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- (71) Applicant: **BIOSENSE TECHNOLOGIES PRIVATE LTD** [IN/IN]; 102 Orion Business Park, Near Cine Wonder Mall, Kapurbawadi, Thane West - 400607, Maharashtra (IN).
- (72) Inventors: **SEN, ABHISHEK**; "Arpan", Plot No.12, Trimbak Nagar, Off Jai Bhavani Road, Nashik Road, Nashik - 422101, Maharashtra (IN). **MIDHA, AMAN**; 30 Ground Floor, Sant Ishar Singh, Nagar, Pakhowal Road, Ludhiana - 141002, Punjab (IN). **SHAAKIR, M**; Quarter No: 102, Fact CD Township, Ambalamedu P.O, Cochin., Kerala 682303 (IN). **PARIYATH, SREYAS V.**; Vadakke-pariyath H., Rajakkad PO, Idukki Dist. 685566, Kerala (IN).
- (74) Agents: **AFSAR, S.** et al.; Krishna & Saurastri Associates, 74/F, Venus, Worli Sea Face, Mumbai 400 018, Maharashtra (IN).

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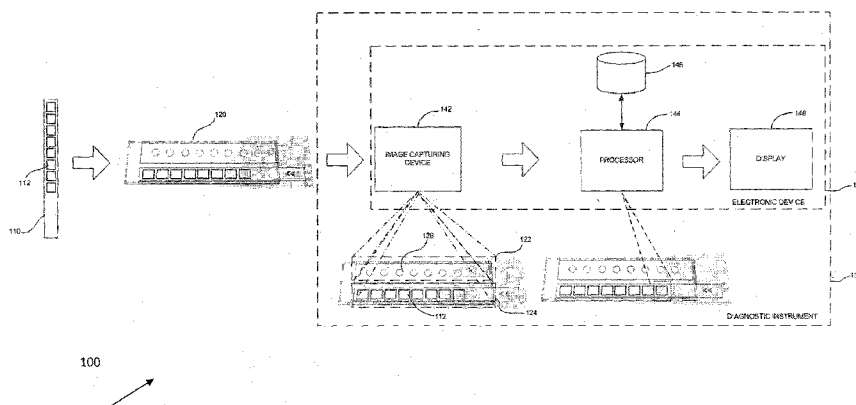


FIGURE 1

(57) Abstract: The invention provides a system and method for testing of a body fluid sample using a diagnostic instrument. In an embodiment, the invention is implemented as an application running on a portable device, such as a cell phone, computer, laptop, or other dedicated portable electronic device. The invention has been designed to minimize user contact and manipulations of data in the fluids.



METHOD AND SYSTEM FOR ANALYSING BODY FLUIDS

FIELD OF THE INVENTION

[001] The invention relates to a system and method for testing of a body fluid sample. . More particularly, the invention relates to analysing the characteristics of body fluids in an automatically calibrated environment.

5 BACKGROUND OF THE INVENTION

[002] Body fluids such as urine, blood, saliva, etc are often analyzed to determine an individual's possible health problems and conditions. For example, urine analysis helps in analysing different components, such as color, clarity, odor, specific gravity, pH, protein, glucose, nitrites, ketones, leukocyte esterase,
10 etc in order to find out the cause of symptoms. Similarly, blood analysis helps in analysing components of bloods such as blood glucose, hemoglobin, etc.

[003] Urine analysis is performed by collecting urine sample from a patient in a specimen cup after which the sample is analysed in a medical clinic or sent to a laboratory to perform the tests. Usually a urine dipstick/test-strip is dipped in the
15 collected sample, after which the dipstick is analysed. A urine dipstick consist of a strip with a number of test-pads which react with urine and produce a characteristic color, and this change in color is used to analyse the urine sample for assessing particular symptoms.

[004] At laboratories an semi-automated strip analyser is used to analyse these
20 urine dipsticks. However, the semi-automated strip analysers are expensive, and require a technician to operate it. These semi-automated strip analysers are thus not available to a home user who wants to conduct say a simple glucose test.

[005] The other available technique is to read the dipsticks manually. Reading these dipsticks manually involves comparing the dipstick with a reference chart,
25 enabling a home user also to conduct the urine test at home. However, most home users find it difficult to compare an exposed dipstick to the chart. Further, this method suffers from less accuracy due to manual matching of colors by naked eye. Also, it is difficult for the user to match the colors at the right intervals of time, which if not followed properly may lead to incorrect reading/results. In
30 addition, the manual visual method is inappropriate for a user suffering from color blindness.

[006] To address these limitations, techniques using mobile devices to provide urine analysis results have been developed. One such technique for urine analysis using a mobile device includes capturing an image of an exposed urine

dipstick using a mobile device/PDA. The captured image is then transmitted to a remote testing apparatus which sends the inspection report back to the mobile phone/PDA. It is to be noted that the mobile phone is only used to capture the image, and the image is then sent to a remote testing apparatus, which requires
5 the mobile phone to have data connectivity. Thus this technique suffers from inherent disadvantage of being dependent on data connectivity and an external device (remote testing apparatus) for providing test results. Further, since the captured image is sent to a remote testing apparatus, for analysis of the captured image, this technique is time consuming and doesn't provide instant results.

10 [007] One another available technique for urine analysis using a mobile device includes capturing an image of an exposed urine dipstick along with a reference urine chart kept next to the urine dipstick. The captured image is then processed, wherein each of the test-pads on the dipstick is directly matched to the values in the reference chart i.e the colors are matched directly with no memory of relation
15 between each of the testpad colors with each of corresponding chart colors. In this technique, the reference chart is directly compared to the test-pad color, however different urine dipstick manufacturers have subtle difference in dry chemistry of the test-pads leading to slightly different colors generated by the test-pads in the urine dipsticks and the position of different test-pads in the
20 dipstick. Owing to this, the reference chart method can be used only with one type/make of dipstick i.e. every dipstick has a different chemical reactivity and hence has to be referenced to a particular reference chart of the manufacturer.

[008] For blood analysis a sample of blood is drawn from a patient and is analysed in a laboratory using automated analysers. Various test kits and
25 portable analysers are also available for measuring certain blood parameters such as glucose at home. One such test kit is a test-strip having one or more test-pads that changes color when exposed to blood. Once the test-strip is exposed to blood, the test-strip is compared with a reference color chart. However, most home users find it difficult to compare an exposed dipstick to the
30 chart. Further, this method suffers from less accuracy due to manual matching of colors by naked eye. Also, it is difficult for the user to match the colors at the right intervals of time, which if not followed properly may lead to incorrect reading/results. In addition, the manual visual method is inappropriate for a user suffering from color blindness. The portable analysers for blood analysis use

electrochemical strips to which blood is exposed and analysed. However, these strips as well as the instrument are expensive.

[009] In view of the above, there is a need in the art for a method and system for body fluid analysis addressing at-least the above mentioned problems.

5

SUMMARY OF THE INVENTION

[010] Accordingly, the present invention provides a system for analysing characteristics of at least one body fluid, the system comprising a diagnostic instrument having receptacle, the receptacle including a plurality of reference color blocks and at least one test-strip having one or more test-pads containing reagents, the test-pads change color in the presence of particular analytes in the body fluid; and an electronic device, including a camera and a processor, adaptable to the diagnostic instrument, the electronic device is for capturing an image of the receptacle, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having the reagent and the processor is configured for identifying the reference color blocks and the position of the test-pads in the captured image; extracting RGB values of the test-pads and normalizing the same with the reference white color block to retrieve a corrected image color value, and comparing the corrected image color value of the test-pad with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte concentration of the analysed fluid.

[011] Accordingly, the present invention in one aspect provides a method for analysing characteristics of at least one body fluid, the method comprising receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip, capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent, identifying the reference color blocks and the position of the test-pads in the captured image, extracting RGB values of the test-pads to retrieve a image color value of the test-pad, and comparing the image color value of the test-pad with pre-stored color values of the corresponding calibrated

analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

[012] In another aspect, the present invention provides a method for analysing characteristics of at least one body fluid, the method comprising receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip, capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent, identifying the reference color blocks and the position of the test-pads in the captured image, extracting RGB values of the test-pads and normalizing the same with the reference white color block to retrieve a corrected image color value of the test-pad and comparing the corrected image color value of the test-pad with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

[013] In another aspect, the present invention provides a method for analysing characteristics of at least one body fluid method for analysing characteristics of at least one body fluid, the method comprising receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip, capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent, identifying the reference color blocks and the position of the test-pads in the captured image, extracting RGB values of each color block and each test-pad, correlating RGB value of at-least one test-pad with each color block to form an array of correlation coefficient of the test-pad with each color block, and comparing the array with a pre-stored array of correlation coefficient of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

[014] In another aspect, the present invention provides a method for analysing characteristics of at least one body fluid, the method comprising receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip, capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent, identifying the reference color blocks and the position of the test-pads in the captured image, extracting RGB values of test-pads and white color block, the white color block is from the plurality of color blocks, and normalizing the same with the extracted RGB values of the test-pads, comparing the normalized values with predetermined values to check the lighting condition; and applying the extracted values of test-pads to an equation, wherein the equation is gained by regression analysis of different concentration of analytes with the predetermined lab values of test-pads in lighting condition, if the RGB value of white color block is lesser than a standard value.

[015] In one another aspect provides a method for analysing characteristics of at least one body fluid, the method comprising providing a test-strip having a first section and a second section, the first section having a reference color chart and the second section having one or more exposed test-pads, capturing one or more images of the test-strip at pre-determined time intervals, wherein the captured image comprises the reference color chart and one or more exposed test-pad having a reagent, identifying the reference color chart and the position of the test-pads in the captured image, extracting RGB values of the test-pads to retrieve a image color value of the test-pad, and comparing the image color value of the test-pad with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

30 **BRIEF DESCRIPTION OF THE DRAWINGS**

[016] Reference will be made to embodiments of the invention, examples of which may be illustrated in the accompanying figures. These figures are intended to be illustrative, not limiting. Although the invention is generally described in the

context of these embodiments, it should be understood that it is not intended to limit the scope of the invention to these particular embodiments.

5 Figure 1 shows a system for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with an embodiment of the invention.

 Figure 2 shows a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with first embodiment of the invention.

10 Figure 3 shows a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with second embodiment of the invention.

 Figure 4 shows a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with third embodiment of the invention.

15 Figure 5 shows a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with fourth embodiment of the invention.

20 Figure 6 shows a system for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with fifth embodiment of the invention.

 Figure 7 shows a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with sixth embodiment of the invention.

25 Figure 8 shows a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with seventh embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

30 [017] The present invention is drawn to diagnostic instruments, systems and methods for testing of a body fluid sample. More particularly, the invention relates to analysing characteristics of at least one body fluid in an automatically calibrated environment. In an example embodiment, the invention is implemented as an application running on a portable device, such as a cell phone, computer,

laptop, or other dedicated portable electronic device. The invention has been designed to minimize user contact and manipulations of data in the fluids.

[018] Figure 1 shows a system 100 for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with first embodiment of the invention. The system 100 as shown includes a test-strip 110, a receptacle 120, a diagnostic instrument 130, and an electronic device 140 adapted to the diagnostic instrument 130.

[019] The diagnostic instrument 130 capable of accommodating the receptacle 120 and at-least one test-strip 110. To analyse the body fluid sample, initially, the test-strip 110 is exposed to the body fluid (e.g. Urine, Blood etc) for which the characteristics to be analysed. The test-strip 110 usually includes one or more test-pads 112 having reagents thereon. Each test-pad 112 reagent reacts colorimetrically with the body fluid sample depending upon characteristics of the body fluid. Depending upon the type of test-strip used, the test-pads 112 of the test-strip strips provide tests for Glucose, Bilirubin, Ketones, Protein, pH, Urobilinogen, Leukocytes, etc. It is to be noted that the test-pads for different parameters react at different time intervals and accordingly the test-pad for a particular parameter has to be measured at the pre-defined time interval. For example glucose is to be read at 30 seconds, ketone is to be read at 60 seconds.

[020] Once, the test-strip is exposed to the body fluid sample, the test-strip is placed at one portion of the receptacle 120. The receptacle 120 includes a first section 122 and a second section 124. The first section 122 which may also refer as a mat region, which has a plurality of color blocks 126 (Red, Green, Blue, Cyan, Magenta, Yellow, White and Grey). The color blocks 126 are preferably round in shape. Alternately the color blocks can also be square in shape. The second section 124 is provided adjacent to the first section 122. More particularly, the second section 124 is a slot or a groove in order to accommodate the exposed test-strip 110. Upon accommodating the exposed test-strip 110 at the receptacle 120, the receptacle 120 is placed in the diagnostic instrument/test kit 130 for analysis. The diagnostic instrument 130 encloses the receptacle 120, and has a means for adapting the electronic device 140 usually at the top portion of the instrument. Enclosing the receptacle 120 in the diagnostic instrument 130 allows the electronic device 140 to reliably detect colour change in test-strips in varying ambient light condition

[021] The electronic device 140 includes an image capturing device 142, a processor 144 and a storage means 146. The electronic device may be an image capturing device, a portable device such as a mobile phone or a PDA having a camera, etc.

5 [022] In an embodiment, the image capturing device 142 of the electronic device 140 is adapted above the receptacle 120 to capture an image of the receptacle 120, where the captured image comprises the plurality of reference color blocks 126 and one or more exposed test-pads 112 having the reagent.

[023] In an embodiment, the processor 144 of the electronic device 140 is
10 configured for processing the captured image of the receptacle 120. The captured image is processed by identifying the reference color blocks 126 and the position of the test-pads 112 in the captured image. Further, the processor 144 extracts RGB values of the test-pad 112 to retrieve a value i.e. an image color value. The RGB values are extracted to determine the color change due to
15 the presence of particular analytes in the test fluid. Upon extracting the RGB values, the processor 144 compares the image color value of the test-pad 112 with the pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte concentration of the analysed fluid.

20 [024] In one another embodiment to analyse the body fluid, the processor 144 may also be configured to process the captured image by identifying the reference color blocks 126 and the position of the test-pads 112 in the captured image. By identifying the test-pad 112, the processor 144 extract RGB values of the test-pads 112 and further normalize the same (i.e. extracted RGB values)
25 with the reference white color block 126 to retrieve a corrected image color value. Further, the processor 144 compares the corrected image color value of the test-pad 112 with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte concentration of the analysed fluid.

30 [025] In one another embodiment to analyse the body fluid, the processor 144 may also be configured to process the captured image by identifying the reference color blocks 126 and the position of the test-pads 112 in the captured image. By identifying the test-pad 112, the processor 144 extract RGB values of

the test-pads 112 and further normalize the same (i.e. extracted RGB values) with the reference white color block 126 to retrieve a corrected image color value.

[026] the normalized values are compared with a predetermined value especially for the white color block to check lighting condition. In this regard when

5 the present invention is used in an open environment, sunlight would affect the analysis of the present invention i.e. the analysis would deviate from the actual readings. The processor compares the normalized values with a predetermined value to verify if the normalized value is below the predetermined value to check effect external lighting conditions like sunlight. If the normalized value is greater
10 than the predetermined level i.e. the standard value of RGB of white color, the normalized values are compared with pre-stored LAB values of corresponding calibrated analytes to obtain and indicate characteristic of the body fluid. In a condition where the normalized value is less than the predetermined level i.e. the standard value of RGB of white color value, the extracted values of the test-pad
15 are applied to an equation, wherein the equation is gained by regression analysis of different concentration of analytes with predetermined lab values of test-pads in lighting condition – sunlight condition.

[027] In one another embodiment to analyse the body fluid, the processor 144 may also possibly configured to process the captured image by identifying the
20 reference color blocks 126 and the position of the test-pads 112 in the captured image. By identifying the test-pad 112, the processor 144 extracts RGB values of each color block 126 and each test-pad 112. The processor 144 further correlates the RGB value of at-least one test-pad 112 with each color block 126 to retrieve an correlation coefficient of the each color block 126. By doing so, the
25 processor 144 is able to form an array of correlation coefficient of the test-pad 112 with each color block 126. Upon forming the array of correlation coefficient of the each color block 126, the processor 144 compares the formed array with a pre-stored array of correlation coefficient s of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic
30 of the analysed fluid.

[028] In an embodiment storage means stores reference data – pre-stored color values (For e.g. RGB values of urine chart) of various body fluid parameter measurements of a parameter color chart (For e.g. urine color chart) with respect to the color blocks 126 in the receptacle. Also, the storage means stores an

array of predetermined correlation coefficients obtained as a result of correlating reference colour block with reference test-strips at different concentration of analytes.

[029] In an embodiment the parameters of the fluid measured by the system
5 can be displayed on a display device 148 and/or printed to indicate the analyte concentration of the analysed fluid. The measured value can also be stored in the storage means of the electronic device.

[030] In an embodiment, the system further comprises at-least one remote server configured via at least one communication network to the electronic device
10 which is capable of receiving the parameter value measured for further analysis

[031] Figure 2 shows a flowchart of a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with first embodiment of the invention. In order to implement such a method, the invention uses a diagnostic instrument which has the environment and capable of handling
15 a test-strip for analysing the characteristics of the body fluids.

[032] At step '2A', the exposed test-strip is placed at one portion of the receptacle. The receptacle as discussed above includes a first section and a second section. The first section has a plurality of color blocks, and the second section adapts the test-strip. Upon placement of the exposed test-strip at the
20 receptacle, the receptacle is placed in the diagnostic instrument/test kit for analysis.

[033] At step '2B', one or more images of the receptacle are captured using the electronic device (i.e. image capturing device). The captured image has the first section which includes the plurality of reference color blocks, and the second
25 section comprising one or more exposed test-pads which have reacted to the body fluid sample. As discussed above, test-pads for different parameters react at different time intervals. Accordingly, the electronic device is configured to capture and process one or more images at different time intervals depending upon parameter to be measured. For e.g. : Four images are captured at intervals
30 of 30 seconds, 45 seconds, 60 seconds and 120 seconds to read Glucose, Ketone, Bilrubin, Protein, and Leukocyte. Once the image is captured, the image is resized (For e.g. $\frac{1}{4}$ of its original size) maintaining its aspect ratio. In an embodiment, the method provides for selecting at-least one parameter of the body fluid to be analysed. Accordingly, depending upon the selection of the

parameter to be analysed one or more images are captured, and accordingly that particular test-pad is analysed.

[034] At step, '2C' receptacle is identified by the image capturing device and confirm the same by eliminating the background region. The receptacle is identified/ separated from background by finding a black pixel. When the black pixel is identified, the image of the receptacle is separated by removing objects from the background. Removing objects from the background of low variance and maintaining the identifying region of high variance. One way of removing the background is to crop the receptacle dynamically or performing a threshold calculation.

[035] At step '2D', once the receptacle is identified, reference color blocks on the first section of the receptacle are identified, and subsequently position of test-pads of the test-strip are also identified based upon location of the reference color blocks. At this step, all the color blocks on the receptacle are identified by setting a threshold to identify a red pixel of the first color block. Once the first color block is identified, subsequently other color blocks are also identified. The identified color block is further used to identify the test-pads by using the starting point of the red color block as the 'X' axis location of the centre of first test-pad, and coordinates of all test-pads are identified. This step also helps in verifying if the receptacle is properly inserted in the diagnostic instrument by verifying if all the color blocks are identified. In case if all the color blocks are not identified, the electronic device indicates the receptacle has not been properly inserted in the diagnostic instrument. Accordingly, the analysis of the image only starts if the receptacle is identified.

[036] At step '2E', once location of the test-pads are identified, RGB values of the test-pads are extracted to retrieve an image color value of the test-pads. Depending upon parameter/characteristic of body fluid to be measured (say glucose which is the last test-pad on the test-strip and is to be measured at 30 seconds), RGB values of the last test-pad of the image captured at 30 seconds is extracted to retrieve an image color value of the glucose test-pad.

[037] At step '2F', image color value of the test-pad is compared with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid. In this regard, euclidean distance of RGB values of test-pad and pre-stored RGB values

of corresponding calibrated analyte is obtained to indicate the characteristic of the body fluid.

[038] Figure 3 shows a flowchart of a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with second embodiment of the invention. Steps 3A to 3D are similar to the steps 2A to 2D of the embodiment shown in Figure 2.

[039] At step '3E', once the test-pads are identified, RGB values of the test-pads are extracted to retrieve an image color value of the test-pads. Depending upon parameter/characteristic of body fluid to be measured (say glucose which is the last test-pad on the test-strip), extracted RGB values of the glucose test-pad is retrieved. Further, extracted RGB values of the test-pads are normalized with reference white color block to retrieve a corrected image color value of the test-pad. Normalizing the image corrects any deviation in the RGB values of the test-pad due to ambient light captured in the image. In an embodiment of the invention, the image color value is retrieved by converting RGB values of the test-pad into LAB space value. Advantageously, converting the image into LAB space will alter the original RGB values due to casting of light. For eg: When the test is performed in a yellow light, the R, G and B values will be slightly altered and this effects the final results generated. LAB values of the test-pads along with the LAB values of reference white circle in the receptacle color chart normalises/compensates for the color cast. Thus it can be used to make accurate color balance corrections.

[040] At step '3F', corrected image color value of the test-pad is compared with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid. In this regard, least distance of LAB values of test with and pre-stored LAB values of corresponding calibrated analyte is obtained to indicate the characteristic of the body fluid. Advantageously, conversion into LAB space enables the method of the invention to be device independent i.e. the analysis of the present invention would be standard and accurate across a variety of devices. Figure 4 shows a flowchart of a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with third embodiment of the invention. Step 4A to 4E are similar to the steps 3A to 3E of the embodiment shown in Figure 3.

[041] At step 4F, the normalized values are compared with a predetermined value especially for the white color block to check lighting condition. In this regard when the present invention is used in an open environment, sunlight would affect the analysis of the present invention i.e. the analysis would deviate from the actual readings. Accordingly at step 4F the normalized values are compared with a predetermined value. If the normalized value is below the predetermined value the method proceeds to step 4G, else the method proceeds to step 4H.

[042] At step 4G where the normalized value is greater than the predetermined level i.e. the standard value of RGB of white color, the normalized values are compared with pre-stored LAB values of corresponding calibrated analytes to obtain and indicate characteristic of the body fluid.

[043] At step 4H, where the normalized value is less than the predetermined level i.e. the standard value of RGB of white color value, the extracted values of the test-pad are applied to an equation, wherein the equation is gained by regression analysis of different concentration of analytes with predetermined lab values of test-pads in lighting condition – sunlight condition. Accordingly, the method by correcting the effect of sunlight on the test-pads provides precise analysis even when used in outdoor conditions (e.g. health camps).

[044] Figure 5 shows a flowchart of a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with fourth embodiment of the invention. Step 5A to 5B is similar to the first two steps of the embodiment shown through Figure 1 to 3.

[045] At step '5C', the reference color blocks and the test-pads are identified. To identify the color blocks image is converted to a binary image to identify the reference color blocks. The binary image is further processed wherein objects which are fewer than a predetermined pixel range (For e.g. 300 pixels) are removed. Removal of these objects helps in identifying the first region having the color blocks. Further a threshold calculation is performed for verifying that the detected round objects - color blocks are in conformity with the threshold value.

[046] At step '5D', the test-pads are identified based on the relative position of the color blocks. To identify the test-pads, firstly angle of inclination of the receptacle is calculated for correcting alignment of the receptacle, which may have occurred during capturing of the image. Subsequently, position of the test-

pad is calculated relative to the color block with required scaling and angle of inclination.

[047] At step '5E', once location of the test-pads are identified RGB value of each color block and test-pad is extracted,

5 [048] At step '5F', the extracted RGB value of each test-pad is correlated with each color block to form an array of correlation coefficient. Accordingly, an array of correlation coefficient is formed for each test-pad.

[049] At step '5G', the array of the correlation coefficient is compared with the pre-stored array of correlation coefficient of the corresponding calibrated analyte
10 to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid. In this regard the pre-stored array is obtained/stored as a result of correlating reference colour block with reference test-strips at different concentration of analytes.

[050] Figure 6 shows a test-strip in accordance with a fifth embodiment of the
15 invention. The test-strip having a first section and a second section. The first section comprises of a reference color chart embedded on the test-strip, and the second section has one or more test-pads adjacent to the reference color chart. The reference color chart is multi-colored comprising of at-least Red, Green, and Blue colors.

20 [051] In an embodiment of the invention, the color chart 220 is a multi-colored bar-code or multi-colored QR code or color blocks.

[052] In an embodiment of the invention, the test-strip may be analyzed by the system illustrated in figure 1, where the diagnostic instrument encloses the test-strip and has a means for adapting the electronic device usually at the top portion
25 of the instrument for analysing the test-strip.

[053] Figure 7 shows a flowchart of a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with sixth embodiment of the invention. In order to implement such a method, the invention uses a test-strip with an embedded reference chart for analysing the
30 characteristics of the body fluids.

[054] At step '7A', the exposed test-strip is placed in a diagnostic instrument. The test-strip as discussed above includes a first section and a second section. The first section has a reference color chart, and the second section has one or more test-pads.

[055] At step '7B', one or more images of the test-strip is captured using the electronic device (i.e. image capturing device). The captured image has the first section which includes reference color chart, and the second section comprising one or more exposed test-pads which have reacted to the body fluid sample. As discussed above, test-pads for different parameters react at different time intervals. Accordingly, the electronic device is configured to capture and process one or more images at different time intervals depending upon parameter to be measured. For e.g. : Four images are captured at intervals of 30 seconds, 45 seconds, 60 seconds and 120 seconds to read Glucose, Ketone, Bilirubin, Protein, and Leukocyte. Once the image is captured, the image is resized (For e.g. $\frac{1}{4}$ of its original size) maintaining its aspect ratio.

[056] At step, '7C' reference color chart is identified by the image capturing device and confirm the same by eliminating the background region. Removing objects from the background of low variance and maintaining the identifying region of high variance. One way of removing the background is to crop the test-strip dynamically or performing a threshold calculation.

[057] At step '7D', once the test-strip is identified, reference color chart on the first section of the test-strip is identified, and subsequently position of test-pads of the test-strip are also identified based upon location of the reference color chart.

At this step, all the colors in the reference color chart are identified and subsequently the test-pads are identified.

[058] At step '7E', once location of the test-pads are identified, RGB values of the test-pads are extracted to retrieve an image color value of the test-pads. Depending upon parameter/characteristic of body fluid to be measured (say glucose which is the last test-pad on the test-strip and is to be measured at 30 seconds), RGB values of the last test-pad of the image captured at 30 seconds is extracted to retrieve an image color value of the glucose test-pad.

[059] At step '7F', image color value of the test-pad is compared with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid. In this regard, euclidean distance of RGB values of test-pad and pre-stored RGB values of corresponding calibrated analyte is obtained to indicate the characteristic of the body fluid.

[060] Figure 8 shows a flowchart of a method for analysing characteristics of at least one body fluid sample drawn from a human body in accordance with seventh embodiment of the invention. Step 8A to 8C is similar to the steps 7A to 7C of the embodiment shown in Figure 7.

5 [061] At step '8D', once location of the test-pads are identified RGB value of each color in the reference color chart and test-pad is extracted,

[062] At step '8E', the extracted RGB value of each test-pad is correlated with each color in the reference chart to form an array of correlation coefficient values. Accordingly, an array of correlation coefficient value is formed for each
10 test-pad.

[063] At step '8F', the array of the correlation coefficient is compared with the pre-stored array of correlation coefficients of the corresponding calibrated analyte to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

15 [064] Advantageously, the present invention provides a point of care solution for body fluid analysis which enables a portable device to analyse a test-strip exposed with body fluid to retrieve analyte characteristic of the body fluid, thereby determining a patient condition, a probable cause of the patient condition, prevalence of diseases, follow-up suggested action, trending of data, etc. Also,
20 the present invention is easy to use, and cost-effective.

[065] While the present invention has been described with respect to certain embodiments, it will be apparent to those skilled in the art that various changes and modification may be made without departing from the scope of the invention as defined in the following claims.

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Claims :

1. A method for analysing characteristics of a body fluid, the method comprising:
 - receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip;
 - capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent;
 - identifying the reference color blocks and the position of the test-pads in the captured image;
 - extracting RGB values of the test-pads to retrieve a image color value of the test-pad; and
 - comparing the image color value of the test-pad with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.
2. The method of claim 1, further comprising:
 - extracting RGB values of a white color block and normalizing the same with the extracted RGB values of the test-pads to retrieve a corrected image color value of the test-pad; and
 - comparing the corrected image color value with the pre-stored color value to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.
3. The method of claim 1, wherein the corrected image color value retrieved is a LAB space value.
4. The method of claim 1, wherein the step of identifying including removing the background region objects having low variance and maintaining the identified region of high variance, the identified region is the region including reference color blocks and the test-pads.

5. The method of claim 1, further comprising
selecting at-least one parameter of the body fluid to be analysed from the
identified test-pad.
- 5 6. The method of claim 1, wherein parameter value which indicates the
analyte concentration of the analysed fluid determines a patient condition, a
probable cause of the patient condition, a follow-up suggested action etc.
7. A system for analysing characteristics of at least one body fluid, the
10 system comprising:
a diagnostic instrument having receptacle, the receptacle including a
plurality of reference color blocks and at least one test-strip having one or more
test-pads containing reagents, the test-pads change color in the presence of
particular analytes in the body fluid; and
15 an electronic device, including a camera and a processor, adaptable to
the diagnostic instrument, the electronic device is for capturing an image of the
receptacle, wherein the captured image comprises the plurality of reference color
blocks and one or more exposed test-pad having the reagent and the processor
is configured for
20 identifying the reference color blocks and the position of the test-
pads in the captured image;
extracting RGB values of the test-pads and normalizing the same
with the reference white color block to retrieve a corrected image color
value; and
25 comparing the corrected image color value of the test-pad with
pre-stored color values of the corresponding calibrated analytes to
retrieve a parameter value which indicates the analyte concentration of
the analysed fluid.
- 30 8. The system of claim 7, further comprising:
at least one remote server configured via at least one communication
network to the electronic device which is capable of receiving the parameter
value indicating the analyte concentration of the analysed fluid for future analysis.

9. The system of claim 7, further comprising:

a display device coupled to the electronic device for displaying the parameter value indicating the analyte concentration of the body fluid as test results.

5

10. A method for analysing characteristics of at least one body fluid, the method comprising:

receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip;

10

capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent;

15

identifying the reference color blocks and the position of the test-pads in the captured image;

extracting RGB values of test-pads and white color block, the white color block is from the plurality of color blocks, and normalizing the same with the extracted RGB values of the test-pads;

20

comparing the normalized values with predetermined values to check the lighting condition; and

applying the extracted values of test-pads to an equation, wherein the equation is gained by regression analysis of different concentration of analytes with the predetermined lab values of test-pads in lighting condition, if the RGB value of white color block is lesser than a standard value.

25

11. The method of claim 10, further comprising:

comparing the normalized values with pre-stored RGB values of corresponding calibrated analyte is obtained to indicate the characteristic of the body fluid, if the RGB value of white color block is greater than the standard value.

30

12. A method for analysing characteristics of at least one body fluid, the method comprising:

receiving an exposed test-strip having one or more test-pads in a receptacle, the receptacle includes at-least two sections, a first section and a second section, the first section having a plurality of reference color blocks and the second section adjacent to the first section to adapt the exposed test-strip;

5 capturing one or more images of the receptacle at pre-determined time intervals, wherein the captured image comprises the plurality of reference color blocks and one or more exposed test-pad having a reagent;

identifying the reference color blocks and the position of the test-pads in the captured image;

10 extracting RGB values of each color block and each test-pad;

correlating RGB value of at-least one test-pad with each color block to form an array of correlation coefficient of the test-pad with each color block; and

comparing the array with a pre-stored array of correlation coefficient of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

13. The method of claim 12, wherein an array of correlation coefficients is formed for each test-pad.

20 14. A method for analysing characteristics of at least one body fluid, the method comprising:

providing a test-strip having a first section and a second section, the first section having a reference color chart and the second section having one or more exposed test-pads;

25 capturing one or more images of the test-strip at pre-determined time intervals, wherein the captured image comprises the reference color chart and one or more exposed test-pad having a reagent;

identifying the reference color chart and the position of the test-pads in the captured image;

30 extracting RGB values of the test-pads to retrieve a image color value of the test-pad; and

comparing the image color value of the test-pad with pre-stored color values of the corresponding calibrated analytes to retrieve a parameter value which indicates the analyte characteristic of the analysed fluid.

15. The method of claim 14, further comprising
extracting RGB values of each color in the color chart;
correlating RGB value of at-least one test-pad with each color of the color
chart to form an array of correlation coefficient of the test-pad with each color
5 block; and
comparing the array with a pre-stored array of correlation coefficient of the
corresponding calibrated analytes to retrieve a parameter value which indicates
the analyte characteristic of the analysed fluid.
- 10 16. The method of claim 14, wherein the reference color chart is a multi-
colored bar-code, multi-colored QR-code or plurality of color blocks.

15

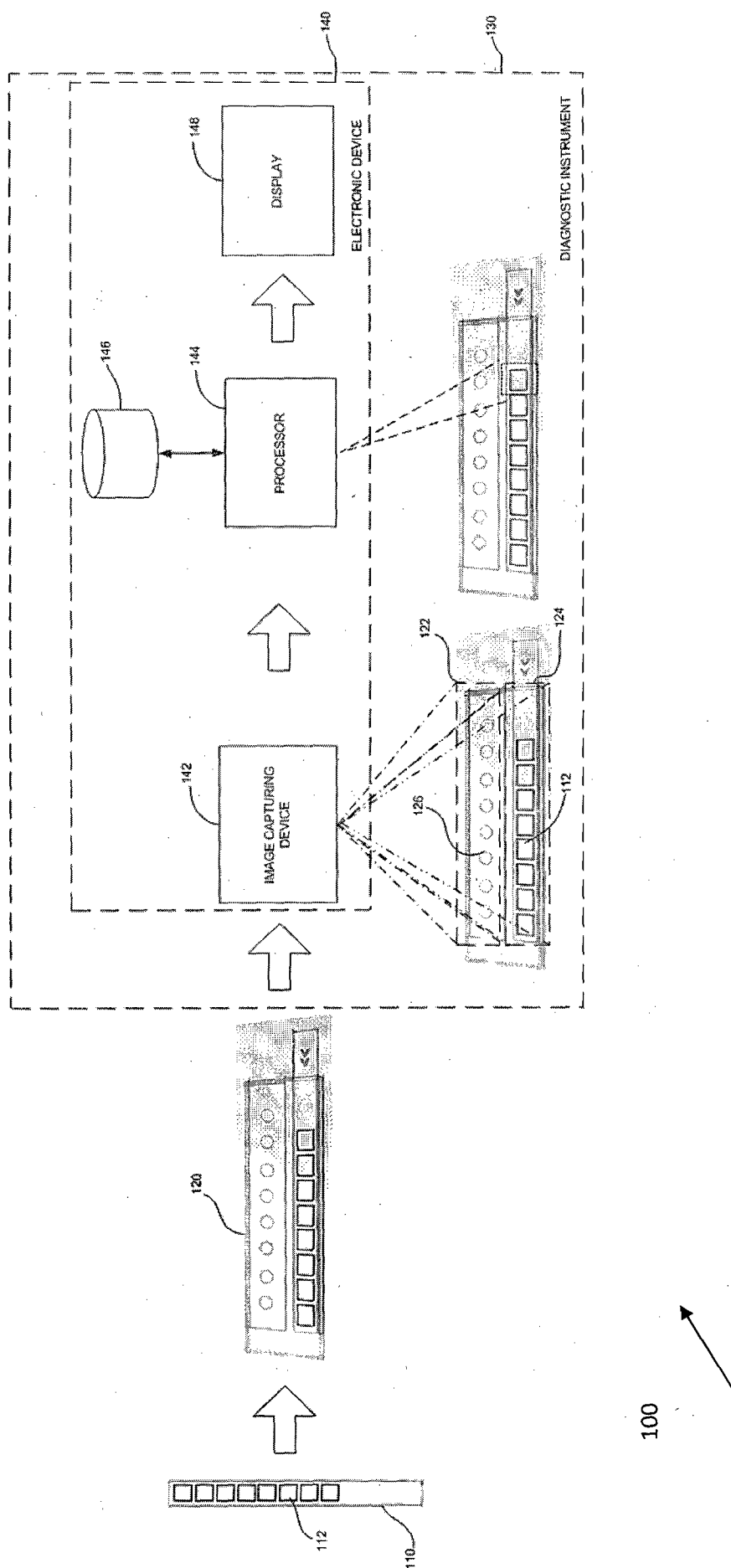


FIGURE 1

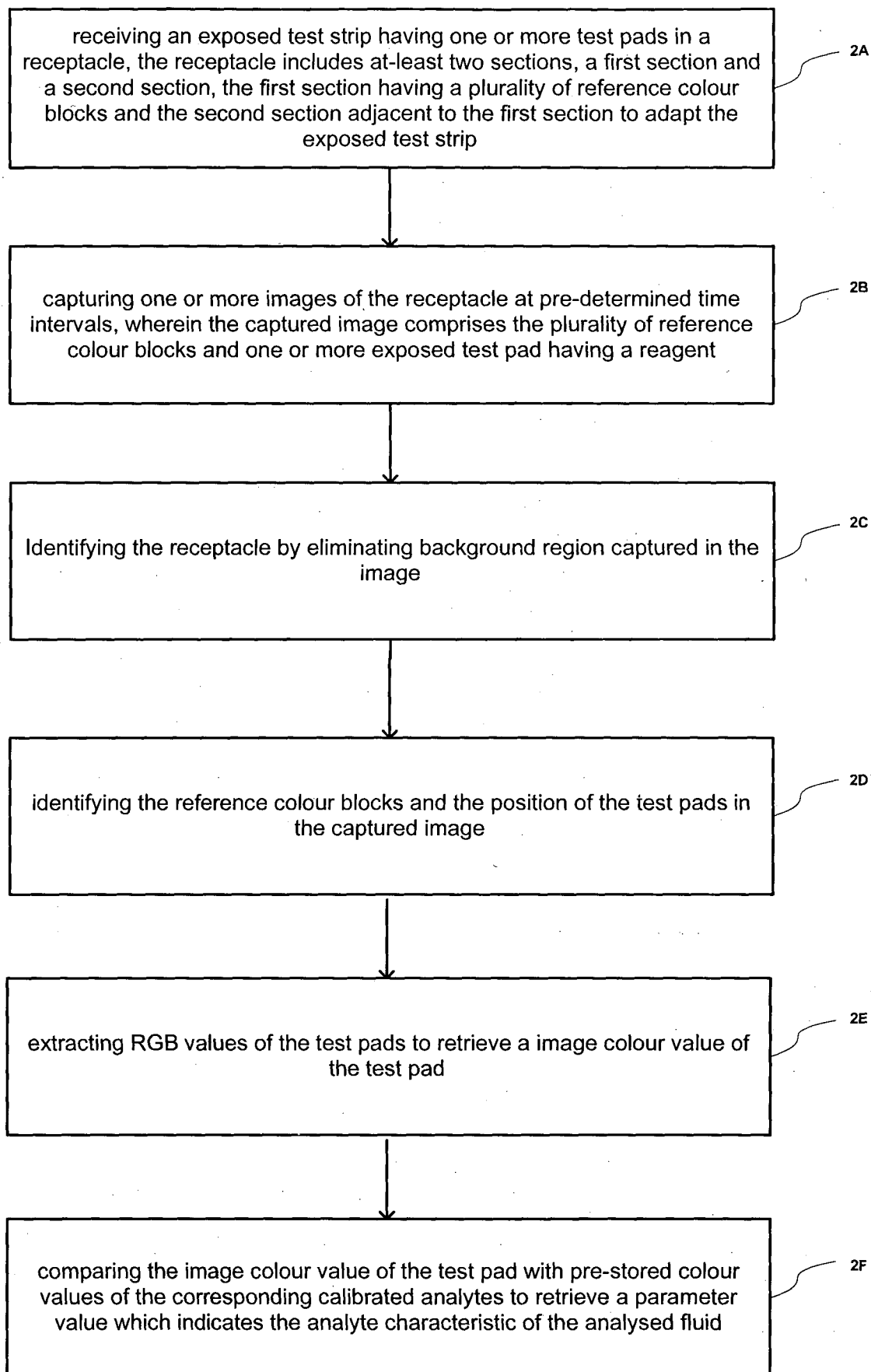


FIGURE 2

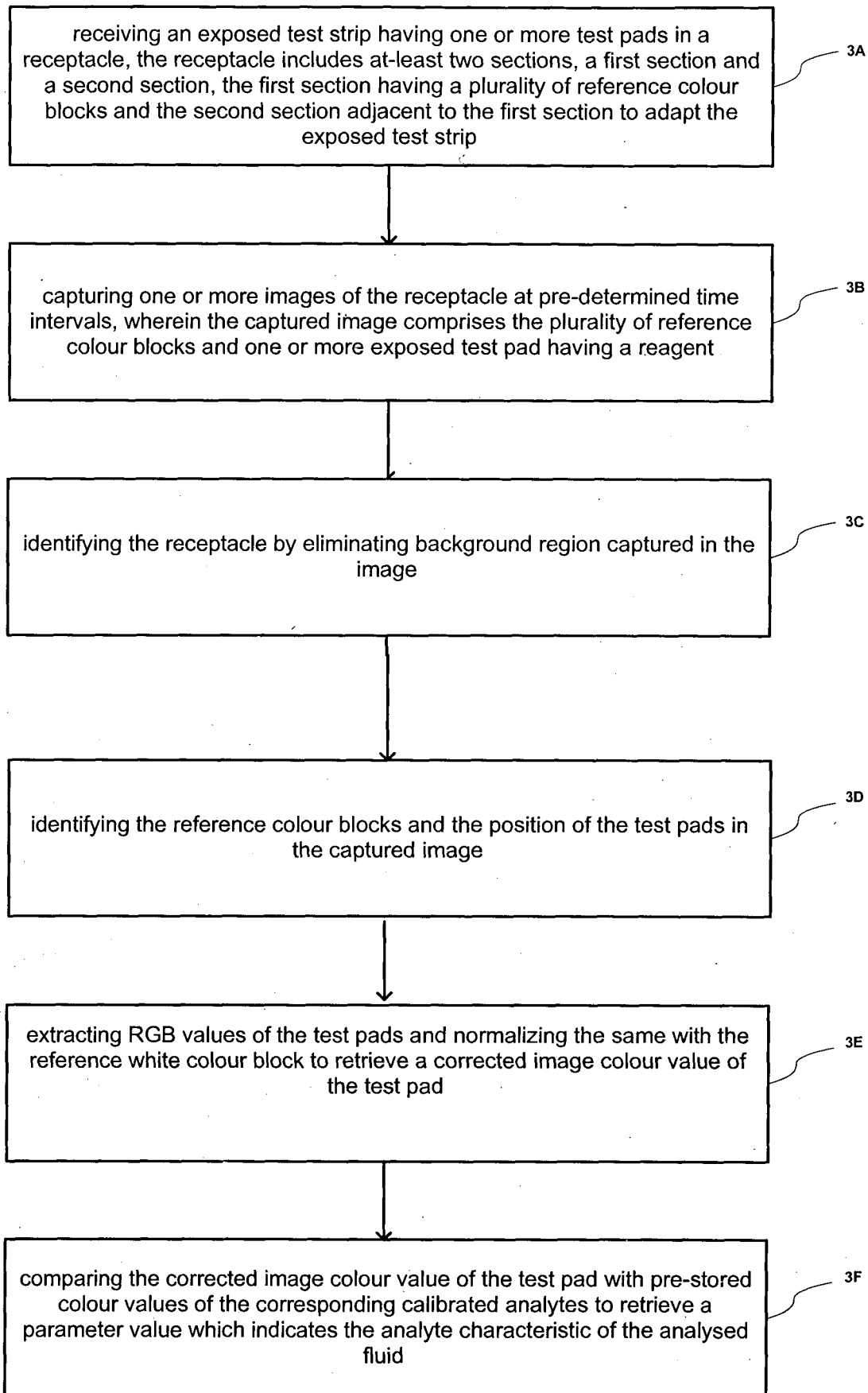


FIGURE 3

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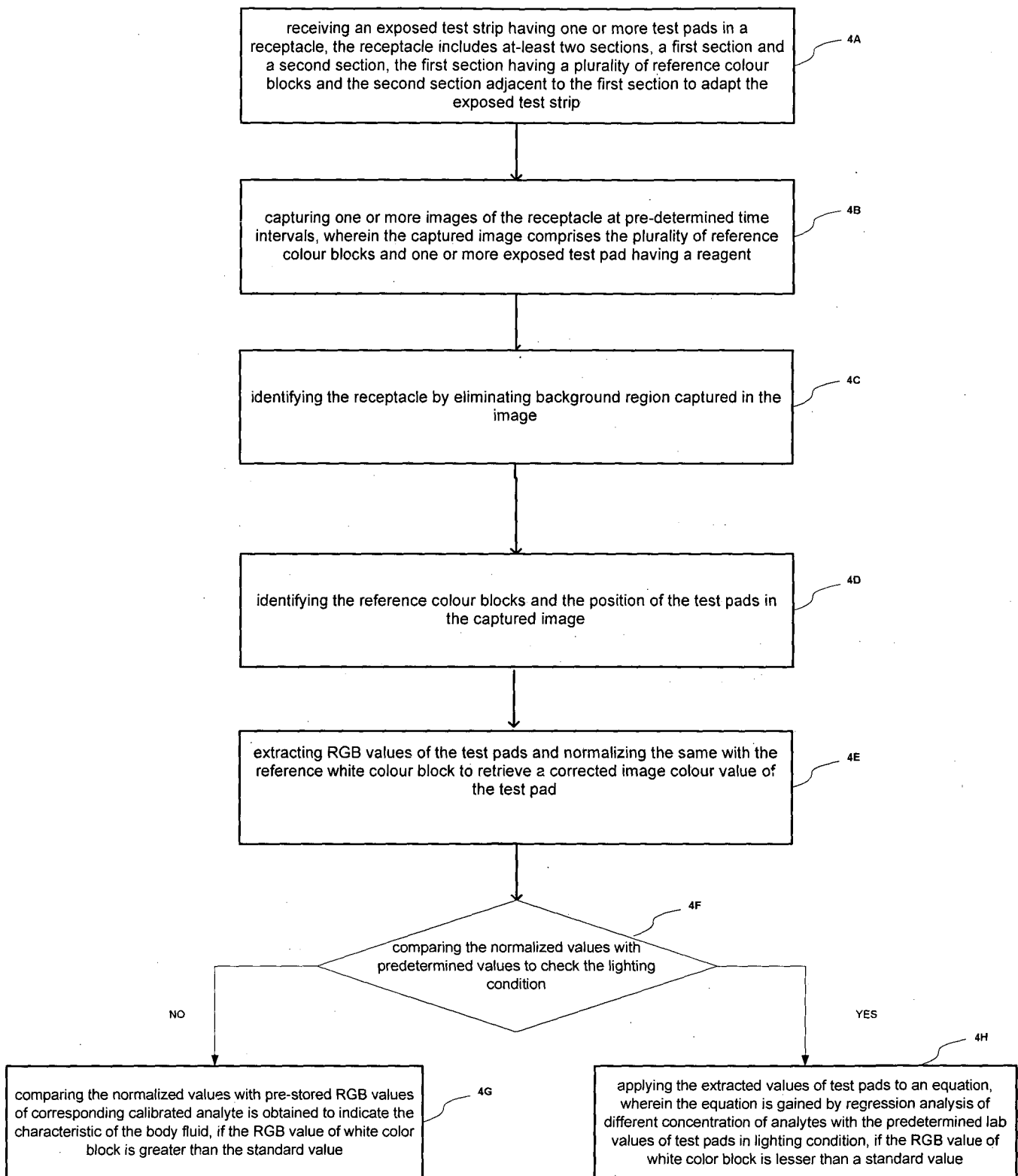


FIGURE 4

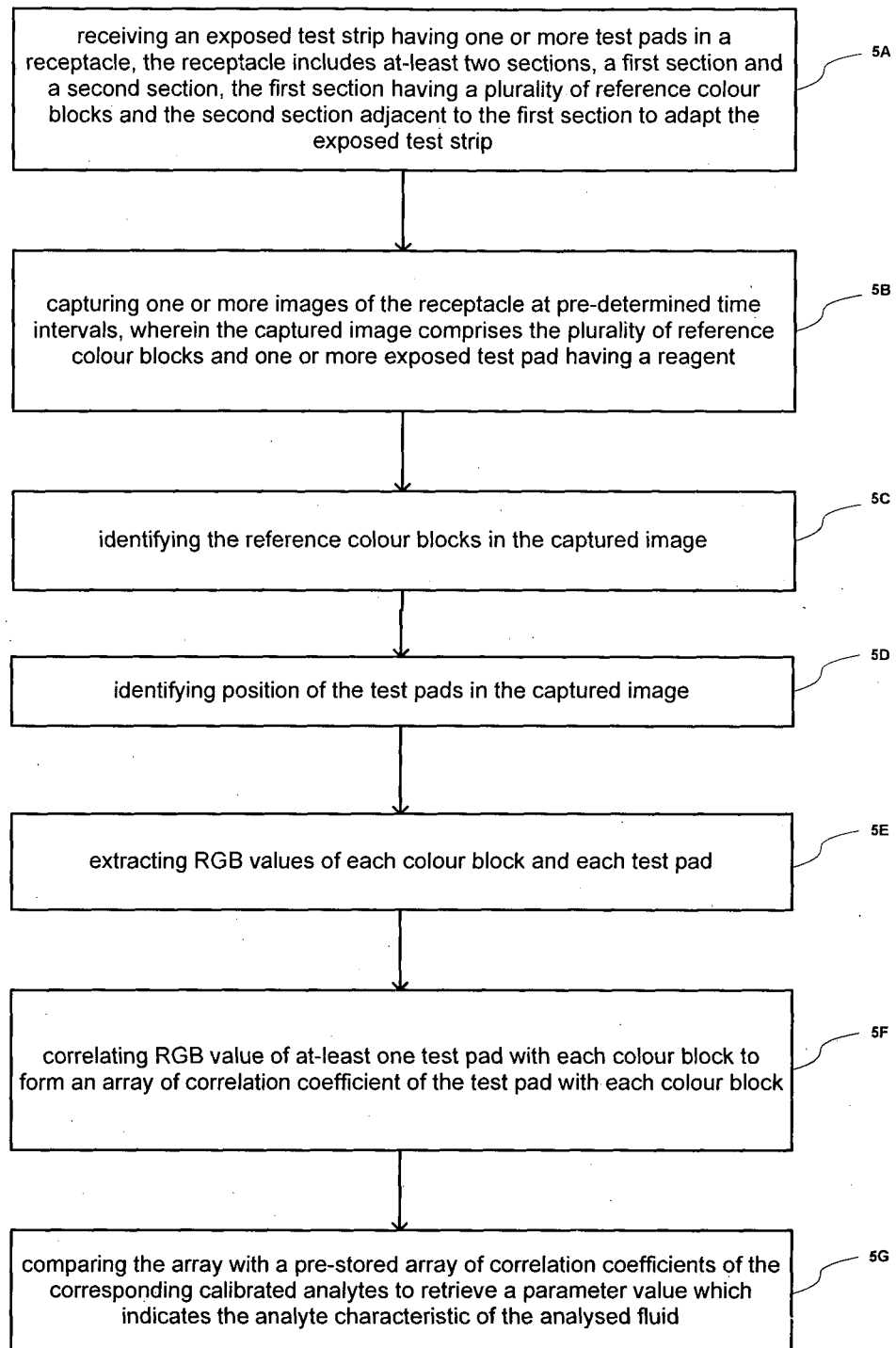


FIGURE 5

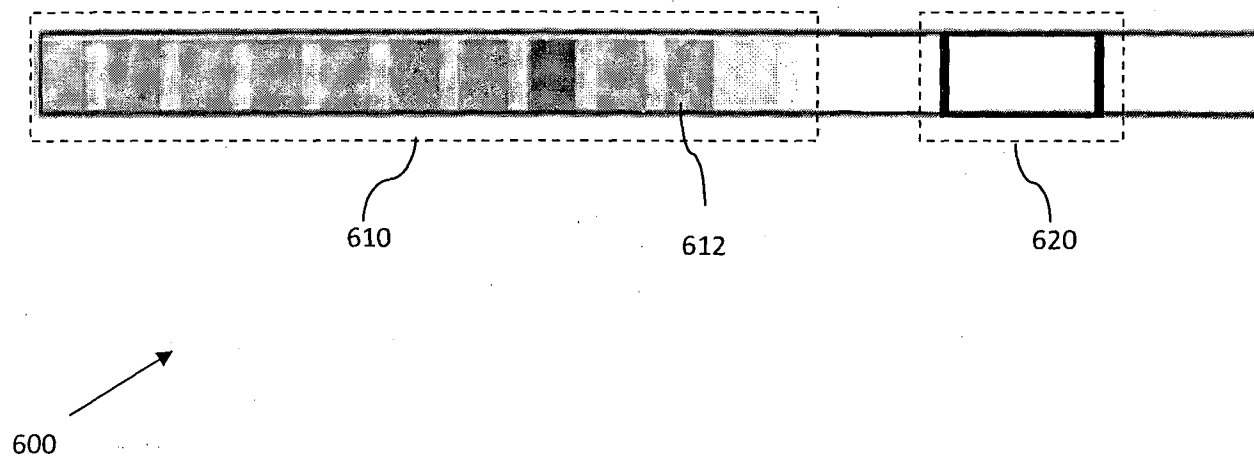


FIGURE 6

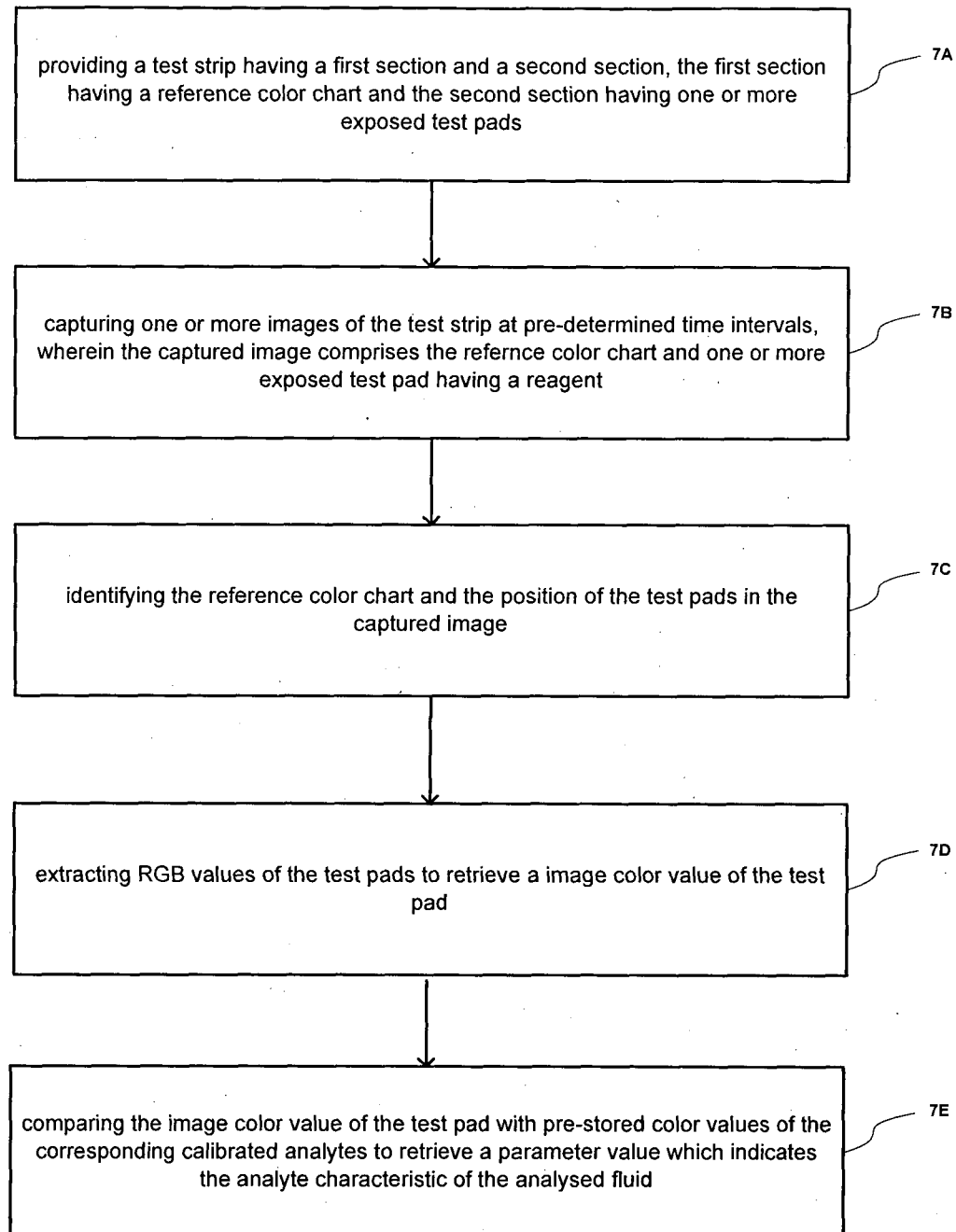


FIGURE 7

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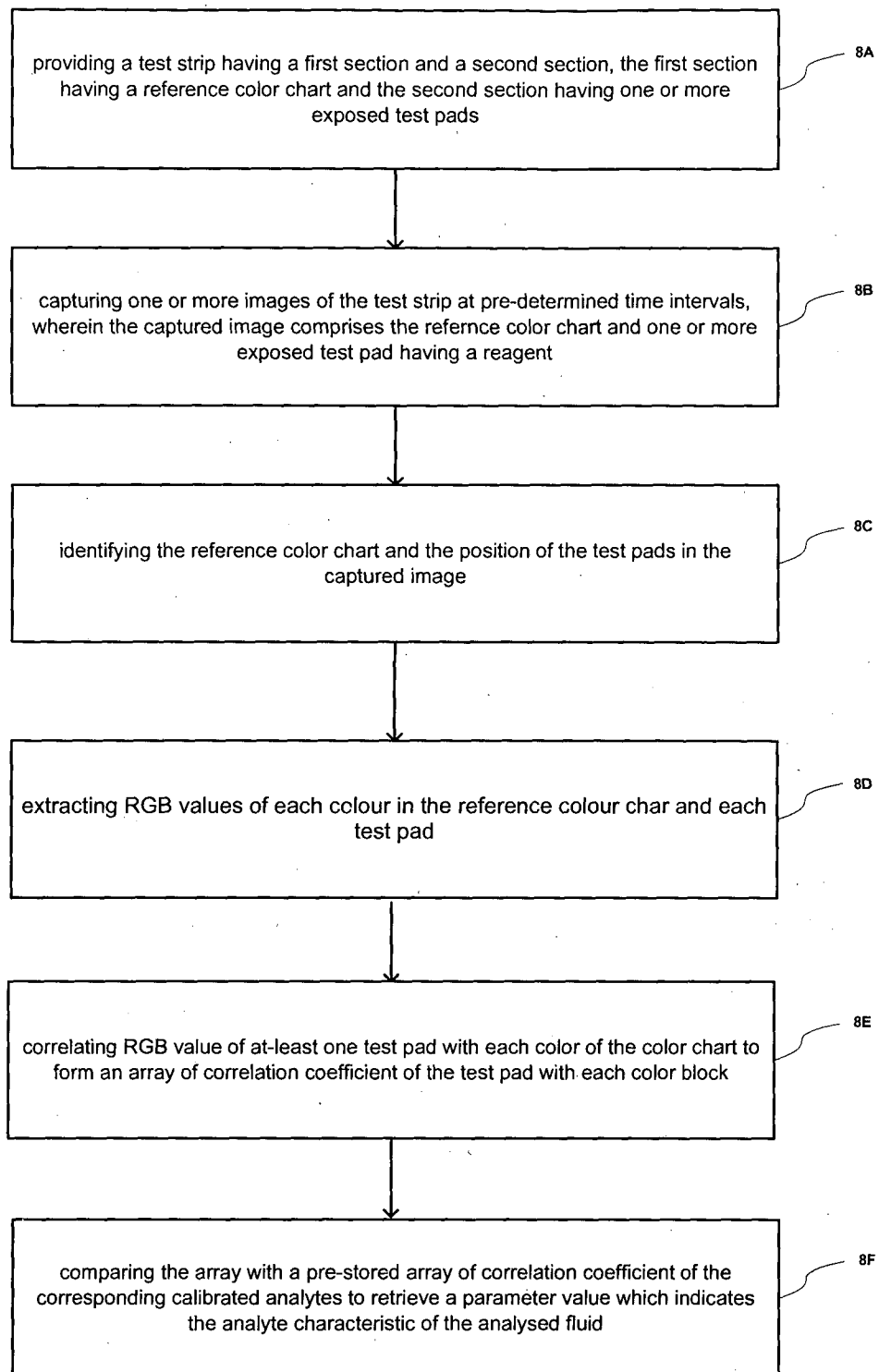


FIGURE 8