

What is Claimed is:

1. A system for measuring analyte concentration in a bodily fluid comprising:
 - a) a durable component comprising a housing having at least one window and containing:
 - i) at least one spectrophotometer adjacent to and optically communicating with the window,
 - ii) a computing system having at least one processor and data storage,
 - iii) means for electronic communication between the computing system and at least one external device;
 - b) an indicator component comprising an indicator zone comprising at least one colorimetric analyte sensing element;
 - c) at least one moisture sensor adjacent to the indicator zone;wherein:
 - I) the indicator component is arranged and configured for attachment to the durable component while the indicator zone is disposed adjacent to and in optical communication with the at least one window and the at least one spectrophotometer,
 - II) the computing system is operatively connected to the moisture sensor and the at least one spectrophotometer,
 - III) the moisture sensor is arranged and configured to communicate the presence of moisture in the colorimetric analyte sensing element to the computing system; and
 - IV) each of the at least one colorimetric analyte sensing element is associated with a spectrophotometer.
2. The system of claim 1 wherein the indicator component further comprises a fluid transport layer in fluid communication with the indicator zone.
3. The system of claim 2 wherein the indicator component further comprises a fluid impervious envelope surrounding the indicator zone, the fluid impervious envelope having a discrete pocket arranged on configured to contain each of the at least one colorimetric analyte sensing elements and each pocket has a unique aperture in fluid communication with the fluid transport layer.

4. The system of claim 3 wherein the indicator zone comprises at least two colorimetric analyte sensing elements, each of the at least two colorimetric sensing elements being isolated from other colorimetric sensing elements.
5. The system of claim 4 wherein the at least one moisture sensor comprises a plurality of moisture sensors, each moisture sensor being arranged and configured to communicate the presence of moisture in each of the at least two colorimetric analyte sensing elements to the computing system.
6. The system of claim 1 wherein the indicator component further comprises:
- i) a top plate;
 - ii) a first flexible web layer;
 - iii) a fluid transport layer adjacent the first flexible web layer;
 - iv) a fluid impervious envelope surrounding the indicator zone adjacent the fluid transport layer;
 - v) a second flexible web layer adjacent the fluid impervious envelope;
 - vi) attachment means disposed on the second flexible web layer; and
 - vii) a holding plate;
- wherein:
- V) the first flexible web layer, fluid transport layer, fluid impervious envelope, and the second flexible web layer are stacked in order and secured between the top plate and the holding plate;
 - VI) the indicator zone comprises at least two colorimetric analyte sensing elements;
 - VII) the fluid impervious envelope has a discrete pocket arranged on configured to contain each of the at least two colorimetric analyte sensing elements and each pocket has a unique aperture in fluid communication with the fluid transport layer;
 - VIII) the fluid transport layer is arranged and configured to inhibit fluid transport between apertures in the fluid impervious envelope.
7. The system of claim 6 wherein the top plate and holding plate are arranged and configured to provide a predetermined spacing to accommodate indicator component layers with predetermined fluid transport capacity to the indicator zone.

8. The system of claim 1 wherein the indicator component further comprises:
- i) a first flexible web layer;
 - ii) a fluid transport layer adjacent the first flexible web layer; and
 - iii) a fluid impervious envelope surrounding the indicator zone adjacent the fluid transport layer;
- wherein:
- V) the first flexible web layer, fluid transport layer, and the fluid impervious envelope are stacked in order and secured together;
 - VI) the indicator zone comprises at least two colorimetric analyte sensing elements;
 - VII) the fluid impervious envelope has a discrete pocket arranged on configured to contain each of the at least two colorimetric analyte sensing elements and each pocket has a unique aperture in fluid communication with the fluid transport layer;
 - VIII) the fluid transport layer is arranged and configured to inhibit fluid transport between apertures in the fluid impervious envelope.
9. The system of claim 8 further comprising:
- iv) a top plate adjacent the first flexible web layer; and
 - v) a holding plate,
- wherein the first flexible web layer, fluid transport layer and fluid impervious envelope are secured between the top plate and the holding plate.
10. The system of claim 1 wherein the indicator component further comprises a coupler.
11. The system of claim 1 wherein the indicator component attached to the durable component.
12. The system of claim 1 arranged and configured for exposure to a source of bodily fluid.
13. The system of claim 12 arranged and configured for placement into a diaper.
14. A handheld device comprising the system of claim 12.

15. A kit for measuring analyte concentration in a bodily fluid comprising:
- a) a durable component comprising a housing having at least one window and containing:
 - i) at least one spectrophotometer adjacent to and optically communicating with the window,
 - ii) a computing system having at least one processor and data storage,
 - iii) means for electronic communication between the computing system and at least one external device;
 - b) a plurality of indicator components, each indicator component enclosed in an individual package and comprising:
 - i) an indicator zone comprising at least one colorimetric analyte sensing element, and
 - ii) a coupler for the durable component;
 - c) at least one moisture sensor adjacent to the indicator zone;
- wherein:
- I) each indicator component is arranged and configured for releasable attachment to the durable component while the indicator zone is disposed adjacent to and in optical communication with the at least one window and the at least one spectrophotometer,
 - II) the computing system is operatively connected to the moisture sensor and the at least one spectrophotometer,
 - III) the moisture sensor is arranged and configured to communicate the presence of moisture in the colorimetric analyte sensing element to the computing system; and
 - IV) each of the at least one colorimetric analyte sensing element is associated with a spectrophotometer.
16. The kit of claim 15 wherein each indicator component further comprises a fluid transport layer in fluid communication with the indicator zone.
17. The kit of claim 16 wherein each indicator component further comprises a fluid impervious envelope surrounding the indicator zone, the fluid impervious envelope having a discrete pocket arranged on configured to contain each of the at least one colorimetric analyte sensing elements and each pocket has a unique aperture in fluid communication with the fluid transport layer.

18. The kit of claim 17 wherein the indicator zone comprises at least two colorimetric analyte sensing elements, each of the at least two colorimetric sensing elements being isolated from other colorimetric sensing elements.

19. The kit of claim 18 wherein the at least one moisture sensor comprises a plurality of moisture sensors, each moisture sensor being arranged and configured to communicate the presence of moisture in each of the at least two colorimetric analyte sensing elements to the computing system.

20. The kit of claim 15 wherein each indicator component further comprises:

- iii) a top plate;
- iv) a first flexible web layer;
- v) a fluid transport layer adjacent the first flexible web layer;
- vi) a fluid impervious envelope surrounding the indicator zone adjacent the fluid transport layer;
- vii) a second flexible web layer adjacent the fluid impervious envelope;
- viii) attachment means disposed on the second flexible web layer; and
- ix) a holding plate;

wherein:

V) the first flexible web layer, fluid transport layer, fluid impervious envelope, and the second flexible web layer are stacked in order and secured between the top plate and the holding plate;

VI) the indicator zone comprises at least two colorimetric analyte sensing elements;

VII) the fluid impervious envelope has a discrete pocket arranged on configured to contain each of the at least two colorimetric analyte sensing elements and each pocket has a unique aperture in fluid communication with the fluid transport layer;

VIII) the fluid transport layer is arranged and configured to inhibit fluid transport between apertures in the fluid impervious envelope.

21. The kit of claim 20 wherein the top plate and holding plate are arranged and configured to provide a predetermined spacing to accommodate indicator component layers with predetermined fluid transport capacity to the indicator zone.

22. The kit of claim 15 wherein the indicator component further comprises:

- iii) a first flexible web layer;
- iv) a fluid transport layer adjacent the first flexible web layer; and
- v) a fluid impervious envelope surrounding the indicator zone adjacent the fluid transport layer;

wherein:

V) the first flexible web layer, fluid transport layer, and the fluid impervious envelope are stacked in order and secured together;

VI) the indicator zone comprises at least two colorimetric analyte sensing elements;

VII) the fluid impervious envelope has a discrete pocket arranged on configured to contain each of the at least two colorimetric analyte sensing elements and each pocket has a unique aperture in fluid communication with the fluid transport layer;

VIII) the fluid transport layer is arranged and configured to inhibit fluid transport between apertures in the fluid impervious envelope.

23. The kit of claim 22 further comprising:

- vi) a top plate adjacent the first flexible web layer; and
- vii) a holding plate,

wherein the first flexible web layer, fluid transport layer and fluid impervious envelope are secured between the top plate and the holding plate.

24. An assembled device wherein the durable component is coupled to a single, unpackaged, indicator component and in which the indicator component is arranged and configured for exposure to a source of bodily fluid.

25. The assembled device of claim 24 arranged and configured for placement into a diaper.

26. The assembled device of claim 24 wherein the diaper is an infant diaper.

27. A handheld device comprising the assembled device of claim 24.

28. A method of measuring analyte concentration in a bodily fluid comprising:

- a) collecting and transporting bodily fluid to at least one colorimetric analyte sensing element,

- b) detecting the presence of bodily fluid in contact with the at least one colorimetric analyte sensing element,
- c) collecting optical data relating to the at least one colorimetric analyte sensing element with at least one spectrophotometer after a predetermined time period after detecting the presence of bodily fluid in contact with the colorimetric analyte sensing element,
- d) communicating the optical data to a computing system having at least one processor and data storage, and
- e) analyzing the optical data to determine at least one analyte concentration in the bodily fluid.

29. The method of claim 28 wherein the bodily fluid is urine.

30. The method of claim 29 wherein the analyte is selected from the group consisting of glucose, ketones, bilirubin, blood, protein, urobilinogen, nitrite, leukocytes, and/or creatinine, and combinations thereof.

31. A method of measuring analyte concentration in a bodily fluid comprising:

- a) obtaining a durable component comprising a housing having at least one window and containing:
 - i) at least one spectrophotometer adjacent to and optically communicating with the window,
 - ii) a computing system having at least one processor and data storage, and
 - iii) means for electronic communication between the computing system and at least one external device, and
 - iv) at least one moisture sensor;
- b) removing an indicator component from an individual package, the indicator component comprising an indicator zone comprising at least one colorimetric analyte sensing element;
- c) coupling the indicator component to the durable component, wherein:
 - I) the indicator zone is disposed adjacent to and in optical communication with the at least one window and the at least one spectrophotometer,
 - II) the computing system is operatively connected to the moisture sensor and the at least one spectrophotometer,

III) the moisture sensor is disposed adjacent the indicator zone, and

IV) each of the at least one colorimetric analyte sensing element is associated with a spectrophotometer; and

- d) placing the assembled device in contact with a source of the bodily fluid;
- e) collecting and transporting the bodily fluid to the at least one colorimetric analyte sensing element;
- f) detecting the presence of the bodily fluid in contact with the at least one colorimetric analyte sensing element;
- g) collecting optical data relating to the at least one colorimetric analyte sensing element with at least one spectrophotometer after a predetermined time period after detecting the presence of bodily fluid in contact with the colorimetric analyte sensing element;
- h) communicating the optical data to a computing system having at least one processor and data storage; and
- i) analyzing the optical data to determine at least one analyte concentration in the bodily fluid.

32. The method of claim 31 in which step (d) comprises attaching the assembled device to a body-facing surface of a diaper.

33. The method of claim 32 in which step (d) comprises contacting the assembled device with the bodily fluid.

34. A method for predicting risk of a future disease condition comprising:

- a) collecting and transporting bodily fluid to at least one colorimetric analyte sensing element,
- b) detecting the presence of bodily fluid in contact with the at least one colorimetric analyte sensing element,
- c) collecting optical data relating to the at least one colorimetric analyte sensing element with at least one spectrophotometer after a predetermined time period after detecting the presence of bodily fluid in contact with the colorimetric analyte sensing element,
- d) communicating the optical data to a computing system having at least one processor and data storage,

- e) analyzing the optical data to determine at least one analyte concentration in the bodily fluid,
- f) identifying a threshold analyte concentration of the at least one analyte in the bodily fluid that is an indicator of the risk of developing a future disease condition; and
- g) recording the at least one analyte concentration in the bodily fluid over time.

35. The method of claim 34 wherein the bodily fluid is urine.

36. The method of claim 34 wherein the analyte is selected from the group consisting of glucose, ketones, bilirubin, blood, protein, urobilinogen, nitrite, leukocytes, and/or creatinine, and combinations thereof.