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(54) **CALIBRATION OF FLUIDIC DEVICES**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,003,379 A 1/1977 Ellinwood
4,146,029 A 3/1979 Ellinwood
4,347,176 A 8/1982 Mehta
4,731,726 A 3/1988 Allen
4,793,825 A 12/1988 Benjamin et al.
4,910,131 A 3/1990 Mellman et al.
4,920,213 A 4/1990 Dale et al.
4,946,795 A 8/1990 Gibbons et al.
5,104,813 A 4/1992 Besemer et al.
5,162,237 A 11/1992 Messenger et al.
5,279,607 A 1/1994 Schentag et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CN 2559986 7/2003

(Continued)

OTHER PUBLICATIONS

Bawendi, et al. The quantum-mechanics of larger semiconductor clusters. Annu. Rev. Phys. Chem. 1990; 41:477-496.

(Continued)

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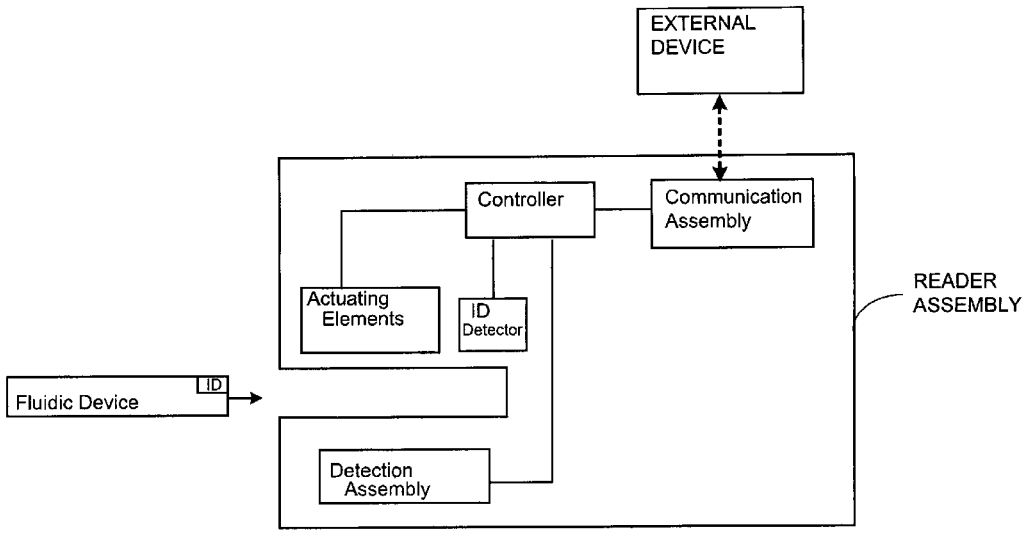
(57) **ABSTRACT**

The present invention provides methods of calibrating a fluidic device useful for detecting an analyte of interest in a bodily fluid. The invention also provides methods for assessing the reliability of an assay for an analyte in a bodily fluid with the use of a fluidic device. Another aspect of the invention is a method for performing a trend analysis on the concentration of an analyte in a subject using a fluidic device.

6 Claims, 23 Drawing Sheets