

media. Data that may be written to such media by such a device includes, but is not limited to, environmental information, such as temperature or humidity, pertaining to an analysis, as well as a diagnostic result, and identifying data for the sample in question.

[0149] The apparatus may further include a computer network connection that permits extraction of data to a remote location, such as a personal computer, personal digital assistant, or network storage device such as computer server or disk farm. The network connection can be a communications interface selected from the group consisting of: a serial connection, a parallel connection, a wireless network connection, and a wired network connection such as an ethernet or cable connection, wherein the communications interface is in communication with at least the processor. The computer network connection may utilize, e.g., ethernet, firewire, or USB connectivity. The apparatus may further be configured to permit a user to e-mail results of an analysis directly to some other party, such as a healthcare provider, or a diagnostic facility, or a patient.

[0150] In various embodiments, there is an associated computer program product that includes computer readable instructions thereon for operating the apparatus and for accepting instructions from a user.

[0151] Apparatus **100** may optionally comprise one or more stabilizing feet that cause the body of the device to be elevated above a surface on which system **100** is disposed, thereby permitting ventilation underneath system **100**, and also providing a user with an improved ability to lift system **100**.

[0152] In some embodiments, the heat sources are operated by an operating system, which operates the device during use. The operating system includes a processor (e.g., a computer) configured to actuate the heat sources according to a desired protocol. Processors configured to operate microfluidic devices are described in, e.g., U.S. application Ser. No. 09/819,105, filed Mar. 28, 2001, which application is incorporated herein by reference.

[0153] In various embodiments, a processor executes instructions from a computer program product that includes computer readable instructions thereon for operating the apparatus.

[0154] In various embodiments, the computer program product can include one or more instructions to cause the system to: output an indicator of the placement of the microfluidic cartridge in the receiving bay; read a sample label or a microfluidic cartridge label; output directions for a user to input a sample identifier; output directions for a user to load a sample transfer member with the PCR-ready sample; output directions for a user to introduce the PCR-ready sample into the microfluidic cartridge; output directions for a user to place the microfluidic cartridge in the receiving bay; output directions for a user to close the lid to operate the force member; output directions for a user to pressurize the PCR-ready sample in the microfluidic cartridge by injecting the PCR-ready sample with a volume of air between about 0.5 mL and about 5 mL; and output status information for sample progress from one or more lanes of the cartridge.

[0155] In various embodiments, the computer program product can include one or more instructions to cause the system to: heat the PCR ready-sample under thermal cycling conditions suitable for creating PCR amplicons from the neutralized polynucleotide; contact the neutralized polynucleotide sample or a PCR amplicon thereof with at least one

probe that is selective for a polynucleotide sequence; independently contact each of the neutralized polynucleotide sample and a negative control polynucleotide with the PCR reagent mixture under thermal cycling conditions suitable for independently creating PCR amplicons of the neutralized polynucleotide sample and PCR amplicons of the negative control polynucleotide; contact the neutralized polynucleotide sample or a PCR amplicon thereof and the negative control polynucleotide or a PCR amplicon thereof with at least one probe that is selective for a polynucleotide sequence; output a determination of the presence of a polynucleotide sequence in the biological sample, the polynucleotide sequence corresponding to the probe, if the probe is detected in the neutralized polynucleotide sample or a PCR amplicon thereof; and/or output a determination of a contaminated result if the probe is detected in the negative control polynucleotide or a PCR amplicon thereof.

[0156] In various embodiments, the computer program product can include one or more instructions to cause the system to automatically conduct one or more of the steps of the method.

EXAMPLES

Example 1

Analyzer Apparatus

[0157] This non-limiting example describes pictorially, various embodiments of an apparatus, showing incorporation of a heater unit and a microfluidic cartridge operated on by the heater unit.

[0158] FIG. **21** shows an apparatus **1100** that includes a housing having a display output **1102**, an openable lid **1104**, and a bar code reader **1106**. The cartridge is positioned in a single orientation in a receiving bay under the lid, FIG. **22**. The lid of the apparatus can be closed to apply pressure to the cartridge, as shown in FIG. **23**. The unit currently weighs about 20 lbs. and is approximately 10" wide by 16" deep by 13" high.

[0159] FIGS. **24** and **25**: The heating stage of the apparatus can be removable for cleaning, maintenance, or to replace a custom heating stage for a particular microfluidic cartridge. FIGS. **24** and **25** also show how a heater unit is insertable and removable from a front access door to an analyzer apparatus.

Example 2

Assembly of an Exemplary Heater Unit

[0160] FIG. **26A** shows an exploded view of an exemplary heater unit. The unit has a top cover and a bottom cover that together enclose a Mux board (control board), a pressure support layer, and insulator film, and a microthermal circuit on a PCB. The last of these is the heat source that selectively heats regions of a microfluidic substrate placed in contact therewith through the top cover.

[0161] An exemplary heater substrate, FIG. **26B**, consists of a photo-lithographically processed glass wafer bonded to a standard 0.100" standard FR4 printed circuit board. The glass wafer is 0.5 mm thick and is cut into a rectangle the size of 3.5x4.25 inches. The glass substrate has numerous metal heaters and resistive temperature sensors photo-lithographically etched on the surface of the glass wafer. The substrate is aligned and bonded to the PCB using a compliant epoxy, ensuring flatness to within 2-3 mils over the surface of the wafer. The cured epoxy should withstand up to 120° C. for