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(54) Title: DEVICES, SYSTEMS AND METHODS RELATING TO *IN SITU* DIFFERENTIATION BETWEEN VIRAL AND NON-VIRAL INFECTIONS

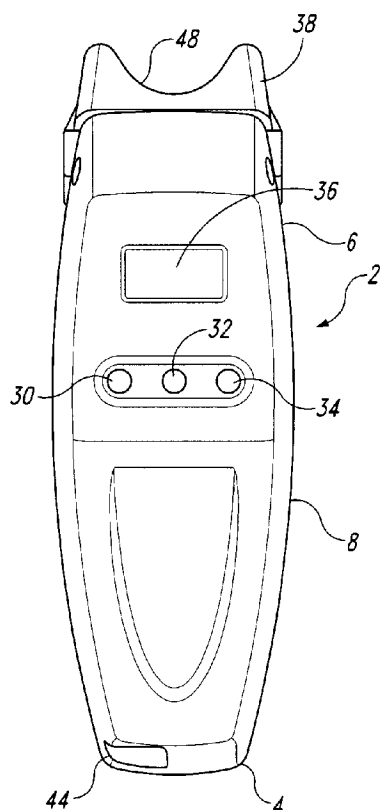


Fig. 1

(57) Abstract: Detection systems and methods configured to scan and interpret a suspected infection at *in vivo* biological target site, comprising emitting excitation light selected to elicit fluorescent light from a suspected infection at the target site; sensing fluorescent light emanating from the target site elicited by such excitation light; sensing heat levels above ambient body temperature emanating from the target site; and then based at least in part on the sensed fluorescent light and the heat levels, determining a probability whether the target site comprises an infection.





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DEVICES, SYSTEMS AND METHODS RELATING TO *IN SITU*
DIFFERENTIATION BETWEEN VIRAL AND NON-VIRAL INFECTIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

- 5 [0001] The present application claims the benefit of copending United States Provisional Patent Application Serial No. 62/255,005, filed November 13, 2015, which application is incorporated herein by reference in its entirety.

BACKGROUND

- 10 [0002] Detection and determination of and between biological infections such as bacterial and viral infections have always been difficult and uncertain processes. The importance of accurate detection and determination has increased with the advent of antibiotic-resistant strains of bacteria such as Methicillin-resistant *Staphylococcus aureus* (MRSA), which some people have attributed to the over-prescription of
15 antibiotics for virtually all forms of infections including patients with sore throats even if those infections are viral and thus not improved by antibiotics.

[0003] Accordingly, there has gone unmet a need to improve the ability of a doctor, nurse, dentist or other person or user to detect and diagnose infections as viral or non-viral, typically bacterial.

- 20 [0004] The present systems and methods, etc., provide these and/or other advantages.

SUMMARY

- [0005] The present systems, devices and methods, etc., relate to photonic and thermic detection systems configured to and capable of detecting and differentiating between
25 viral and non-viral/bacterial infections in an animal body, such as in the throat, on the skin, or in the mouth, gut, vagina, lungs or other location capable of hosting such infections. In one aspect, the system contains an appropriate sensor (CCD, CMOS, thermopiles, etc.) configured to capture at least two groups of data, one corresponding to emitted fluorescence wavelengths, typically autofluorescence, from a suspected viral
30 or non-viral infection, for example such as bacteria, and one for capturing a heat signature caused by such non-viral agent - or not present in the case of a viral infection. Exemplary excitation wavelengths include about 340nm and 380nm-500nm, and

detection wavelengths include 500nm to 700nm for fluorescence signatures and 700nm+ for heat signatures (thermal data) when heat is being detected using IR (infrared). The thermal infrared region for room temperature objects is generally considered to be about 1000-1500nm depending on which technology is being used to
5 measure it. Suitable thermopiles for use herein can look at window of about 800-1400nm. Other methods of heat/thermal data detection or measurement can also be employed such as measurement of heat conduction or convection, which can in some instances be measured using a contact measurement device such as a contact thermometer. Exemplary temperature levels include any substantial increase over
10 ambient body temperature for the patient/organism commensurate with heat generated by bacteria, for example increases of about 0.5°C, 1°C, 2°C, or 3°C.

[0006] The fluorescence can come from fluorophores contained in or caused by the target bacteria such as porphyrins or can be introduced into to the target area if desired, for example as fluorophores that have been immuno-tagged to be species-specific or
15 that are egested by specific species. Further, in the event of a viral infection, the autofluorescent signature of the native, ambient tissue is reduced or eliminated, and thus the loss of native autofluorescence is an indicator of a viral infection. If desired, the system can also detect other wavelengths or wavelengths bands of light such as white light, all visible light, or selectively blue light or red light, or selectively IR (infrared)
20 etc. Such systems can also provide photographs or video, including real-time or live photographs or video.

[0007] The systems can also comprise light sources suitable to provide interrogative light for the examination of the target area. Such light sources can include, for example, a broad spectrum light source with appropriate selective light filters to pass
25 only desired wavelengths such as blue wavelengths suitable for exciting autofluorescence, infrared wavelengths suitable for heating the target area, as well as visible-light imaging wavelengths such as red-green-blue (rgb) or cyan-yellow-magenta (cym) wavelengths. The light source can also comprise a plurality of different light sources each tasked with providing a desired set(s) of wavelengths or a wavelength
30 range(s); such sources can also be used in combination if desired. Examples of such sources include LED, metal halide, and xenon light sources.

[0008] The detected fluorescence and heat-based radiation provide a set(s) of captured data. The captured data can be viewed in real-time by a user and/or can be sent to a desired location. For example, the data can be sent as a file or set of files preferably with an image representing the target site, to a computer such as desktop
5 computer, laptop computer, an iPad® or PDA, where the data is processed and/or can be viewed by human interrogators. The processed data can be interpreted by the user and/or a computer to identify the type of target organism (e.g., whether it is a virus or bacterium). Such information can be useful for determining appropriate treatment options - or non-treatment options such as choosing not to use antibiotics against a viral
10 infection.

[0009] In some embodiments, the processed data/image can provide a score of the combined data points based on infrared hypothermic and/or hyperthermic values and can also incorporate or provide a spatial organization of aggregated amounts of abnormal thermal and fluorescent conditions within the target area. Generally
15 speaking, a lack of thermic activity above ambient body temperature indicates that an infection is viral, whereas presence of substantial thermic activity above ambient body temperature indicates the infection is bacterial. Such spatial organization can be provided to the practitioner to improve the ability to visualize the affected area, and can also be incorporated in the diagnosis aspect of the systems herein as spatial
20 organization, such as presence, color and shape of bacterial colonies, can be indicative of different types of infections.

[00010] In other words, in some embodiments the devices, etc., herein can distinguish between bacterial and viral infections and if desired can also help determine the location of the infection(s) within a target area. For the example of a patient arriving at
25 a clinic (or other provider) with a sore throat, the processed information can indicate to the caregiver a probability, such as more than about 50%, 80%, 90%, 95%, 98%, 99% or 100%, that the sore throat is an infection and if so, whether it is a bacterial infection or viral infection, as well as, if desired, location(s) in the throat of the infections.

[00011] The devices can rely on auto-generated radiation such as autofluorescence
30 generated autonomously within the infecting organism or a heat signature (or lack thereof in the case of viruses), or the devices can emit fluorescence-inducing light and/or heat-inducing light if desired.

[00012] In some aspects, the current application is directed to detection systems configured to scan and interpret a suspected infection at *in vivo* biological target site, the detection system comprising a housing comprising at least one light emitter configured to emit excitation light selected to elicit fluorescent light from the suspected infection at the target site, a light sensor configured to detect the fluorescent light, and a heat sensor configured to detect and identify thermal data indicating heat above ambient body temperature emanating from the suspected infection at the target site, the detection system further operably connected computer-implemented programming configured to a) accept fluorescent light data associated with the fluorescent light and thermal data associated with the heat levels above ambient body temperature, and b) interpret the data to determine a probability whether the target site contains an infection.

[00013] The system can be further configured to determine whether the suspected infection can be a viral infection or a non-viral infection, can further comprise an imaging system aimed and configured to provide an image of the target site. The image of the target site can identifies a spatial organization of the suspected infection and the system can utilizes such spatial organization when determining the probability whether the infection can be a viral infection or a non-viral infection and/or when determining an identity of an infectious agent in the suspected infection. When the suspected infection is a non-viral infection, the computer implemented programming can further identify whether the infection may be bacterial.

[00014] The at least one light emitter, the light sensor and the heat sensor can be all located at a distal end of the housing and can be all forward-facing and aimed to substantially cover a same area of the target site. The housing can be configured to be held in a single hand of a user and can be configured to fit within a human oral cavity and to scan at least a rear surface of such oral cavity or a throat behind such oral cavity.

[00015] The system further can comprise a separable distal element sized and configured to removably attach to the distal end of the housing, wherein the separable distal element comprises at least one of light-blocking sides and/or a forward-facing window configured to transmit at least the excitation light, the fluorescent light and the heat levels without substantial alteration. If desired, at least two sides of the separable distal element comprise recesses configured to keep the sides out of a view of the heat sensor. The distal end of the housing and the separable distal element can be

cooperatively configured such that the separable distal element can be snapped on and off the distal end of the housing, for example via cooperative projections and detents configured such that the separable distal element can be snapped on and off the distal end of the housing.

- 5 [00016] The distal end of the housing can be configured to be mounted onto a single circuit board when the housing can be not being used for scanning, and can further comprise a display screen on a dorsal side of the housing.

[00017] The system can be configured to account for heat level distortions due to ambient conditions at the target site, for example using specific anti-distortion
10 structures and/or by using at least one algorithm configured to account for the heat level distortions.

[00018] In further aspects, the current application is directed methods of scanning *in vivo* biological target site for a suspected infection, the methods comprising:

- 15 - emitting excitation light selected to elicit fluorescent light from a suspected infection at the target site
- sensing fluorescent light emanating from the target site elicited by such excitation light;
- sensing thermal data indicating heat above ambient body temperature emanating from the target site
- 20 - based at least in part on the sensed fluorescent light and the heat levels, determining a probability whether the target site comprises an infection.

[00019] Such methods can comprise, utilize or implement the structures and devices discussed herein. Such methods can also comprise making such structures and devices discussed herein

- 25 [00020] These and other aspects, features and embodiments are set forth within this application, including the following Detailed Description and attached drawings. Unless expressly stated otherwise, all embodiments, aspects, features, etc., can be mixed and matched, combined and permuted in any desired manner. In addition, various references are set forth herein, including in the Cross-Reference To Related
30 Applications, that discuss certain systems, apparatus, methods and other information; all such references are incorporated herein by reference in their entirety and for all their

teachings and disclosures, regardless of where the references may appear in this application.

BRIEF DESCRIPTION OF THE DRAWINGS

5 [00021] Figure 1 depicts a top plan view of an exemplary scanning and detection device as discussed herein.

[00022] Figure 2 depicts a side plan view of an exemplary scanning and detection device as discussed herein.

10 [00023] Figure 3 depicts a bottom plan view of an exemplary scanning and detection device as discussed herein.

[00024] Figure 4 depicts a perspective view of a distal end of an exemplary scanning and detection device as discussed herein.

[00025] Figure 5 depicts a perspective view of a separable end piece for a distal end of an exemplary scanning and detection device as discussed herein.

15 [00026] Figure 6 depicts a perspective view of a distal end of an exemplary scanning and detection device as discussed herein with the disposable end piece in place.

[00027] Figure 7 depicts a perspective view of an exemplary array of emitters and sensors for a scanning and detection device as discussed herein.

20 [00028] Figure 8 depicts a side view of an exemplary array of emitters and sensors for a scanning and detection device as discussed herein.

[00029] Figure 9 depicts a side perspective view of further embodiment of an array of emitters and sensors for a scanning and detection device as discussed herein.

[00030] Figure 10 depicts an exemplary block diagram for a scanning and detection device as discussed herein.

25 [00031] Figure 11 depicts a flow chart for one approach to accounting for ambient temperature variations.

[00032] Figure 12 depicts a flow chart for a second approach to accounting for ambient temperature variations.

30 DETAILED DESCRIPTION

[00033] Turning to a general discussion of the devices and systems herein, the illumination and detection aspects of the systems herein can be maintained in a scope or

other device configured to emit the selected interrogation wavelengths (for example via distally carried LED light emitters or via proximally located light sources where such light is conducted through appropriate conductors such as optic fibers to the target site) and then to carry the elicited photonic data (fluorescence data) and heat data/thermal data (photonic or otherwise) gathered from the interrogation site to the user such as a doctor or other health care provider. The scope can if desired include elements to conduct an optical image directly from the target site to the viewer/user. The system can also include computers and the like, for example located proximally via hardwire or wireless links or within the interrogative device, to process the data and if desired provide estimates of the presence or absence of bacteria at the interrogation/target site, and estimates of whether the suspected infection, if present, is or is not viral.

[00034] The device can be sized and configured to be held by a human hand, i.e., is a "hand-held", for certain embodiments and can be a device shaped to be maintained outside the body as shown, for example, in US patent application no. 20050234526, or can be a catheter or endoscope or other configuration (e.g., colposcope, laparoscope, etc.) shaped to be inserted into or otherwise introduced into or aimed toward the body of a patient.

[00035] The scope, for example where the scope provides an image to an ocular, can comprise a hollow casing with desired optics that returns light from the target tissue to the detector and/or an ocular eye piece. The hollow casing if desired can also transmit light from an external (typically proximally-located) light source to the target tissue. Suitable ocular eye pieces include an eye cup or frosted glass, and can be monocular or binocular as desired. If desired, the scope can alternatively, or additionally, be configured to contain one or more internal light sources, distally located light sources (such as LEDs), and/or proximally located light sources, and one or more fiber optic light guides, fiber optic cables or other such light transmission guides, in addition to, or instead of, the light guide formed by the hollow casing discussed above.

[00036] Typically, the scope comprises a power source suitable to power the light sources and/or sensors, data transmitters, and other electronics associated with the device. The power source can be an external power source such as a battery pack connected by a wire, a battery pack maintained in the handle or otherwise within the scope itself, or a cord and plug or other appropriate structure linking the device to a

wall outlet or other power source. In some embodiments, the housing of the light source includes a retaining structure configured to hold the scope to a desired location when not in use.

[00037] As noted previously, the scope comprises one or more sensors such as CCDs, CIDs, CMOSs, thermopiles, etc., and/or is operably connected to one or more display devices, which can be located on the scope and/or in an operably connected computer. Such sensors, either in combination or as wide-sensing singular sensors, can detect at least any desired fluorescence, such as autofluorescence in the 400nm-600nm range and 700nm+ range. Suitable sensors including infrared (IR) and detectors are well known.

[00038] Exemplary display devices include CRTs, flat panel displays, computer screens, etc. The diagnostic systems include one or more computers that control, process, and/or interpret the data sets and if desired various other functions of the scope, including, for example, diagnostic, investigative and/or therapeutic functions. Typically, a computer comprises a central processing unit (CPU) or other logic-implementation device, for example a stand-alone computer such as a desk top or laptop computer, a computer with peripherals, a handheld, a local or internet network, etc. Computers are well known and selection of a desirable computer for a particular aspect or feature is within the scope of a skilled person in view of the present disclosure.

[00039] As noted above, suitable heat detectors include well known infrared (IR) and including for example thermopiles and microbolometer arrays, provided that when such devices are included within the scopes/housings herein, such are suitably sized to fit within or on the scope without making the overall device too large for its purpose. Where the detection light gathered from the target sight is transported, such as by fiber optics, outside the scope and body, size concerns for the heat detector elements (and other detection elements) are reduced. Such sensors can also comprise heat-neutralization structures configured to reduce or eliminate improper ambient heat readings due to outside influences, such as a patient's breath when interrogating the back of the mouth or throat. Heat-neutralization structures can include, for example, an anti-fog element such as a hydrophobic material, a spray or coating that does not skew the signal determined by the sensor, or a dichroic mirror that transmits the signal to a proximate sensor removed from the impeding outside influence.

[00040] Turning to the Figures, Figures 1-3 depict three views of an exemplary scanning and detection device 2 as discussed herein. The embodiment depicted is configured for use in a human oral cavity (mouth and if desired upper throat). The scanning and detection device can be any desired shape suitable for a given target site,
5 for example a catheter or endoscope or other configuration (e.g., colposcope, laparoscope, etc.) shaped to be inserted into or otherwise introduced into or aimed toward the body of a patient.

[00041] In these Figures, scanning and detection device 2 comprises a proximal end 4 and a distal end 6, with the distal end 6 configured to introduced into or aimed toward
10 an *in vivo* biological target site suspected of having an infection. Scanning and detection device 2 comprises housing 8 having an excitation light emitter 10 at the distal end 6, the excitation light emitter 10 configured to emit excitation light selected to elicit fluorescent light from the suspected infection at the target site; if desired, multiple excitation light emitters can be provided, each for a different
15 wavelength/wavelength band of excitation light. The scanning and detection device 2 further comprises a light sensor 12 as well as a heat sensor 14 (refer, e.g., to Figures 4 and 6). Light sensor 12 is configured to detect at least fluorescent light emanating from the target site, and heat sensor 14 is configured to at least detect and identify heat levels above ambient body temperature emanating from the infection at the target site.

20 [00042] As discussed further elsewhere herein, the detection system further comprises operably connected computer-implemented programming configured to a) accept fluorescent light data associated with the fluorescent light and thermal data associated with the heat levels above ambient body temperature, and b) interpret the data to determine a probability whether the target site contains an infection. Such computer-
25 implemented programming can be contained within housing 8 or can be located externally.

[00043] Scanning and detection device 2 also contains three buttons for user interaction. The first control button 30 controls the illumination LED (white light emitter). The second button 32 initiates an image/scan acquisition procedure such as a
30 fluorescent image/sensing procedure. The third control button 34 initiates a temperature acquisition procedure. Other or fewer buttons can also be provided as desired.

[00044] As shown in Figures 4 and 6, scanning and detection device 2 can comprise illumination light emitter 16 and an imaging system 26 comprising a camera 18. One or more filters configured to transmit only desirable wavelengths/indicators of light or heat can also be provided, such as first emanating light filter 20, emanating heat filter 22, and second emanating light filter 24.

[00045] Scanning and detection device 2 further contains a display screen 36, which can display spectrographic results, images of the target site, diagnostic results, false-color representations of the data received from the target site, and the like. The display can also convey other information if desired, such as date, time, patient name, etc. Also shown is an easily removable separable distal element 38 sized and configured to removably attach to the distal end of the housing. The separable distal element 38 can comprise light-blocking sides 40 and if desired a forward-facing window 42, as shown in Figure 5, configured to transmit at least the excitation light, the fluorescent light and the heat levels without substantial alteration. separable distal element 38 can also comprise recesses 48, 50 to accommodate expected physical structures at a target site, to avoid a side wall from impacting an image/increase scanning/imaging field of view, etc. The distal end 6 of the housing 8 and the separable distal element 38 can be cooperatively configured such that the separable distal element 38 can be snapped on and off the distal end 6 of the housing 8. For example, the distal end 6 of the housing 8 and the separable distal element 38 can comprise cooperative projections 52 and detents 54 configured such that the separable distal element 38 can be snapped on and off the distal end 6 of the housing 8 by cooperatively engaging and releasing such elements. Scanning and detection device 2 can further comprise a plug-port 44 and a battery bay 46.

[00046] In the embodiment depicted in Figures 1-6, the housing 8 is configured to be held in a single hand of a user, and is configured to fit within a human oral cavity and to scan at least a rear surface of such oral cavity and/or a throat behind such oral cavity.

[00047] Figures 7 and 8 show further information about the light emitters, light sensors and heat sensors. In this embodiment, all are located at the distal end 6 of the housing 8 (not shown in the figures) and are all forward-facing and aimed to substantially cover a same area of the target site, as demonstrated by the overlapping fields of view in the

figures. Also in this embodiment, excitation light emitters include red LED 56, green LED 58, and blue LED 60.

[00048] Figure 9 shows a further embodiment concerning light emitters, light sensors and heat sensors. In this embodiment, the array includes two white light emitting LEDs 5 62, and two blue LEDs 60, as well as a camera 18 and a radiant heat sensor 14.

[00049] Figure 10 depicts an exemplary block diagram for a scanning and detection device 2 as discussed herein.

[00050] In some embodiments, it may be difficult to obtain accurate and repeatable ambient body temperature measurements for example due to a patient's breath 10 impacting on the heat sensor such as a thermopile. Thus, the thermopile may exhibit logarithmic temperature increase readings when moved from ambient air temperature to an intra-oral measurement scenario. Structures or software can be provided to alleviate such situations.

[00051] For two examples of suitable software approaches, the measurement technique 15 can be substantially the same as otherwise implemented herein, for example the heat sensor is placed in the desired measurement position, but then the person under test should hold their breath with their tongue in a rested position until the algorithm completes. A first embodiment can be labeled a "Snap-shot Average" method, and a second embodiment can be labeled a "Rolling Average Slope" method. Examples of 20 these methods are discussed below and also shown in Figures 10 and 11, respectively.

[00052] For these two methods, when the measurement device herein is held for a significantly long duration of time, such as about 1, 2, 3 or 5 seconds, in a measurement position, such as pointing at a target area inside a mouth, the temperature-scanning results tend to flatten to a near zero slope at a temperature that is roughly 6-7°F (3-4°C) 25 lower than normal human body temperature. These embodiments provide algorithms that collect a diagnostically meaningful measurement in a reasonable amount of time while accounting for the non-linear temperature measurement.

[00053] In the first embodiment, which as noted can be called the "Snap-shot Average Method" and is depicted in Figure 11, the following exemplary steps can be taken:

- 30
- The thermopile temperature register is read with 5ms per sample in a polling loop

- Samples are thrown away until the temperature rises above a parameterized threshold
- When the threshold is surpassed, the algorithm sleeps for a parameterized time to allow the logarithmic temperature to stabilize
- 5 • When the algorithm wakes up, it proceeds to take a parameterized number of samples at the 5ms sample rate
- After sample collection is complete the samples are averaged and the simple mean is recorded
- The first order standard deviation is calculated on the samples and recorded
- 10 • The samples are then run through a loop that throws out all samples that were outside of the standard deviation
- The average of the remaining samples is calculated
- A parameterized number of minimum samples determines whether the result contains too few good measurements to have a quality reading; error is returned
- 15 • if the number of good samples was too low
- The result is then added to a parameterized constant offset to compensate for the lower average temperature in the mouth

[00054] In the second embodiment, which as noted can be called the "Rolling Average Slope Method" and is depicted in Figure 12, the following exemplary steps can be taken

- 20 • The thermopile temperature register is read with 5ms per sample in a polling loop
- Samples are pushed into a rolling average queue with a parameterized number of samples
- On each pass of the loop the new measurement is added into the sum of all
- 25 samples and the oldest value is subtracted out of the sum of all samples
- The average is calculated
- The slope for a parameterized number of previous samples including the current sample is calculated
- When the slope decreases beyond a parameterized threshold the temperature is
- 30 recorded (ideally the slope would become zero during the measurement, but this is not feasible due to duration and variability in reported temperature)
- The result is then added to a parameterized constant offset to compensate for the lower average temperature in the mouth

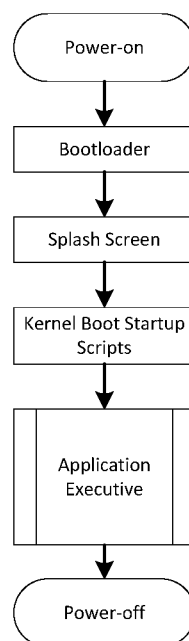
35 EXAMPLES

Example 1: Exemplary Software Design

[00055] An exemplary system comprises embedded system software and host client software. Some features of this example are shown in Figure 10. The embedded

system software will run on a Raspberry PI (RPI) Compute Module. This software will comprise device drivers, kernel services, the Linux kernel and bootloader, and application level software. The host software is a client Graphical User Interface (GUI) that will run on a PC. The client GUI aids users in interacting with the system.

- 5 [00056] Table 1 below shows an exemplary system level software lifecycle for system during a typical use case scenario. Aspects of the system functionality can be encapsulated within the “Application Executive” sub-process.



10

Table 1: System Software Lifecycle

EMBEDDED SYSTEM SOFTWARE

- [00057] The embedded hardware platform will comprise a RPI Compute Module with a number of hardware peripherals that make use of the Compute Module’s Input/Output (I/O). The compute module utilizes a Broadcom BCM2835 processor with on-board 512MB of RAM and 4GB of eMMC flash. Additionally the Compute Module pulls out all of the I/O pins of the processor for developer use. The Compute Module has a rich embedded Linux ecosystem making it ideally suited for rapid prototyping and deployment of embedded Linux. The embedded software implementation will provide a custom streamlined Linux Kernel, the necessary kernel-mode drivers, and user-mode
- 15
- 20

application functions suitable to implement the unit. Table 2 below shows the embedded software architecture and its composition of individual software components.

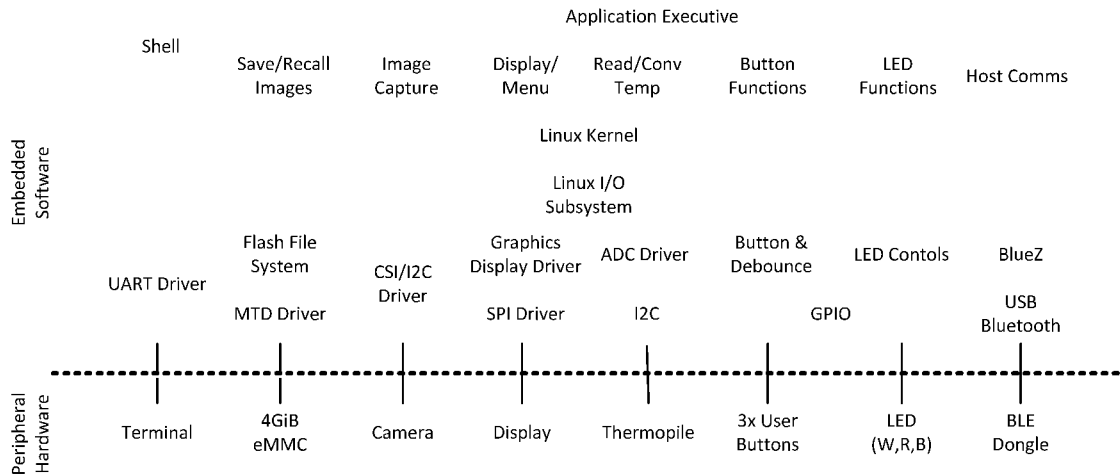


Table 2: Embedded Software Functional Components

[00058] Exemplary embedded system software is described in the following sections:

APPLICATION EXECUTIVE

[00059] The Application Executive is a Linux User-mode Process that is launched at boot that runs until the unit is powered off. The purpose of the Application Executive is to serve as a high level state machine that coordinates the various underlying functional components of the system based on user interaction with the unit.

[00060] Table 3 shows a high level state diagram of the Application Executive which is comprised of a loop and a number of functional components and sub-processes that handles user-events and the various interactions with the hardware components of the system.

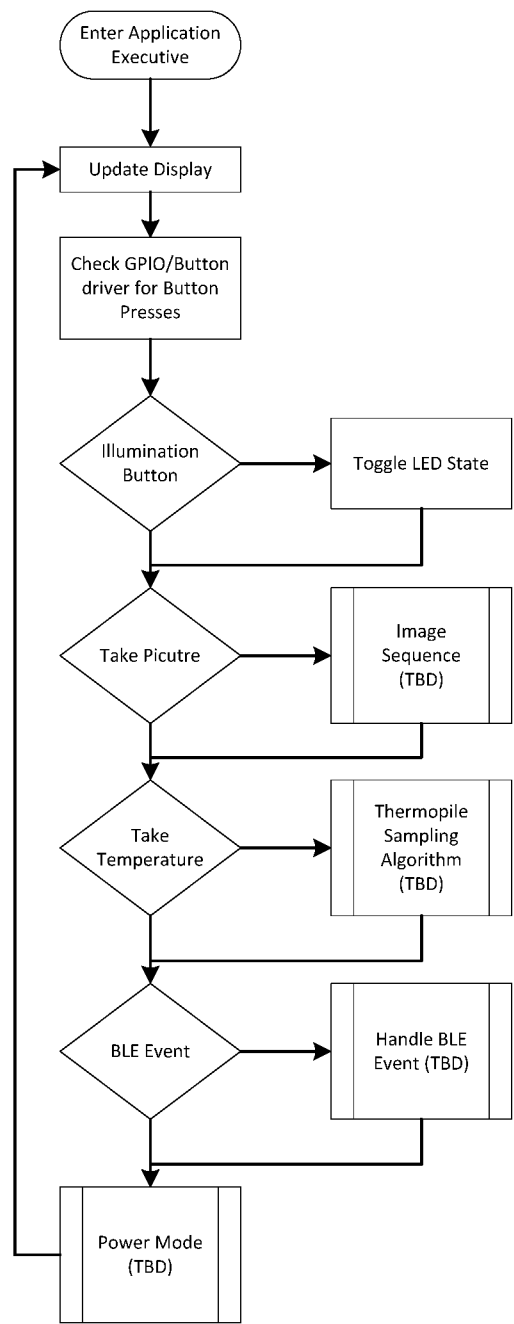


Table 3: Application Executive State Diagram

[00061] The application executive can launch automatically at system boot.

[00062] The application executive can start within a desired number of seconds after

5 power-on.

[00063] The application executive can run continuously until power-off.

IMAGE STORAGE

- [00064] The unit will be capable of storing images within its flash file system. Image storage will persist through power cycles. The user of the unit will have the ability to associate a unique patient identifier to a grouping of one or more images. The file system will reside on the same flash part that contains the Linux Kernel and application software; a region of 40MB will be reserved for system software binary storage.
- [00065] A 40MB partition of flash can be reserved for Linux Kernel and application software storage.
- [00066] There can be a Memory Technology Device (MTD) driver suitable to control the eMMC flash interface for use with a Flash File System (FFS)
- [00067] There can be a FFS implemented.
- [00068] Image storage can persist through power-cycle.
- [00069] There can be a unique patient identifier associated with each image.
- [00070] There can be a method to erase files from the FFS.
- [00071] Images can be stored using a desired compression algorithm.

IMAGE CAPTURE

- [00072] The unit will be capable of using its camera to capture images for analysis.
- [00073] There can be a Camera Serial Interface (CSI) driver for image upload from the camera.
- [00074] There can be an I2C driver for Camera Control Interface (CCI) functionality.
- [00075] Image data can automatically be written to flash.
- [00076] Image acquisition sequence can occur automatically when prompted by the user.

DISPLAY AND MENU

- [00077] The unit will have a Serial Peripheral Interface (SPI) 128x64 graphical/character. The display will show information pertaining to the current state or function of the unit, as well as host communication status. The display will also be capable of displaying Unique Identifier (UID) information pertaining to the specific unit as well as the current patient. Note: on-device display can be capable or incapable of presenting camera images as desired.
- [00078] There can be a SPI driver for communications with the display.

[00079] The display can be capable of showing current state information.

[00080] The display can show a splash screen during system boot.

[00081] The display can show the Bluetooth UID of the unit.

[00082] The display can show the temperature measurements when prompted by user.

5 [00083] The display can show the current UID of the patient under test.

TEMPERATURE ACQUISITION

[00084] The unit will be capable of reading a thermal sensor for patient temperature
10 acquisition.

[00085] There can be an I2C driver for communication with a thermopile sensor

[00086] There can be an algorithm for temperature acquisition.

[00087] The unit can acquire temperature when prompted by the user.

[00088] There can be a method to associate and store temperature data with the patient
15 UID.

[00089] Button Controls

[00090] The unit will have three buttons for user interaction. The first button controls
the illumination LED (white). The second button initiates the image acquisition
20 procedure. The third button initiates the temperature acquisition procedure. Other
buttons can also be provided

[00091] There can be a GPIO driver for controlling three button inputs.

[00092] There can be a button de-bounce algorithm implemented to filter button noise.

[00093] Button-1 can control the state of the illumination LED.

25 [00094] Button-2 can initiate the image acquisition procedure.

[00095] Button-3 can initiate the temperature acquisition procedure.

LED CONTROLS

[00096] The unit will have three LEDs comprising a white illumination LED, and a red
30 and blue LED used in the image acquisition.

[00097] There can be a GPIO driver for controlling three LED outputs.

[00098] The white illumination LED output can go active or inactive when prompted
by the user.

[00099] The red and blue LEDs can be controlled automatically as part of the image acquisition sequence.

[000100] Host Communications

- 5 [000101] Communications with the host PC will be achieved through the incorporation of an integrated USB-Bluetooth dongle implementing Bluetooth Low Energy (BLE). Device pairing is performed on the host PC.

[000102] There can be a USB-Bluetooth driver and firmware to control the USB-Bluetooth dongle.

- 10 [000103] After Bluetooth driver registration is complete, the Bluetooth unique identifier can be read and displayed.

[000104] The Kernel can include the BlueZ Bluetooth stack.

[000105] The unit can present itself as a Basic Imaging Profile (BIP) Bluetooth device if desired.

- 15 [000106] The unit can transfer images to the host at any desired rate.

DEBUG CONSOLE (TERMINAL)

[000107] The unit will have a serial port used for displaying the Linux Terminal for development and debug.

- 20 [000108] There can be a UART for serial I/O debug console.

[000109] The embedded Linux distribution can include a Terminal console such as bash.

HOST CLIENT GUI SOFTWARE GRAPHICAL USER INTERFACE

25

[000110] The host client software will comprise a GUI with minimal functions to utilize the unit. The GUI will have the ability to execute Bluetooth device pairing, file upload and browsing, patient ID display, image display, device wiping, and possibly other functions as desired.

- 30 [000111] The GUI can be designed to run on the Windows7 or 10 Operating Systems.

[000112] The GUI can provide an interface for Bluetooth device pairing with one or more units based on the unique Bluetooth device ID.

[000113] The GUI can provide an interface to browse the filesystem on the paired unit.

[000114]The GUI can provide an interface to upload files from the paired unit to the host PC filesystem.

[000115]The GUI can provide the ability to erase files from the paired unit.

[000116]The GUI can provide a method of displaying the association of patient unique
5 identifier with patient images and temperature if desired.

[000117]The GUI can provide a method of opening and displaying image files.

[000118]Turning to some other embodiments and other general discussion, in some
embodiments the light path can comprise an illumination light path extending from the
10 scope to the target and the scope can comprise in order a collimator, 430+/-30 nm filter
(filter 1), a dichroic filter (filter 2), an unwanted-light absorber, then a glass or other
transmissive/transparent window. Such a window can both enhance cleaning and
reduce cross-contamination of the device and/or between patients. The illumination
light contacts the mucosal tissue or other target tissue then returns through a dichroic
15 filter (filter 2 (the light can pass back past the same dichroic filter), a 475 long pass
filter (filter 3), a 590 nm notch filter (filter 4), a filter configured to receive IR and/or
NIR light, and then be passed to the detectors and if desired an eyepiece ocular. The
filters can be either separate (discrete) or combined (e.g., reflective coatings).

[000119]The systems can if desired comprise binocular eyepieces such as loops/filtered
20 glasses or sunglasses/goggles with/without magnification. Some other features that can
be included are a light wand, a treatment light, a mirror and/or fiber optic, typically
collimated, or an LED on the wand which can have a sleeve with a filter at the end to
provide particularly desired light and thus function as the light wand, and thus as the
light source or as an additional light source for fluorescence or other desired response.

[000120]The scopes' designs can have multi-wavelength light processing within and
25 outside the detector or camera. The light can be piped through the system or a light
source can be incorporated or there can be a separate sleeve (or other suitable light
emitter) with its own light. The sleeve could have appropriate wavelength
emission/excitation filters. Filter and other optical element position can vary within the
30 pathway provided the desired functions are achieved.

[000121]The illumination light and viewing pathways can be combined or separate as
in a light source with loupes/eyewear. The pathways can enhance user ability to use the

device to have a standard method of viewing and illumination. The size of the spot of interrogation in some embodiments is sized to compare a full lesion to surrounding normal tissue, which enhances viewing and identifying anatomical landmarks for location.

- 5 [000122] In some embodiments, intensity is optimized to bathe the tissue with excitation light for detection and diagnosis, to excite the necessary fluorophores, to induce or avoid heat-based responses, etc. The wavelengths/fluorescence enhance the ability to recognize a shift in the fluorescent emission spectra to permit differentiation between normal and abnormal for cancerous tissue. For example, dual monitoring of
- 10 two wavelength bands from about 475-585 and from about 595 and up enhances monitoring of cellular activity for the metabolic co-factors NAD and FAD. NAD and FAD produce fluorescence with peak levels at such wavelengths.

- [000123] In certain embodiments, it is desirable to get as much power as possible without smearing emission signal too much, to keep the output spectrum narrow to
- 15 prevent Stokes shift, and to exclude UV light and to avoid illuminating/exciting with light in the emission band (overlapping fluorescence).

- [000124] In certain embodiments, the systems can further comprise a diffuser to make spot-size more regular, remove hot spots, etc. Also sometimes desirable is a collimator to straighten light out at the filter, and to limit the divergence of the beam with
- 20 increases in power density, or to use a liquid light guide and not fibers so as to get more efficiency by reducing wasted space between fibers, and achieving better transmission per cost and higher numerical aperture (which contributes to better light collection). In still other embodiments, the systems can further comprise metal halide light sources to enhance power in certain emission ranges, dichroic filters or similar optical elements to
- 25 enhance overlapping viewing and illumination light paths (can simultaneously direct illumination light away from the source and emanation light from the tissue). A glass or other transparent window at the front of the scope can keep out the dust, bodily fluids, infectious organisms, etc. The scopes can be black internally to absorb stray reflected illumination and released fluorescent (unwanted fluorescent feedback) light.

- 30 [000125] The shape of the scope can be preferably set to be ergonomically comfortable, optimize the excitation and emission pathways. The proximal eyepiece can be set at a length, such that tilting the proximal filter (e.g., a 590 nm notch filter) creates a

geometry such that incoming ambient light (if any is relevant) from behind the practitioner can be reduced and what passes can be reflected into the absorbing internal tube surface. This reduces reflection and prevents the user from seeing themselves. For example, the proximal filter can be tilted with its top closer to the clinician and bottom
5 closer to the dichroic mirror so as to make a reflecting surface that would direct incoming light into the bottom of the optical pathway tube.

[000126] As noted elsewhere, sometimes multiple light sources can be provided with a single scope. For white light viewing if desired, there could be provision for a greater bandwidth in the output. The larger bandwidth could be obtained by having an extra
10 light (LED, halide, etc.) or by using different filters at the output of a single light source. The systems can also provide illumination with multiple peaks. For example, pharmacology/physiology testing of biological markers may sometimes use this for when fluorescence emitted (by the tissue, markers, or chemical signals) changes in the presence of various ions/molecules/pH. This can also be used to provide a
15 normalization as the power of fluorescence produced by each wavelength can be being compared, normalized against each other.

[000127] All terms used herein, are used in accordance with their ordinary meanings unless the context or definition clearly indicates otherwise. Also unless expressly indicated otherwise, the use of "or" includes "and" and vice-versa. Non-limiting terms
20 are not to be construed as limiting unless expressly stated, or the context clearly indicates, otherwise (for example, "including," "having," and "comprising" typically indicate "including without limitation"). Singular forms, including in the claims, such as "a," "an," and "the" include the plural reference unless expressly stated, or the context clearly indicates, otherwise.

[000128] The scope of the present systems and methods, etc., includes both means plus function and step plus function concepts. However, the terms set forth in this application are not to be interpreted in the claims as indicating a "means plus function" relationship unless the word "means" is specifically recited in a claim, and are to be interpreted in the claims as indicating a "means plus function" relationship where the
25 word "means" is specifically recited in a claim. Similarly, the terms set forth in this application are not to be interpreted in method or process claims as indicating a "step plus function" relationship unless the word "step" is specifically recited in the claims,
30

and are to be interpreted in the claims as indicating a "step plus function" relationship where the word "step" is specifically recited in a claim.

[000129] The innovations herein include not just the devices, systems, etc., discussed herein but all associated methods including methods of making the systems, making
5 elements of the systems such as particular devices of the scopes, as well as methods of using the devices and systems, such as to interrogate a tissue (or otherwise using the scope to diagnose, treat, etc., a tissue).

[000130] From the foregoing, it will be appreciated that, although specific embodiments have been discussed herein for purposes of illustration, various modifications may be
10 made without deviating from the spirit and scope of the discussion herein. Accordingly, the systems and methods, etc., include such modifications as well as all permutations and combinations of the subject matter set forth herein and are not limited except as by the appended claims or other claim having adequate support in the discussion and figures herein.

What is claimed is:

1. A detection system configured to scan and interpret a suspected infection at *in vivo* biological target site, the detection system comprising a housing
5 comprising at least one light emitter configured to emit excitation light selected to elicit fluorescent light from the suspected infection at the target site, a light sensor configured to detect the fluorescent light, and a heat sensor configured to detect and identify thermal data indicating heat above ambient body temperature emanating from the suspected infection at the target site, the detection system
10 further operably connected computer-implemented programming configured to a) accept fluorescent light data associated with the fluorescent light and thermal data associated with the heat levels above ambient body temperature, and b) interpret the data to determine a probability whether the target site contains an infection.
15
2. The detection system of claim 1 wherein the system is further configured to determine whether the suspected infection is a viral infection or a non-viral infection.
- 20 3. The detection system of claim 1 wherein the housing further comprises an imaging system aimed and configured to provide an image of the target site.
4. The detection system of claim 3 wherein the image of the target site identifies a spatial organization of the suspected infection.
25
5. The detection system of claim 4 wherein the system utilizes the spatial organization when determining the probability whether the infection is a viral infection or a non-viral infection
- 30 6. The detection system of any one of claims 1 to 5 wherein, when the suspected infection is a non-viral infection, the computer implemented programming further identifies whether the infection is bacterial.

7. The detection system of any one of claims 1 to 6 wherein the at least one light emitter, the light sensor and the heat sensor are all located at a distal end of the housing and are all forward-facing and aimed to substantially cover a same area of the target site.
8. The detection system of any one of claims 1 to 7 wherein the housing is configured to be held in a single hand of a user.
9. The detection system of any one of claims 1 to 8 wherein the housing is configured to fit within a human oral cavity and to scan at least a rear surface of such oral cavity or a throat behind such oral cavity.
10. The detection system of any one of claims 1 to 9 wherein the system further comprises a separable distal element sized and configured to removably attach to the distal end of the housing, wherein the separable distal element comprises at least one of light-blocking sides and a forward-facing window configured to transmit at least the excitation light, the fluorescent light and the heat levels without substantial alteration.
11. The detection system of claim 10 wherein the separable distal element does not comprise the forward-facing window.
12. The detection system of claim 10 wherein the separable distal element comprises both the light-blocking sides and the forward-facing window.
13. The detection system of any one of claims 10 to 11 wherein at least two sides of the separable distal element comprise recesses configured to keep the sides out of a view of the heat sensor.
14. The detection system of any one of claims 10 to 13 wherein the distal end of the housing and the separable distal element are cooperatively configured such that

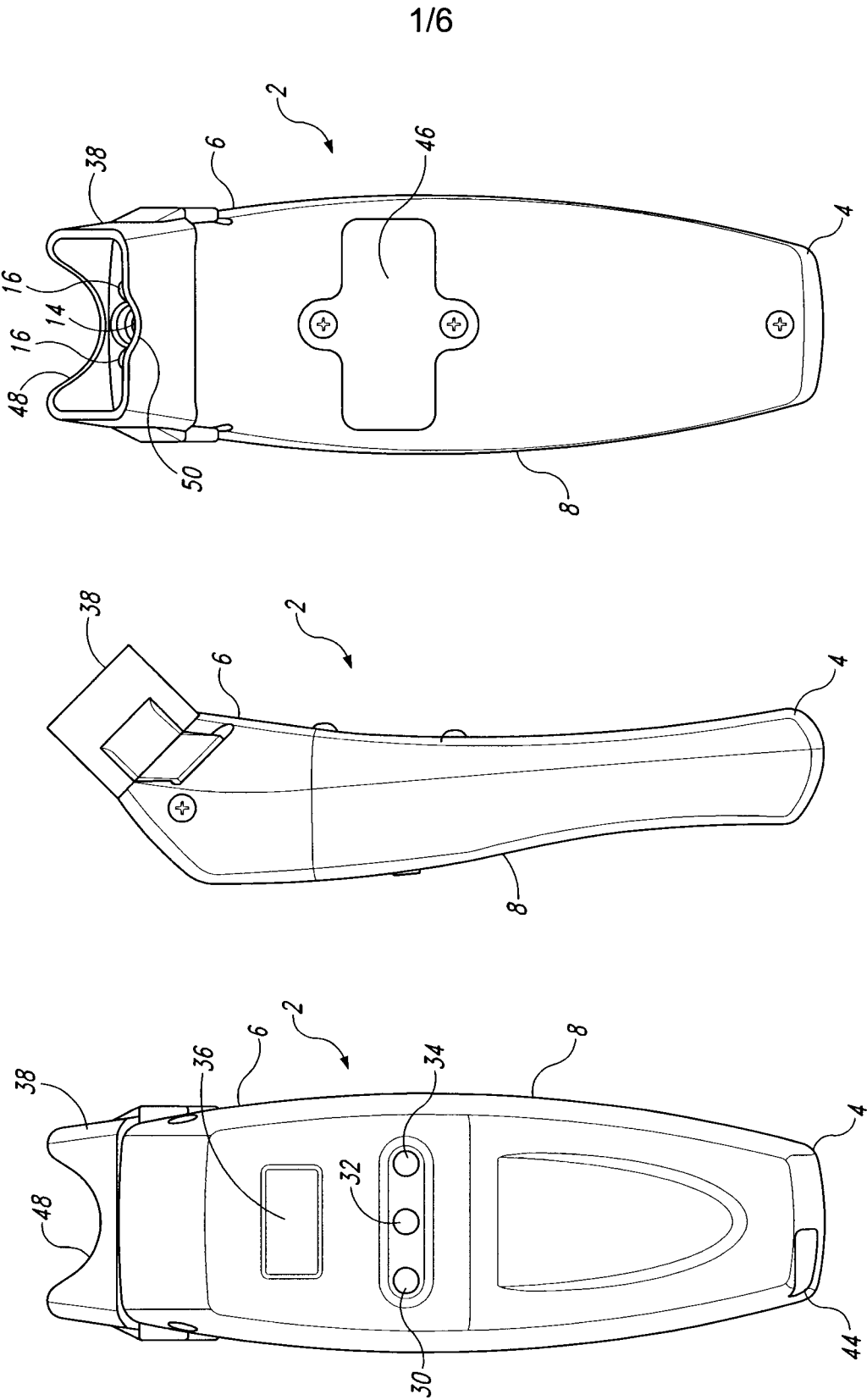
the separable distal element can be snapped on and off the distal end of the housing.

15. The detection system of any one of claims 10 to 13 wherein the distal end of the housing and the separable distal element comprise cooperative projections and detents configured such that the separable distal element can be snapped on and off the distal end of the housing.
16. The detection system of any one of claims 10 to 14 wherein the distal end of the housing is configured to be mounted onto a single circuit board when the housing is not being used for scanning.
17. The detection system of any one of claims 1 to 16 wherein the housing further comprises a display screen on a dorsal side of the housing.
18. The detection system of any one of claims 1 to 17 wherein the system is configured to account for heat level distortions due to ambient conditions at the target site.
19. The detection system of claim 18 wherein the system further comprises at least one algorithm configured to account for the heat level distortions.
20. A method of scan *in vivo* biological target site for a suspected infection, the method comprising:
- emitting excitation light selected to elicit fluorescent light from a suspected infection at the target site
 - sensing fluorescent light emanating from the target site elicited by such excitation light;

- sensing thermal data indicating heat above ambient body temperature emanating from the target site
 - based at least in part on the sensed fluorescent light and the heat levels, determining a probability whether the target site comprises an infection.
21. The method of claim 20 further comprising determining a probability whether the suspected infection is a viral infection or a non-viral infection.
22. The method of claim 21 wherein the method further identifies a spatial organization of the suspected infection.
23. The method of claim 22 wherein the method further utilizes the spatial organization when determining the probability whether the suspected infection is a viral infection or a non-viral infection.
24. The method of any one of claims 20 to 22 wherein, when the suspected infection is a non-viral infection, the method further distinguishes whether the infection is bacterial.
25. The method of any one of claims 20 to 24 wherein the excitation light is emitted by a light emitter located at a distal end of a housing of a hand-held scanning system, and the fluorescent light and the heat levels are detected by sensors located at the distal end of the housing, wherein such light emitter and sensors are all forward-facing and aimed to substantially cover a same area of the target site.
26. The method of claim 25 wherein the housing is configured to be held in a single hand of a user.

27. The method of claim 25 or 26 wherein the housing is configured to fit within a human oral cavity and to scan at least a rear surface of such oral cavity or a throat behind such oral cavity.
- 5 28. The method of any one of claims 25 to 27 wherein the system further comprises a separable distal element sized and configured to removably attach to the distal end of the housing, wherein the separable distal element comprises at least one of light-blocking sides and a forward-facing window configured to transmit at least the excitation light, the fluorescent light and the heat levels without
10 substantial alteration, and the method further comprises adding the distal element to and separating the distal element from the housing.
29. The method of claim 28 wherein the separable distal element does not comprise the forward-facing window.
15
30. The method of claim 28 wherein the separable distal element comprises both the light-blocking sides and the forward-facing window.
31. The method of any one of claims 28 to 29 wherein at least two sides of the
20 separable distal element comprise recesses configured to keep the sides out of a view of the heat sensor.
32. The method of any one of claims 28 to 31 wherein the distal end of the housing and the separable distal element are cooperatively configured such that the
25 separable distal element can be snapped on and off the distal end of the housing.
33. The method of any one of claims 28 to 31 wherein the distal end of the housing and the separable distal element comprise cooperative projections and detents
30 configured such that the separable distal element can be snapped on and off the distal end of the housing.

34. The method of any one of claims 28 to 32 wherein the distal end of the housing is configured to be mounted onto a single circuit board when the housing is not being used for scanning.
- 5 35. The method of any one of claims 20 to 34 wherein the housing further comprises a display screen on a dorsal side of the housing.
36. The method of any one of claims 20 to 35 wherein the method further accounts for heat level distortions due to ambient conditions at the target site.
- 10 37. The method of any one of claims 20 to 35 wherein the system further comprises at least one algorithm configured to account for heat level distortions due to ambient conditions at the target site.



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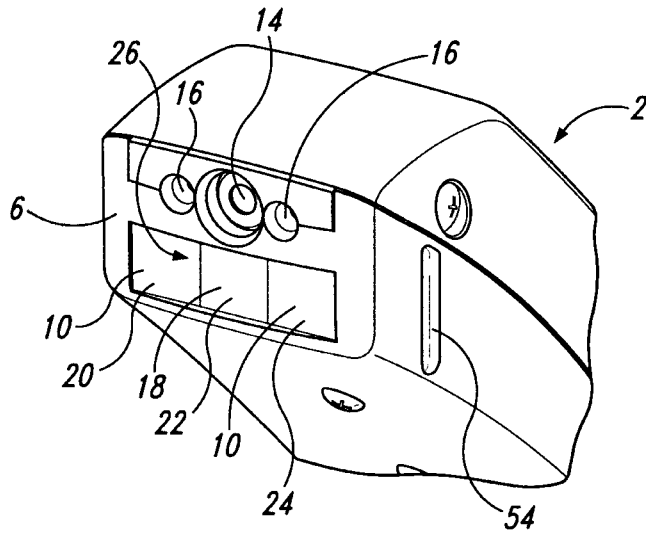


Fig. 4

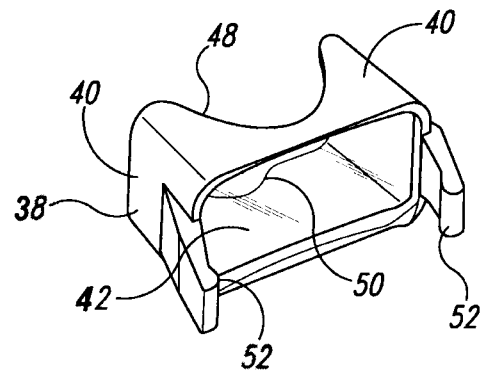


Fig. 5

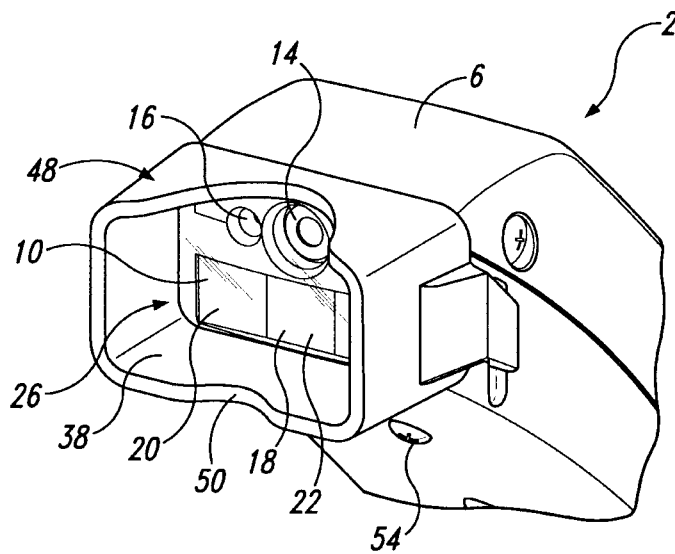


Fig. 6

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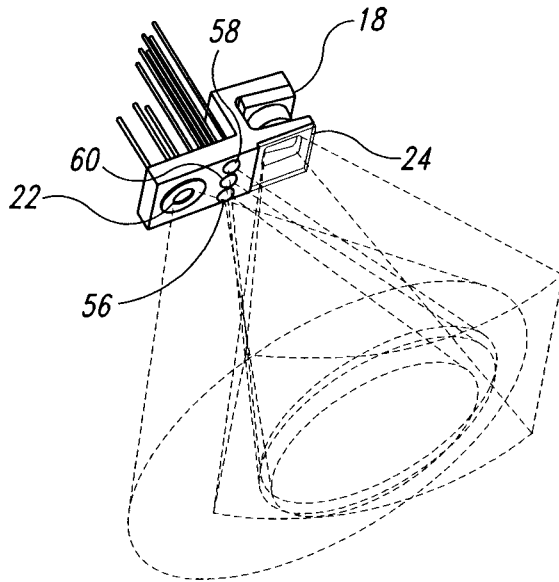


Fig. 7

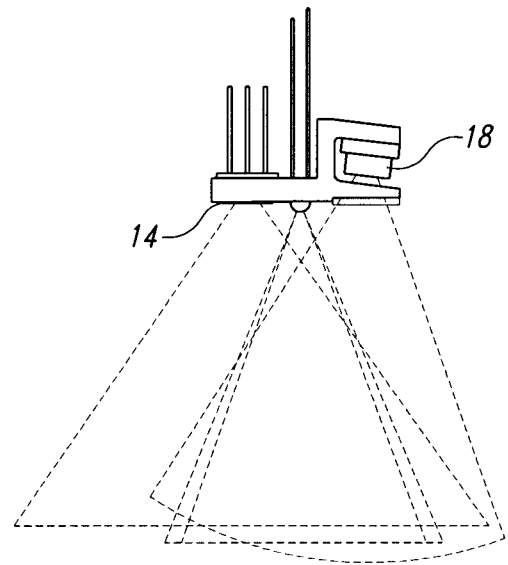


Fig. 8

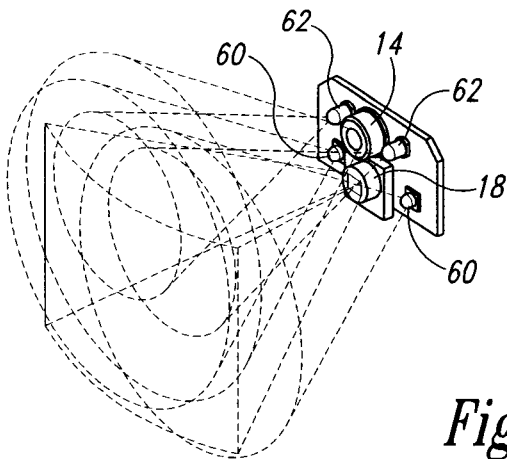


Fig. 9

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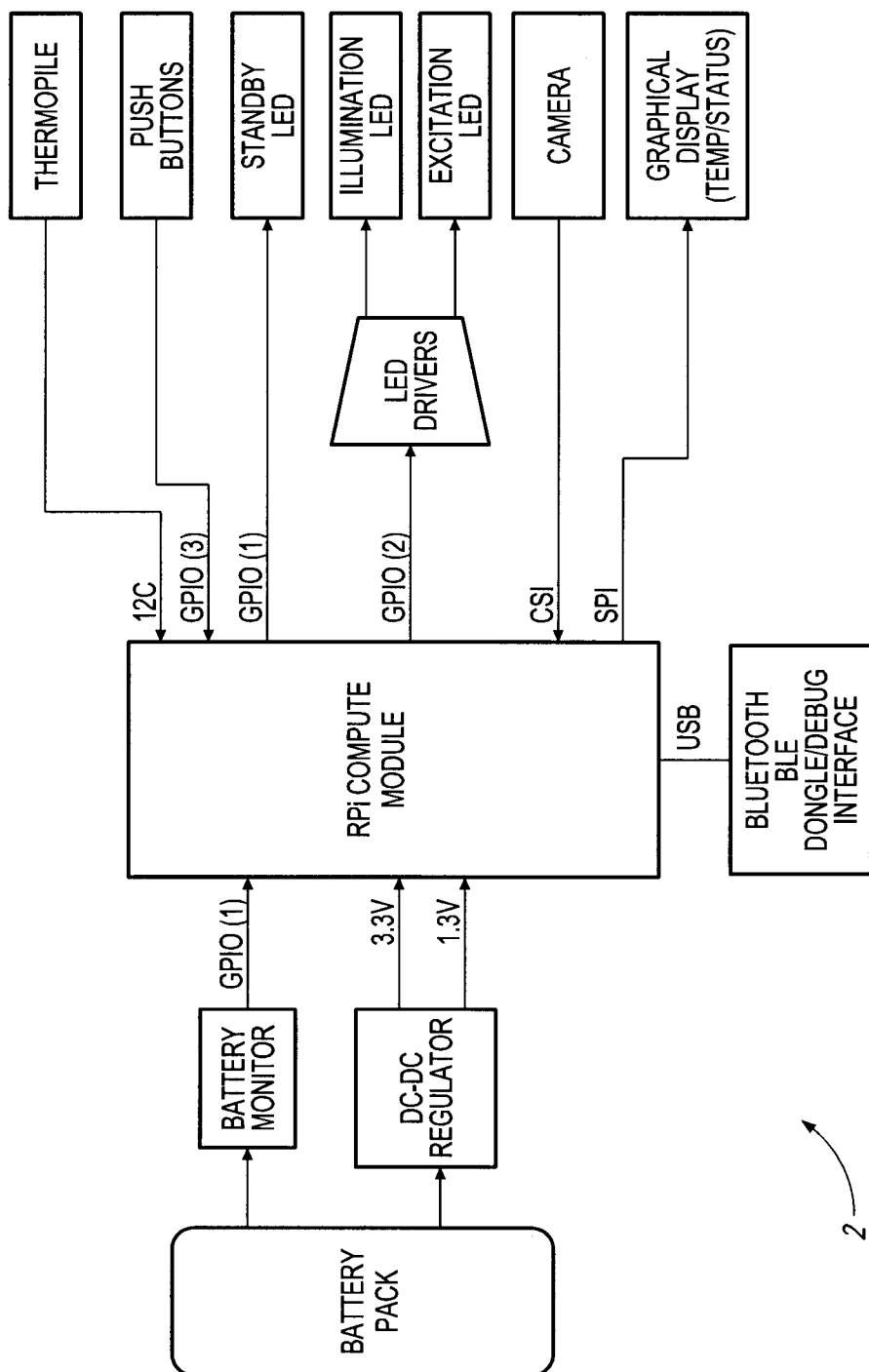
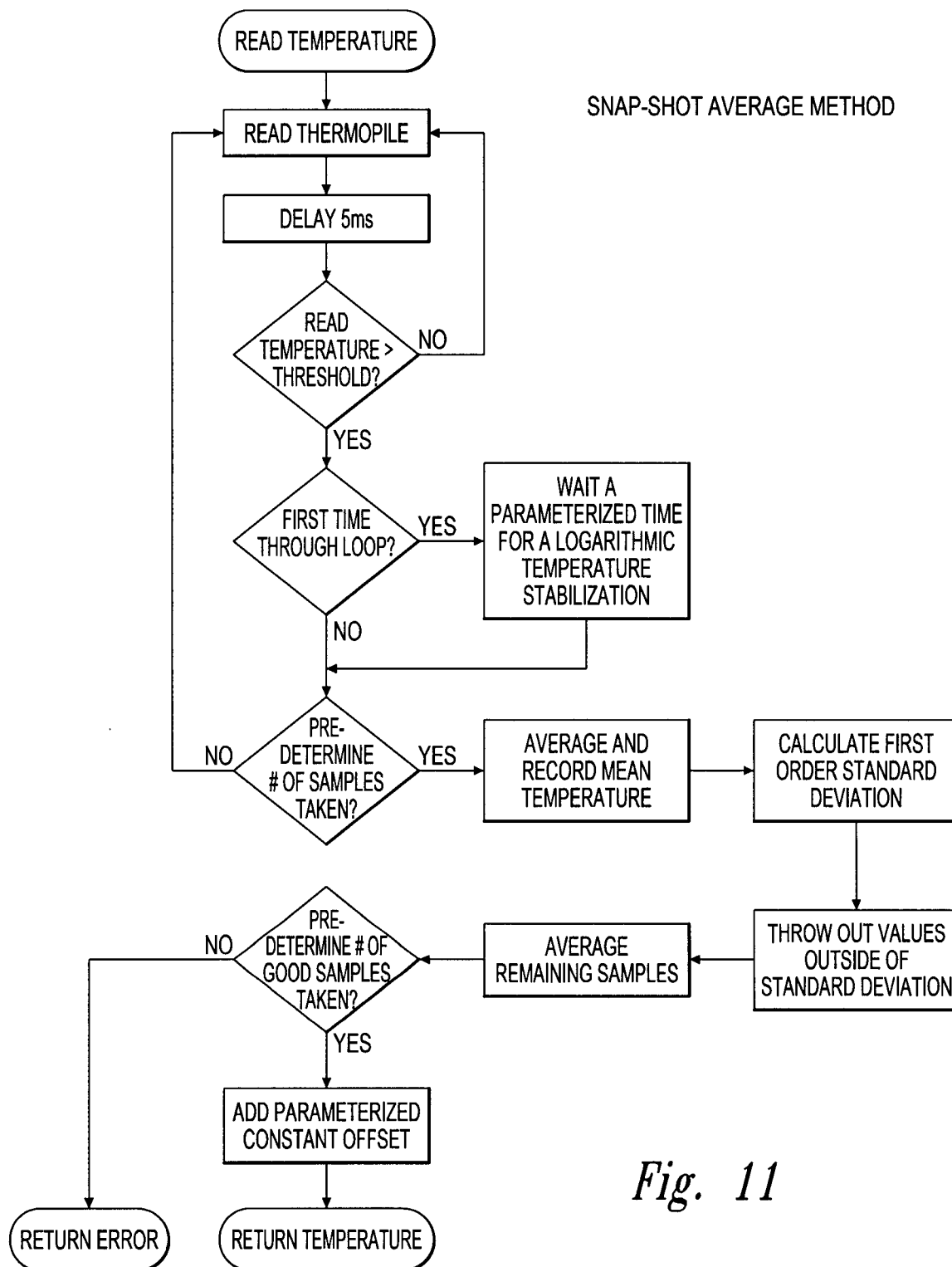


Fig. 10

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*Fig. 11*

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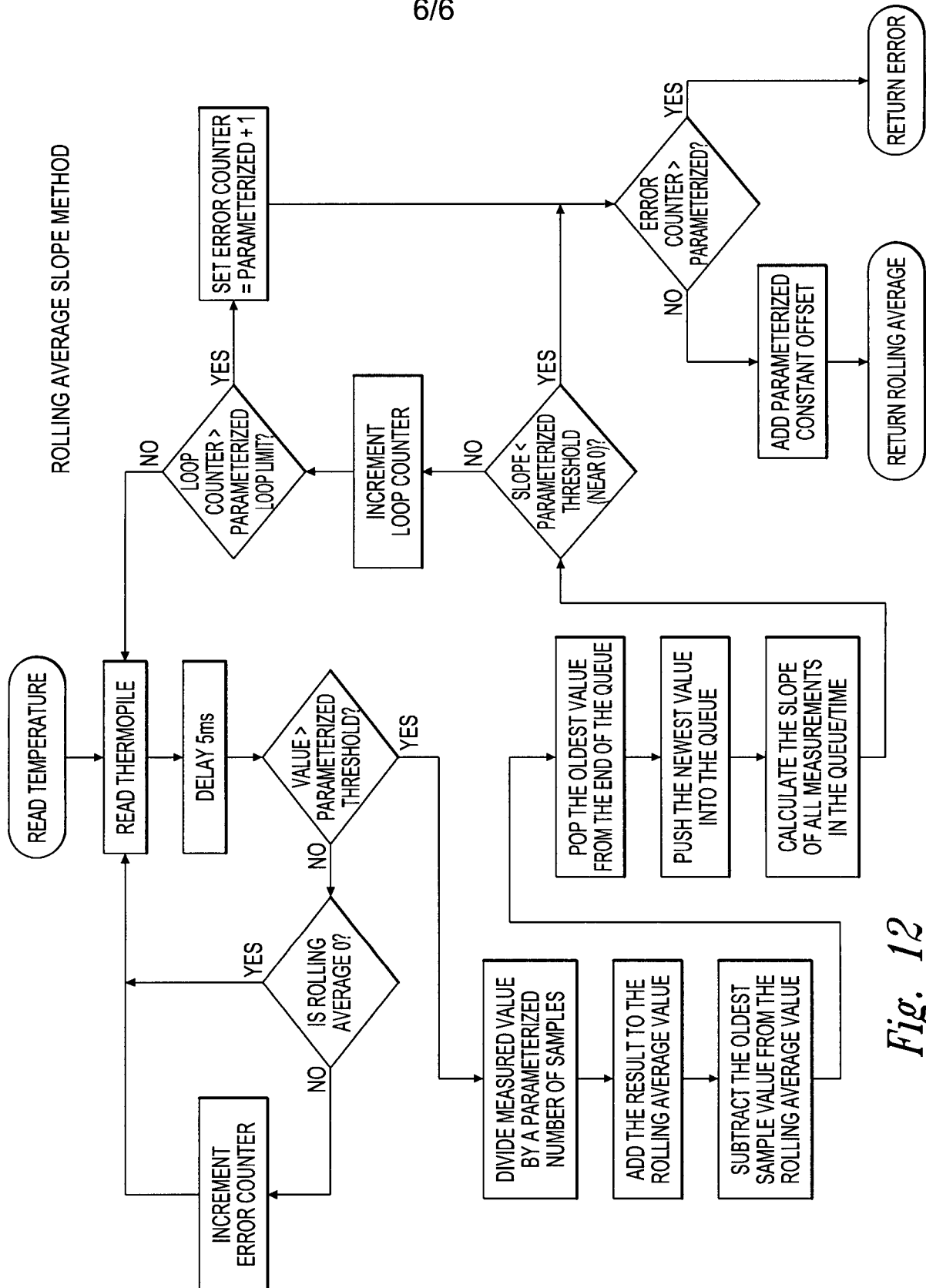


Fig. 12

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CA2016/051323

A. CLASSIFICATION OF SUBJECT MATTER
 IPC: **A61B 5/00** (2006.01) , **A61B 1/24** (2006.01) , **A61B 6/00** (2006.01)

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)

IPC: **A61B 5/00** (2006.01) , **A61B 1/24** (2006.01) , **A61B 6/00** (2006.01)

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

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

Databases: CPD (Canadian Patent Database), Questel Orbit, Google Patents

Keywords: detection, scan, interpret, biological, infection, site, housing, emitter, excitation, heat, sensor, thermal and data fluorescent, light, heat, levels, body, temperature, probability

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US20100302544(A1) 02 December 2010 (02-12-2010) by Duer ** see abstract, entire document**	1-36
A	US8812368(B1) 19 Aug. 2014 (19-08-2014) by Gazdinski **see abstract, entire application**	1-36

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

☒ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent but published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
 20 February 2017 (20-02-2017)

Date of mailing of the international search report
 22 February 2017 (22-02-2017)

Name and mailing address of the ISA/CA
 Canadian Intellectual Property Office
 Place du Portage I, C114 - 1st Floor, Box PCT
 50 Victoria Street
 Gatineau, Quebec K1A 0C9
 Facsimile No.: 819-953-2476

Authorized officer

Karen Oprea (819) 639-8255

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2016/051323

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
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		US2015208907A1	30 July 2015 (30-07-2015)

专利名称(译)	与原位有关的装置，系统和方法		
公开(公告)号	EP3373800A4	公开(公告)日	2019-07-17
申请号	EP2016863282	申请日	2016-11-14
[标]申请(专利权)人(译)	生物技术有限公司		
申请(专利权)人(译)	是生物技术有限公司		
当前申请(专利权)人(译)	是生物技术有限公司		
[标]发明人	WHITEHEAD PETER		
发明人	WHITEHEAD, PETER		
IPC分类号	A61B5/00 A61B1/24 A61B6/00		
CPC分类号	A61B5/0071 A61B5/0084 A61B5/01 A61B5/445 A61B5/6815 A61B5/682 A61B5/742 A61B2560/0252 A61B2576/00		
优先权	62/255005 2015-11-13 US		
其他公开文献	EP3373800A1		
外部链接	Espacenet		

摘要(译)

被配置为扫描和解释体内生物靶位点的疑似感染的检测系统和方法，包括发射选择的激发光以从靶位点处的疑似感染引发荧光;感测从这种激发光引出的目标部位发出的荧光;感应从目标部位发出的高于环境体温的热量;然后，至少部分地基于所感测的荧光和热水平，确定目标部位是否包括感染的概率。