the channel flag can be set to a leak condition, the moisture clear timer can be set to a predetermined value such as 0 and the timeout scan can be set to a predetermined negative condition (e.g., False) and processing proceeds to step 910 (FIG. 12). In step 1026, the timeout scan and the run leak scan can both be set to an affirmative condition (e.g., True). In step 1028, the moisture clear timer can be set to equal 0 and the moisture active timer can be increased by the  $\Delta t$  time. In step 1030, the maintain state (FIG. 12) can be processed.

**[00115]** According to example embodiments presented herein, if at any time while the channel is in a moisture active state the sensor level can be greater than or equal to the channel level. Where such condition occurs, the channel can immediately enter a leak state, all moisture timers can be reset, and timeout scan can be set to false. If a channel remains in a moisture active state for at least a predetermined threshold, for example 10 hours (moisture active timer), the moisture timeout is reached and the timeout and run leak scans can be set to true. While in a moisture active state, if the median value for the channel is greater than or equal to an upper predetermined threshold, for example, a value associated with a resistance of  $2M\Omega$ , then a moisture clear timer can be incremented, otherwise the moisture clear timer can be reset to a predetermined base value such as 0 and the moisture active timer can continue to increment. If the moisture clear timer reaches a predetermined threshold, for example 15 minutes, the channel can enter a normal state and the normal channel flag data can be sent to the mobile device 20 to clear the moisture active channel

display.

**[00116] Sensor Processing**

**[00117]** FIG. 14 illustrates an error/low check process 1100 according to example embodiments presented herein. As shown schematically in FIG. 14, process 1100 can comprise a determination step 1110 to evaluate if there are at least three channels in a low value state. If the outcome of such determination is yes, the process can advance to step 1114, and if no, the process can advance to step 1112. In step 1114, the system flag out can be set to channel low. In step 1112, a determination can be made if there are at least three channels in an error state and if the outcome of such evaluation is no then the process can continue to FIG. 15. If the outcome of such evaluation is yes, the process can advance to step 1116. In step 1116, the system flag out can be set to channel error. After steps 1114 and 1116, processing proceeds to step 1210 (FIG. 15).

**[00118]** FIG. 15 illustrates a channel process 1200 according to example embodiments presented herein and is run for each channel of the sensor. As shown schematically in FIG. 15, channel process 1200 can comprise a determination step 1210 to evaluate if the run leak scan for the current channel is equal to an affirmative condition (e.g. True). If yes, the process can advance to step 1212. Otherwise, if any channel remains to be processed, processing returns to step 1210 to begin processing another channel. If all of the channels have been processed, processing proceeds to step 110 (FIG. 4). In step 1212, the leak scan can be processed as shown in FIG. 16. In step 1214, the moisture clear timer can be increased by the  $\Delta t$  time and processing proceeds to step 110 (FIG. 4).

**[00119]** FIG. 16 illustrates a leak scan process 1300 according to example embodiments presented herein. As shown schematically in FIG. 16, leak scan process 1300 can comprise a determination step 1310 to evaluate if there are any channels in a moisture active state. If the

outcome of such determination is yes, the process can advance to step 1322 and if no, the process can advance to step 1312. In step 1312, a determination can be made to identify whether a predetermined level of the channel (the leak scan) is less than or equal to sensor level. If the outcome of such determination is yes, the process can advance to step 1324, and if no, the process can advance to step 1314. In step 1314, the active channels can be set. In step 1316, a determination can be made to identify if there is a gap greater than two levels between the active channels. If the outcome of such determination is yes, the process can advance to step 1324, and if no, the process can advance to step 1318. In step 1318, the sensor state can be set equal to the channel level that initiated the scan. In step 1320, the user is alerted that the sensor level has changed and thereafter processing returns to step 1210 to begin processing another channel if all of the channels have not been processed. If all of the channels have been processed, processing proceeds to step 110 (FIG. 4). In step 1322, a determination can be made to evaluate whether any moisture active channels have timed out and, if so, the process can continue to FIG. 17 so that a timer out scan can be processed. Otherwise, in step 1324, the maintain sensor state (FIG. 12) can be processed.

**[00120]** FIG. 17 illustrates a timeout scan process 1400 according to exemplary embodiments presented herein. As shown schematically in FIG. 17, at step 1410, all of the channels that have the same level as the current sensor level and those channels that have timed out are identified and the identified channels are sorted in accordance with the level associated therewith. In step 1412, a value of the variable Sensor Next Level is set to the highest channel level at which a leak has been detected. In step 1414, a determination can be made if the sensor next level is greater than the current sensor state. If the outcome of such determination is yes, the process can advance to step 1416, and if no, step 1418 can be taken. In step 1416, the sensor state can be set to an alert condition (e.g. sensor next level alert user of new sensor level). In step 1418, the maintain sensor

state can be processed, that is, the Sensor State is not changed. After steps 1416 and 1418, processing proceeds to step 110 (FIG. 4).

**[00121]** In an example embodiment, if at least three channels are all in a low value state or at least three channels are all in an error state, an output flag can be set to channel low or channel error condition respectively (FIG. 15). This output flag may trigger a notification to a user to take action. According to example embodiments, each channel can be checked to see if a Run Leak Scan flag was set (FIG. 15) and if so, a leak scan (FIG. 16) can be run. If no channels are in a moisture active state and the level of the channel that has a Run Leak Scan Flag set to true is less than or equal to the current sensor state, the sensor level can be maintained. However, if the channel level is greater than the sensor level and there is no more than a two-level gap between “Active Channels” (any channel in a leak state or with an active leak delay timer), the sensor state can be incremented to the level of the channel that called the scan and a leak alert can be issued to the user. For example, for channel levels 1-5, if channel level 5 has a run leak scan flag set and channel levels 2 and 4 are in a leak state, then the sensor level can be increment to level 5.

**[00122]** In an example embodiment, if any channel is in a moisture active state and none have hit a timeout, the current sensor state can be maintained. If one or more channels are in a moisture active state and a channel has hit a Timeout, a Timeout Scan (FIG. 17) can be run. The current sensor level and all timed out channel levels can be sorted in an array. The sensor level can be incremented to the highest level in the sorted array with a gap of two or less levels between each prior level in the array if that level is greater than the current sensor level. If the sensor level increments, then the user can be notified of the new leak level.

**[00123]** FIG. 18 shows a process 1800 for displaying a leakage level according to example embodiments. The steps of the process 1800 may be undertaken by a computing device such as a

wearable device, mobile device, personal computer or server, and the like.

**[00124]** In step 1810, the computing device executing the method 1800 can obtain channel data of at least one channel.

**[00125]** In step 1812, the device can determine that the channel data is a leak value.

**[00126]** In step 1814, the device can determine that the at least one channel is in an activating state based on a previously recorded state and the leak value.

**[00127]** In step 1816, the wearable device can determine that the at least one channel is in an active state based on the activating state and a time threshold value. The active state can include an active leak state, an active moisture state, and a prompt state.

**[00128]** In step 1818, the wearable device can output the active state. After step 1818, processing returns to step 1810.

**[00129]** FIG. 19 shows a process 1900 for displaying a leakage level according to example embodiments. The steps of the process 1900 may be undertaken by a computing device such as a wearable device, mobile device, personal computer or server, and/or the like.

**[00130]** In step 1910, the computing device executing the method can obtain channel data of at least one channel.

**[00131]** In step 1912, the device can determine that the channel data is a leak value.

**[00132]** In step 1914, the device can obtain a previously recorded state.

**[00133]** In step 1916, the device can determine that the previously recorded state is a normal state.

**[00134]** In step 1918, the device can determine that the leak value was detected for a time greater than or equal to a leak time threshold.

**[00135]** In step 1920, the device can determine that the at least one channel is in an active state

based on the activating state and a time threshold value. The active state can include an active leak state, an active moisture state, and a prompt state.

**[00136]** In step 1922, the device can output the active state. After step 1922, processing returns to step 1910.

**[00137]** FIG. 20 shows an embodiment of the sensing region 22 of the sensing accessory 12 comprising a sensor circuit 34 disposed thereon to define a plurality of channels 2200 of the sensing region 22. FIG. 20 shows the sensing region 22 having 8 channels 2200a – 2200h, however, other embodiments of the sensing region 22 may have more or fewer channels. Some channels, e.g., 2200a, 2200b, 2200g, and 2200h define a substantially circular ring that spans a portion of the conductive sensor 36 and other channels, e.g., 2200c, 2200d, 2200e, and 2200f span segments of a circular ring disposed in different quadrants (or other portions of rings or other regions) of the sensor 22. As described herein, a resistance value (or other characteristic) measured between one or more conductive traces that comprise a channel 2200 may indicate the presence or absence of moisture in the region of associated with the channel 2200. Further, detection of moisture in the channels 2200 over a period of time may be tracked and such information may be used to determine whether moisture detected by the sensor 22 is due to leakage of effluent from stoma or is moisture not related to such leakage (e.g., the moisture is due to sweat, humidity, and the like).

**[00138]** In some cases, if over time, moisture is detected in a first channel (e.g., the channel 2200h) proximate to the inlet opening 28, then moisture is detected in a second channel (e.g., the channel 2200) further from the inlet opening 28 than the first channel, and thereafter moisture is detected in a third channel further from the inlet opening 28 than the second channel (e.g., one or more of the channels 2200c, 2200d, and 2200e), the wearable subsystem 18 may determine that

such moisture is spreading from proximate the inlet opening 28 toward an outer circumference 2202 of the sensor 36, the processing undertaken by the wearable subsystem 18 may determine that such moisture may be due to leakage of effluent that requires the users attention and alert the user as described above.

**[00139]** Further, a channel level may be associated with each of the channels 2200, wherein channel level 0 is associated with the channel 2200h that forms the innermost ring, channel level 1 is associated with the channel 2200g that forms the next innermost ring, channel 2 is associated with the channels 2200f, 2200e, 2200d, and 2200c that collectively form a ring, and channels 3 and 4 may be associated with the two outermost rings 2200b and 2200a, respectively.

**[00140]** FIG. 21 shows a flowchart 2250 of processing undertaken by the wearable subsystem 18 to determine if detected moisture is from an external source or if the moisture is due to leakage of effluent from the stoma or from a source other than the stoma. The processing shown in FIG. 2250 may be undertaken as part of the step associated with the leak scan 1212 (FIG. 15) and steps 1310-1324 (FIG. 16) discussed above.

**[00141]** Referring to FIG. 21, at step 2252, the wearable subsystem 18 sets a value of a variable current-channel to zero. At step 2254, wearable subsystem 18 checks if the value of the variable current-channel is equal to the number of channels 2200 in the sensor 36 and if so the wearable subsystem 18 determines that the leak scan 1212 has completed and proceeds to, for example, step 1214 (FIG. 15) or step 910 (FIG. 12). Otherwise, at step 2256, the wearable subsystem 18 determines if moisture has been detected on the channel 2200 that corresponds to the value of the variable current-channel. If moisture has not been detected, the value of the variable current-channel is incremented at step 2258 and processing returns to step 2254. In some embodiments, the innermost channel 2200 (i.e., the channel most proximate to the inlet opening 28) corresponds

to a current-channel value of 0, the next innermost channel corresponds to a current-channel value of 1, and so on. Thus, in the embodiment of the sensor 36 shown in FIG. 20, the channels 2200a, 2200b, ... 2200h correspond to current-channel values 7, 6, 5, ... 0, respectively. Thus, the wearable subsystem 18 checks for moisture from channel closest to the inlet opening 28 and proceeds outward away from the inlet opening 28.

**[00142]** If at step 2256, the wearable subsystem 18 determines that moisture has been detected on the channel associated with the value of the variable current-channel, then at step 2260 determines if a value of a moisture timer associated with the is zero (i.e., no moisture was detected on the channel the last time a leak scan was undertaken). If so, processing proceeds to step 2262. Otherwise processing proceeds to step 2264. At step 2262 the wearable subsystem 18 determines if the value of the moisture timer is greater than a predetermined moisture threshold value and if so proceeds to step 2264. That is, moisture has persisted for an amount of time associated with the predetermined moisture threshold and, e.g., has not evaporated within such amount of time. Moisture previously detected that is due to a source other than the stoma may evaporate after a period of time after the source of moisture is removed whereas persistent leakage may not typically evaporate. Otherwise, processing proceeds to step 2258.

**[00143]** At step 2264, the wearable subsystem 18 determines if the channel level with associated with the value current-channel (i.e., the current channel level) is less than or equal to one (i.e., such channel is one of the two innermost rings) and if so proceeds to step 2266. Otherwise, processing proceeds to step 2268.

**[00144]** At step 2268, the wearable subsystem 18 sets a value of a variable prev-leak-levels to sum of levels less than current channel level that are true. Thus, for example, assuming the value the variable current channel is 7 associated with channel 2200b and thus the current channel level

is 3, and leaks have been detected on channel 2200h (channel level 0), channel 2200g (channel level 1) and channels 2200e and 2200f (collectively channel level .2), then the value of prev-leak-level is set to 3.

**[00145]** After step 2268, the wearable subsystem 18 at step 2270 checks if the current channel level is less than or equal to the value prev-leak-levels plus 1, and if so, proceeds to step 2266. Otherwise, processing proceeds to step 2258.

**[00146]** At step 2266, the wearable subsystem 18 sets the channel-state of the channel associated with the value current-channel to leak. At step 2272, the wearable subsystem 18 sets leak level of the sensor in accordance with the leak level of the current channel as described above in connection with FIGS. 16 and 17.

**[00147]** The processing described in connection with FIG. 21, detects and identifies a moisture pattern as a leak if such moisture pattern processes from the innermost channel 2200 of the sensor and progresses outward. Further, for the state of the current channel 2200 to be set to leak, moisture has to have been detected on and persisted for at least the predetermined moisture timer threshold amount of time on all but one of the levels between the current level and the inlet opening 28, and thus a leak is detected if the sensor 36 fails to detect moisture in a channel associated with one level. Further, if there are two or more channel levels between the current channel level and the inlet opening 28 in which moisture has not been detected, then the state of the current channel will not be set to leak (i.e., the state will be either moisture detected or normal.)

**[00148]** In some embodiments, the wearable subsystem 18 may automatically detect if a barrier change has occurred (i.e., if the ostomy barrier appliance 14 has been replaced). FIGS. 21 and 21A illustrate a flowchart of steps undertaken by an embodiment of the wearable subsystem 18 to determine when the barrier change has occurred. To detect a barrier change, the wearable

subsystem 18 determines a first number of the channels of the sensor accessory 12 that were associated a resistance levels (or another characteristic) less than a pre-determined value during an earlier leak scan and a second number of the channels of the sensor accessory 12 that are currently associated with a resistance level less than the pre-determined value. A barrier change may have occurred if the first number of channels is more than zero and if the second number of channels is zero. The first number being greater than zero indicates that at least one of the channels was associated with an error condition (resistance too low) or presence of moisture when the previous leak scan was undertaken and the second number being zero indicates that no channels are presently associated with an error condition or presence of moisture. Such difference in the first and second number of channels would occur if a dirty barrier appliance 14 were replaced with a new one.

**[00149]** Referring to FIGS. 21 and 21A, the wearable subsystem 18 sets a value of a variable prev-channels-sub-threshold to zero at step 2300 and value of a variable current-channel to zero at step 2302. At step 2304, the wearable subsystem 18 determines the value of the variable current-channel is equal to the number of channels and if so proceeds to step 2306. Otherwise, at step 2308, the wearable subsystem 18 determines if the filtered resistance (or other characteristic) value (i.e., the value that results from filtering or determining the median of the values in the ring buffer) associated with value of current channel is less than a predetermined value barrier-change threshold. In some embodiments, the value barrier-change threshold is associated with a measured resistance of 10 K $\Omega$ . If such filtered resistance is not less than the barrier-change-threshold processing proceeds to step 2310. Otherwise, the wearable subsystem 18 increments the value of the variable prev-channels-sub-threshold by one at step 2312 and proceeds to step 2310. At step 2310, the value of the variable current channel is incremented by one and processing proceeds to

step 2304.

**[00150]** After the resistance of all of the channels of the sensor 36 have been compared to the value barrier-change-threshold, the value of the variable prev-channels-sub threshold indicates the number of such channels that have a resistance less than barrier-change-threshold.

**[00151]** Thereafter, at step 2306, the wearable subsystem 18 checks if the value of prev-channels-sub-threshold is greater than zero or if the sensor state is not normal and exits because no barrier change has occurred.

**[00152]** Otherwise, at step 2314, the wearable subsystem 18 sets the value of the variable current-channel to zero and a value of a variable new-channels-sub-threshold to zero. At step 2316, wearable subsystem 18 determines if the value of the variable current channel is greater than the number of channels in the sensors 36 and if so proceeds to step 2318. Otherwise, at step 2320, the wearable subsystem 18 obtains a new resistance measurement for the channel associated with the value channel-number and determines if the new resistance measurement is less than the predetermined value barrier-change-threshold. Alternately, the wearable subsystem 18 may compare the most recently acquired value in the ring buffer instead of obtaining a new measurement. If the new resistance value is not less than the value barrier-change-threshold, the wearable subsystem 18 proceeds to step 2322. Otherwise, processing proceeds to step 2324. At step 2322, the current channel number is incremented by one and processing proceeds to step 2316.

**[00153]** At step 2324, the value of the variable new-channels-sub-threshold is incremented by one and processing proceeds to step 2322.

**[00154]** Between steps 2316 and 2324, the wearable subsystem 18 rescans all of the channels to determine the number of such channels that have a measured resistance value less than barrier-change-threshold and stores such number in the variable new-channels-sub-threshold.

**[00155]** At step 2318, the wearable subsystem 18 determines if the value of new-channels-sub-threshold is zero and, if it is not, determines that no barrier change has taken place and returns to, for example, step 910 (FIG. 12).

**[00156]** Otherwise, if value of new-channels-sub-threshold is greater than zero, a barrier changed may have taken place and, at step 2326, sets the value of barrier change timer active to true and sets the barrier change start time to the current time at step 2328, and proceeds to for example, step 910 (FIG. 12).

**[00157]** Although the foregoing describes certain steps as being undertaken by the wearable subsystem 18, it should be apparent to one who has ordinary skill in the art that such steps may be undertaken by the mobile application on the mobile device 20 or another component associated with the ostomy system 10.

**[00158]** FIG. 23 shows a computing environment 2400 that comprise the wearable device 18 and/or the mobile device 20. According to example embodiments shown schematically in FIG. 23, the computing environment 2410 can be connected to a user interface 2450 and a communication unit 2460. The computing environment 2410 can include a processor 2420, a memory 2430, and an I/O interface 2440.

**[00159]** The processor 2420 can typically control the overall operations of the computing environment 2410, such as the operations associated with data acquisition, data processing, and data communications. The processor 2420 can include one or more processors to execute instructions to perform all or some of the steps in the above-described methods. Moreover, the processor 2020 can include one or more modules that facilitate the interaction between the processor 2020 and other components. The processor may be or include a Central Processing Unit (CPU), a microprocessor, a single chip machine, a graphical processing unit (GPU) or the like.

**[00160]** The memory 2430 can store various types of data to support the operation of the computing environment 2410. Memory 2430 can include predetermined software 2431 (i.e., computer executable instructions). Examples of such data and predetermined software 2431 include instructions for any applications or methods operated on the computing environment 2410, raw data, leak data, moisture data, resistance values, etc. The memory 2430 may be implemented by using any type of volatile or non-volatile memory devices, or a combination thereof, such as a static random-access memory (SRAM), an electrically erasable programmable read-only memory (EEPROM), an erasable programmable read-only memory (EPROM), a programmable read-only memory (PROM), a read-only memory (ROM), a magnetic memory, a flash memory, a magnetic or optical disk.

**[00161]** The I/O interface 2440 can provide an interface between the processor 2420 and peripheral interface modules, such as an external port, an audio and speaker circuitry, accelerometer, display controller, haptic feedback controller, other input controllers, light output including LEDs, and buttons. The buttons may include but are not limited to, a settings button, a power button, and volume buttons.

**[00162]** The user interface 2450 can include haptic feedback motor, speaker, lights, display or other similar technologies for communicating with the user.

**[00163]** Communication unit 2460 provides communication between the processing unit, an external device, mobile device, and a webserver (or cloud). The communication can be done through, for example, WIFI or BLUETOOTH hardware and protocols. The communication unit 2060 can be within the computing environment or connected to it.

**[00164]** In some embodiments, there is also provided a non-transitory computer-readable storage medium comprising a plurality of programs, such as comprised in the memory 2430,

executable by the processor 2420 in the computing environment 2410, for performing the above-described methods. For example, the non-transitory computer-readable storage medium may be a ROM, a RAM, or the like.

**[00165]** The non-transitory computer-readable storage medium has stored therein a plurality of programs for execution by a computing device having one or more processors, where the plurality of programs when executed by the one or more processors, cause the computing device to perform the above-described method for motion prediction.

**[00166]** In some embodiments, the computing environment 2410 may be implemented with one or more application-specific integrated circuits (ASICs), digital signal processors (DSPs), digital signal processing devices (DSPDs), programmable logic devices (PLDs), field-programmable gate arrays (FPGAs), graphical processing units (GPUs), controllers, micro-controllers, microprocessors, or other electronic components, for performing the above methods.

**[00167]** From the foregoing it will be observed that numerous modifications and variations can be effectuated without departing from the true spirit and scope of the novel concepts of the present disclosure. It is to be understood that no limitation with respect to the specific embodiments illustrated is intended or should be inferred. The disclosure is intended to cover by the appended claims all such modifications as fall within the scope of the claims.

## CLAIMS

What is claimed is:

1. A method for determining ostomy fluid leak is detected comprising:
  - obtaining channel data of at least one channel;
  - determining that the channel data is a leak value;
  - determining that the at least one channel is in an activating state based on a previously recorded state and the leak value;
  - determining that the at least one channel is in an active state based on the activating state and a time threshold value, wherein the active state comprises an active leak state, an active moisture state, and a prompt state; and
  - outputting the active state.
2. The method of claim 1, wherein determining that the channel data is the leak value comprises:
  - determining that the channel data has a value greater than a low threshold value; and
  - determining that the channel data has a value less than a resistance threshold value.
3. The method of claim 1 or claim 2, wherein determining the at least one channel is in an active state comprises determining a first and a second channel are in active leak states and the first and second channels are adjacent channels.

4. The method of any of the preceding claims, wherein the resistance threshold value is associated with resistance of 1M ohms.

5. The method of any of preceding claims, wherein the low threshold value is associated with a resistance of 30k ohms.

6. The method of any of the preceding claims, wherein determining that the at least one channel is in the activating state based on the leak value comprises:

- obtaining a previously recorded state;
- determining that the previously recorded state is a normal state; and
- determining that the leak value was detected for a time greater than or equal to a leak time threshold.

7. The method of claim 6, wherein the leak time threshold comprises 15 minutes.

8. The method of any of the preceding claims, wherein determining that the at least one channel is in the active state based on the activating state and the time threshold value comprises:

- obtaining a leak scan delay timer, wherein the leak scan delay timer is started at when the at least one channel is in the activating state;

- determining that the leak scan delay timer is greater than or equal to the time threshold value; and

- determining that the active state is the active leak state, wherein the active leak state comprises an ostomy fluid leak.

9. The method of claim 8, wherein the time threshold value is 1 hour.

11. The method of claim 1, wherein the at least one channel is associated with a sensor associated with a barrier appliance, further including the step of determining the barrier appliance has been replaced.

12. The method of any of the preceding claims, wherein determining that the at least one channel is in the active state based on the activating state and the time threshold value comprises:

obtaining a leak scan delay timer, wherein the leak scan delay timer is started at when the at least one channel is in the activating state;

determining that the leak scan delay timer stops in a time less than the time threshold value;  
and

determining that the active state is the active moisture state, wherein the active moisture state comprises moisture detected in an ostomy.

13. The method of claim 12, wherein the time threshold value is 30 minutes.

14. The method of any of the preceding claims, wherein determining that the at least one channel is in the active state based on the activating state and the time threshold value comprises:

obtaining a leak scan delay timer, wherein the leak scan delay timer is started at when the at least one channel is in the activating state;

determining that the leak scan delay timer stops in a time between a first and second time threshold value; and

determining that the active state is a prompt state, wherein the prompt state comprises outputting a sensor state reevaluation.

15. The method of claim 14, wherein the first time threshold value comprises 30 minutes and the second time threshold value is 1 hour.

16. The method of any of the preceding claims, further comprising:

obtaining an overall sensor level;

determining that the overall sensor level is greater than or equal to the channel data; and

determining that the at least one channel is in the active leak state.

17. The method of any of the preceding claims, wherein determining that the channel data is a leak value comprises:

filtering channel data of at least one channel, wherein filtering comprises a median filter that filters out noise and prevent false leakage detection; and

determining that the channel data is a leak value.

18. The method of any of the preceding claims, wherein determining that the channel data is a leak value comprises:

determining, at a wearable device, that the channel data is a leak value.

19. A computing device comprising:

one or more processors;

a non-transitory computer-readable storage medium storing instructions executable by the one or more processors, wherein the one or more processors are configured to:

obtain channel data of at least one channel;

determine that the channel data is a leak value;

determine that the at least one channel is in an activating state based on a previously recorded state and the leak value;

determine that the at least one channel is in an active state based on the activating state and a time threshold value, wherein the active state comprises an active leak state, an active moisture state, and a prompt state; and

output the active state.

20. The computing device of claim 18, wherein the one or more processors configured to determine that the channel data is the leak value are further configured to:

determine that the channel data has a value greater than a low threshold value; and

determine that the channel data has a value less than a resistance threshold value.

21. The computing device of claim 19 or claim 20, wherein the resistance threshold value is 1M ohms and the low threshold value is 30k ohms.

22. The computing device of any claims 19-21, wherein the one or more processors configured to determine that the at least one channel is in the activating state based on the leak value are further configured to:

obtain a previously recorded state;

determine that the previously recorded state is a normal state; and

determine that the leak value was detected for a time greater than or equal to a leak time threshold.

22. A non-transitory computer-readable storage medium storing a plurality of programs for execution by a computing device having one or more processors, wherein the plurality of programs, when executed by the one or more processors, cause the computing device to perform acts comprising:

obtaining channel data of at least one channel;

determining that the channel data is a leak value;

determining that the at least one channel is in an activating state based on a previously recorded state and the leak value;

determining that the at least one channel is in an active state based on the activating state and a time threshold value, wherein the active state comprises an active leak state, an active moisture state, and a prompt state; and

outputting the active state.

23. The non-transitory computer-readable storage medium of claim 21, wherein the plurality of programs further cause the computing device to perform:

determining that the channel data has a value greater than a low threshold value; and

determining that the channel data has a value less than a resistance threshold value.

24. The non-transitory computer-readable storage medium of claims 22 or claim 23, wherein the plurality of programs further cause the computing device to perform:

obtaining a previously recorded state;

determining that the previously recorded state is a normal state; and

determining that the leak value was detected for a time greater than or equal to a leak

time threshold.

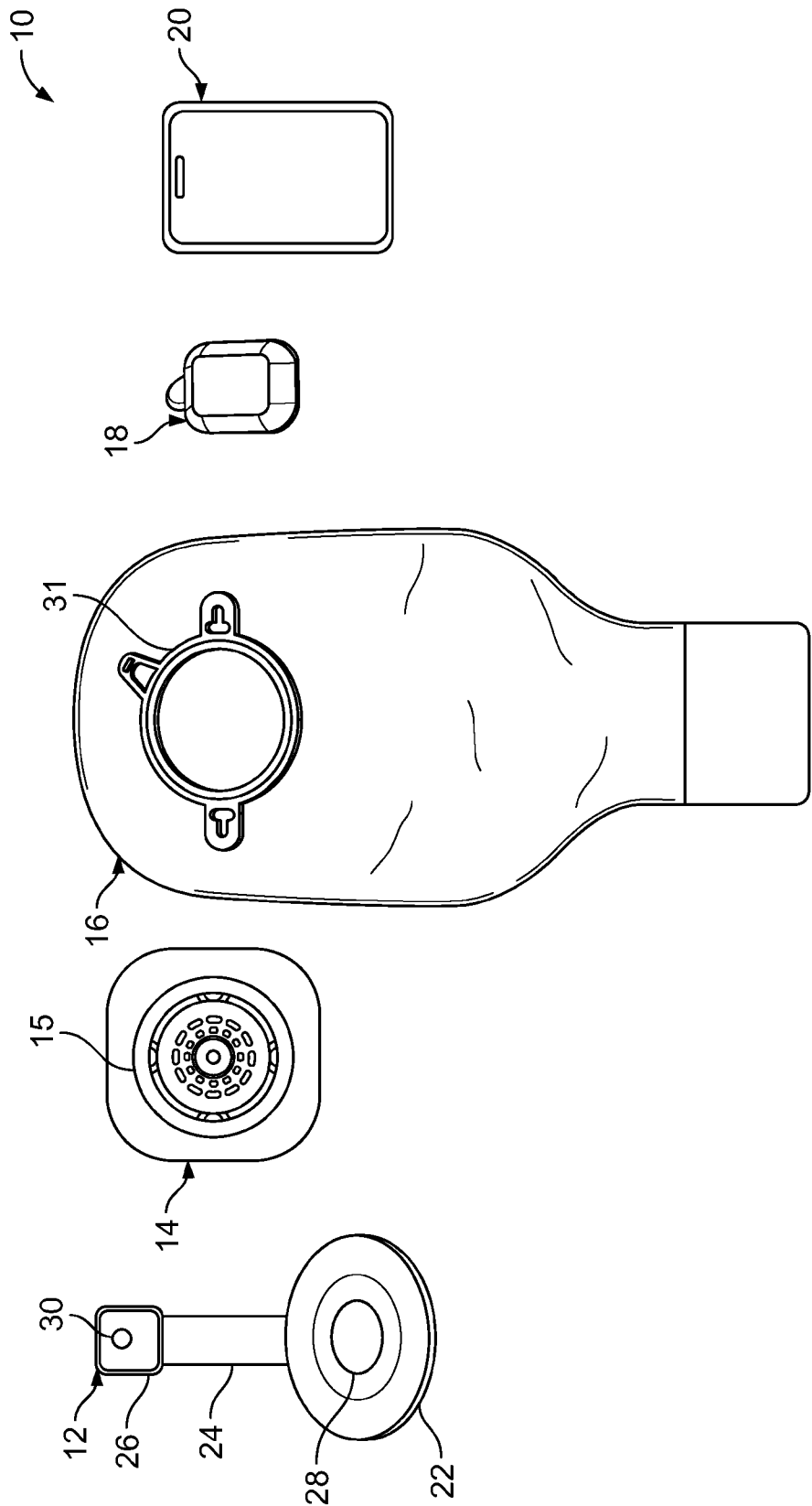


FIG. 1

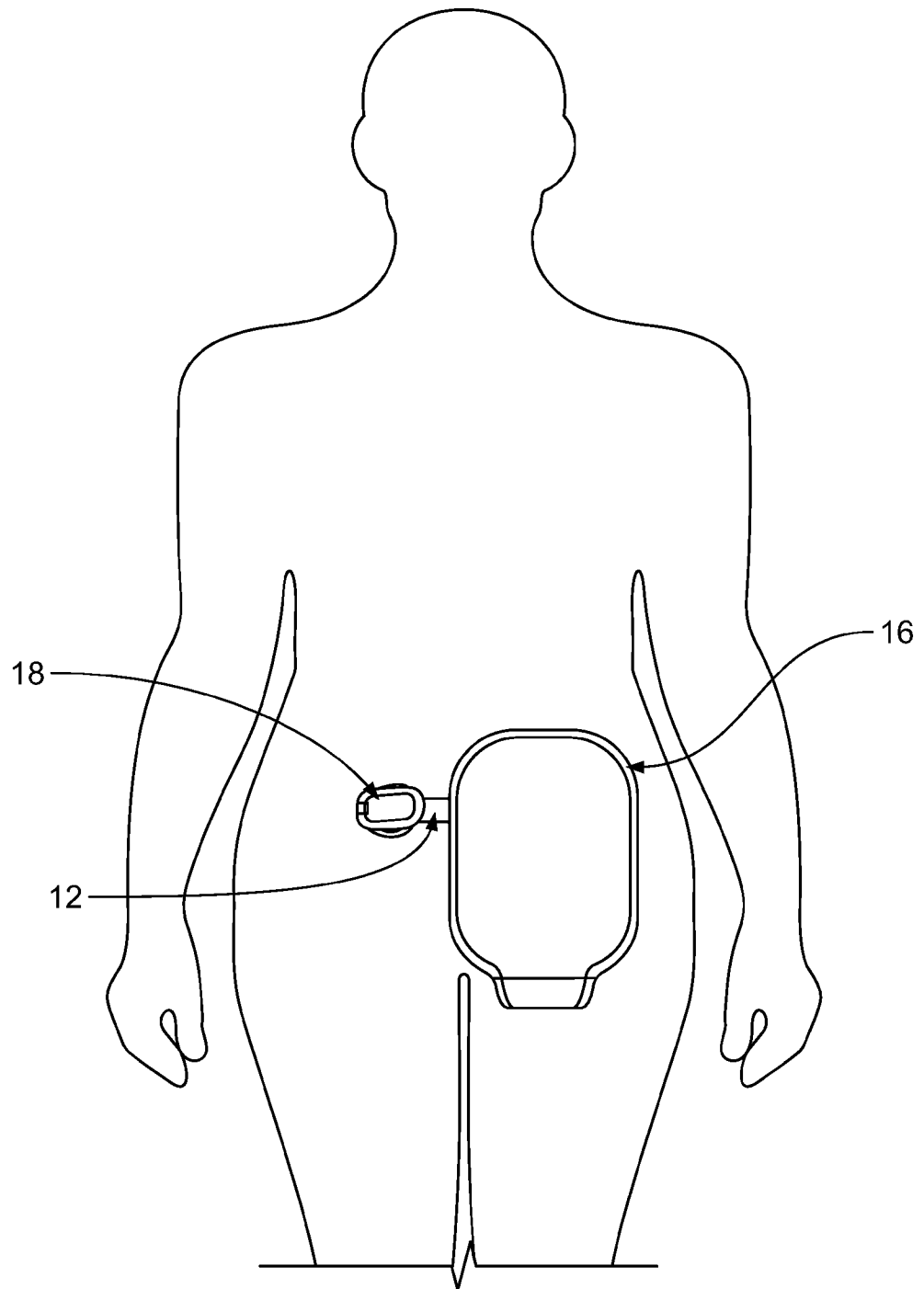


FIG. 2

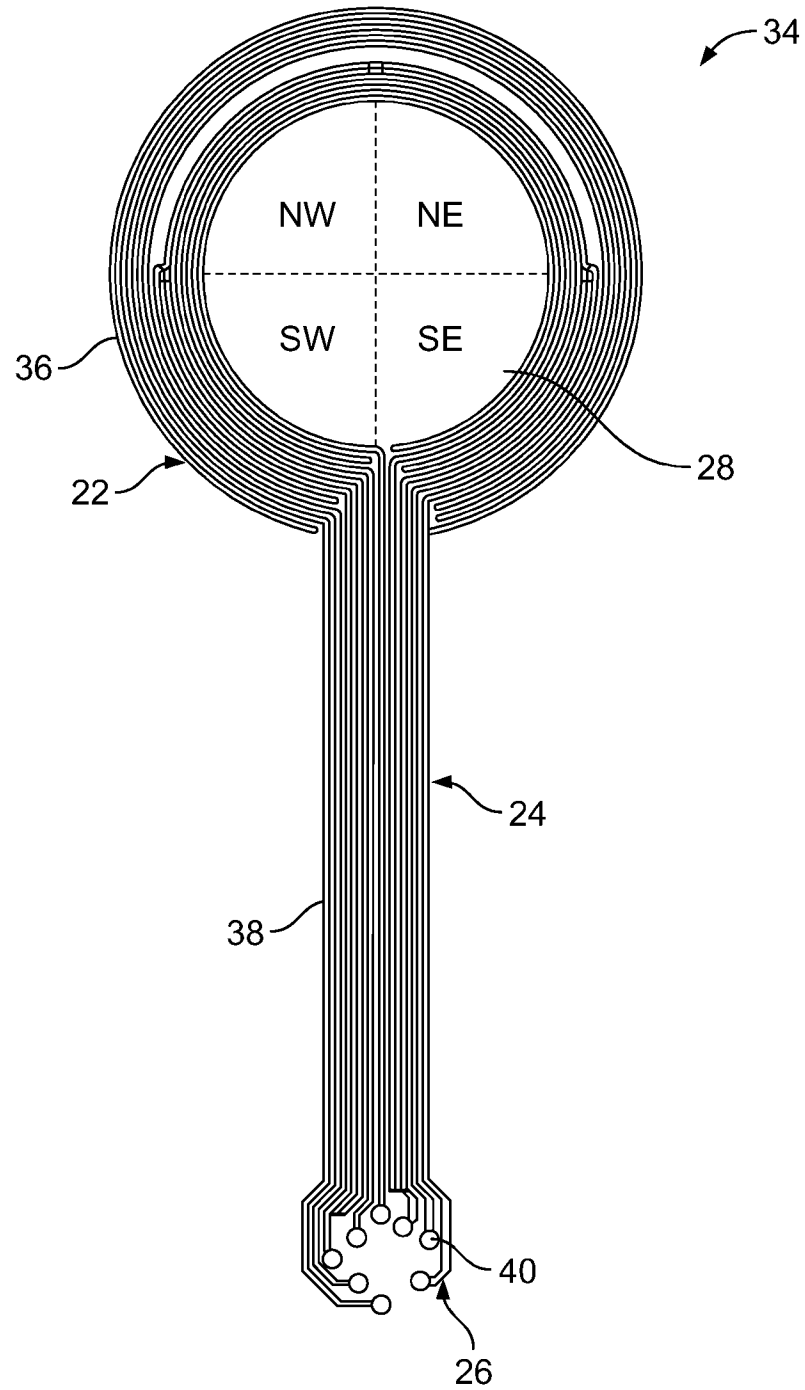


FIG. 3A

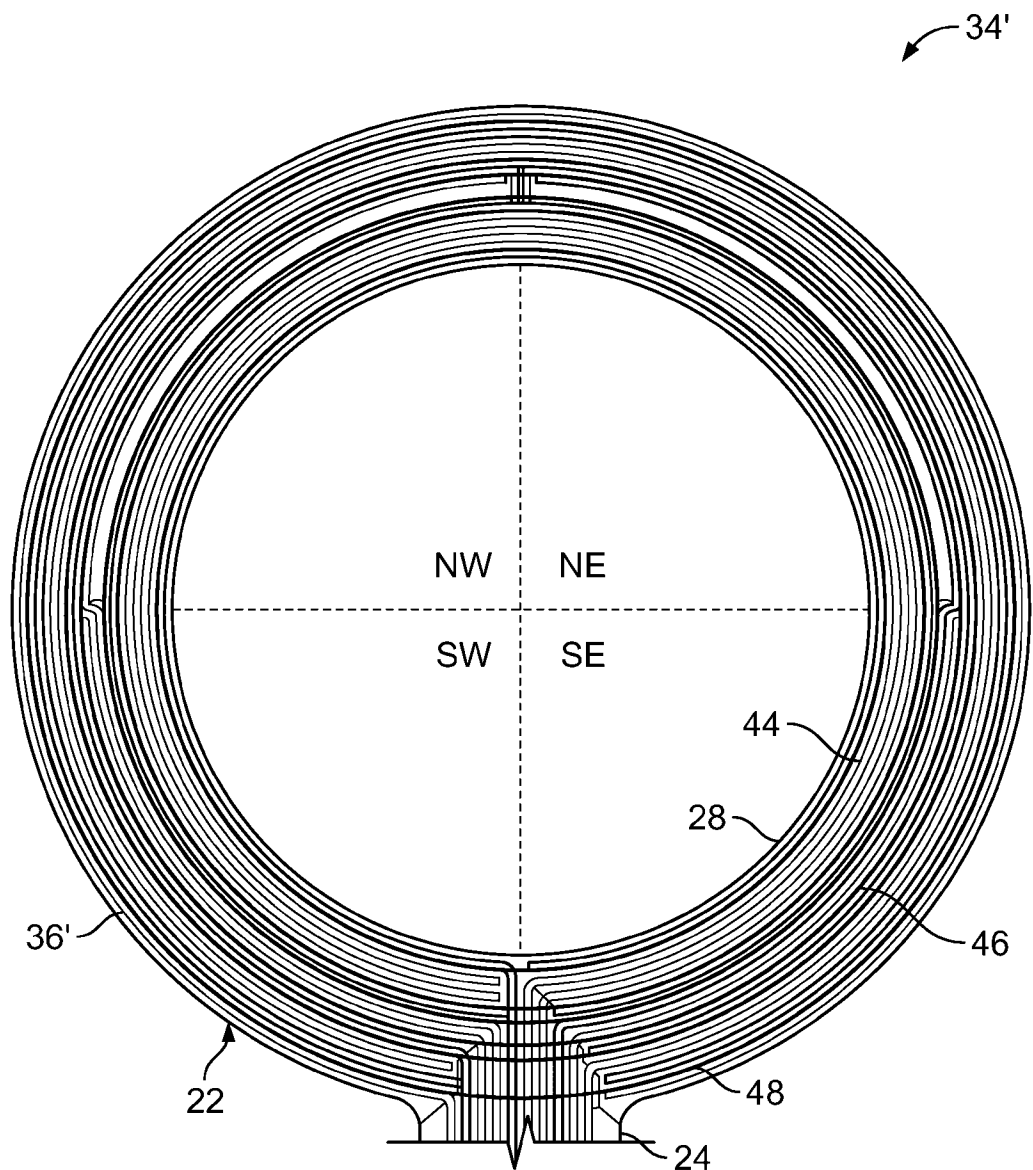


FIG. 3B

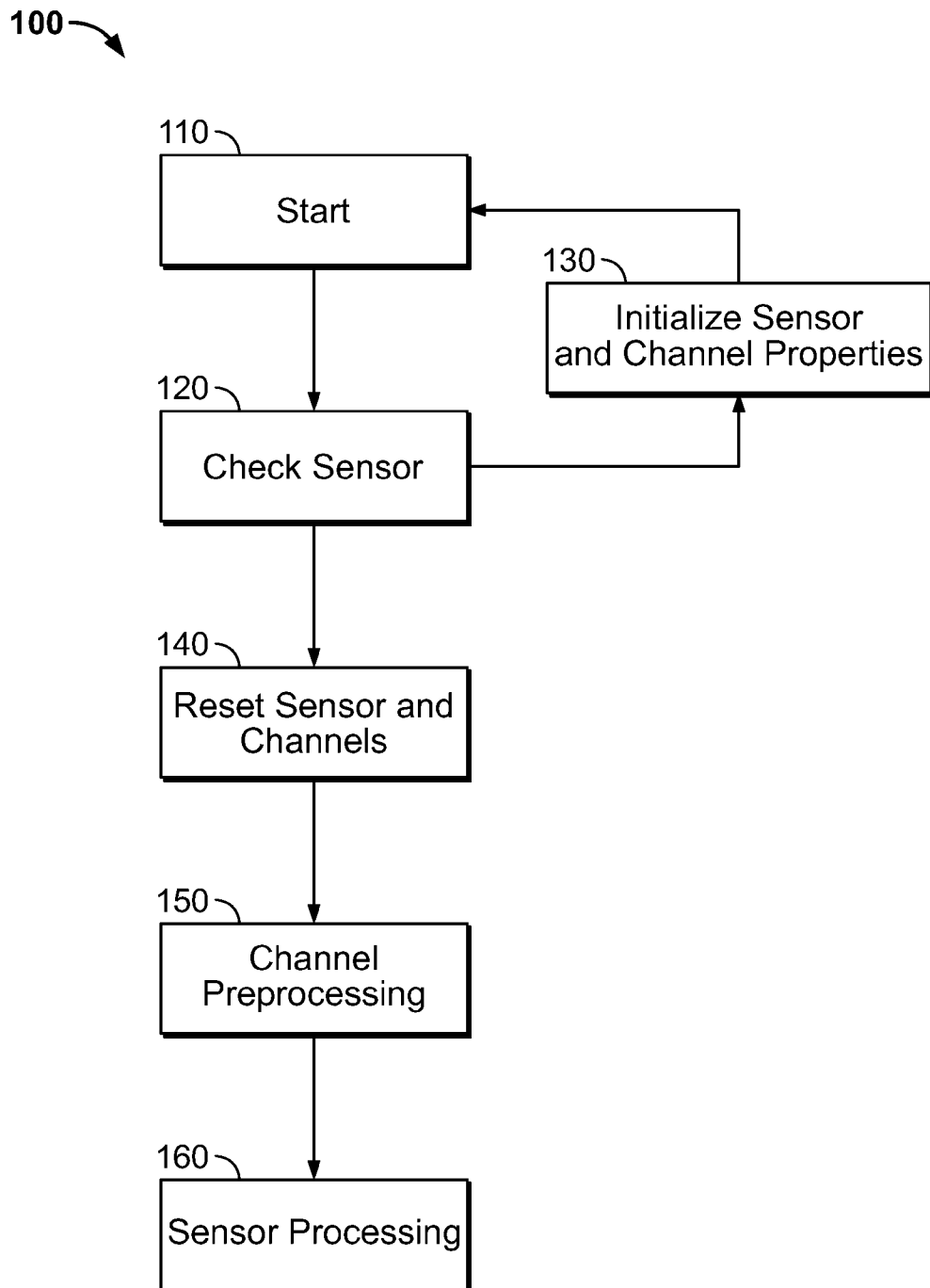


FIG. 4

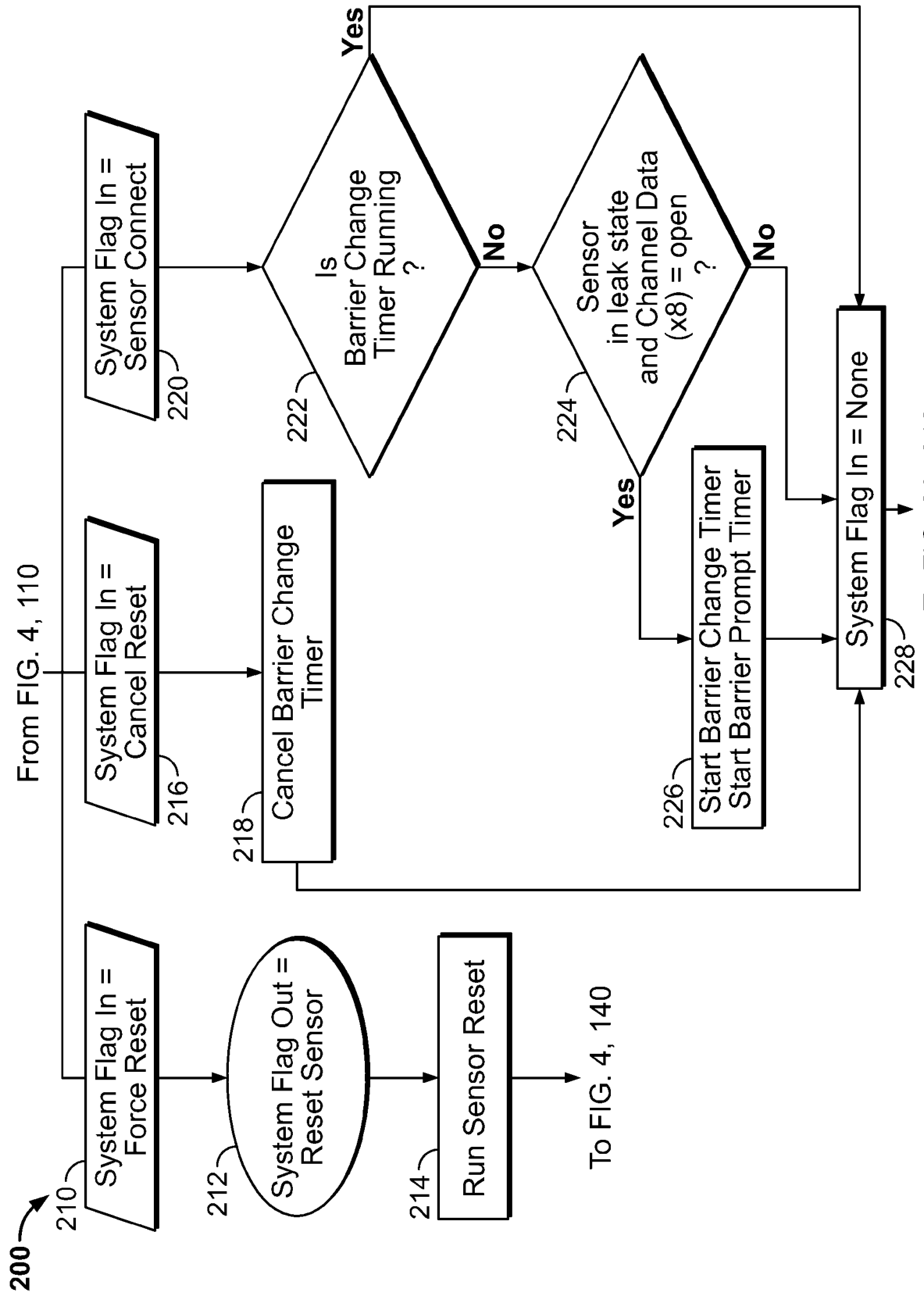


FIG. 5

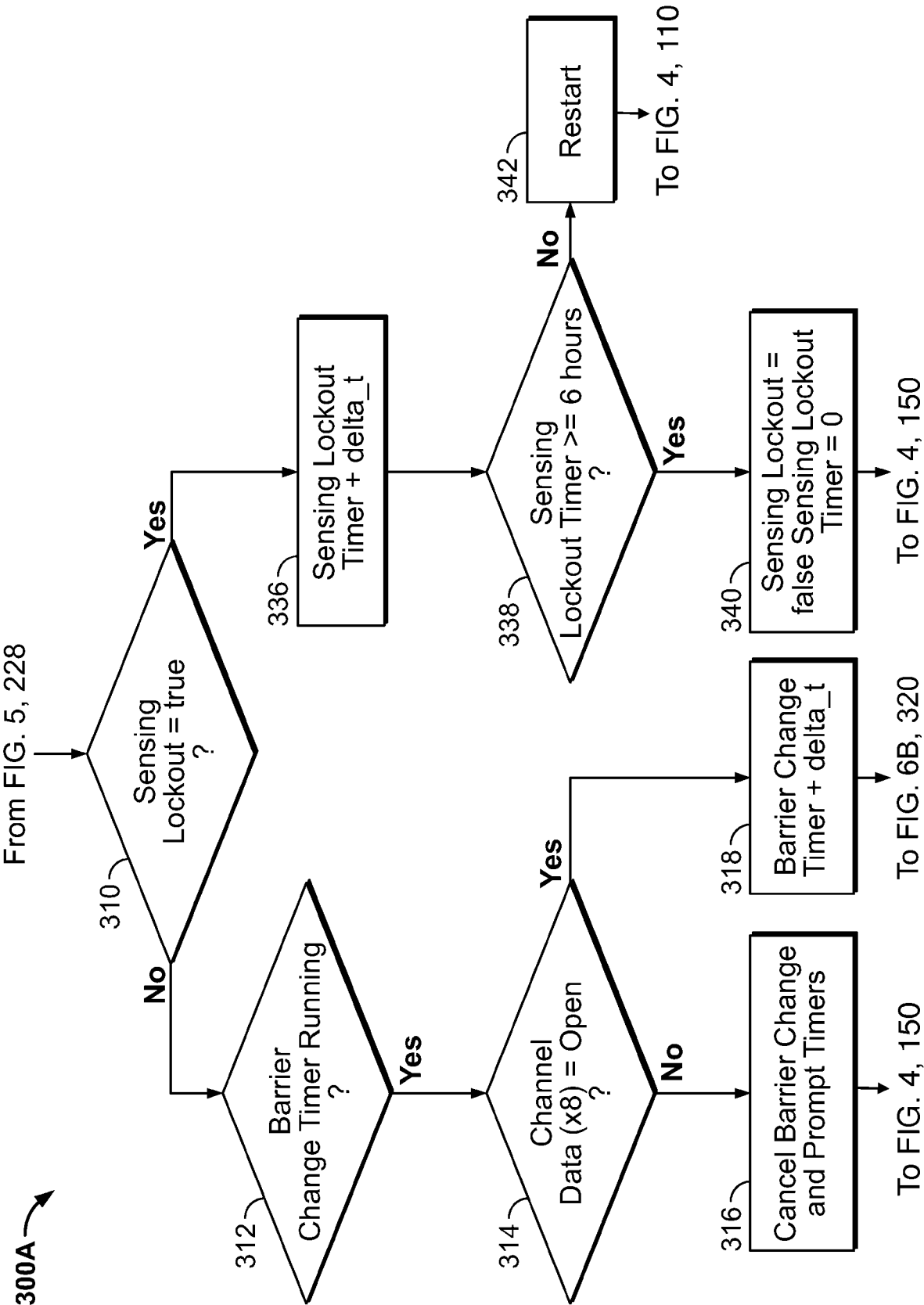


FIG. 6A

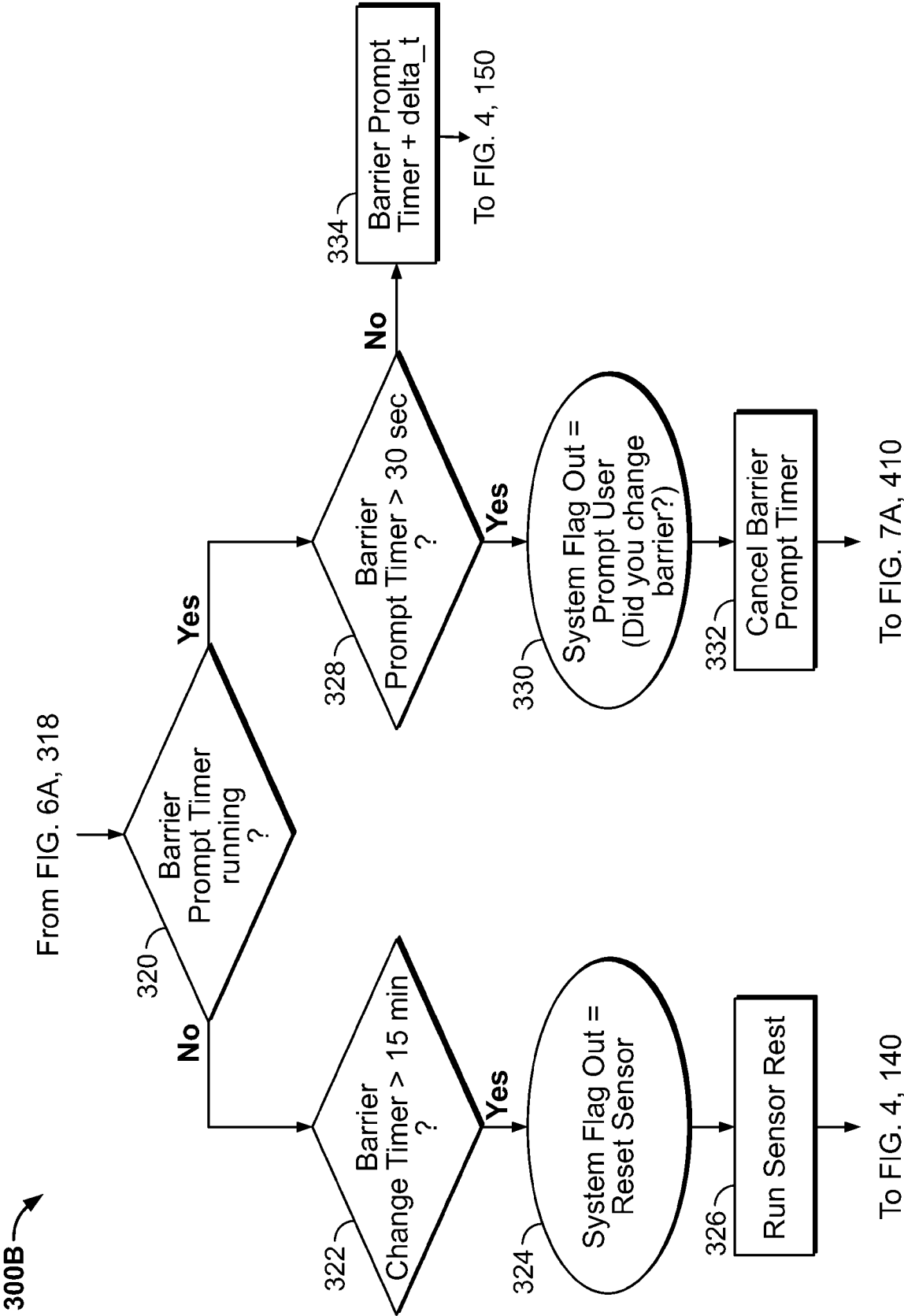


FIG. 6B

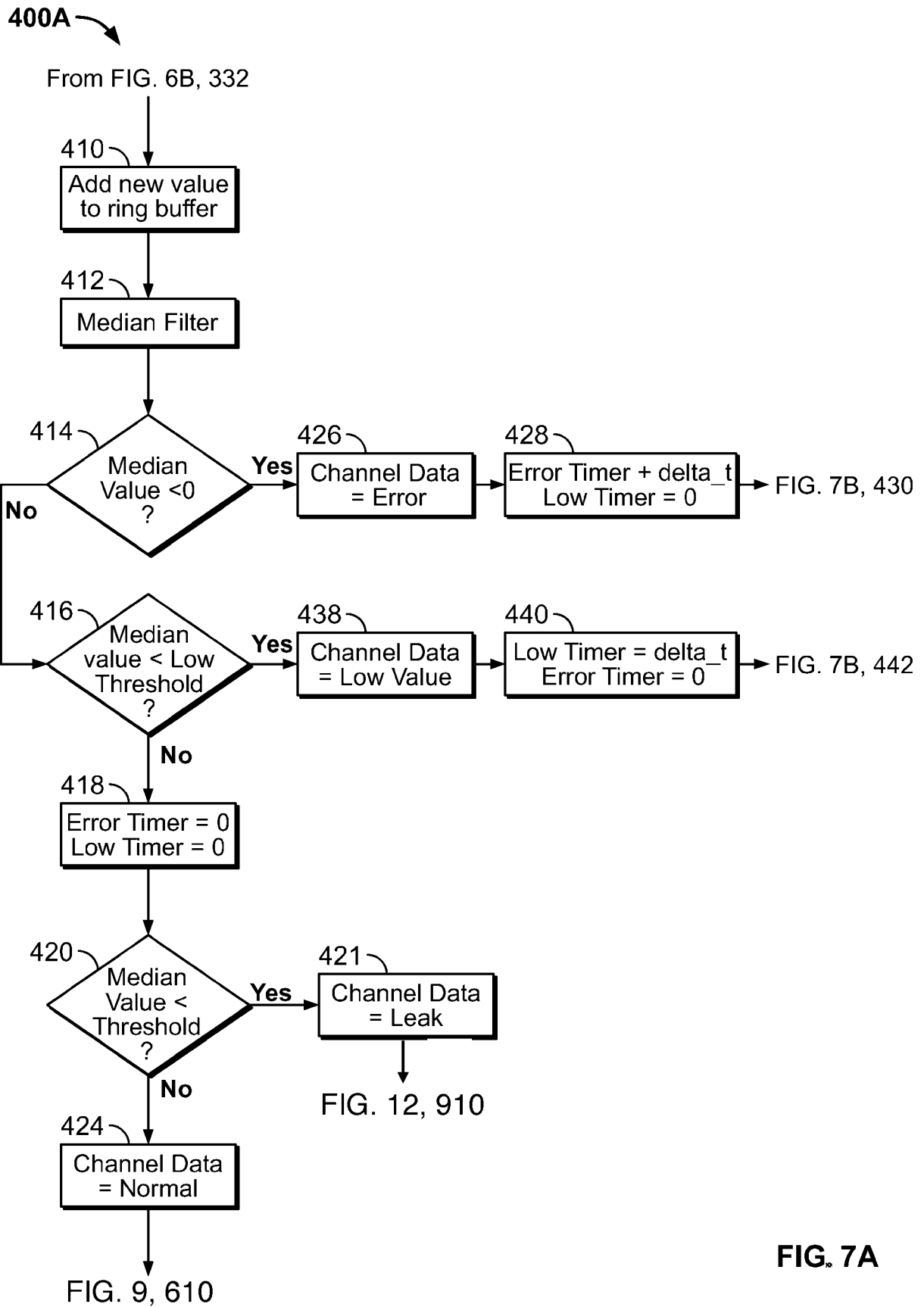
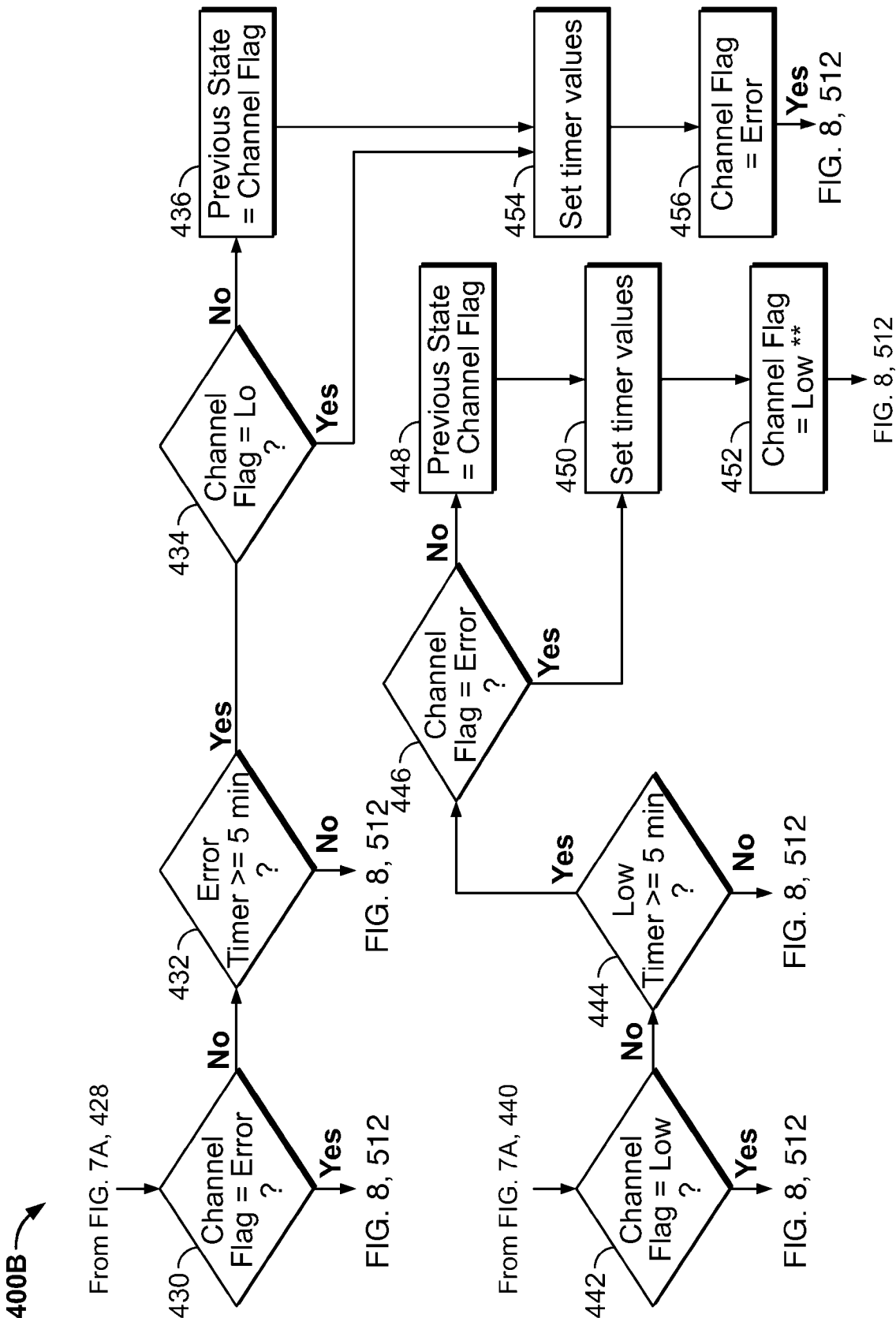


FIG. 7A



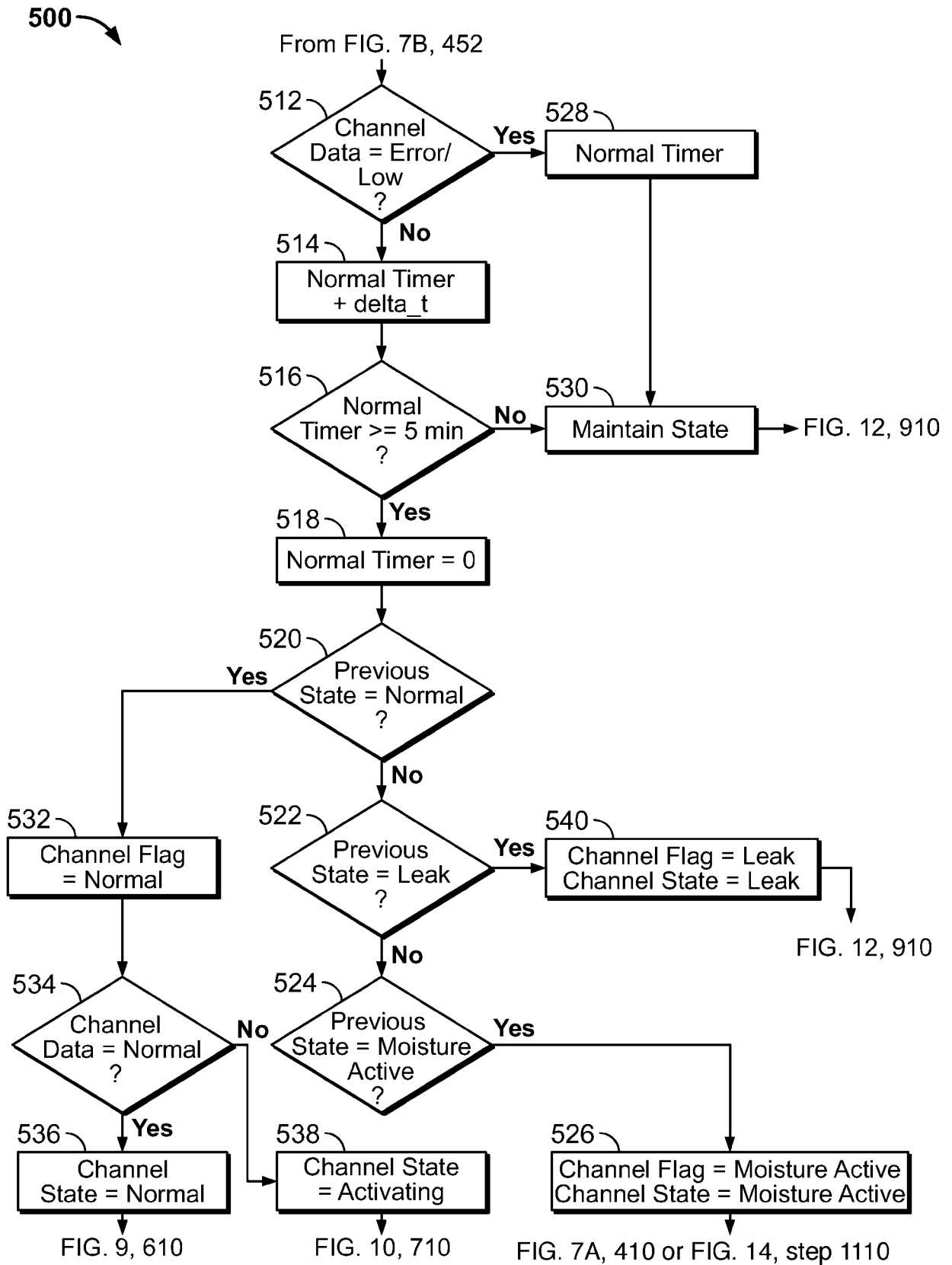


FIG. 8

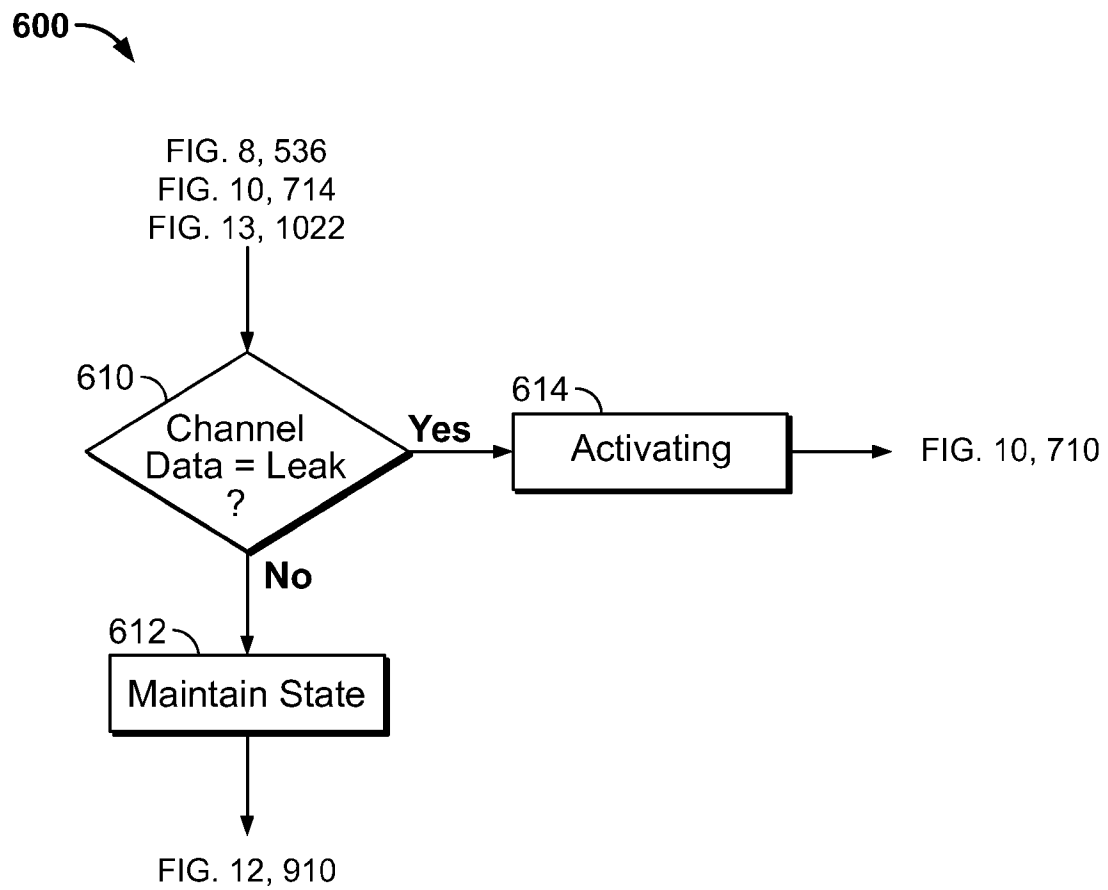
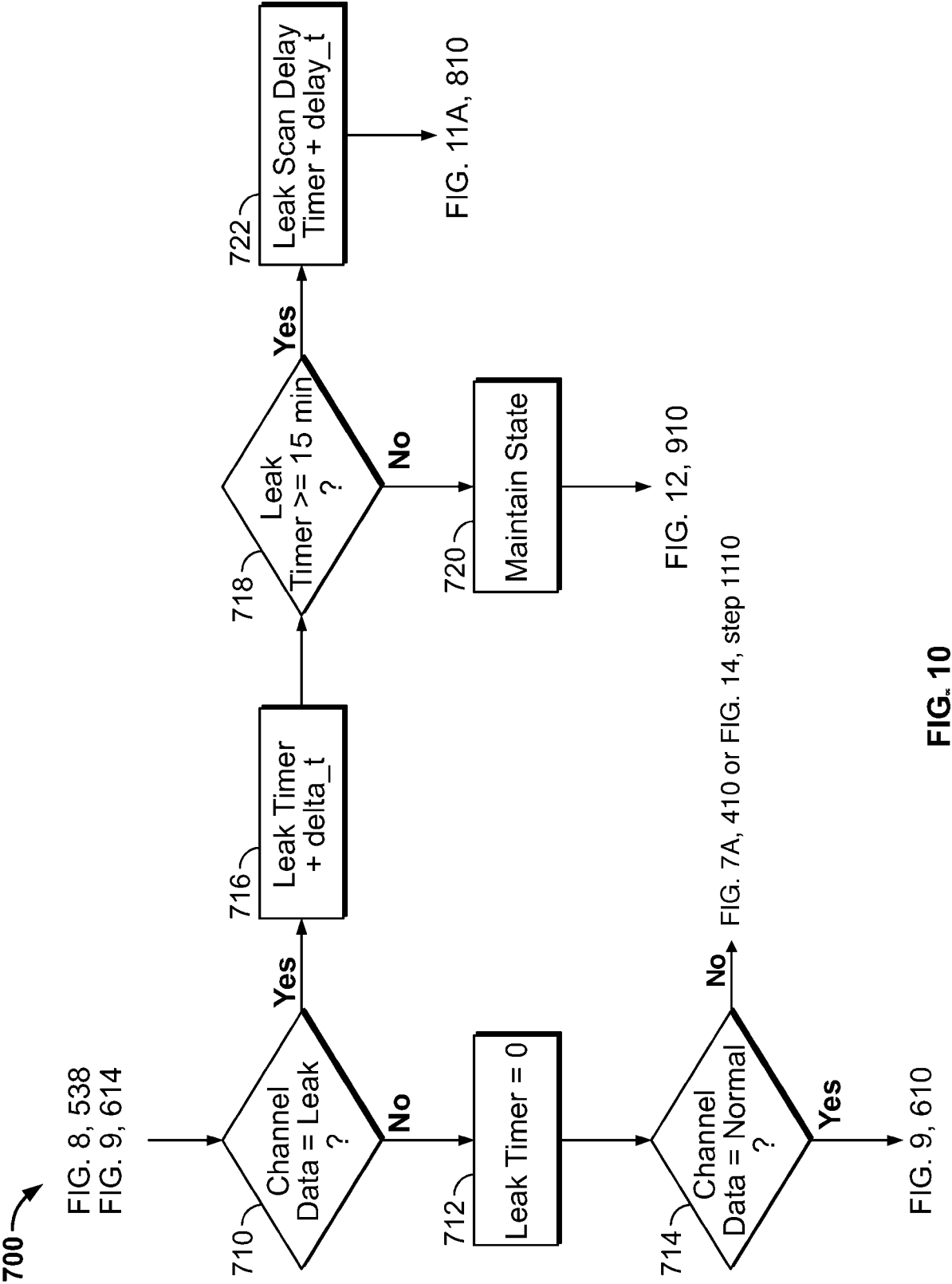
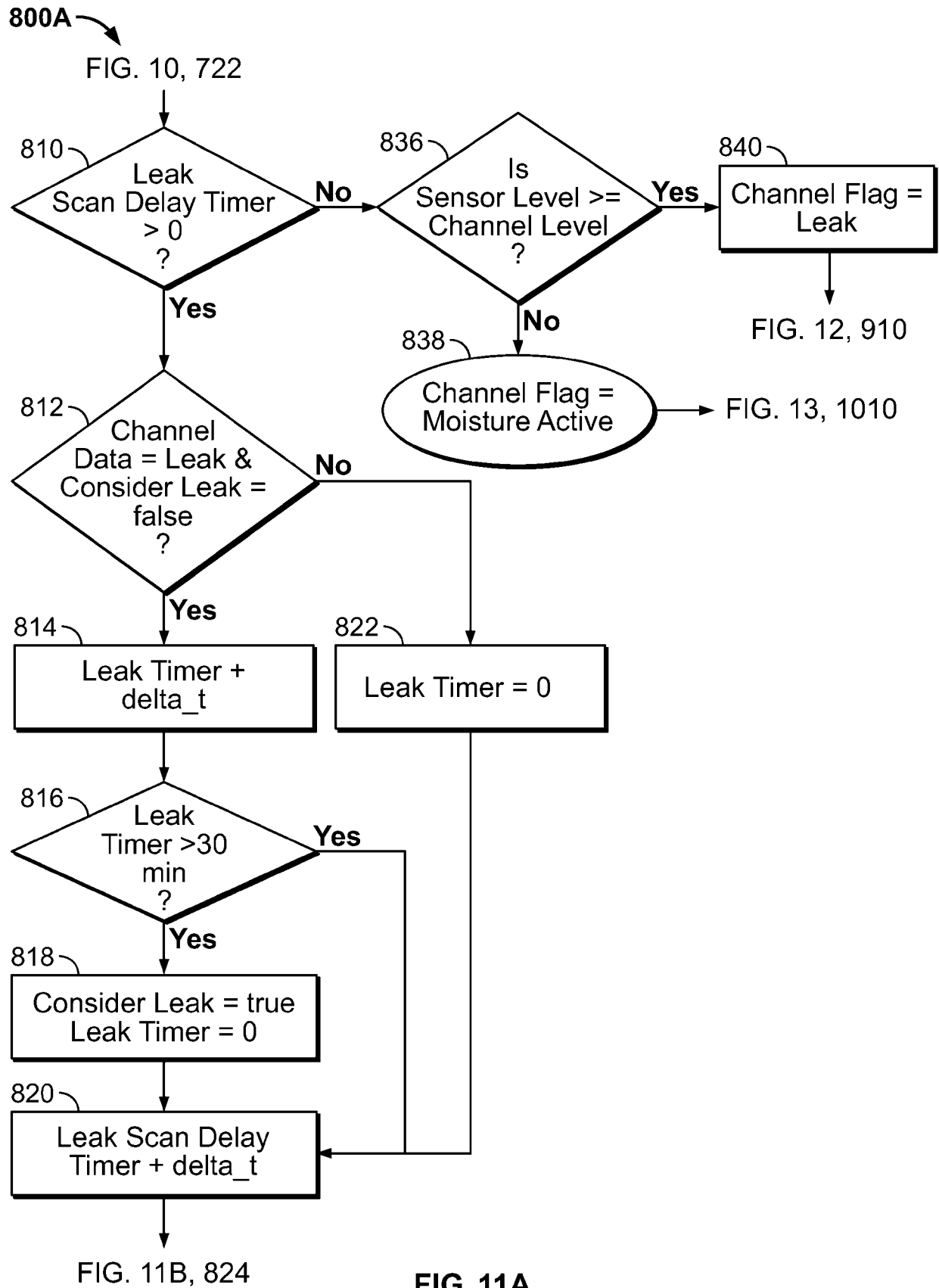


FIG. 9





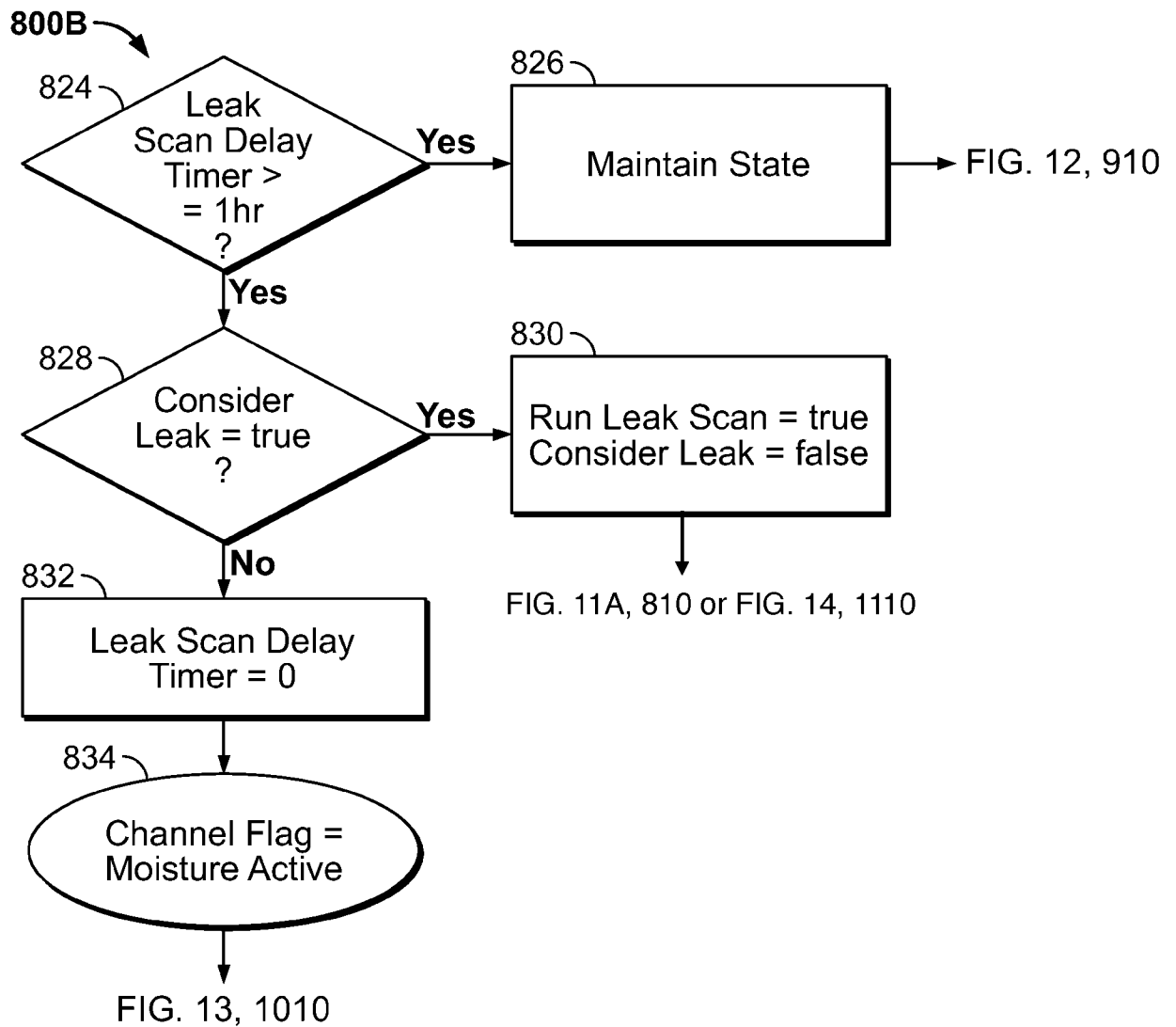


FIG. 11B

900

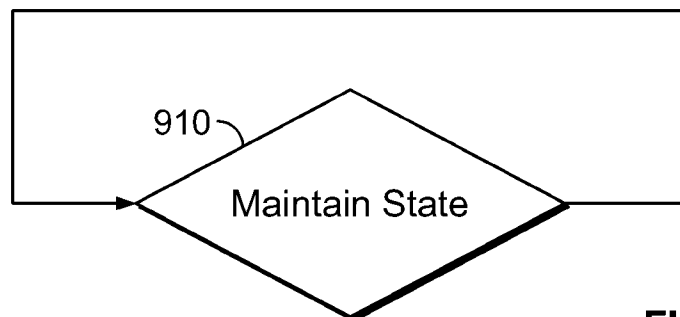
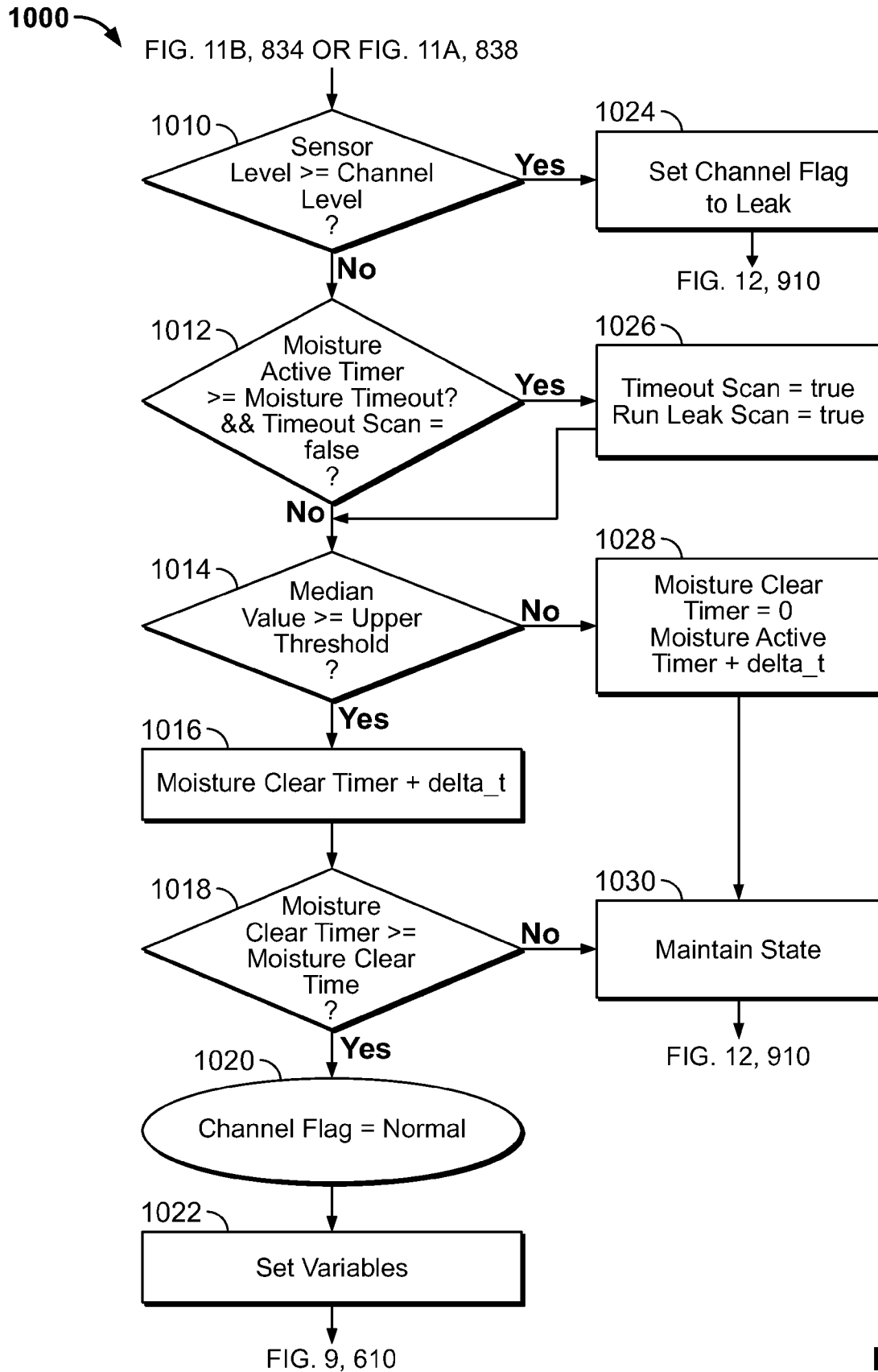


FIG. 12



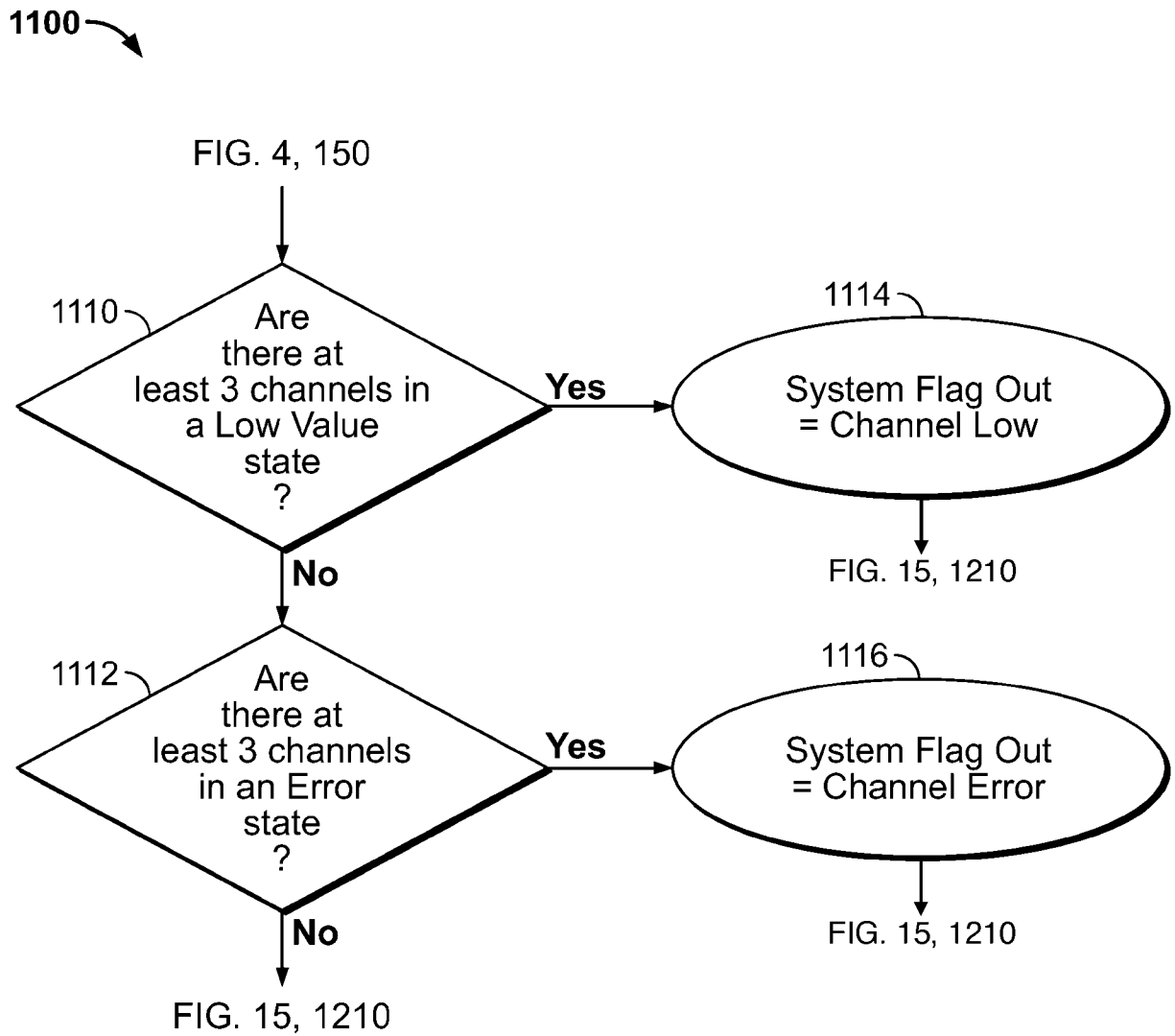


FIG. 14

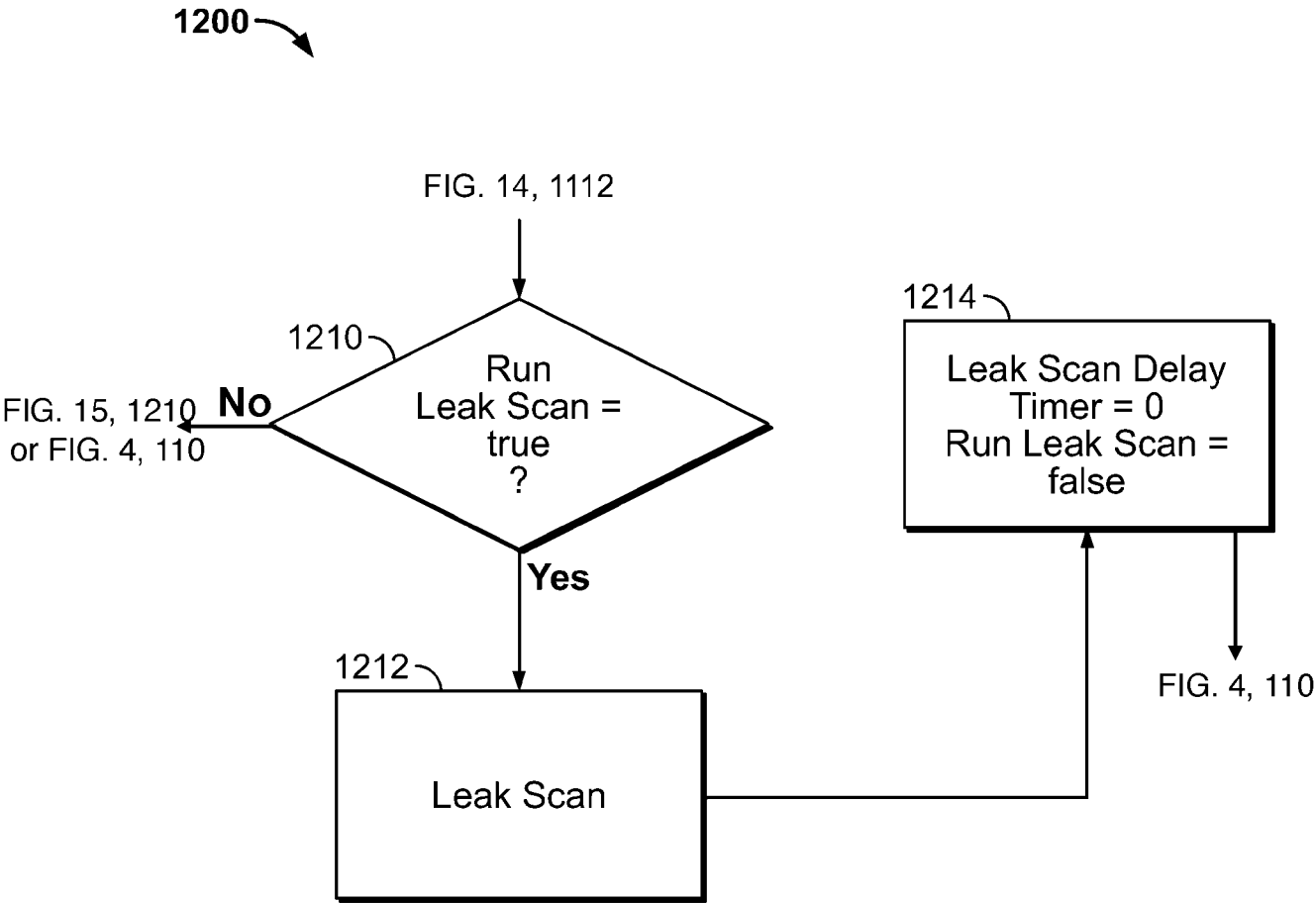


FIG. 15

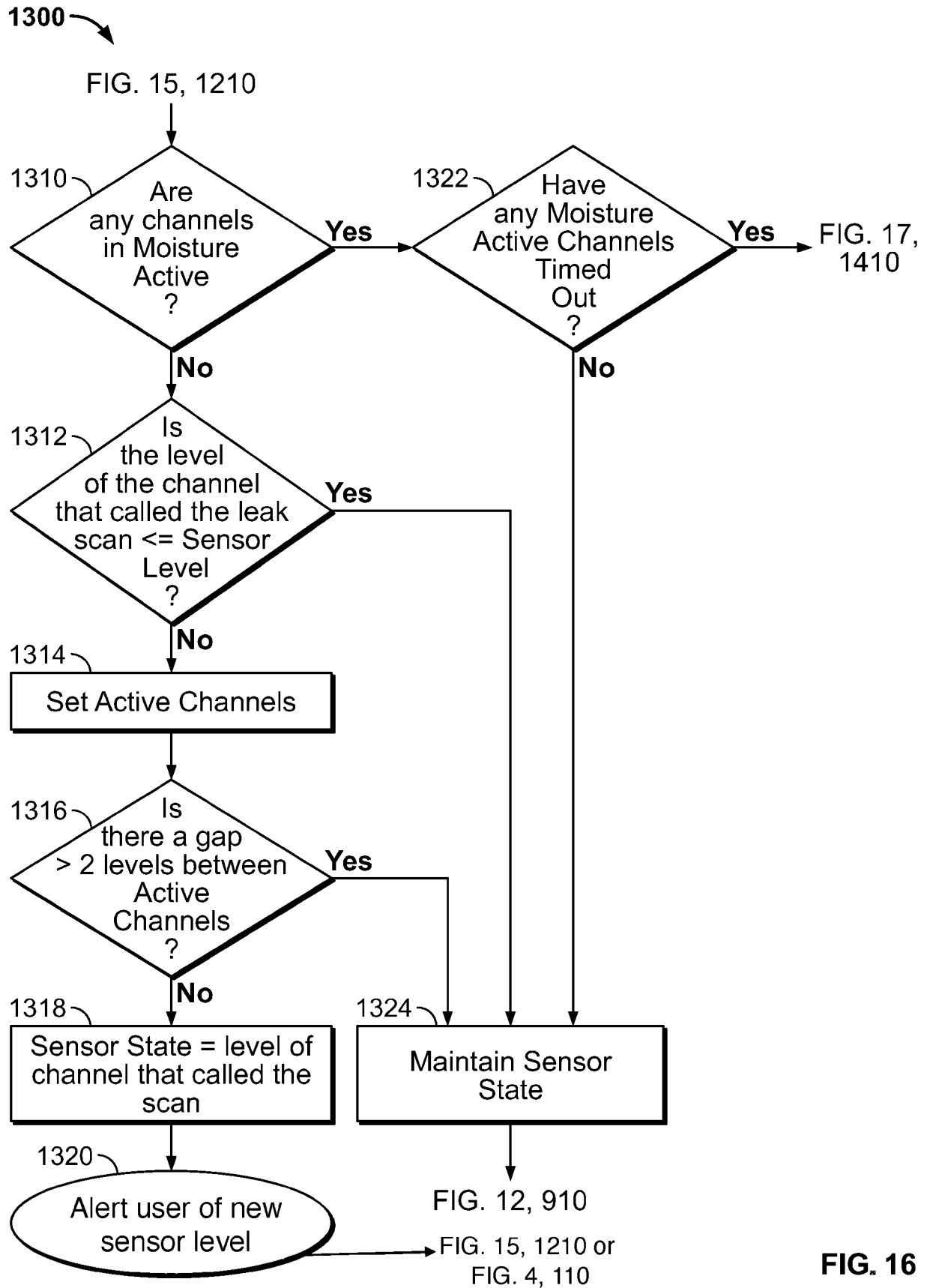


FIG. 16

1400

FIG. 16, 1322

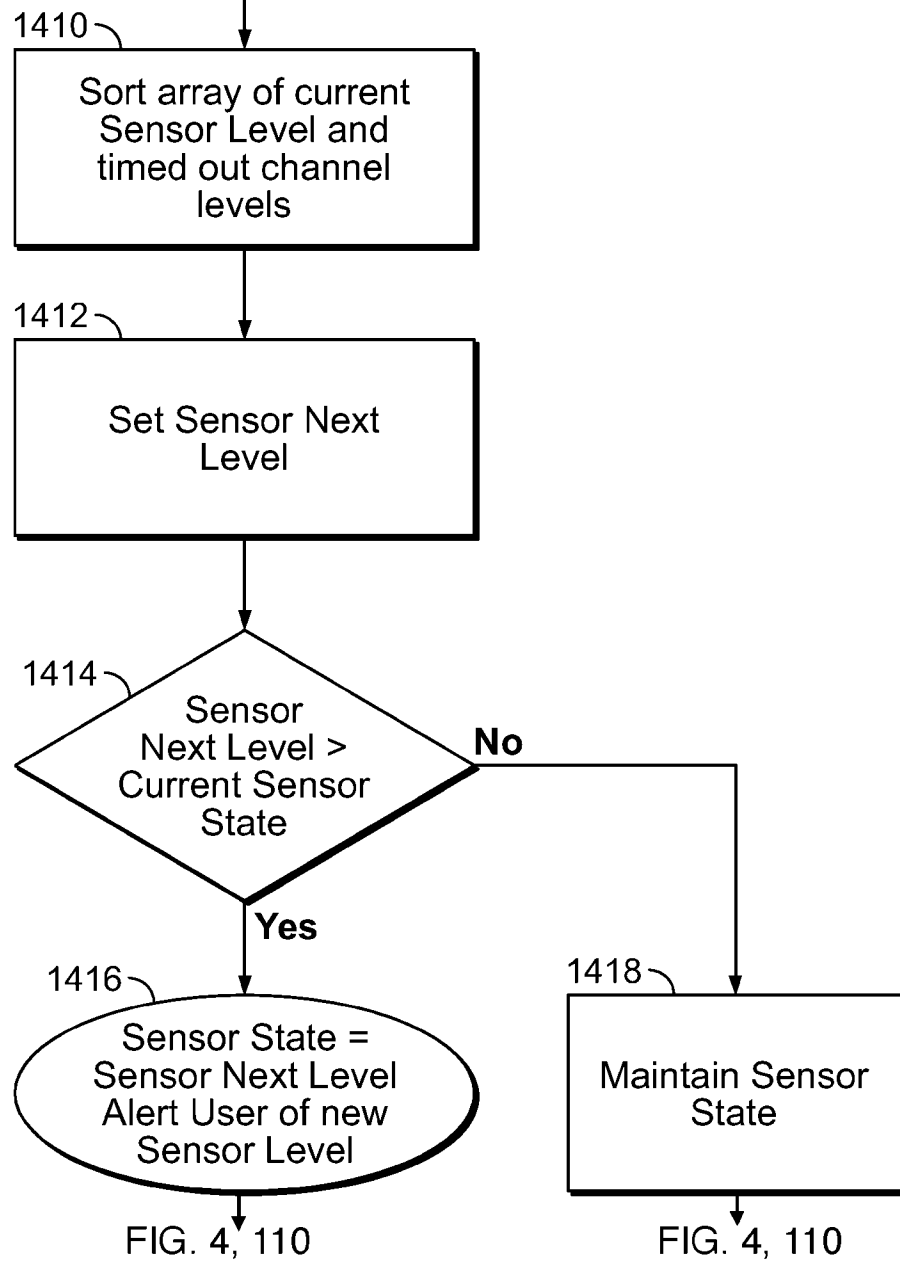


FIG. 17

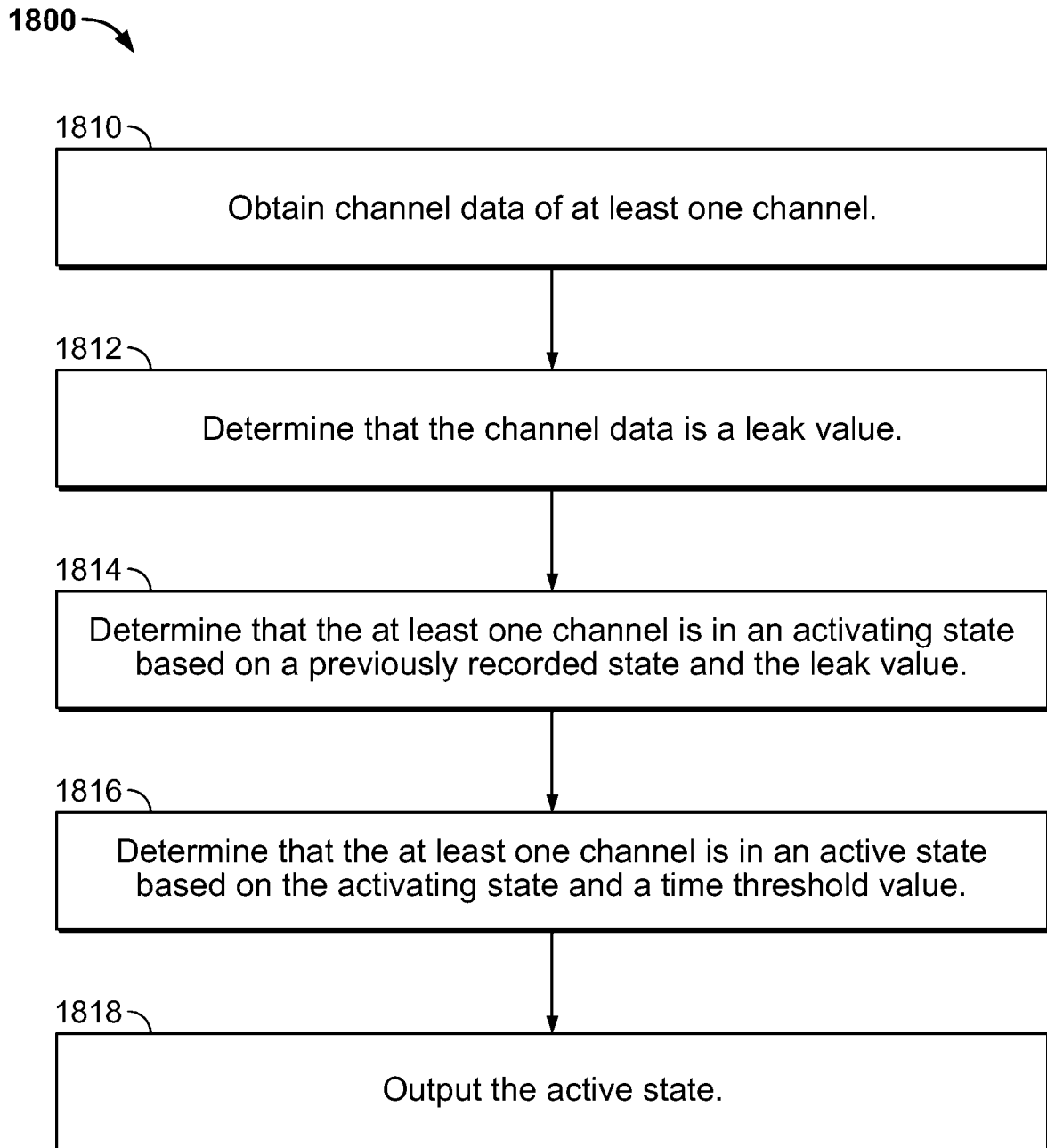


FIG. 18

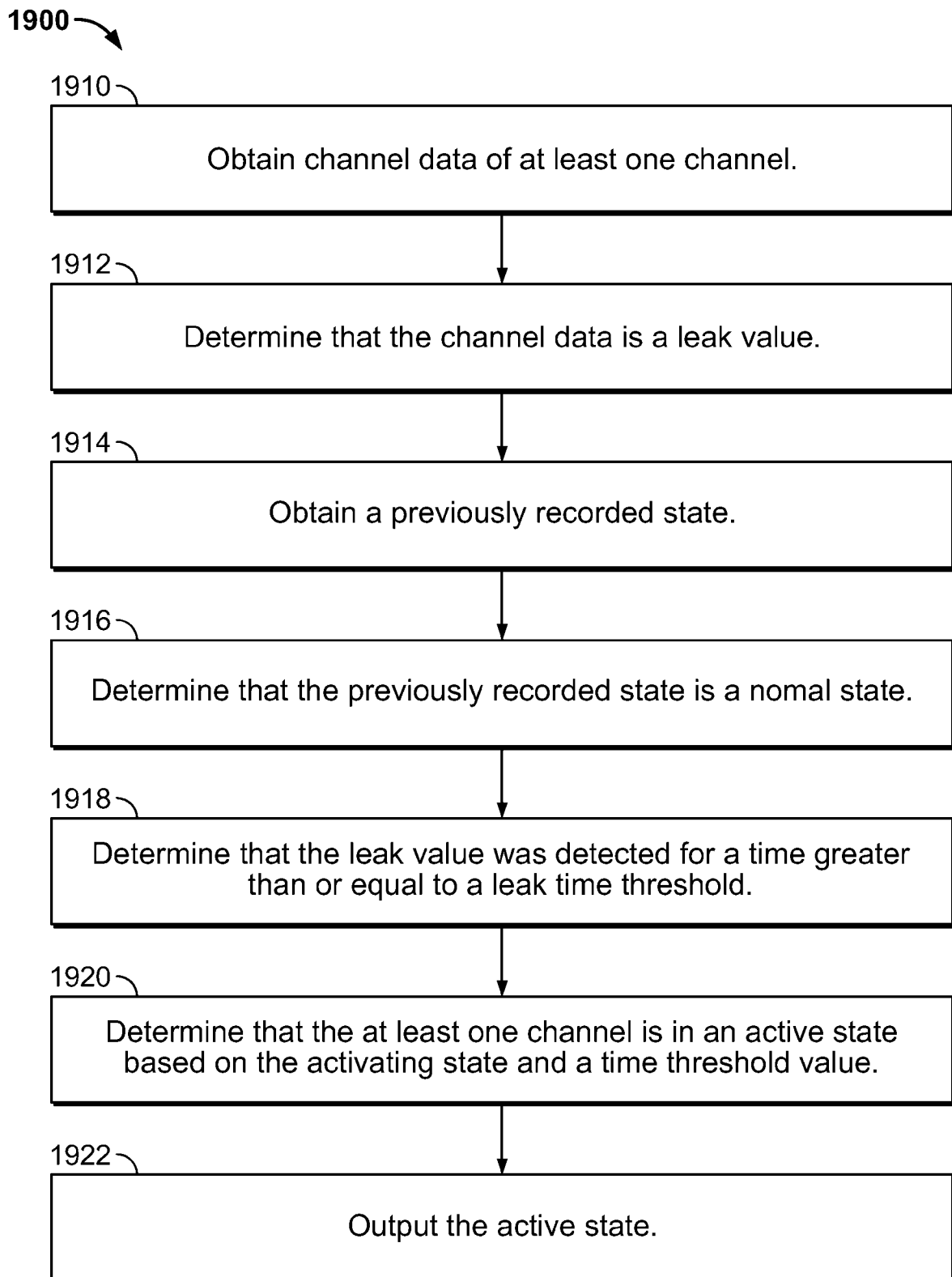
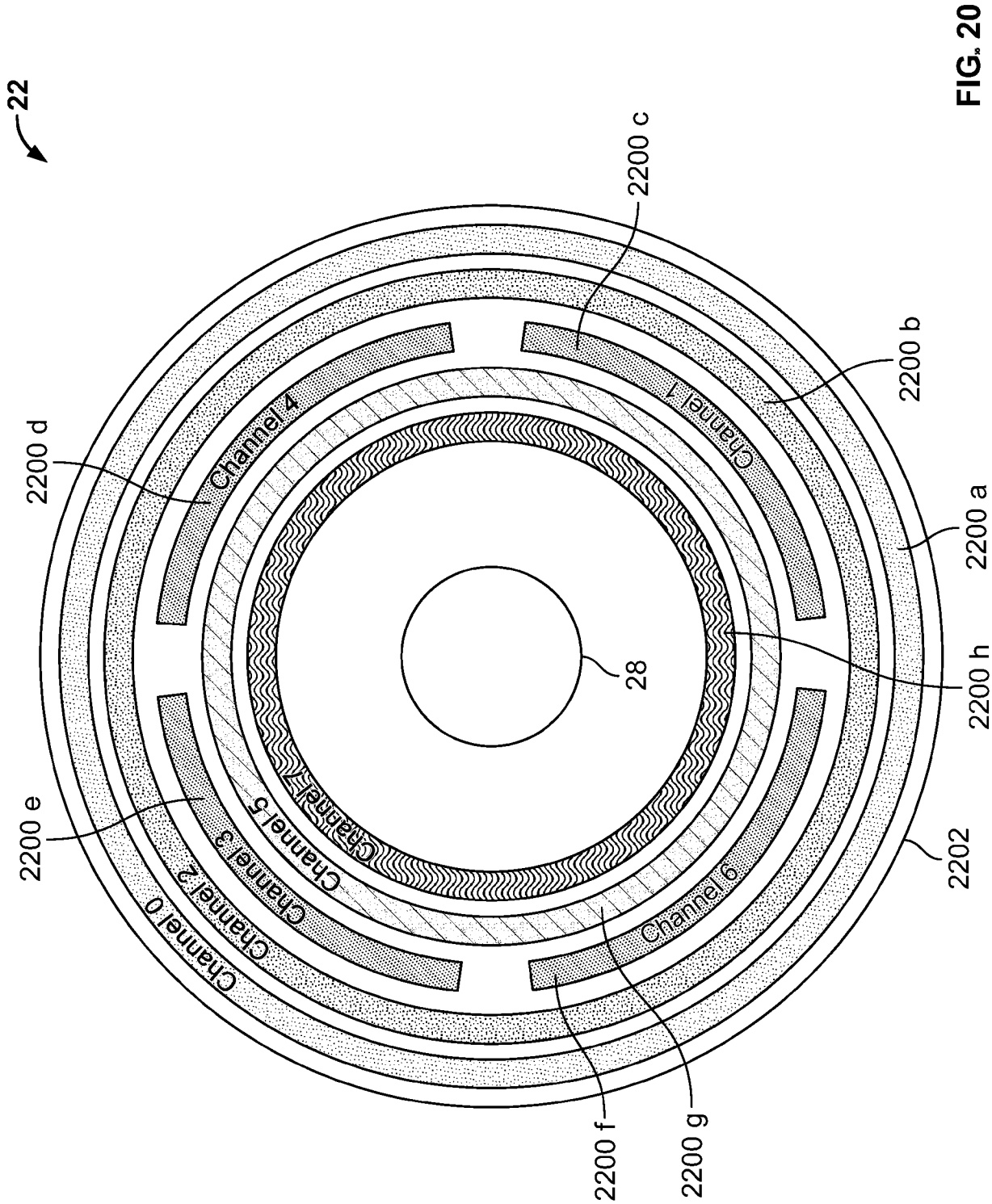
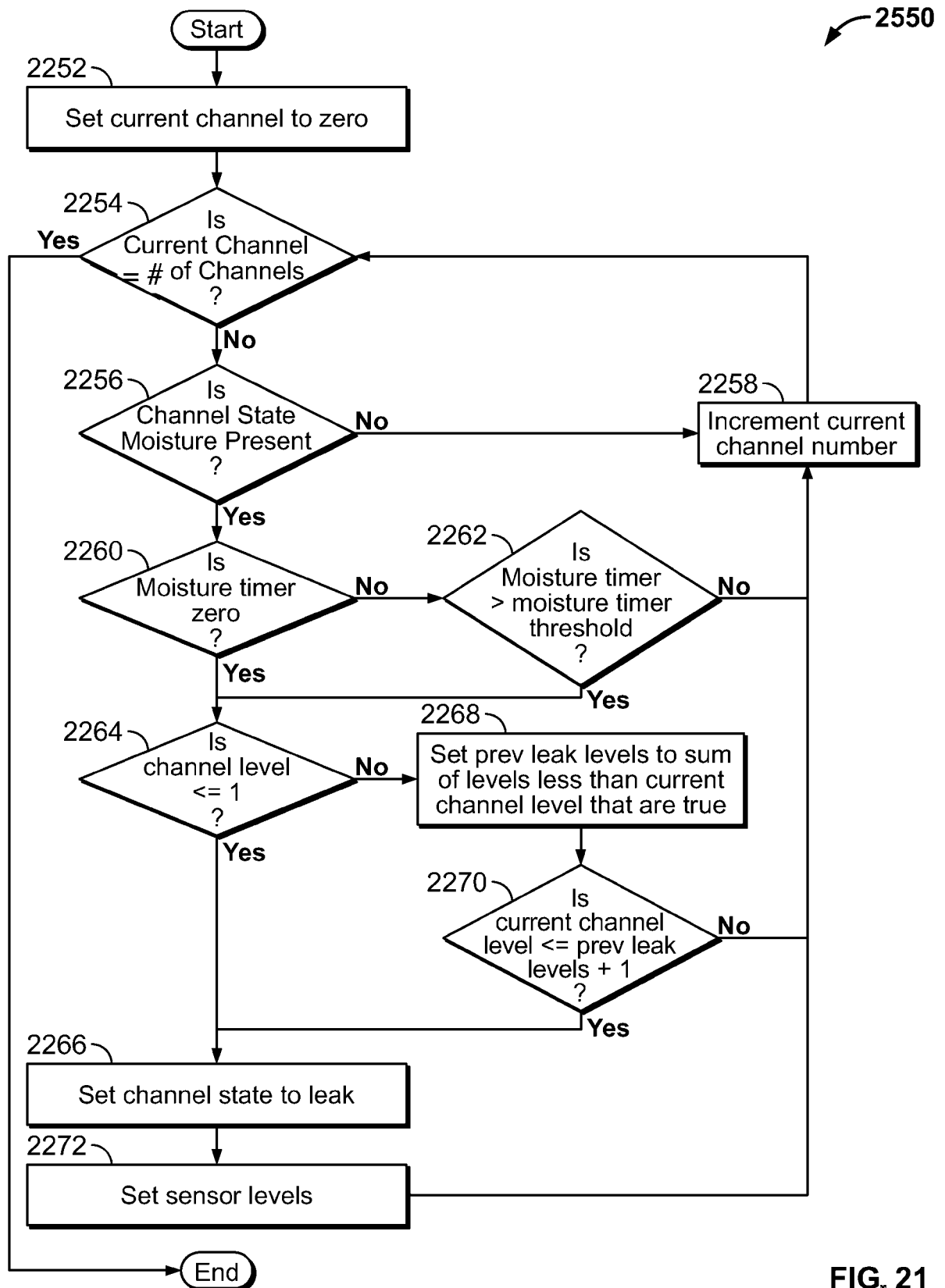


FIG. 19





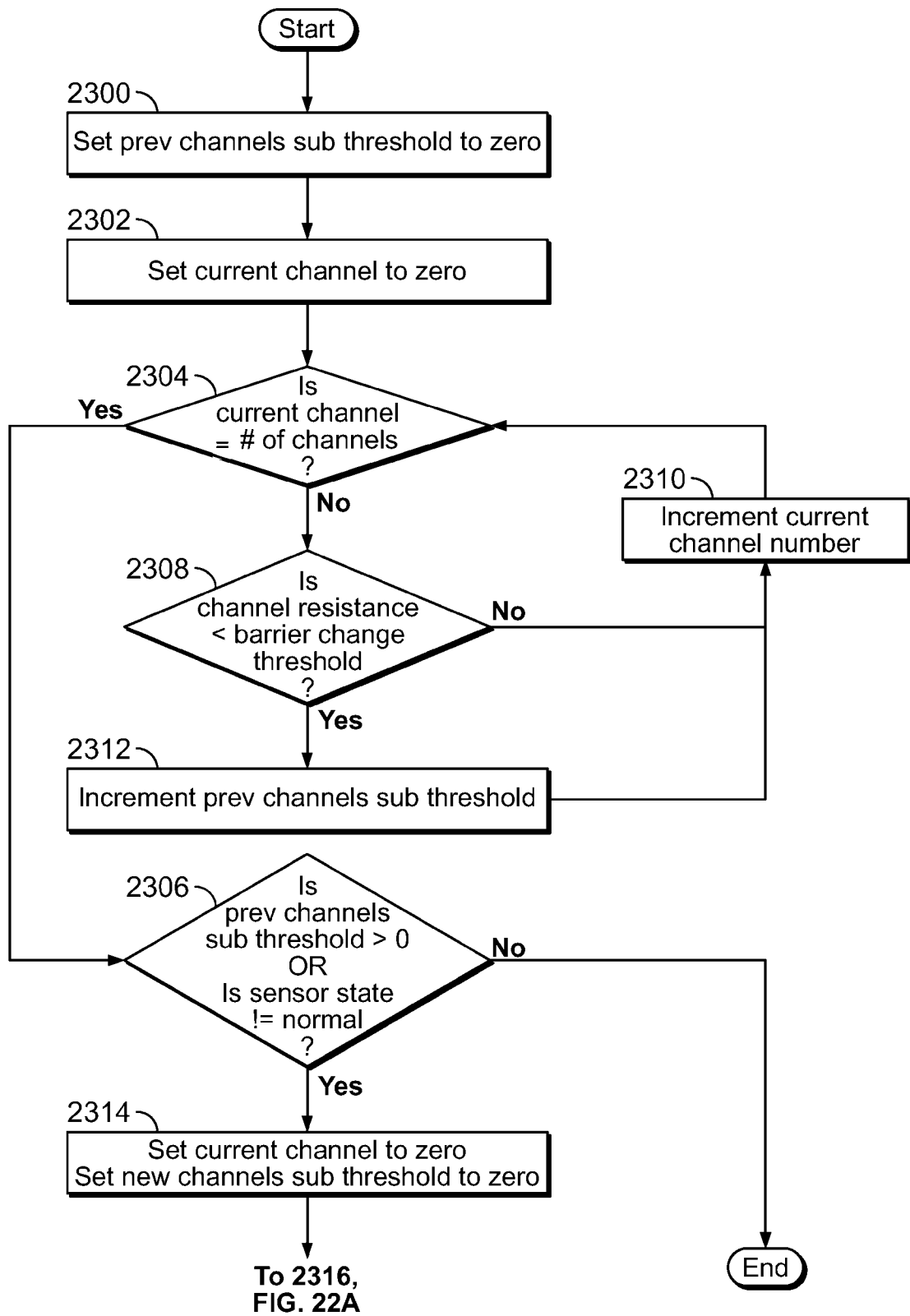


FIG. 22

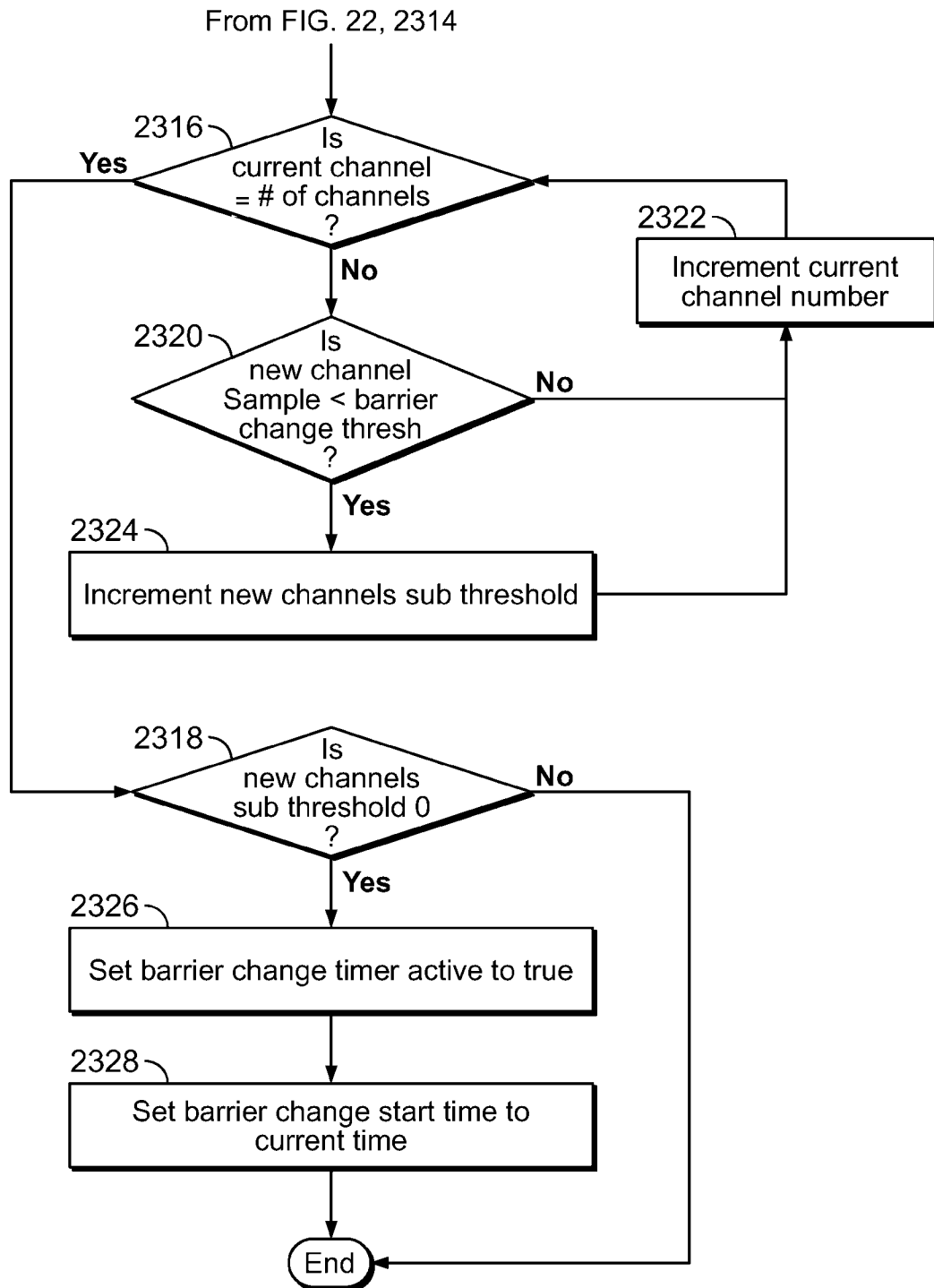
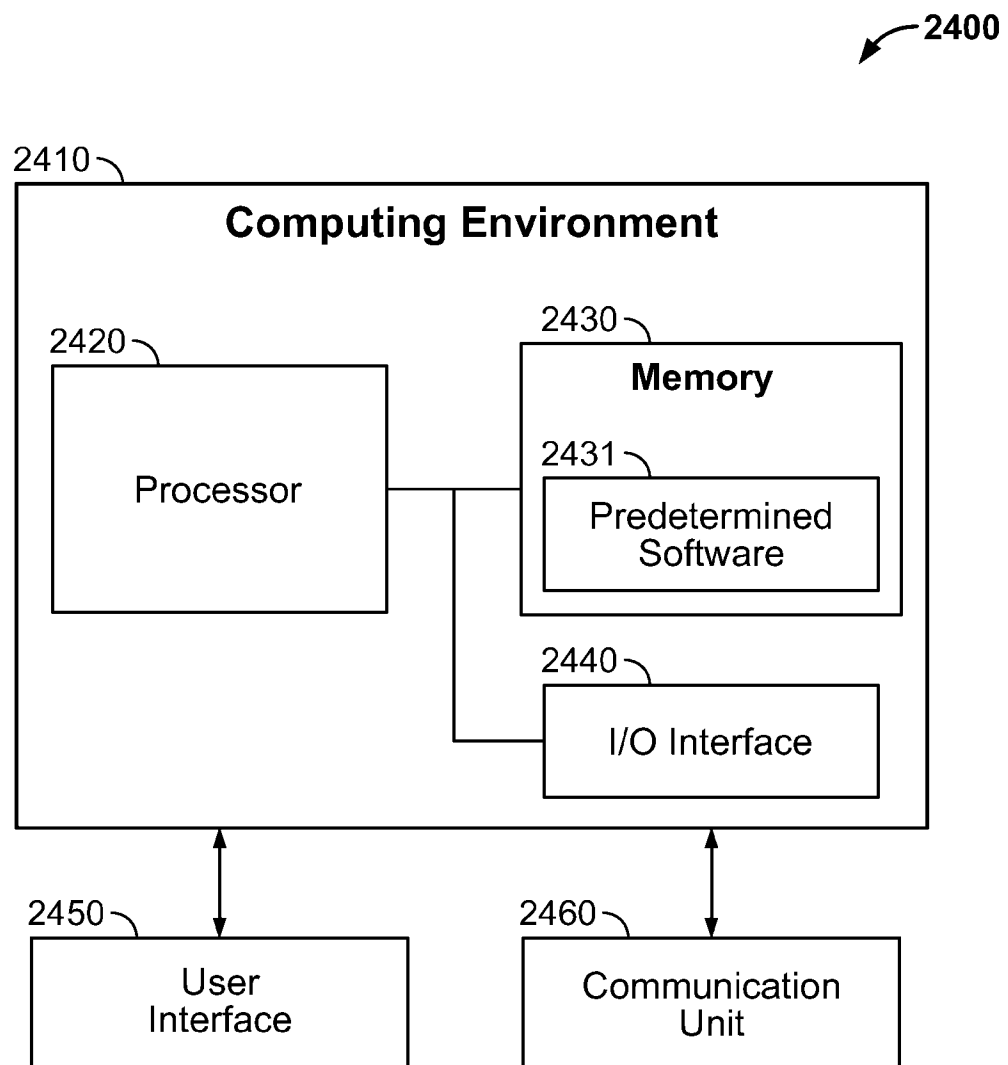


FIG. 22A

**FIG. 23**

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2024/036006

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                   |                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>INV. A61F5/445 A61F5/44<br>ADD.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                   |                                                                      |
| According to International Patent Classification (IPC) or to both national classification and IPC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                   |                                                                      |
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>A61F<br><br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br><br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>EPO-Internal                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                   |                                                                      |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                   |                                                                      |
| Category*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Citation of document, with indication, where appropriate, of the relevant passages                                                                | Relevant to claim No.                                                |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | WO 2022/082215 A1 (11 HEALTH AND TECH INC [US]) 21 April 2022 (2022-04-21) paragraphs [0054], [0107] - [0108], [0131] - [0134]<br>-----           | 1 - 24                                                               |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | WO 2020/123771 A2 (11 HEALTH AND TECH LIMITED [GB]) 18 June 2020 (2020-06-18) paragraphs [0055], [0061], [0063], [0100], [0160] - [0166]<br>----- | 1 - 24                                                               |
| X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | EP 3 998 051 A1 (COLOPLAST AS [DK]) 18 May 2022 (2022-05-18) paragraphs [0416], [0433]<br>-----                                                   | 1, 16, 18, 22                                                        |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                   |                                                                      |
| <p>* Special categories of cited documents :</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"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</p> <p>"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</p> <p>"&amp;" document member of the same patent family</p> |                                                                                                                                                   |                                                                      |
| Date of the actual completion of the international search<br><br>17 September 2024                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                   | Date of mailing of the international search report<br><br>07/10/2024 |
| Name and mailing address of the ISA/<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                   | Authorized officer<br><br>Harnack, Hanna                             |

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2024/036006

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|-------------------------------------------|---------------------|----------------------------|---------------------|
| WO 2022082215 A1                          | 21-04-2022          | AU 2021361238 A1           | 25-05-2023          |
|                                           |                     | CA 3198681 A1              | 21-04-2022          |
|                                           |                     | CN 116829108 A             | 29-09-2023          |
|                                           |                     | CO 2023004876 A2           | 21-07-2023          |
|                                           |                     | EP 4228563 A1              | 23-08-2023          |
|                                           |                     | JP 2023545504 A            | 30-10-2023          |
|                                           |                     | US 2022117771 A1           | 21-04-2022          |
|                                           |                     | WO 2022082215 A1           | 21-04-2022          |
| -----                                     |                     |                            |                     |
| WO 2020123771 A2                          | 18-06-2020          | CA 3121523 A1              | 18-06-2020          |
|                                           |                     | CN 113473948 A             | 01-10-2021          |
|                                           |                     | EP 3893822 A2              | 20-10-2021          |
|                                           |                     | JP 7479371 B2              | 08-05-2024          |
|                                           |                     | JP 2022515345 A            | 18-02-2022          |
|                                           |                     | US 2020188161 A1           | 18-06-2020          |
|                                           |                     | US 2023076423 A1           | 09-03-2023          |
|                                           |                     | WO 2020123771 A2           | 18-06-2020          |
| -----                                     |                     |                            |                     |
| EP 3998051 A1                             | 18-05-2022          | AU 2018391313 A1           | 09-07-2020          |
|                                           |                     | CN 111465374 A             | 28-07-2020          |
|                                           |                     | DK 3727240 T3              | 07-03-2022          |
|                                           |                     | EP 3727240 A1              | 28-10-2020          |
|                                           |                     | EP 3998051 A1              | 18-05-2022          |
|                                           |                     | JP 7372919 B2              | 01-11-2023          |
|                                           |                     | JP 2021507744 A            | 25-02-2021          |
|                                           |                     | JP 2023174655 A            | 08-12-2023          |
|                                           |                     | LT 3727240 T               | 10-03-2022          |
|                                           |                     | US 2021369197 A1           | 02-12-2021          |
|                                           |                     | WO 2019120432 A1           | 27-06-2019          |
| -----                                     |                     |                            |                     |