

The optical sensor microarray scanning device provides an electronic signal to a biorecognition device based on the fluorescence of the interaction between bioactive agent and analyte excited by an evanescent wave produced by the laser. The optical sensor frequency is determined based on a cost tradeoff between laser, PIN diode, and fluorescent molecule costs.

The non-disposable evanescent sensor fiber (microarray scanning device within the Assay Reader Device) is attached to the disposable blood draw fluidics subsystem (containing the microarray in the Assay Device) to create a complete single use assay device. The assay device is packaged in groups of 6 and 12 per assay reader device.

For testing the maximum size of an integrated system is similar to the body media device which is show in FIG. 14.

Blood flows through the micro needles into the blood reservoir. The buffer and blood form a laminar flow through the channel (FIG. 5; shown in black). A 660 nm laser excites fluorophore, which are bound to the surface of the fiber (in gray). Drugs in blood displace the labeled drugs on the fiber, and the intensity of the fluorescence is decreased. A sensor on the end of the fiber in the Reader detects a reduction in signal level. This reduction is reported to the biometric recognition device's associated database.

The devices are formed into a comb like structure; the 12-unit assay model is shown in FIG. 7. In the figures the control electronics are mounted in the top portion of the device (assay reader device). The actuation mechanisms are in the bottom of the device (assay device).

The end view of the reader shows the cavity for the assay device in the bottom of the reader. An optical and mechanical interface exists between the two components.

Along the top of the cavity are 12 springs which are used to force the micro needles into the skin. Also there is a solenoid that releases the spring. Each spring presses on the top of one of the 12 disposable components.

One end of each of the assay device fingers forms a hinge within the assay device, so the spring forces the assay device down through a layer of film, which covers the bottom of the assay device.

The optical fiber passes over the hinge and terminates at an optical splitter, which is mounted on the bottom of the electronics printed circuit board. The interface between the assay device and the assay reader device is a small air gap.

This end view of one of the 12 assay device fingers shows the package. The assay device is inside a sterile patch package. Under the micro needles there is a portion of the patch that is designed to allow the needles to penetrate and enter skin. The patch is held in place with an adhesive as shown in FIG. 6. Finally there is a protective cover. The top of the patch is designed to allow insertion into the reader. The optical signal passes through a portion of this seal between the end of the fiber and the splitter.

In this disclosure there is described only the preferred embodiments of the invention and but a few examples of its versatility. It is to be understood that the invention is capable of use in various other combinations and environments and is capable of changes or modifications within the scope of the inventive concept as expressed herein. Thus, for example, those skilled in the art will recognize, or be able to ascertain, using no more than routine experimentation, numerous equivalents to the specific substances and procedures described herein. Such equivalents are considered to be within the scope of this invention, and are covered by the following claims.

What is claimed is:

1. A medical device comprising a disposable patch capable of detecting an analyte of unknown concentration in a bodily fluid, said patch comprising:
 - a at least one microneedle capable of obtaining a sample of a bodily fluid;
 - a buffer reservoir;
 - a microchannel having at least a first inlet, a second inlet, and a microarray attached onto the microchannel, said microarray comprising at least one bioactive agent, wherein the first inlet is in fluid communication with the at least one microneedle and channels a flow of bodily fluid into the microchannel, and wherein the second inlet channels a flow of buffer from said buffer reservoir into the microchannel, such that the analyte in the bodily fluid diffuses into the flow of buffer to effect an interaction between the bioactive agent and the analyte therein;
 - a microarray scanning device to detect the interaction between the bioactive agent and the analyte in the bodily fluid; and
 - an interface device capable of facilitating communications between said microarray scanning device and a biometric recognition device.
2. The medical device of claim 1, wherein the microarray comprises an antibody specifically binding the analyte in the bodily fluid.
3. The medical device of claim 1, wherein the biometric recognition device is located outside of the device and the communication is through wireless transmission.
4. The medical device of claim 1, wherein the device is worn on the skin as a patch.
5. The medical device of claim 1, further comprising:
 - a reservoir having a therapeutic agent therein; and
 - a therapeutic agent releasing device, capable of controlling release of a therapeutic agent from a reservoir in response to an instruction from the biometric recognition device.
6. The medical device of claim 1 wherein the bodily fluid is blood.
7. The medical device of claim 1 wherein the patch comprises a plurality of microneedles.
8. The medical device of claim 1 wherein the microneedle is between about 10 and about 200 microns in diameter.
9. The medical device of claim 1 wherein the microneedle is capable of drawing about 100 nanoliters of blood.
10. The medical device of claim 1 wherein the analyte in the bodily fluid competitively displaces labeled analyte from binding the biological agent.
11. The medical device of claim 10 wherein the labeled analyte is provided in a predetermined amount.
12. The medical device of claim 10 wherein the labeled analyte is labeled with a fluorescent moiety.
13. The medical device of claim 1 wherein the microarray scanning device comprises a total internal reflection fluorescence (TIRF) spectrometer.
14. The medical device of claim 1 wherein the analyte is insulin and the bioactive agent is an antibody specific for insulin.
15. The medical device of claim 1 wherein the analyte is glucose and the bioactive agent is an antibody specific for glucose.
16. The medical device of claim 5 wherein the analyte is glucose and the therapeutic agent is insulin.
17. The medical device of claim 5 wherein the analyte is the same as the therapeutic agent.