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(54) **Title**: A GENETIC TEST CONTROL APPARATUS

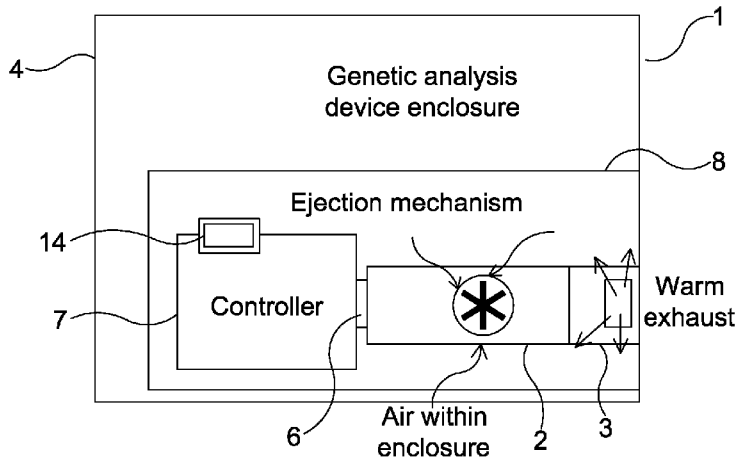

Figure 3

(57) **Abstract**: A test control apparatus (4) for electrically coupling a genetic material analyser (2), such as for DNA sequencing or nucleic acid amplification and assay, and associated test cartridge (3) to a computer system is provided. The apparatus (4) disclosed incorporates all the components of an electronic microchip-based genetic test apparatus within a single enclosure. The apparatus (4) minimizes the number of steps required for a user to run a genetic test and is configured to provide temperature control through heating or cooling to a genetic material analyser (2) and associated test cartridge (3) within the enclosure. The test control apparatus (4) includes as well an ejection mechanism (8) for ejecting the analyser (2) and test cartridge (3) after genetic test completion.

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A GENETIC TEST CONTROL APPARATUS

Field Of Invention

The present invention relates to a genetic test control apparatus for controlling a genetic test performed by a genetic material analyser and associated test cartridge.

Background

Various advances in technology have led to the availability of electronic microchip-based methods and apparatus for performing DNA analysis, sometimes referred to as "lab-on-a-chip" analysis. Such solutions to DNA analysis are typically faster and more cost-effective than traditional DNA analysis methods, which may require fluorescent dyes, labels or precision optics. Electronic microchip-based DNA tests can often be performed and processed outside of the laboratory with no requirement for samples of DNA to be sent elsewhere for analysis. The electronic form of the results from electronic microchip-based tests means that it is possible to connect the testing apparatus to a computer system, which can subsequently be connected to a network or the Internet. Data recorded by the DNA analysis apparatus can be compared with, and or processed in combination with, data stored on various databases located within a computer system, computer networks or the Internet. Due to the simple and scalable characteristics of electronic microchip-based genetic testing, on-site and over-the counter DNA testing services are being introduced.

An electronic microchip-based solution may comprise a disposable test cartridge housing a silicon chip, and a re-useable genetic material analyser with which the test chip is engaged. A sample of genetic material to be tested, e.g. obtained using a cheek swap, is applied to the test cartridge and the cartridge engaged with the analyser. When engaged, the genetic material analyser and associated test cartridge are electrically coupled. The genetic material analyser is further electrically coupled to a computer system to which it can send and receive data and instructions, e.g. via a USB interface. The genetic material analyser can be unplugged from the computer system between tests to assist handling and attachment/detachment of the test cartridges.

Tests carried out using lab-on-a-chip solutions are generally subject to upper and lower temperature limits. During the running of a test, the associated functioning of electronics including the silicon chip can generate significant heat, potentially causing the temperature of the device to rise above the specified upper temperature limit. Provision must therefore be made for cooling, and potentially heating, devices in order to ensure optimal operation.

An exemplary microchip-based solution for performing analysis of genetic material is produced by DNA Electronics, London, United Kingdom, using their proprietary Genalysis® platform. A typical analyser and associated test cartridge are shown and illustrated schematically in Figure 1. To complete the set-up in Figure 1 for performing a genetic test, the analyser needs to be connected to a controller configured appropriately for transmitting instructions and receiving data from the analyser. This controller could be a computer system or similar device with the required software and drivers pre-installed.

To overcome or at least mitigate the problem of potential overheating during the running of genetic tests, an analyser and associated test cartridge, such as that illustrated in Figure 1, may have active cooling components located at areas requiring temperature regulation. The associated test cartridge may be provided with a ventilation opening, with the analyser and test cartridge both comprising air ducts. These air ducts are configured so that, when the analyser and test cartridge are engaged together, the separate air ducts mate to form one continuous air duct connecting the interiors of both components. When a genetic test is being carried out, the miniature fan draws air in through the ventilation opening on the analyser and into the interior of the analyser housing. Air within the analyser housing is then circulated into the connected test cartridge through the air ducts described. Air is expelled from the ventilation opening in the test cartridge. This arrangement generally provides for sufficient cooling to maintain the test cartridge temperature within the desired operating range.

In a retail outlet, DNA testing services would be severely constrained if the test apparatus would have to be operated by a highly skilled person, such as a formally trained laboratory worker. Instead, it would be useful to further simplify the apparatus

for conducting genetic tests to achieve robust and consistent performance, even when the operator is not formally trained to work in a scientific laboratory. In addition, with current analyser/test cartridge arrangements, there is the scenario where a test may be aborted by an operator who has unintentionally unplugged the test cartridge from the analyser. Furthermore, the test cartridge may be at risk of disconnection from an accidental bump or nudge (by the user). Any disconnection of the test cartridge prior to completion of a genetic test may have significant cost and time implications as a test would need to be repeated with a new test cartridge.

Summary of the Invention

Thus, it is desirable to minimize the steps required to operate a genetic test, for example reducing the entire operation to a single step of inserting a cartridge prepared with reagents and a genetic sample to the analyser to initiate a test, and upon completion, to return the results. Furthermore, it is desirable to ensure that the maintenance of the apparatus is kept as simple as possible. To this end, a straight-forward solution would be to incorporate all the elements of the test apparatus within a single enclosure, including the controller, analyser and supporting components (such as cables, brackets etc). In addition, it is desirable for the test cartridge to be secured in a configuration so as to prevent the scenario where a test is aborted by an operator who has unintentionally unplugged the cartridge from the analyser.

While such a set-up would ensure simple and robust operation, the degree of cooling of the analyser and test cartridge by convection and conduction may also be reduced, as a consequence of it being embedded within an enclosure and no longer exposed to the ambient surroundings for maximal heat exchange with the ambient environment. It would therefore be favorable for the enclosure proposed to be configured so as to provide cooling for the analyser and test cartridge.

According to a first aspect of the present invention there is provided a test control apparatus for controlling a genetic test performed using a genetic material analyser and associated test cartridge, where the test cartridge is removable from the analyser. The apparatus comprises a housing defining a housing port within which the analyser can be

slidably mounted such that, when the test cartridge is engaged with the analyser, the analyser and test cartridge are pushed into the housing to prevent a user from disengaging the test cartridge from the analyser. The apparatus further comprises an ejection mechanism for ejecting the analyser and test cartridge outwardly within the port, following completion of a genetic test, to permit user removal of the test cartridge. The apparatus further comprises at least one air circulating fan for circulating air within the housing to cool and or heat the analyser and test cartridge during performance of a genetic test.

The test control apparatus further comprises a controller within the housing and being configured to send instructions to, and receive data from, the analyser when connected thereto, the controller being connected to the analyser both when pushed into the housing port and when ejected therefrom, at least prior to any subsequent removal of the analyser from the port by a user.

According to a second aspect of the present invention there is provided a test control apparatus for controlling a genetic test performed using a genetic material analyser and associated test cartridge, where the test cartridge is removable from the analyser. The apparatus comprises a housing defining a housing port within which the analyser can be slidably mounted such that, when the test cartridge is engaged with the analyser, the analyser and test cartridge are pushed into the housing to prevent a user from disengaging the test cartridge from the analyser and an ejection mechanism for ejecting the analyser and test cartridge outwardly within the port, following completion of a genetic test, to permit user removal of the test cartridge. The apparatus further comprises at least one air circulating fan for circulating air within the housing to cool and or heat the analyser and test cartridge during performance of a genetic test, and a controller for receiving sensed temperature information from the test cartridge and for controlling said air circulating fan and a further air circulating fan provided in said analyser to achieve a substantially optimal operating temperature within the test cartridge.

According to a third aspect of the present invention there is provided an analyser and test cartridge for use with the test control apparatus of the above second aspect of the

invention, the analyser comprising an air circulating fan and a first air flow port, and the test cartridge comprising a second air flow port that is coupled to said first air flow port when the test cartridge is engaged with the analyser to allow cooling and /or heating of the test cartridge by the air circulating fan, the test cartridge further comprising a temperature sensor for sensing an operating temperature within the test cartridge.

Brief Description of the Drawings

Figure 1 illustrates a known genetic material analyser and associated test cartridge;

Figure 2 illustrates a test control apparatus for interconnecting an analyser to a computer system, with the analyser in a first state;

Figure 3 illustrates the test control apparatus of Figure 2 with the analyser in a second state;

Figure 4 illustrates the test control apparatus in the state of Figure 3, further illustrating air ducting within the apparatus;

Figure 5 illustrates a test control apparatus configured to receive a plurality of analysers, with the analysers shown in a first state; and

Figure 6 illustrates a test control apparatus configured to receive a plurality of analysers, with the analysers shown in a second state.

Detailed Description

There will now be described a test control apparatus for controlling a genetic material analyser and associated test cartridge in order to perform a test on a sample of genetic material, whereby the steps required to operate the genetic test are reduced and simplified as compared to conventional test architectures. Configurations of the test control apparatus intended to reduce the risk of accidental disconnection of the components during the running of a genetic test will be described. Configurations of the test control apparatus intended to regulate the temperature of the genetic material analyser and associated test cartridge during a genetic test will also be described.

It is assumed here that the analyser and test cartridge conform to known designs, e.g. those available from DNA Electronics, such that they may be plugged directly into a computer system, e.g. using a USB interface, although other configurations are also contemplated. The test control apparatus is configured to instruct and control the steps

of an electronic micro-chip based genetic test and, optionally, transmit results (which may be intermediate results) of the test to a remote data centre. The test control apparatus may also receive data from the remote data centre, including programming instructions, data for performing the test, and processed result data (including intermediate data). The test control apparatus may communicate with the remote data centre via a wireless link, e.g. via a wireless network.

Figure 2 illustrates schematically a test control apparatus 1 in one operational state, hereby referred to as the ejected operational state, where an analyser 2 and test cartridge 3 are shown partially ejected from the test control apparatus 1. With reference to Figures 2 to 4 it can be seen that the test control apparatus 1 comprises a housing enclosure 4. At one side of the housing enclosure 4 there is provided an entry port 5. The port 5 houses a sliding carriage 6 configured to receive and support a genetic material analyser 2. Figure 3 illustrates schematically the test control apparatus in another operational state, hereby referred to as the inserted operational state, where an analyser 2 and test cartridge 3 are fully inserted within the housing enclosure 4.

The test control apparatus comprises an internal USB socket integrated into the sliding carriage 6 for connection to the USB plug provided on a genetic material analyser. The USB socket is connected internally to a controller, as will be described below.

The test control apparatus includes an internal controller 7 configured to send instructions to, and receive data from, the analyser 2. The controller 7 has logic components and drivers installed for the purpose of initializing, controlling and ending a genetic test carried out by an analyser 2 and test cartridge 3 electrically coupled to it. The controller 7 is capable of receiving wireless commands from a remote human interface and transmitting the results of genetic tests to a remote data consumer. The controller 7 is further configured to appropriately signal to an ejection mechanism, as will be described further below. Drivers and logic components are installed on the controller 7 for this purpose. The test controller further comprises a data and program memory 14.

The sliding carriage 6 is configured to be slideable in a direction parallel to the base of the housing enclosure 4 and, as noted above, to receive a genetic material analyser 2, such as that illustrated in Figure 1. The test control apparatus 1 further comprises an ejection mechanism 8, connected to the controller 7, within the interior of the housing enclosure 4. The ejection mechanism 8 is mechanically coupled to the sliding carriage 6 and configured to provide force to move the sliding carriage 6 within the port 5.

The test control apparatus 1 further comprises air ducts 9,10. In the example shown in Figure 4, the two air ducts are configured to "mate" with the openings present in the genetic material analyser 2 and associated test cartridge 3. Air circulating fans 11,12 are located at openings of the air ducts 9,10.

The operation of the test control apparatus is now considered, again with reference to Figures 2 to 4. In order to initiate a test, a user will apply a sample of genetic material (to be tested) to the test cartridge 3 and will connect the test cartridge 3 to the genetic material analyser 2. To initialize a genetic test the user inserts the analyser and test cartridge into the port. At this point, the sliding carriage 6 is fully retracted into the port 5, allowing the plug on the end of the analyser 2 to be securely engaged with the corresponding USB socket provided on the sliding carriage 6. At the position where the USB port on the analyser 2 is fully engaged, the end of the test cartridge 3 is flush with the surface of the housing enclosure 4, i.e. the analyser 2 and test cartridge 3 are fully within the port 5 so there is no possibility for the user to manually remove the analyser 2 and test cartridge 3. In some embodiments, once the USB plug on the analyser 2 is engaged with the internal USB port of the test control apparatus, further removal of the analyser be prevented by some locking mechanism, with the analyzer only being removable when the control apparatus permits release (see further explanation of use given below).

Electrical signaling from the analyser 2 through the USB port indicates to the controller 7 that an analyser 2 and test cartridge 3 are engaged with the test control apparatus 1. The controller 7 then interacts, through electrical signaling, with the analyser 2 to initiate the test. Appropriate signaling is exchanged between the analyser 2 and the controller 7 until the test is completed. During the genetic test, data from the analyser 2

is transferred to the controller 7 which may then transmit the results through a wireless connection to a remote data centre. Upon completion, signaling from the controller 7 causes the ejection mechanism 8 to eject the sliding carriage 6, whereupon the end of the test cartridge 3 and analyser 2 project outward from the port 5 so that they can be removed from the test control apparatus 1. In the case where removal of the analyser 2 is locked, only the test cartridge 3 will be removable by the user. In order to perform a subsequent test, the user need only push a new test cartridge into engagement with the analyser 2 and further push both components into the receiving port.

An advantage that arises from allowing removal of the cartridge only after it has been ejected from the housing is that separation of the housing and the analyser can only occur outside of the housing. In the unlikely event that biological material leaks from the cartridge after separation of the cartridge from the analyser, this material will not contaminate the interior of the housing. Such contamination could result in the gateway being unusable for further tests.

Figure 4 illustrates the test control apparatus 1 in more detail, showing in particular the air ducts 9,10 connecting the interior and exterior of the housing enclosure 4, and the associated air circulating fans 11,12. By adjusting the speed of the air circulating fans 11,12, the quantity of air flow through the air ducts 9,10 can be adjusted. By increasing the quantity of air flow through the air ducts 9,10, the upper limit of the ambient temperature range at which a genetic analyser 2 can carry out a genetic test, when plugged into the test control apparatus 1, can be increased. During a genetic test, should the temperature of the genetic material analyser 2 become too low, the air circulating fans 11,12 associated with the air ducts 9,10 can be stopped or slowed to allow heat buildup in the genetic material analyser 2 and associated test cartridge 3. The fans 11,12 are controlled by via the internal controller 7. This control process may further facilitated by one or more temperature sensors 13 contained within the housing enclosure 4. In addition, or alternatively, temperature may be sensed within the analyser 2 and or test cartridge 3 via integrated temperature sensors.

In another embodiment, the internal controller 7 may have non-volatile storage to retain the results of the genetic test in persistent media (storage memory) for future read out.

The internal controller may also have a wired connection to a data centre or other controller (e.g. a pc). This wired connection may be relayed through an electrical plug-socket combination, e.g a USB connection, located outside of the housing enclosure 4. The data centre could be a computer system, computer server or other electrical device configured to interpret or transmit the results of a genetic test.

The test control apparatus 1 may optionally electrically couple the genetic material analyser 2 to the controller 7 through alternative electrical connections to the USB connection described in the above example.

The test control apparatus 1 may optionally comprise any number of air ducts connecting any part of the interior of the housing enclosure to its exterior. These air ducts may comprise any number of associated air circulating fans. The air ducts can be purposely built for the input of fresh air at ambient temperature, the expulsion of warm air or a combination thereof. The speed of the air circulating fan or fans associated with the air ducts could optionally be under the control of the controller 7, direct user control through a control unit located on the exterior of the housing enclosure 4, a processing unit electrically coupled to the fan or fans, or any combination of these options.

The test control apparatus 1 may optionally comprise any number of electronic measurement devices. These devices could be placed and configured to measure the temperature of any component or area within the interior or on the exterior of the housing enclosure 4. The electronic measurement devices could enable accurate recording of the temperature of the genetic material analyser 2 and or the associated test cartridge 3. Any number of these electronic measurement devices could be electrically coupled to the test control apparatus 1, any component therein, or any external electronic device.

Figures 5 and 6 illustrate a preferred embodiment of the invention in which a modified test control apparatus is configured to receive four analyser/test cartridge arrangements in parallel. As with the embodiment described above, each receiving port of the housing is configured such that an analyser and test cartridge must be fully inserted before a test is initiated. Only upon completion of a test is the analyser and test

cartridge ejected to allow final manual removal. The test control apparatus is such that the tests may be performed in parallel or in series as appropriate.

In the preferred embodiment, each analyser is mounted on a sliding carriage which is coupled to a spring-loaded ejection mechanism. The carriage is designed to travel between two stable positions. The first position is when the analyser is in the ejected state, where the tray is close to the front-panel of the housing enclosure 4 to allow a test cartridge 3 to be plugged into the analyser. In the second position, the tray is recessed inside the housing enclosure 4 and it is held in position by a latch which is also spring-loaded. This latch is connected to a solenoid which, when activated momentarily, releases the tray to spring back to the first position.

The preferred embodiment makes use of springs to store the energy to allow the carriage to be released quickly with minimal force. Furthermore, when the cartridge pushes in the analyser and the tray, the mechanical latching action provides an affirmative feedback to the user. Instead of motors or other electromechanical mechanisms, the use of the solenoid enables the ejection to be done in a simple fashion without the need for any positional feedback. In order to enact the ejection, the solenoid requires only a short pulse of electric current, which is not required to flow in a specific direction. The preferred embodiment is designed to be simple to assemble and easy to operate.

It will be appreciated by the person of skill in the art that various modifications may be made to the above described embodiments without departing from the scope of the present invention.

Claims:

1. A test control apparatus for controlling a genetic test performed using a genetic material analyser and associated test cartridge, where the test cartridge is removable from the analyser, the apparatus comprising:

a housing defining a housing port within which the analyser can be slidably mounted such that, when the test cartridge is engaged with the analyser, the analyser and test cartridge are pushed into the housing to prevent a user from disengaging the test cartridge from the analyser;

an ejection mechanism for ejecting the analyser and test cartridge outwardly within the port, following completion of a genetic test, to permit user removal of the test cartridge;

at least one air circulating fan for circulating air within the housing to cool and or heat the analyser and test cartridge during performance of a genetic test; and

a controller within the housing and being configured to send instructions to, and receive data from, the analyser when connected thereto, the controller being connected to the analyser both when pushed into the housing port and when ejected therefrom, at least prior to any subsequent removal of the analyser from the port by a user.

2. A test control apparatus according to claim 1 and comprising a controller within the housing and electrically coupled to the at least one air circulating fan to control the speed of the fan in order to achieve an optimal test temperature.

3. A test control apparatus according to claim 2 and further comprising at least one temperature sensor for sensing a temperature within the housing and for providing a sensed temperature signal to said controller.

4. A test control apparatus according to claim 2 or 3, wherein said ejection mechanism is movable from an inserted state to an ejected state by an ejection signal received from the controller.

5. A test control apparatus according to any one of claims 2 to 3 and comprising a program memory for storing program code, this code being readable from the memory by the controller.

6. A test control apparatus according to any one of the preceding claims and comprising one or more air ducts for communicating air to or from the or each air circulating fan to one or more ventilation openings provided in the genetic material analyser and/or test cartridge.

7. A test control apparatus according to any one of the preceding claims and comprising a USB port arranged within said housing port for receiving a USB connector of the genetic material analyser.

8. A test control apparatus according to any one of the preceding claims, the ejection mechanism being configured to lock the analyzer within the port, thereby preventing user removal of the housing in an ejected state whilst permitting removal of the test cartridge.

9. A test control apparatus according to any one of the preceding claims and comprising a wireless interface for exchanging data with a remote data centre.

10. A test control apparatus according to any one of the preceding claims, said housing port being configured such that, in an inserted state, the outermost surface of a test cartridge is substantially flush with the surface of the housing.

11. A test control apparatus for controlling a genetic test performed using a genetic material analyser and associated test cartridge, where the test cartridge is removable from the analyser, the apparatus comprising:

a housing defining a housing port within which the analyser can be slidably mounted such that, when the test cartridge is engaged with the analyser, the analyser and test cartridge are pushed into the housing to prevent a user from disengaging the test cartridge from the analyser;

an ejection mechanism for ejecting the analyser and test cartridge outwardly within the port, following completion of a genetic test, to permit user removal of the test cartridge;

at least one air circulating fan for circulating air within the housing to cool and or heat the analyser and test cartridge during performance of a genetic test; and

a controller for receiving sensed temperature information from the test cartridge and for controlling said air circulating fan and a further air circulating fan provided in said analyser to achieve a substantially optimal operating temperature within the test cartridge.

12. An analyser and test cartridge for use with the test control apparatus of claim 11, the analyser comprising an air circulating fan and a first air flow port, and the test cartridge comprising a second air flow port that is coupled to said first air flow port when the test cartridge is engaged with the analyser to allow cooling and /or heating of the test cartridge by the air circulating fan, the test cartridge further comprising a temperature sensor for sensing an operating temperature within the test cartridge.

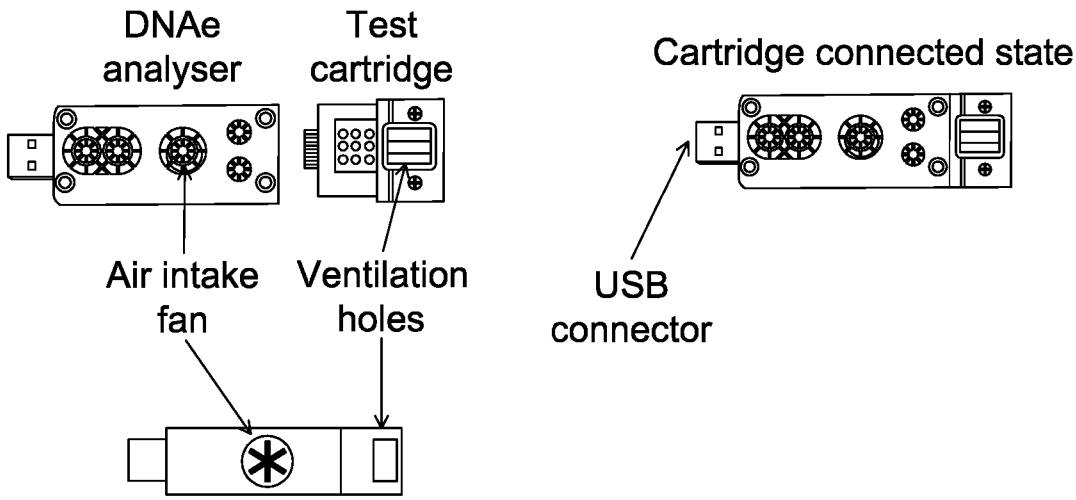

Figure 1

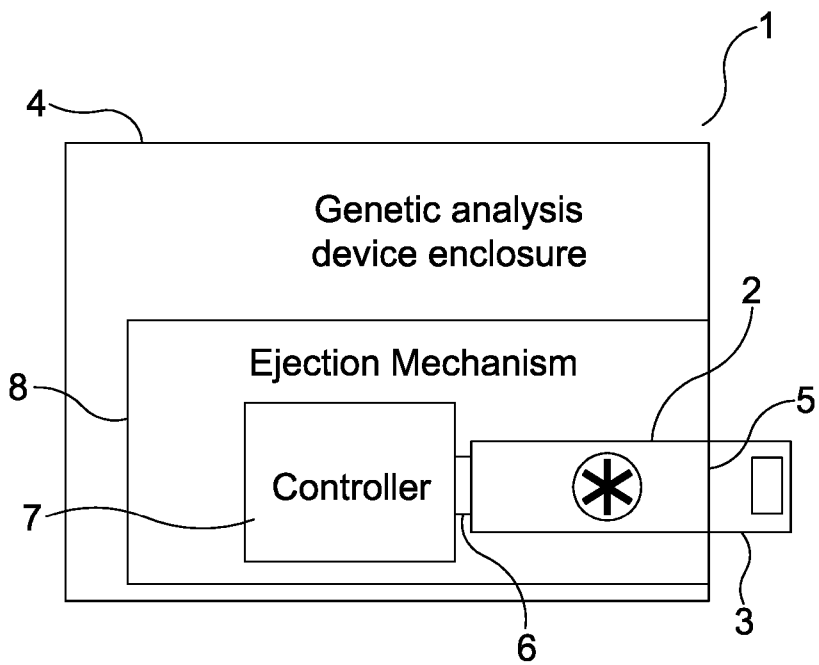

Figure 2

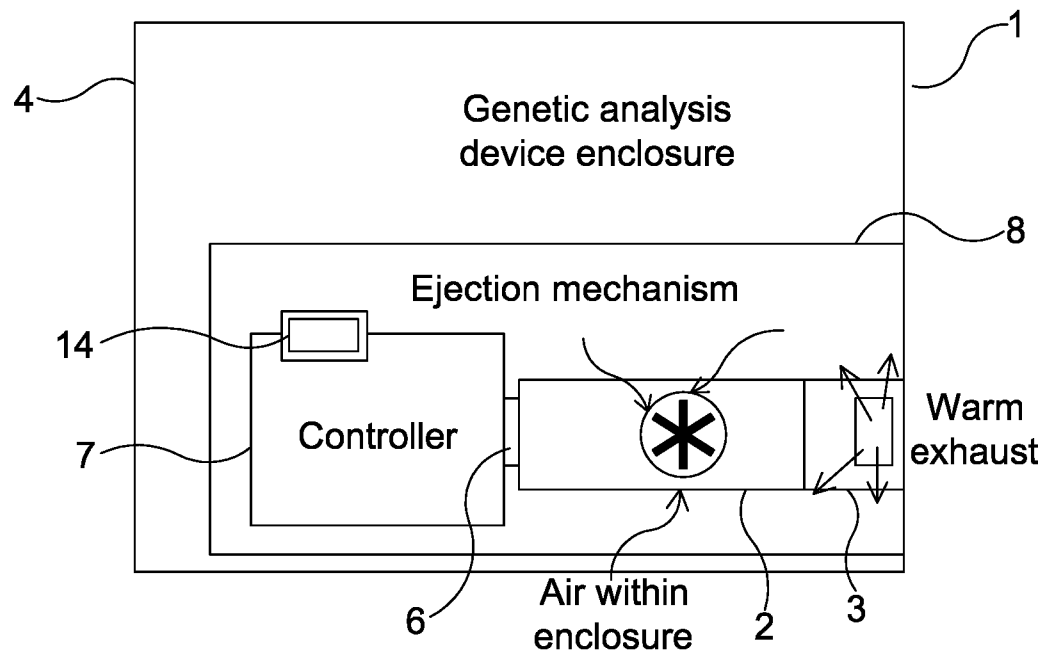

Figure 3

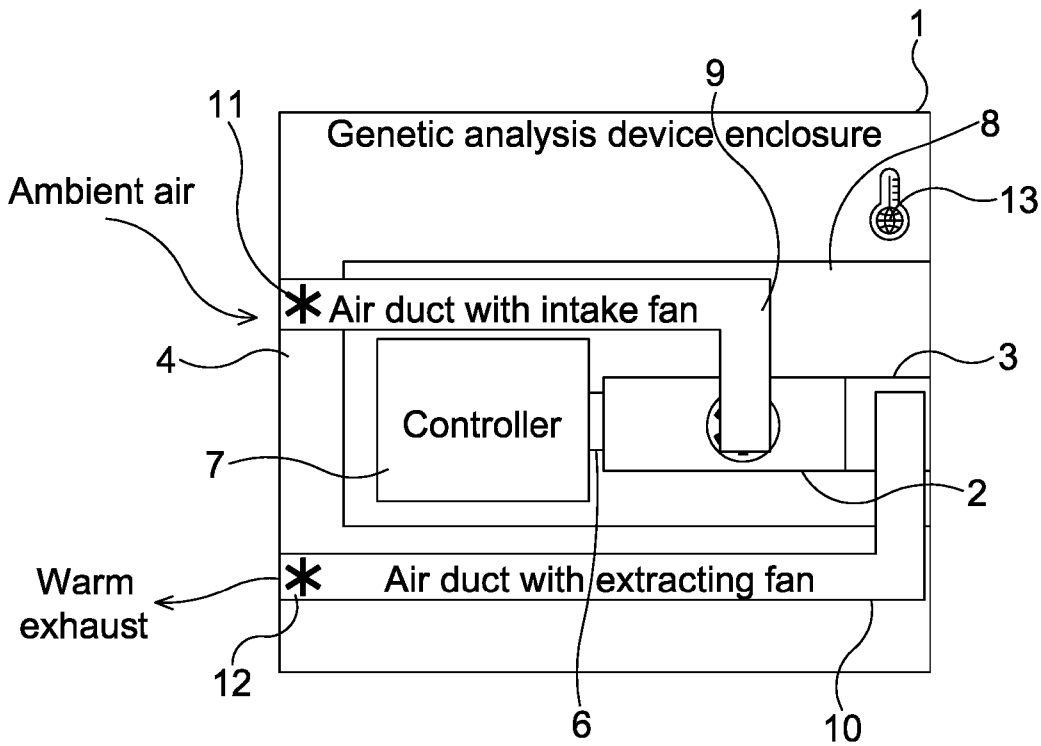

Figure 4

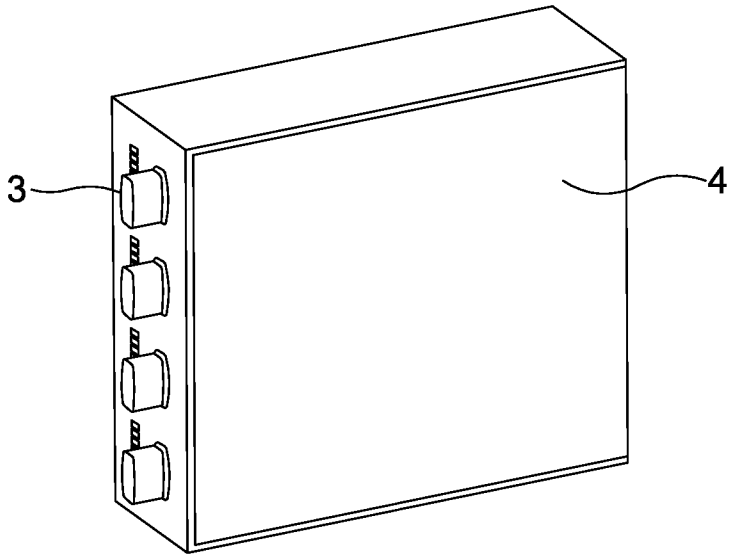

Figure 5

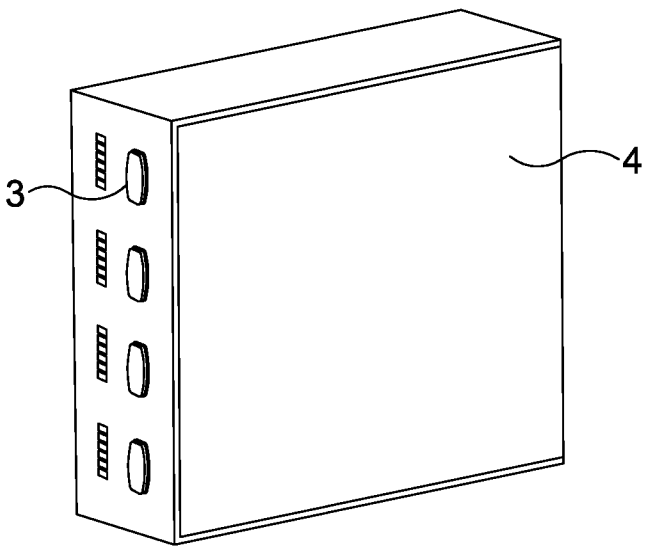

Figure 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2014/053147

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N33/487 B01L3/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G01N B01L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 8 041 463 B2 (POLLACK MICHAEL G [US] ET AL) 18 October 2011 (2011-10-18) column 6, line 15 - column 7, line 23 column 9, lines 20-39 figures 1,4	11,12
Y	US 7 379 294 B2 (CHEN GRACIE L [US]) 27 May 2008 (2008-05-27) column 2, lines 4-59 figures 1,2	11,12
Y	GB 2 500 658 A (DNA ELECTRONICS LTD [GB]) 2 October 2013 (2013-10-02) page 7, paragraph 4-27 page 15, lines 12-28 page 19, line 6 - page 20, line 5 page 22, lines 1-18 figures 1,11-15,20,21	11,12

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
18 December 2014	07/01/2015

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2014/053147

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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