

The GUI can also implement an algorithm to arrive on diagnosis from fluorescence data. The GUI provides access control to unit and in some embodiments has an HIS/LIS interface.

**[0123]** The Control Board Power Monitor software monitors power supplies, current and voltage, and signals error in case of a fault.

**[0124]** The Optics Software performs fluorescence detection which is precisely timed to turn on/off of LED with synchronous digitization of the photodetector outputs. The Optics Software can also monitor power supply voltages. The Optics Software can also have self test ability.

**[0125]** The Heater Mux Module software implements a "protocol player" which executes series of defined "steps" where each "step" can turn on sets of heaters to implement a desired microfluidic action. The Heater Mux Module software also has self test ability. The Heater Mux Module software contains a fuzzy logic temperature control algorithm.

**[0126]** The Heater Mux Power Monitor software monitors voltage and current levels. The Heater Mux Power Monitor software can participate in self-test, synchronous, monitoring of the current levels while turning on different heaters.

#### Overview of Apparatus for Receiving a Microfluidic Cartridge

**[0127]** The present technology relates to a heater unit, cartridge, complementary apparatus, and related methods for amplifying, and carrying out diagnostic analyses on, nucleotides from biological samples. The technology includes a heater unit for heating selective regions of a microfluidic substrate, such as contained in a disposable or reusable microfluidic cartridge containing multiple sample lanes capable of processing samples in parallel as further described herein, and a reusable apparatus that is configured to selectively actuate on-cartridge operations, to detect and analyze the products of the PCR amplification in each of the lanes separately, in all simultaneously, or in groups simultaneously, and, optionally, can display the progression of analyses and results thereof on a graphical user interface. Such a reusable apparatus is further described in U.S. patent application Ser. No. \_\_\_\_\_, entitled "Microfluidic System For Amplifying And Detecting Polynucleotides In Parallel" and filed on Nov. 14, 2007, and which is incorporated herein by reference in its entirety.

**[0128]** An Analyzer unit can contain typical hardware/firmware that can be employed to drive and monitor the operations on the cartridges as well as software to interpret, communicate and store the results. Typical components of the Analyzer can include: (a) Control Electronics (DAQ), (b) Heater/Sensor Unit, (c) Fluorescent Detection Module, (d) Mechanical Fixtures, (e) Software and (f) User Interface (LCD/Touch screen) (g) Peripherals (CD-ROM, USB/Serial/Ethernet communication ports, barcode scanner, optional keyboard).

**[0129]** FIG. 20 shows a perspective view of an exemplary apparatus 100 consistent with those described herein, as well as various components thereof, such as exemplary cartridge 200 that contains multiple sample lanes, and exemplary read head 300 that contains detection apparatus for reading signals from cartridge 200. The apparatus 100 of FIG. 20 is able to carry out real-time PCR on a number of samples in cartridge 200 simultaneously. Preferably the number of samples is 12 samples, as illustrated with exemplary cartridge 200, though other numbers of samples such as 4, 8, 10, 16, 20, 24, 25, 30,

32, 36, 40, and 48 are within the scope of the present description. In preferred operation of the apparatus, a PCR-ready solution containing the sample, and, optionally, one or more analyte-specific reagents (ASR's) is prepared, as further described elsewhere (see, e.g., U.S. patent application publication 2006-0166233, incorporated herein by reference), prior to introduction into cartridge 200.

**[0130]** In some embodiments, an apparatus includes: a receiving bay configured to selectively receive a microfluidic cartridge as described herein; at least one heat source thermally coupled to the receiving bay; and a processor coupled to the heat source, wherein the heat source is configured to selectively heat individual regions of individual sample lanes in the cartridge, and the processor is configured to control application of heat to the individual sample lanes, separately, in all simultaneously, or in groups simultaneously; at least one detector configured to detect one or more polynucleotides or a probe thereof in a sample in one or more of the individual sample lanes, separately or simultaneously; and a processor coupled to the detector to control the detector and to receive signals from the detector.

**[0131]** The receiving bay is a portion of the apparatus that is configured to selectively receive the microfluidic cartridge. For example, the receiving bay and the microfluidic cartridge can be complementary in shape so that the microfluidic cartridge is selectively received in, e.g., a single orientation. The microfluidic cartridge can have a registration member that fits into a complementary feature of the receiving bay. The registration member can be, for example, a cut-out on an edge of the cartridge, such as a corner that is cut-off, or one or more notches or grooves that are made on one or more of the sides in a distinctive pattern that prevents a cartridge from being loaded into the bay in more than one distinct orientation. By selectively receiving the cartridge, the receiving bay can help a user to place the cartridge so that the apparatus can properly operate on the cartridge. The cartridge can be designed to be slightly smaller than the dimensions of the receiving bay, e.g., by approximately 200-300 microns, for easy placement and removal of the cartridge.

**[0132]** The receiving bay can also be configured so that various components of the apparatus that operate on the microfluidic cartridge (heat sources, detectors, force members, and the like) are positioned to properly operate thereon. For example, a contact heat source can be positioned in the receiving bay such that it can be thermally coupled to one or more distinct locations on a microfluidic cartridge that is selectively received in the bay. Microheaters in the heater unit are aligned with corresponding heat-requiring microcomponents (such as valves, pumps, gates, reaction chambers, etc). The microheaters can be designed to be slightly bigger than the heat requiring microfluidic components so that even though the cartridge may be off-centered from the heater, the individual components can still function effectively.

**[0133]** As further described herein, the lower surface of the cartridge can have a layer of mechanically compliant heat transfer laminate that can enable thermal contact between the microfluidic substrate and the microheater substrate of the heater unit. A minimal pressure of 1 psi can be employed for reliable operation of the thermal valves, gates and pumps present in the microfluidic cartridge.

**[0134]** The apparatus can further include a sensor coupled to the processor, the sensor configured to sense whether the microfluidic cartridge is selectively received.