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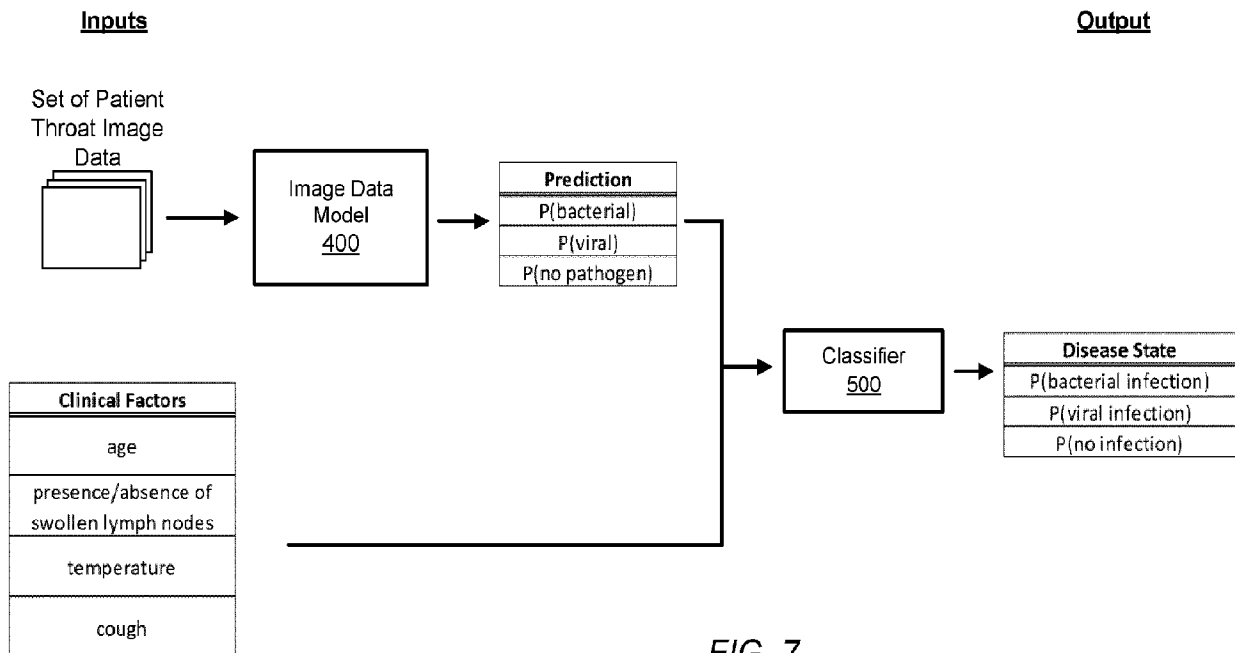


FIG. 7

(57) **Abrégé/Abstract:**

A method for determining a disease state prediction, relating to a potential disease or medical condition of a subject, includes accessing a set of subject images, the subject images capturing a part of a subject's body, and accessing a set of clinical factors from the subject. The clinical factors are collected by a device or a medical practitioner substantially contemporaneously with the capture of the subject images. The subject images are inputted into an image data model to generate disease metrics for disease prediction for the subject. The disease metrics generated by the image data model and the clinical factors are inputted into a classifier to determine the disease state prediction, and the disease state prediction is returned.

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Abstract:

A method for determining a disease state prediction, relating to a potential disease or medical condition of a subject, includes accessing a set of subject images, the subject images capturing a part of a subject's body, and accessing a set of clinical factors from the subject. The clinical factors are collected by a device or a medical practitioner substantially contemporaneously with the capture of the subject images. The subject images are inputted into an image data model to generate disease metrics for disease prediction for the subject. The disease metrics generated by the image data model and the clinical factors are inputted into a classifier to determine the disease state prediction, and the disease state prediction is returned.

INFECTION DETECTION USING IMAGE DATA ANALYSIS

BACKGROUND

FIELD OF ART

[0001] The disclosure relates to image processing and particularly to using image data describing a subject's throat to evaluate for the presence of disease without culturing.

DESCRIPTION OF THE RELATED ART

[0002] A rapid and accurate diagnosis of a viral infection such as COVID-19 or a bacterial infection such as a streptococcal infection is challenging for medical practitioners. Current tests which traditionally involve culturing in vitro for presence of a viral or bacterial infection can be slow, are difficult to administer properly, especially in children, and as such can be inaccurate and put health care providers administering the test at risk. There is a clear need for a more reliable, fast and automatic detection process.

BRIEF DESCRIPTION OF DRAWINGS

[0003] FIG. 1 shows a detection system for analyzing a combination of image data describing a subject's throat and subject-associated clinical factors to determine a disease state prediction for the subject, according to one embodiment.

[0004] FIG. 2 is a high-level block diagram illustrating an example of a computing device used either as a client device, application server, and/or database server, according to one embodiment.

[0005] FIGs. 3A-3I depicts various views of an image capture device, according to one embodiment.

[0006] FIG. 3J is an interaction diagram for the image capture of a subject's throat, according to one embodiment.

[0007] FIG. 4 illustrates a process for training of an image data model within a chained model, according to one embodiment.

[0008] FIG. 5 illustrates a process for training of a classifier within a chained model, according to one embodiment.

[0009] FIG. 6 illustrates a process for generating disease state predictions using a chained model, according to one embodiment.

[0010] FIG. 7 illustrates example input and output vectors relevant to the chained model, according to one embodiment.

[0011] FIG. 8 is a flowchart of returning a disease state prediction for subject determined by a chained model, according to one embodiment

[0012] The figures depict various embodiments of the presented invention for purposes of illustration only. One skilled in the art will readily recognize from the following discussion that alternative embodiments of the structures and methods illustrated herein may be employed without departing from the principles described herein.

DETAILED DESCRIPTION

I. System Architecture

[0013] FIG. 1 shows a detection system for analyzing a combination of image data describing the inside of a subject's throat and subject-associated clinical factors to determine a disease state prediction for the subject (also referred to herein as the "patient"), according to one embodiment. Image data is data that may be used to visualize a region. Image data may include, e.g., an image, a sonogram, a hologram, video, some other form of data describing the region (e.g., in 2-dimensions or 3-dimensions), or some combination thereof. A disease state prediction is related to a disease or medical condition the subject may potentially have. For example, the disease state prediction may indicate a presence or probability of the subject having a viral infection such as COVID-19, a bacterial infection such as a streptococcal infection, or other disease or condition. The detection system analyzes image data (e.g., images, sonograms, holograms, etc.) provided by an image data capture device 120 and clinical factors provided by a medical professional 112 or device to determine a disease state related to a type of infection present in the subject. In some embodiments, the detection system 100 is used for detecting \infections in subjects experiencing known symptoms.

[0014] The detection system 100 includes client computing devices 110, 111, an image data capture device 120, an application server 130, also referred to herein as server 130, database server 140, and a chained model 150. Although FIG. 1 illustrates only a single instance of most of the components of the detection system 100, in practice more than one of each

component may be present, and additional or fewer components may be used. In one embodiment, the chained model 150 is a part of the client device 110, and functions of the chained model 150 are performed locally on the client device 110.

I. A. CLIENT DEVICE AND APPLICATION

[0015] The client devices 110, 111 interact with the detection system 100 via a network 160. In one embodiment, the network 160, system 100, client devices 110, 111, and/or server 130 are a secure network handling sensitive or confidential information, for example they may be designed to provide for restricted data access, encryption of data, and otherwise may be compliant with medical information protection regulations such as HIPAA. For purposes of explanation and clarity it is useful to identify at least two different types of users. One type of user is a subject who potentially has pharyngitis or another throat related disease and makes use of the system 100 at least in part to obtain a disease state prediction provided by the server 130. As will be explained below, a set of subject throat image data (e.g., images, sonogram, etc.) of the subject's throat collected by an image data capture device 120 are provided to a client device 110, which in turn reports to the application server 130, which in turn can initiate a process to determine a disease state prediction which is provided to the user through the client device 110.

[0016] Another type of user is a medical professional 112 who provides clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the set of subject throat image data to a client device 111 (which may also be the same as client device 110), which in turn reports to the application server 130, which in turn can be combined with the subject throat image data to initiate a process to determine a disease state prediction which is provided to the user through the client device 110. The medical professional 112 may operate the image data capture device 120 and client device 110. Alternatively, the subject may instead operate the image data capture device 120 and the client device 110.

[0017] The client device 110, 111 is a computer system. An example physical implementation is described more completely below with respect to FIG. 2. The client device 110, 111 is configured to communicate (e.g., wirelessly or via a wired link) with the detection system 100 via network 160. With network 160 access, the client device 110 transmits to the

detection system 100 the set of subject throat image data captured by the image data capture device 120, and the client device 111 transmits to the detection system 100 the clinical factors provided by the medical professional 112.

[0018] In addition to communicating with the application server 130, client devices 110, 111 connected to the detection system 100 may also exchange information with other connected client devices 110, 111.

[0019] The client device 110 may also perform some data and image processing on the set of subject throat image data locally using the resources of client device 110 before sending the processed data through the network 160. The client device 111 may also perform some data processing on the clinical factors locally using the resources of client device 111 before sending the processed data through the network 160. Image data and clinical factors sent through the network 160 are received by the application server 130 where they are analyzed and processed for storage and retrieval in conjunction with database server 140. The application server 130 may direct retrieval and storage request to the database system 130 as required by the client devices 110, 111.

[0020] The client devices 110 may communicate with the image data capture device 120 using a network adapter and either a wired or wireless communication protocol, an example of which is the Bluetooth Low Energy (BTLE) protocol. BTLE is a short-ranged, low-powered, protocol standard that transmits data wirelessly over radio links in short range wireless networks. In other implementations, other types of wireless connections are used (e.g., infrared, cellular, 4G, 5G, 802.11).

[0021] Although client devices 110 and image capture devices 120 are described above as being separate physical devices (such as a computing device and an image sensor, respectively), in an embodiment, the image data capture device 120 may include aspects of the client device 110. For example, an image capture device may include an audiovisual interface including a display or other lighting elements as well as speakers for presenting audible information. In such an implementation the image data capture device 120 itself may present the contents of information obtained from server 130, such as the disease state prediction determined by the detection system 100, provided by the server 130 directly, in place of or in addition to presenting them through the client devices 110.

[0022] In one embodiment, the client device 110 may be a smartphone, and part of the image

data capture device 120 may be a smartphone attachment. In such an implementation, a built-in camera of the smart phone combined with optical elements of the smartphone attachment provide the functionality of the data capture device 120.

[0023] In further embodiments, a smart phone operates as both the client device 110 and the image data capture device 120, without necessarily requiring any separate attachment. In this case, an integrated camera of the smart phone performs the functions attributed to the image data capture device 120.

[0024] In one embodiment, one client device may act as both the client device 110 and the client device 111.

I.B. APPLICATION SERVER

[0025] The application server 130 is a computer or network of computers. Although a simplified example is illustrated in FIG. 2, typically the application server will be a server class system that uses powerful processors, large memory, and faster network components compared to a typical computing system used, for example, as a client device 110. The server typically has large secondary storage, for example, using a RAID (redundant array of independent disks) array and/or by establishing a relationship with an independent content delivery network (CDN) contracted to store, exchange and transmit data. Additionally, the computing system includes an operating system, for example, a UNIX operating system, LINUX operating system, or a WINDOWS operating system. The operating system manages the hardware and software resources of the application server 130 and also provides various services, for example, process management, input/output of data, management of peripheral devices, and so on. The operating system provides various functions for managing files stored on a device, for example, creating a new file, moving or copying files, transferring files to a remote system, and so on.

[0026] The application server 130 includes a software architecture for supporting access to and use of detection system 100 by many different client devices 110, 111 through network 160, and thus at a high level can be generally characterized as a cloud-based system. The application server 130 generally provides a platform for subjects and medical professionals 112 to report data recorded by the client devices 110, 111 associated with the subject's symptoms, collaborate on treatment plans, browse and obtain information relating to their

condition, and make use of a variety of other functions.

[0027] Generally, the application server 130 is designed to handle a wide variety of data. The application server 130 includes logical routines that perform a variety of functions including checking the validity of the incoming data, parsing and formatting the data if necessary, passing the processed data to a database server 140 for storage, and confirming that the database server 140 has been updated.

[0028] The application server 130 stores and manages data at least in part on a subject by subject basis. Towards this end, the application server 130 creates a subject profile for each user. The subject profile is a set of data that characterizes a subject 113 of the detection system 100. The subject profile may include identify information about the subject such as age, gender, a subject's relevant medical history, and a list of non-subject users authorized to access the subject profile. The profile may further specify a device identifier, such as a unique media access control (MAC) address identifying the one or more client devices 110, 111 or image capture devices 120 authorized to submit data (such as a set of subject throat image data) for the subject.

[0029] The application server 130 also creates profiles for health care providers 112. A health care provider profile may include identifying information about the health care provider 112, such as the office location, qualifications and certifications, and so on. The health care provider profile also includes information about their subject population. The provider profile may include access to all of the profiles of that provider's subjects, as well as derived data from those profiles such as aggregate demographic information. This data may be further subdivided according to any type of data stored in the subject profiles, such as by geographic area (e.g., neighborhood, city) over by time period (e.g., weekly, monthly, yearly).

[0030] The application server 130 receives client factors and subject throat image data from the client devices 110, 111 triggering a variety of routines on the application server 130. In the example implementations described below, the chained model 150 executes routines to access subject throat image data as well as clinical factors, analyze the images and data, and output the results of its analysis to subjects or medical professionals 112.

I.C. DATABASE SERVER

[0031] The database server 140 stores subject and healthcare provider related data such as

profiles, medication events, subject medical history (e.g., electronic medical records). Subject and provider data is encrypted for security and is at least password protected and otherwise secured to meet all Health Insurance Portability and Accountability Act (HIPAA) requirements. Any analyses that incorporate data from multiple subjects and are provided to users is de-identified so that personally identifying information is removed to protect subject privacy.

[0032] Although the database server 140 is illustrated in FIG. 1 as being an entity separate from the application server 130 the database server 140 may alternatively be a hardware component that is part of another server such as server 130, such that the database server 140 is implemented as one or more persistent storage devices, with the software application layer for interfacing with the stored data in the database is a part of that other server 130.

[0033] The database server 140 stores data according to defined database schemas. Typically, data storage schemas across different data sources vary significantly even when storing the same type of data including cloud application event logs and log metrics, due to implementation differences in the underlying database structure. The database server 140 may also store different types of data such as structured data, unstructured data, or semi-structured data. Data in the database server 140 may be associated with users, groups of users, and/or entities. The database server 140 provides support for database queries in a query language (e.g., SQL for relational databases, JSON NoSQL databases, etc.) for specifying instructions to manage database objects represented by the database server 140, read information from the database server 140, or write to the database server 140.

[0034] With respect to the descriptions of Figs. 4-6, the contents of the databases described with respect to those figures may be stored in databases physically proximate to the application server 130 and separate from database server 140 as illustrated.

I.D. NETWORK

[0035] The network 160 represents the various wired and wireless communication pathways between the client devices 110, 111, the image data capture device 120, the application server 130, and the database server 140. Network 160 uses standard Internet communications technologies and/or protocols. Thus, the network 160 can include links using technologies such as Ethernet, IEEE 802.11, integrated services digital network (ISDN), asynchronous

transfer mode (ATM), etc. Similarly, the networking protocols used on the network 160 can include the transmission control protocol/Internet protocol (TCP/IP), the hypertext transport protocol (HTTP), the simple mail transfer protocol (SMTP), the file transfer protocol (FTP), etc. The data exchanged over the network 160 can be represented using technologies and/or formats including the hypertext markup language (HTML), the extensible markup language (XML), etc. In addition, all or some links can be encrypted using conventional encryption technologies such as the secure sockets layer (SSL), Secure HTTP (HTTPS) and/or virtual private networks (VPNs). In another embodiment, the entities can use custom and/or dedicated data communications technologies instead of, or in addition to, the ones described above.

II. EXAMPLE COMPUTING DEVICES

[0036] FIG. 2 is a high-level block diagram illustrating physical components of an example computer 200 that may be used as part of a client device 110, 111, application server 130, and/or database server 140 from FIG. 1, according to one embodiment. Illustrated is a chipset 210 coupled to at least one processor 205. Coupled to the chipset 210 is volatile memory 215, a network adapter 220, an input/output (I/O) device(s) 225, a storage device 230 representing a non-volatile memory, and a display 235. In one embodiment, the functionality of the chipset 210 is provided by a memory controller 211 and an I/O controller 212. In another embodiment, the memory 215 is coupled directly to the processor 205 instead of the chipset 210. In some embodiments, memory 215 includes high-speed random access memory (RAM), such as DRAM, SRAM, DDR RAM or other random access solid state memory devices.

[0037] The storage device 230 is any non-transitory computer-readable storage medium, such as a hard drive, compact disk read-only memory (CD-ROM), DVD, or a solid-state memory device. The memory 215 holds instructions and data used by the processor 205. The I/O device 225 may be a touch input surface (capacitive or otherwise), a mouse, track ball, or other type of pointing device, a keyboard, or another form of input device. The display 235 displays images and other information from for the computer 200. The network adapter 220 couples the computer 200 to the network 160.

[0038] As is known in the art, a computer 200 can have different and/or other components

than those shown in FIG. 2. In addition, the computer 200 can lack certain illustrated components. In one embodiment, a computer 200 acting as server 140 may lack a dedicated I/O device 225, and/or display 218. Moreover, the storage device 230 can be local and/or remote from the computer 200 (such as embodied within a storage area network (SAN)), and, in one embodiment, the storage device 230 is not a CD-ROM device or a DVD device.

[0039] Generally, the exact physical components used in a client device 110, 111 will vary in size, power requirements, and performance from those used in the application server 130 and the database server 140. For example, client devices 110, 111 which will often be home computers, tablet computers, laptop computers, or smart phones, will include relatively small storage capacities and processing power, but will include input devices and displays. These components are suitable for user input of data and receipt, display, and interaction with notifications provided by the application server 130. In contrast, the application server 130 may include many physically separate, locally networked computers each having a significant amount of processing power for carrying out the analyses introduced above. In one embodiment, the processing power of the application server 130 provided by a service such as Amazon Web Services™ or Microsoft Azure™. Also in contrast, the database server 140 may include many, physically separate computers each having a significant amount of persistent storage capacity for storing the data associated with the application server.

[0040] As is known in the art, the computer 200 is adapted to execute computer program modules for providing functionality described herein. A module can be implemented in hardware, firmware, and/or software. In one embodiment, program modules are stored on the storage device 230, loaded into the memory 215, and executed by the processor 205.

III. IMAGE CAPTURE AND CLINICAL FACTORS

III.A. IMAGE CAPTURE DEVICE

[0041] FIGs. 3A-3C depict three views of an exemplary image data capture device 120, according to one embodiment. The embodiment depicted is configured for use in a human oral cavity (mouth and if desired upper throat). In other embodiments, the image capture device is configured to capture images of other parts of the body or other objects. For example, in one embodiment, the image data capture device 120 is configured to capture images of a subject's skin. Note, in embodiments, not shown in FIGs. 3A-3C, the image data

capture device is configured to capture sonograms, holograms, images, videos, some other form of data describing the part of the human body (e.g., in 2-dimensions or 3-dimensions), or some combination thereof. The scanning and detection device can be any desired shape suitable for a given target site, 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 subject.

[0042] In one embodiment, the image data capture device 120 comprises a proximal end 4 and a distal end 6, with the distal end 6 configured to introduce into or aim towards an in vivo biological target site suspected of having an infection. Image data capture device 120 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 wavelength/wavelength band of excitation light. The image data capture device 120 may further comprise a light sensor as well as a heat sensor 14 (refer, e.g., to FIG. 3D and 3F). The light sensor 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.

[0043] In one embodiment, the detection system further comprises operably connected computer-implemented programming configured to accept fluorescent light data associated with the fluorescent light and thermal data associated with the heat levels above ambient body temperature and interpret the data to determine a probability whether the target site contains an infection. Such computer-implemented programming can be contained within housing 8 or can be located externally.

[0044] Image data capture device 120 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 fluorescent image/sensing procedure. The third control button 34 initiates a temperature acquisition procedure. Other or fewer buttons can also be provided as desired.

[0045] As shown in FIGs. 3D and FIG. 3F, image data capture device 120 can comprise an 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.

[0046] Image data capture device 120 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, subject 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 FIG. 3E, configured to transmit at least the excitation light, the fluorescent light and the heat levels without substantial alteration. The 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. Image data capture device 120 can further comprise a plug-port 44 and a battery bay 46.

[0047] In the embodiment depicted in FIGs. 3A-3F, 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.

[0048] FIG. 3G and 3H 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) 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.

[0049] FIG. 3I shows a further embodiment concerning light emitters, light sensors and heat sensors. In this embodiment, the array includes two white light emitting LEDs 62, and two blue LEDs 60, as well as a camera 18 and a radiant heat sensor 14.

[0050] FIG. 3J shows an interaction diagram of the image capture process for providing the

set of subject throat image data to the detection system 100, according to one embodiment. For white images, the illumination emitter 16 provides light input to the subject's throat, and the camera 18 simultaneously records a white image of the throat. The white image of the throat may be formed by collecting light reflected from the throat of the subject. For excitation images, also referred to herein as an "blue images," the excitation emitter 10 provides light input to the subject's throat at a specific excitation wavelength, and the camera 18 simultaneously records a blue image of the throat, according to one embodiment. The blue image may be formed by collecting light emitted from the throat of the subject as a result of auto-fluorescence, in addition to light reflected by the throat of the subject. In some cases, the light from auto-fluorescence is a different wavelength than the excitation wavelength. In one embodiment, the excitation emitter 10 provides light input to another part of the subject's body, and the camera 18 simultaneously records an excitation image of the part of the subject's body. In some embodiments, the excitation emitter 10 provides blue light input, but in other embodiments, the excitation emitter may provide light input at wavelengths corresponding to other colors. In some embodiments, the subject throat image data include images other than the white images and the blue images. For example, the captured subject throat image data may include images captured in multiple wavelengths and multiple lighting conditions. In embodiments where the detection system 100 targets other diseases and/or medical conditions, the captured subject images may include images other than the white images and the blue images. Note that while the collection of image data is described above in the context of images, the image captured device 120 may be modified to collect other forms of image data (e.g., sonograms, holograms, etc.) in addition to and/or in alternative to the images.

[0051] The excitation emitter 10 causes the targeted virus or other factor to fluoresce in response to the light input from the excitation emitter 10. In the case where targeted bacterial pathogens (such as streptococcal bacteria) are present in the subject's throat, fluorescent hosts in the bacteria, for example a porphyrin, cause the bacteria to auto-fluoresce in response to the light input from the excitation emitter 10. The camera 18 will capture this auto-fluorescence as part of the blue image.

[0052] The white image and blue image are included in the set of subject throat image data provided to the chained model 150 for use in determining a disease state prediction of the

subject. In one embodiment, more than one blue image or white image may be included in the set of subject throat image data. In another embodiment, images other than the blue image or white image may be included in the set of subject throat image data, for example images with illumination conditions from the image data capture device 120. For example, the subject throat image data provided to the chained model 150 may include images captured in other colors or other wavelengths of light, according to some embodiments.

[0053] In another example, the detection system 100 may be used to detect diseases and conditions related to skin lesions present on a subject. In such a case, the image data capture device 120 captures white images and excitation images of the skin lesions. In some embodiments, the image data capture device 120 only captures white images. In other embodiments, the image data capture device 120 only captures excitation images of the skin lesions. The captured image data (e.g., images) are provided to the chained model 150 to determine a disease state prediction related to the skin lesion.

III.B. COLLECTION OF CLINICAL FACTORS

[0054] Clinical factors for the subject are collected substantially contemporaneously with the capture of subject throat image data by the image data capture device 120. In one embodiment, the clinical factors for a subject are collected by the medical professional 112 and submitted to the chained model 150 using the client device 111. In another embodiment, the clinical factors are provided by a subject without the aid of or without interacting with the medical professional 112. For example, the subject may report the clinical factors through an application on a client device 110, such as a smartphone. In alternate embodiments, one or more of the clinical factors are not collected contemporaneously to the capture of images by the image data capture device 120. For example, if age is a clinical factor for predicting a presence of a disease, the age of the subject may be recorded at a different time than the image capture.

III.C. IMAGE CAPTURE AND PREPROCESSING

[0055] For diagnosing an infection case, the colored light spectra is filtered by specific wavelength. It is then captured by the image capture device's camera 18 as white light and blue light digital images. These images are then curated, centered and cropped by an image pre-processing algorithm that assess the quality and suitability of these images for use in the

image data model.

[0056] Good image pre-processing leads to a robust AI model for accurate predictions. Pre-Processing techniques that may be performed on the set of subject throat image data may include: uniform aspect ratio, rescaling, normalization, segmentation, cropping, object detection, dimensionality deduction/increment, brightness adjustment, data augmentation techniques to increase the data size like: Image Shifting, flipping, zoom in/out, rotation etc., determining quality of the image to exclude bad images from being a part of training dataset, image pixel correction, and performing a FV image florescence brightness algorithm.

IV. CHAINED MODEL

IV.A. IMAGE DATA MODEL TRAINING

[0057] In one embodiment, the chained model 150 includes an image data model 400 and a classifier 500. The training of the image data model 400 and classifier 500 will be discussed below.

[0058] FIG. 4 illustrates a process for training of an image data model 400 within a chained model 150, according to one embodiment. The image data model 400 is trained on a first set of training image data associated with a first set of training subjects and a corresponding first set of training labels. The image data (also referred to as throat image data) describes a body part affiliated with the throat (e.g., throats, orifices, cripts, some other part of the throat, or some combination thereof). The throat image data may include, e.g., images, sonograms, holograms, videos, some other form of data describing the body part, (e.g., in 2-dimensions or 3-dimensions), or some combination thereof. In one embodiment, the training images are of throats captured under fluorescent light, white light, and ambient light. The fluorescent light may contain blue light at a wavelength for fluorescing.

[0059] Each training subject has one of several pre-determined labels. In one embodiment, the pre-determined labels distinguishes the subject as having A) a viral pathogen such as COVID-19 (or other similar viral infection) or B) an absence of a pathogen. Alternatively, the labels may distinguish subjects having A) a bacterial pathogen (such as streptococcal bacteria), B) a viral pathogen such as COVID-19 (or other similar viral infection), or C) an absence of a pathogen. The label may be a categorical label (e.g., {A, B} or {A, B C}), or it may be a numerical label (e.g., {0, 1} or {-1, 0, 1}). The first set of training throat image data

and the associated labels are provided by a training database 415. The first set of training image data may be captured by the image data capture device 120. The labels for the first set of training subjects is provided on the basis that disease states of the first set of training subjects are previously known, for example as determined by traditional cell culturing and evaluation by one or more medical professionals evaluating the training set of subjects.

[0060] The image data model 400 is trained by determining image data parameter coefficients 430, each associated with a corresponding image parameter, (not shown). Collectively, the image data parameter coefficients 430 are determined so as to best represent the relationship between the first set of training subject throat image data input into a function of the image data model 400 and their associated labels. Generally, the image data model 400 is a supervised machine learning technique. In one embodiment, the image data model 400 is a convolutional neural network model. In a further embodiment, the convolutional neural network is trained using transfer learning with fine tuning. In other embodiments, the image data model 400 is specifically a VGG neural network, a ResNet neural network, or an Inception V4 neural network. In other embodiments, other types of machine learning models and training methods may be used, examples of which include but are not limited to: stochastic gradient descent, transfer learning algorithms, learning rate annealing, cyclic learning rates, differential learning rates, regularization techniques such as batch normalization, ensembling neural networks, etc.

[0061] Once the parameter coefficients are known, the image data model 400 may be used for prediction, as discussed in FIG. 5 and FIG. 6 by accessing the image data parameter coefficients 430 and the function specified by the model, and inputting input values for the image parameters to generate a prediction of pathogen presence. The prediction generated for a subject by the image data model 400 may include one or more of: a probability of a presence of a bacterial pathogen or specific type of bacterial pathogen (such as streptococcal bacteria), a probability of a presence of a viral pathogen, a probability of a presence of a specific class of pathogens (e.g., coronaviruses), a probability of a presence of a specific viral pathogen such as COVID-19, and a probability of an absence of a pathogen. The prediction may be output in the form of a vector including one or more of the above numerical values. The prediction may also output a separate numerical confidence in the prediction.

[0062] In one embodiment, the prediction may include one or more of: a probability of a

presence of exudate, a probability of a presence of petechiae, a probability of a presence of swollen tonsils, and a probability of a presence of a swollen uvula. In this embodiment, the image data model 400 is training with training images and corresponding training labels indicating the presence or absence of these conditions. Again, the prediction may be output in the form of a vector including one or more of the above numerical values, and the prediction may also output a separate numerical confidence in the prediction. In some embodiments, where the detection system 100 is used for different diseases and/or medical conditions, the prediction may include one or more of: a presence of viral pathogens, a presence of plaque, a presence of oral mucosa, a presence of cancer, gastroesophageal reflux disease (GERD) detection, and a presence of bacterial pathogens (e.g., streptococcal bacteria, ecoli, salmonella, and other pathogens).

[0063] In other embodiments, the image data model 400 is any machine learning model that directly or indirectly generates a prediction of a presence of a disease factor such as a viral pathogen, a bacterial pathogen, a presence of or property of a tumor, or a degree of swelling of a body part. In one embodiment, the image data model 400 is a machine learning model that performs feature detection on images (e.g., white images, blue images, or images in other wavelengths or lighting conditions) of a subject's throat, as well as color classification.

According to some embodiments the feature detection and color classification may be used to determine targeted feature metrics including, but not limited to: presence/size/shape/location of the oral cavity, oral cavity symmetry, presence/size/shape/location tonsils, tonsil redness, tonsil swelling, a soft or hard palate, presence of red spots on the palate, streaks of pus, white patches, and dry mouth. Each of the feature metrics may correspond to an identified feature in an image. For example, a feature metric may indicate a presence of an identified feature or a property of an identified feature. In some embodiments, feature detection on the white images may complement the feature detection performed on the blue images.

[0064] In some embodiments, for the blue images, the feature detection and the color classification determines targeted infection metrics including, but not limited to: presence/size/shape/location of an infected area, an intensity, and a pattern identification. In some embodiments the feature detection and the color classification is used for images other than the blue images. In some embodiments, one or more of the targeted infection metrics generated by the image model for the blue images indicate characteristics of auto-

fluorescence in one or more regions of a subject's throat captured in the blue image, in response to illumination from an excitation light source (e.g., blue light from the image capture device). Each of the infection metrics may correspond to an infection in the subject. For example, an infection metric may indicate a presence of a certain infection (e.g., a viral infection such as COVID-19 or a bacterial infection) in the subject or a property of an infection. In one embodiment the determined feature metrics and infection metrics may then be provided independently of or alongside the prediction of a presence of a pathogen according to the methods described above to the classifier as inputs for generating a patient's disease state prediction. In other embodiments, the determined feature metrics and infection metrics may be provided without the prediction of a presence of a pathogen to the classifier as inputs for generating a patient's disease state. In one embodiment, feature detection and color classification is performed using k-means clustering, however other unsupervised machine learning techniques may also be used.

[0065] In an embodiment specific to detection of COVID-19, the image model may be trained to identify features of the red channel in RGB images of the throat that are indicative of COVID-19. For example, spectral analysis shows that the viral images demonstrate a significant peak of high value red pixels of high density closer to the 255 values when compared to healthy images. In an example training process, a set of positive images may be selected from patients that exhibited certain clinical factors associated with COVID-19 including mild to high fever (100F to 104F), cough, and sore throat. The images may be curated to exclude blur images and images in which the uvula or tonsils were obstructed. Then white light images of these patients may be analyzed to look for these features of viral manifestation such as: swollen tonsils, redness in tonsils, red spots on tongues, crusty tongues, inflammation (redness) in throats, redness in pharyngeal arch. Images with the presence of exudate on tonsils and swollen uvula may be excluded. Because of the filters the emitted light is more orange than red, spectra analysis of the respective RGB channels may be performed. Features associated with the red channel may be derived from the positive set of training images together with similar features from a set of negative training images (associated with healthy patients) to train the image data model 400 for detection of COVID-19.

IV.B. Classifier Training

[0066] FIG. 5 illustrates a process for training of a classifier within a chained model 150, according to one embodiment. The classifier 500 is trained using a set of training predictions of pathogen presence generated by the pre-trained image data model 400 based on a second set of training throat image data, training clinical factors associated with a second set of training subjects, and a corresponding second training set of labels. In one embodiment, the classifier 500 is trained using feature metrics and infection metrics generated by the pre-trained image data model 400 based on the second set of training throat image data, in addition to or independently of the training data described above. As with the first set of training labels, each subject from the second set of training subjects has a corresponding pre-determined label distinguishing the subject as having a bacterial pathogen, a viral pathogen, or an absence of a pathogen. Again, these labels may be determined by traditional cell culturing and evaluation by one or more medical professionals evaluating the training set of subjects. The labels may alternatively be determined by other methods.

[0067] Again, the second set of training subject throat image data and the associated labels are provided by the training database 415. The training clinical factors are provided by a training clinical database 515. The training clinical database 515 contains clinical factors for each of the second set of training subjects collected by a medical professional or device 120. These images are generally collected substantially simultaneously with the capture of the corresponding training subject throat image data for that subject.

[0068] The classifier 500 is trained by determining classifier parameter coefficients 530, each associated with each classifier parameter (not shown). The coefficients are trained so as to collectively best represent the relationship between the input values (predictions of pathogen presence and clinical factors) of the second set of training subjects and a function of the classifier to the second set of training labels.

[0069] Generally, the classifier 500 is trained using a supervised machine learning technique. In one embodiment, the classifier 500 is a neural network model, trained using trained using stochastic gradient descent. In other embodiments, other types of classifiers and training methods may be used, examples of which include but are not limited to linear, logistic, and other forms of regression (e.g., elastic net, multinomial regression), decision trees (e.g., random forest, gradient boosting), support vector machines, classifiers (e.g. Naïve Bayes

classifier), fuzzy matching. In other embodiments, the classifier may perform classical statistical analysis methods that include, but are not limited to: correlations, hypothesis tests, and analysis of variance (ANOVA).

[0070] Once the parameter coefficients are known, the classifier model 500 may be used for prediction, as discussed in FIG. 6 by accessing the classifier parameter coefficients 530 and the function specified by the classifier, and inputting input values for the parameters to generate a prediction of disease state. The disease state prediction of the subject generated by the classifier 500 may include a probability of a presence or absence of a viral infection. Alternatively, the prediction may include one or more of: a probability of bacterial infection, a probability of viral infection, and a probability of no infection. Additionally, or alternatively, the disease state prediction may include probabilities indicating the presence of anatomical morphologies or symptoms. In one embodiment, the probabilities indicating the presence of anatomical morphologies or systems include one or more of: a probability of a presence of exudate, a probability of a presence of petechiae, a probability of a presence of swollen tonsils, and a probability of a presence of a swollen uvula. In cases where diseases or conditions other than pharyngitis are targeted, the disease state predictions may indicate probabilities of other morphologies or symptoms.

IV.C. CLINICAL FACTORS

[0071] In one embodiment, the set of clinical factors of the subject used by the classifier 500 in the chained model 150 may include, but are not limited to: an age, gender, race, history of testing for a specific infection (e.g., COVID-19), recent health history, history of tonsillectomy or other diagnoses (e.g., diabetes, high blood pressure, inflamed tonsils / adenoids, cardiovascular disease, acid reflux), a smoking history, a presence or absence of swollen lymph nodes, a subject temperature, a presence or absence of a fever, a presence or absence of coughing symptoms, a presence or absence of a runny nose, a presence or absence of nasal congestion, a presence or absence of a headache, a presence or absence of body aches, a presence or absence of vomiting, a presence or absence of diarrhea, a presence or absence of fatigue, a presence or absence of chills, a presence or absence of a cough, a presence or absence of lost sense of smell, a presence or absence of a sore throat, a duration of pharyngitis, and a set of symptoms correlated with the Centor procedure.

V. MODEL INFERENCE

[0072] FIG. 6 illustrates a process for generating disease state predictions using a chained model 150, according to one embodiment. The chained model 150 receives as input a set of subject throat image data (e.g., images, sonograms, etc.) from a subject and a set of clinical factors collected by a medical professional 112 substantially contemporaneously to the capture of the set of subject throat image data. In one embodiment, the image data are images of the subject are of sore throats captured under fluorescent light, white light, and ambient light. The chained model 150 generates disease state prediction for the subject. In some embodiments, the input set of subject throat image data may include only white images captured with white lighting conditions or ambient lighting conditions, or only blue images captured using illumination from an excitation light source for fluorescence. In other embodiments, the input set of subject throat image data may include subject throat image data captured under other lighting conditions. For example, the input set of subject throat image data may include multiple images capturing multiple wavelengths of light.

[0073] The generation of the disease state prediction for the subject is a two-step process. A first step includes inputting the set of subject throat image data to the image data model 400. The image data model 400 accesses the image data parameter coefficients 430 and generates a pathogen presence prediction for the subject. The pathogen presence prediction is provided together with the set of clinical factors as inputs to the classifier 500. The classifier 500 accesses the classifier parameter coefficients 530 and together with clinical factors and pathogen presence prediction generates a disease state prediction for the subject. The disease state prediction may then be provided to the client device 110 and displayed to a medical professional or the subject.

[0074] In one embodiment, the chained model 150 can provide a disease state prediction solely using the pathogen presence prediction without accessing the clinical factors for the subject. In this case, the set of subject throat image data is sufficient for determining the disease state prediction, and only the output of the image data model 400 is used.

[0075] In some embodiments, the image data model 400 is trained using blue images, white images, images captured in a different wavelength of light or different lighting conditions, or some combination thereof, but when generating disease state predictions, the chained model 150 may have input subject throat image data that are captured in a different wavelength of

light or different lighting conditions than the training images. For example, the image data model 400 may be trained using a combination of white images and blue images, but only white images may be used as inputs for the chained model 150 when generating disease state predictions for a subject.

[0076] FIG. 7 illustrates example input and output vectors relevant to the chained model 150, according to one embodiment. The input vectors include the set of subject throat image data (e.g., images) and the clinical factors. The resulting output vector of the chained model is a disease state prediction, which includes probabilities for various types of infections in the subject.

[0077] In the example, shown in FIG. 7, the clinical factors include age, a presence or absence of swollen lymph nodes, a body temperature, and a presence or absence of a cough. The set of subject throat image data includes white images and blue images of the subject's throat captured with the image data capture device 120. The disease state prediction includes a probability of a bacterial infection, a probability of a viral infection, and a probability of no infection, as determined by the chained model 150, based on the input vectors. The input vectors and resulting output vectors of the chained model 150 may be different than what is shown in FIG. 7. For example, the input vectors and resulting output vectors may be relevant to the targeted disease. In alternative embodiments, the prediction and disease state may be limited to predicting whether the image corresponds to either a viral infection or an absence of the viral infection. In other embodiments, the prediction and disease state may correspond to a specific class of viral infections (e.g., coronaviruses), or a specific viral infection (e.g., COVID-19).

[0078] FIG. 8 is a flowchart 800 of returning a disease state prediction for subject determined by a chained model 150, according to one embodiment. The disease state prediction indicates a probability of a subject having a disease or medical condition, according to some embodiments. The chained model 150 accesses 810 a set of subject image data associated with the subject. The subject image data depict a part of the subject's body. For example, the subject image data may be an image of the subject's throat. The chained model 150 accesses 820 a set of clinical factors for the subject. The clinical factors are recorded substantially contemporaneously with the capture of the subject images. The subject image data is inputted 830 into the image data model 400 to generate disease metrics. The generated

disease metrics and the clinical factors are then inputted into the classifier 500 to determine the disease state prediction for the subject, and the determined disease state prediction is returned 850.

VI. BENEFITS

[0079] The detection system described herein provides for dry in-situ clinical prediction of the presence/absence of viral pathogen infections (and/or bacterial infections) without the need for any pathological or laboratory tests. The detection system, according to some embodiments, may provide subjects with a home diagnostic tool for COVID-19, streptococcal infection, or other related infections. This may effectively reduce the financial burden for both healthcare providers and subjects, reduce the time necessary to determine an accurate diagnosis, and improve safety for test administrators. Additionally, the detection system may provide accurate predictions for other diseases and conditions.

[0080] In an embodiment, a mobile application provides step-by-step instructions to enable a patient to enter relevant clinical factors and capture a throat image of sufficient quality to enable diagnosis and further training of the image data model 400. For example, the mobile application may include a user interface that begins with a set of questions, asking the patient to input information such as age, gender, race, infection testing history (for COVID-19, streptococcal infection, or other infections), recent health history, tonsillectomy history, recent symptoms (e.g., cough, lost sense of smell, fever, nasal congestion, runny nose, sore throat, etc.), medical conditions (e.g., diabetes, high blood pressure, inflamed tonsils/adenoids, cardiovascular disease, acid reflux, etc.), and smoking history. The user interface then provides guided assistance for capturing a throat image with the integrated camera of the mobile device. For example, the user interface may instruct the user to turn on the flash and provide instructions and/or a diagram illustrating where to position and orient the camera. The user interface may furthermore provide instructions for capturing the image using a mirror and provide diagrams illustrating the specific features of the throat that should be within view. Upon capturing an image, the image may be uploaded and processed. In some instances, the mobile application may automatically evaluate the quality of the image and instruct the patient if a new image should be captured.

VII. EXAMPLE

[0081] The present invention is further illustrated by the following experimental example. This example is provided merely for illustration purposes and shall not be interpreted to limit the scope or content of the present invention in any way.

[0082] This example includes experimental results related to a pharyngeal disease classifier. In this example, a CNN-based classifier was trained with the intent of discriminating COVID-19 diseased pharyngeal images with reference to non-diseased images taken of a subject's mouth/throat.

VII.A. METHODOLOGY

[0083] The scientific goal of the experiment was to develop multiple CNN algorithms that would enable the combined use of high-resolution smartphone images that showed the desired anatomical features from multiple devices in the population embedded with the necessary clinical data. Subjects take one or more images of their mouths/throats with their smartphone and send or otherwise make those images available to the detection system/server. Since these images are taken with a smartphone, they may contain various anomalies, including having certain noise or inconsistency in shape, or may be low resolution. The clinical study trials were conducted in such a manner to obtain the necessary symptoms, demographic and laboratory data, and other clinical factors needed to compare diseased subjects to non-diseased or healthy subjects.

VII.B. TRAINING DATA

[0084] A training dataset comprising 183 images was prepared, one image per patient. Clinical symptoms, medications consumed, and other co-morbidities present at the time of imaging/PCR test were used to determine if these patients met the clinical criteria needed to qualify for selection for the clinical trial.

[0085] The final dataset included 83 images which were healthy (no disease), 100 which were COVID positive based on the results of a polymerase chain reaction (PCR) test. The training dataset was randomly split into a train group and a validation group in the ratio 80/20, respectively.

VII.C. TRAINING APPROACH

[0086] An automated method was applied to the algorithm to identify and focus on target artifacts to help the classifier with feature extractions and define ground truth between the diseased and non-diseased classes. A RESNet-18 CNN architecture pre-trained on 14 million images from ImageNet was used, which enhanced transfer learning to the designed classifier.

VII.D. TRAINING RESULTS

[0087] After 20 epochs of training, the best accuracy on the validation set was close to 95%, and the CNN weights associated with that result were captured and stored.

VII.E. MODEL TESTING AND RESULTS

[0088] A completely new and independent TEST set was constructed for scoring purposes. Images of subjects' mouths/throats in the new TEST set were carefully selected from clinical trials data to ensure no overlap with the previous training or validation sets. The same clinical inclusion and exclusion was criteria applied to the TEST dataset as was applied to the training and validation sets.

[0089] The TEST dataset comprised 97 images, of which 32 were healthy and 65 were known to be COVID positive. The results are summarized below as predicted by the CNN in the confusion matrix:

True Positives = 59,

True Negatives =22,

False Positives =6 and False Negatives= 10

[0090] Using a Disease Diagnostic Sensitivity / Specificity calculator, following results were calculated for the model using independent TEST data assuming a COVID-19 disease prevalence rate in the population of 0.5%.

Results

Statistic	Value	95% CI
Sensitivity	85.51%	74.96% to 92.83%
Specificity	78.57%	59.05% to 91.70%
Positive Likelihood Ratio	3.99	1.95 to 8.16
Negative Likelihood Ratio	0.18	0.10 to 0.34
Disease prevalence (*)	5.00%	
Positive Predictive Value (*)	17.36%	9.31% to 30.06%
Negative Predictive Value (*)	99.04%	98.25% to 99.17%
Accuracy (*)	78.92%	69.46% to 86.54%

VII.F. CONCLUSIONS

[0091] The system generally uses the Sensitivity, Specificity and Accuracy as metrics for comparison across different CNN diagnostic classifier algorithms.

[0092] The Sensitivity indicates the probability that the model's prediction will be positive when COVID-19 disease is present with 85.51 % with a confidence interval (CI) ranging from 74.96% to 92.83%. This is also known as the True Positive Rate.

[0093] The Specificity indicates the probability that the model's prediction will be negative when COVID-19 disease is absent with 78.57 % with a confidence interval (CI) ranging from 59.05% to 91.7%. This is also known as the True Negative Rate.

[0094] Accuracy is overall probability that a subject is correctly predicted with compensation for disease prevalence as given in the formula: $\text{Accuracy} = \text{Sensitivity} \times \text{Prevalence} + \text{Specificity} \times (1 - \text{Prevalence})$ where COVID-19 prevalence is assumed to be 5%. In the independent TEST set, the model was able to classify true positives and true negatives with an accuracy of 78.92% within a CI of 69.46% to 86.54%. This is indicative that the model is performing well and able to generalize its classification across novel images and patient data that is obtained from the population at large.

[0095] As a rule of thumb, CI with narrower margins and closer to 100% indicates statistical confidence that the model scores and that the results could not have occurred by chance or biased sampling.

[0096] It has also been possible to achieve better Sensitivity and Specificity results with larger and properly curated clinical data sets.

[0097] Positive Likelihood Ratio is defined as True positive rate / False positive rate and is indicative that the odds ratio of a patient having the disease given a COVID-19 positive

prediction.

[0098] Negative Likelihood Ratio is defined as the False negative rate / True negative rate and is indicative that the odds ratio of a patient having the disease given a healthy prediction.

[0099] Positive predictive value is the probability that COVID-19 disease is present when the test is positive.

[00100] Negative predictive value is the probability that COVID-19 disease is not present when the test is negative.

VIII. ADDITIONAL CONSIDERATIONS

[00101] Although the discussion above includes examples focusing on pharyngitis and strep throat specifically, all systems and processes described herein are equally applicable to other conditions.

[00102] It is to be understood that the figures and descriptions of the present disclosure have been simplified to illustrate elements that are relevant for a clear understanding of the present disclosure, while eliminating, for the purpose of clarity, many other elements found in a typical system. Those of ordinary skill in the art may recognize that other elements and/or steps are desirable and/or required in implementing the present disclosure. However, because such elements and steps are well known in the art, and because they do not facilitate a better understanding of the present disclosure, a discussion of such elements and steps is not provided herein. The disclosure herein is directed to all such variations and modifications to such elements and methods known to those skilled in the art.

[00103] Some portions of above description describe the embodiments in terms of algorithms and symbolic representations of operations on information. These algorithmic descriptions and representations are commonly used by those skilled in the data processing arts to convey the substance of their work effectively to others skilled in the art. These operations, while described functionally, computationally, or logically, are understood to be implemented by computer programs or equivalent electrical circuits, microcode, or the like. Furthermore, it has also proven convenient at times, to refer to these arrangements of operations as modules, without loss of generality. The described operations and their associated modules may be embodied in software, firmware, hardware, or any combinations thereof.

[00104] As used herein any reference to “one embodiment” or “an embodiment” means that a particular element, feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. The appearances of the phrase “in one embodiment” in various places in the specification are not necessarily all referring to the same embodiment.

[00105] As used herein, the terms “comprises,” “comprising,” “includes,” “including,” “has,” “having” or any other variation thereof, are intended to cover a non-exclusive inclusion. For example, a process, method, article, or apparatus that comprises a list of elements is not necessarily limited to only those elements but may include other elements not expressly listed or inherent to such process, method, article, or apparatus. Further, unless expressly stated to the contrary, “or” refers to an inclusive or and not to an exclusive or. For example, a condition A or B is satisfied by any one of the following: A is true (or present) and B is false (or not present), A is false (or not present) and B is true (or present), and both A and B are true (or present).

[00106] In addition, use of the “a” or “an” are employed to describe elements and components of the embodiments herein. This is done merely for convenience and to give a general sense of the invention. This description should be read to include one or at least one and the singular also includes the plural unless it is obvious that it is meant otherwise.

[00107] While particular embodiments and applications have been illustrated and described, it is to be understood that the disclosed embodiments are not limited to the precise construction and components disclosed herein. Various modifications, changes and variations, which will be apparent to those skilled in the art, may be made in the arrangement, operation and details of the method and apparatus disclosed herein without departing from the spirit and scope of the ideas described herein.

What is claimed is:

1. A method comprising:

accessing a set of subject throat image data from a subject capturing an inside of the subject's throat;
accessing a set of clinical factors from the subject, the clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the subject throat image data;
inputting the subject throat image data into an image data model to generate a prediction regarding at least a viral pathogen presence prediction for the subject;
inputting the viral pathogen presence prediction and the clinical factors into a classifier to determine a disease state prediction; and
returning the disease state prediction.

2. The method of claim 1, wherein the image data model comprises:

a set of image data parameter coefficients trained using a first set of training throat image data and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
a viral label indicating a presence of a viral pathogen,
a bacterial label indicating a presence of a bacterial pathogen, and
a clear label indicating an absence of pathogens; and
a function relating one of the throat image data and the image data parameter coefficients to the pathogen presence prediction.

3. The method of claim 1, wherein the classifier comprises:

a set of classifier parameter coefficients trained using a set of training pathogen presence predictions, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,
the second set of training labels comprising:
a viral label indicating a presence of a viral pathogen,
a bacterial label indicating a presence of a bacterial pathogen, and
a clear subset indicating an absence of pathogens,

the set of training pathogen presence predictions generated by inputting a second set of training throat image data corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training throat image data, and

a function relating the pathogen presence predictions, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

4. The method of claim 1, wherein the set of training throat image data were captured using the same image capture device used to capture the set of subject throat image data.
5. The method of claim 4, wherein the set of training throat image data and the set of subject throat image data each comprise
 - a plurality of throat image data captured under ambient light conditions,
 - a plurality of throat image data captured under fluorescent light, and
 - a plurality of throat image data captured under white light illumination.
6. The method of claim 1, wherein the set of subject throat image data is recorded with an image capture device comprising:
 - a housing;
 - a light emitter configured to emit excitation light at a wavelength selected to elicit auto-fluorescence of a pathogen;
 - a light sensor configured to detect light emissions or an absence of light emissions resulting from the auto-fluorescence of the pathogen; and
 - a display.
7. The method of claim 6, wherein the disease state prediction is displayed on the display of the image capture device.

8. The method of claim 1, wherein the set of subject throat image data is recorded by a mobile phone device.
9. The method of claim 8, wherein the disease state prediction is displayed on the mobile phone device.
10. The method of claim 1, wherein the set of subject throat image data comprises at least one blue throat image captured using a blue light emitter; and and at least one white throat image captured using a white light emitter.
11. The method of claim 1, wherein the subject throat image data captures data regarding multiple wavelengths of light.
12. The method of claim 1, wherein at least one of the subject throat image data captures infrared light image data.
13. The method of claim 1, wherein the set of subject throat image data are pre-processed before being input into the image data model, the pre-processing comprising at least one from the group consisting of:
 - uniform aspect ratio correction,
 - rescaling,
 - normalization,
 - object detection,
 - segmentation,
 - cropping,
 - dimensionality reduction,
 - dimensionality increment,
 - brightness adjustment,
 - image shifting,
 - image flipping,
 - zoom in or out,

image rotation,
image quality filtering, and
image pixel correction.

14. The method of claim 1, wherein the image data model is a convolutional neural network (CNN).

15. The method of claim 1, wherein the classifier is trained using one of: linear regression, logistic regression, multinomial regression, elastic net regression.

16. The method of claim 1, wherein the classifier is one of a random forest classifier, a gradient boosted classifier, a support vector machine classifier, and a Naïve Bayes classifier.

17. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:

a probability of a presence of a viral pathogen,
a probability of a presence of a bacterial pathogen, and
a probability of an absence of a pathogen.

18. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:

a probability of a presence of exudate,
a probability of a presence of petechiae,
a probability of a presence of swollen tonsils, and
a probability of a presence of a swollen uvula.

19. The method of claim 1, the disease state prediction comprises at least one of:

a probability of viral pathogen infection,
a probability of bacterial pathogen infection, and
a probability of no pathogen infection.

20. The method of claim 1, wherein the set of clinical factors comprises at least one from the group consisting of:

- age,
- a presence or absence of swollen lymph nodes,
- subject temperature,
- a presence or absence of a fever, and
- a presence or absence of a cough.

21. The method of claim 1, wherein the set of clinical factors comprises at least one from the group consisting of:

- age,
- a presence or absence of swollen lymph nodes,
- subject temperature,
- a presence or absence of fever
- a presence or absence of a cough,
- a presence or absence of a runny nose,
- a presence or absence of a headache,
- a presence or absence of body aches,
- a presence or absence of vomiting,
- a presence or absence of diarrhea,
- a presence or absence of fatigue,
- a presence or absence of chills, and
- a duration of pharyngitis.

22. The method of claim 1, wherein the image data model comprises:

- a set of image data parameter coefficients trained using a first set of training throat image data and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
 - a viral label indicating a presence of a viral pathogen, and
 - a clear label indicating an absence of pathogens; and

a function relating one of the throat image data and the image data parameter coefficients to the pathogen presence prediction.

23. The method of claim 1, wherein the image data model comprises:
a set of image data parameter coefficients trained using a first set of training throat image data and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
a viral label indicating a presence of a coronavirus pathogen, and
a clear label indicating an absence of the coronavirus pathogen; and
a function relating one of the throat image data and the image data parameter coefficients to the pathogen presence prediction.
24. The method of claim 1, wherein the image data model comprises:
a set of image data parameter coefficients trained using a first set of training throat image data and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
a viral label indicating a presence of a COVID-19 infection, and
a clear label indicating an absence of the COVID-19 infection; and
a function relating one of the throat image data and the image data parameter coefficients to the infection presence prediction.
25. The method of claim 1, wherein the classifier comprises:
a set of classifier parameter coefficients trained using a set of training pathogen presence predictions, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,
the second set of training labels comprising:
a viral label indicating a presence of a viral pathogen, and
a clear subset indicating an absence of pathogens,
the set of training pathogen presence predictions generated by inputting a second set of training throat image data corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training throat image data, and
a function relating the pathogen presence predictions, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

26. The method of claim 1, wherein the classifier comprises:

a set of classifier parameter coefficients trained using a set of training pathogen presence predictions, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,

the second set of training labels comprising:

a viral label indicating a presence of a coronavirus pathogen, and

a clear subset indicating an absence of the coronavirus pathogens,

the set of training pathogen presence predictions generated by inputting a second set of training throat image data corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training throat image data, and

a function relating the pathogen presence predictions, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

27. The method of claim 1, wherein the classifier comprises:

a set of classifier parameter coefficients trained using a set of training pathogen presence predictions, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,

the second set of training labels comprising:

a viral label indicating a presence of a COVID-19 infection, and

a clear subset indicating an absence of the COVID-19 infection,

the set of training pathogen presence predictions generated by inputting a second set of training throat image data corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training throat image data, and

a function relating the pathogen presence predictions, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

28. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:

a probability of a presence of a viral pathogen, and
a probability of an absence of the viral pathogen.

29. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:

a probability of a presence of a coronavirus pathogen, and
a probability of an absence of the coronavirus pathogen.

30. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:

a probability of a presence of a COVID-19 infection, and
a probability of an absence of the COVID-19 infection.

31. The method of claim 1, wherein the disease state prediction comprises at least one of:

a probability of a presence of a viral pathogen, and
a probability of an absence of the viral pathogen.

32. The method of claim 1, wherein the disease state prediction comprises at least one of:

a probability of a presence of a coronavirus pathogen, and

a probability of an absence of the coronavirus pathogen.

33. The method of claim 1, wherein the disease state prediction comprises at least one of:
a probability of a presence of a COVID-19 infection, and
a probability of an absence of the COVID-19 infection.
34. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:
a probability of a symptoms of a coronavirus infection.
35. The method of claim 1, wherein the pathogen presence prediction comprises at least one of:
a probability of a symptoms of a COVID-19 infection.
36. The method of claim 1, wherein the set of clinical factors comprises at least one symptom associated with a coronavirus presence.
37. The method of claim 1, wherein the set of clinical factors comprises at least one symptom associated with a COVID-19 infection.
38. A computer system comprising a computer processor and a memory, the memory storing computer program instructions that when executed by the computer processor cause the processor to perform any of the methods of claims 1-37.
39. A non-transitory computer readable storage medium comprising computer program instructions that when executed by a computer processor cause the processor to perform any of the methods of claims 1-37.
40. A method comprising:
accessing a set of subject images, the subject images capturing a part of a subject's body;

accessing a set of clinical factors from the subject, the clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the subject images;

inputting the subject images into an image data model to generate disease metrics for disease prediction for the subject;

inputting the disease metrics and the clinical factors into a classifier to determine a disease state prediction, the disease state prediction relating to a disease or medical condition; and

returning the disease state prediction.

41. The method of claim 40, wherein the disease metrics comprise:
feature metrics corresponding to identified features in the subject image, and
infection metrics corresponding to a presence of a bacterial or viral infection in the part of the subject's body.
42. The method of claim 40, wherein the disease metrics comprise:
feature metrics corresponding to identified features in the subject image, and
infection metrics corresponding to a presence of a coronavirus infection in the part of the subject's body.
43. The method of claim 40, wherein the disease metrics comprise:
feature metrics corresponding to identified features in the subject image, and
infection metrics corresponding to a presence of a COVID-19 infection in the part of the subject's body.
44. The method of claim 40, wherein the image data model comprises:
a set of image data parameter coefficients trained using a first set of training subject images and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
a viral label indicating a presence of a viral pathogen,
a bacterial label indicating a presence of a bacterial pathogen, and

a clear label indicating an absence of pathogens; and
a function relating one of the subject images and the image data parameter coefficients to the disease metrics.

45. The method of claim 40, wherein the image data model comprises:
a set of image data parameter coefficients trained using a first set of training subject images and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
a viral label indicating a presence of a coronavirus pathogen,
a clear label indicating an absence of the coronavirus pathogens; and
a function relating one of the subject images and the image data parameter coefficients to the disease metrics.
46. The method of claim 40, wherein the image data model comprises:
a set of image data parameter coefficients trained using a first set of training subject images and a first set of training labels, each corresponding to a first set of training subjects, the first set of training labels comprising:
a viral label indicating a presence of a COVID-19 infection,
a clear label indicating an absence of the COVID-19 infection; and
a function relating one of the subject images and the image data parameter coefficients to the disease metrics.
47. The method of claim 40, wherein the classifier comprises:
a set of classifier parameter coefficients trained using a set of training disease metrics, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,
the second set of training labels comprising:
a viral label indicating a presence of a viral pathogen,
a bacterial label indicating a presence of a bacterial pathogen, and
a clear subset indicating an absence of pathogens,

the set of training disease metrics generated by inputting a second set of training subject images corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training subject images, and

a function relating the disease metrics, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

48. The method of claim 40, wherein the classifier comprises:

a set of classifier parameter coefficients trained using a set of training disease metrics, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,

the second set of training labels comprising:

a viral label indicating a presence of a coronavirus pathogen,

a clear subset indicating an absence of the coronavirus pathogen,

the set of training disease metrics generated by inputting a second set of training subject images corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training subject images, and

a function relating the disease metrics, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

49. The method of claim 40, wherein the classifier comprises:

a set of classifier parameter coefficients trained using a set of training disease metrics, a set of training clinical factors, and a second set of training labels, each corresponding to a second set of training subjects,

the second set of training labels comprising:

a viral label indicating a presence of a COVID-19 infection,

a clear subset indicating an absence of the COVID-19 infection,

the set of training disease metrics generated by inputting a second set of training subject images corresponding to the second set of subjects into the image data model;

the set of training clinical factors collected by a device or a medical practitioner substantially contemporaneously with the capture of the second set of training subject images, and

a function relating the disease metrics, the clinical factors, and the classifier parameter coefficients to the disease state prediction.

50. A method for generating a machine-learned model for predicting viral infections, comprising:

obtaining a plurality of throat image data including a set of positive images depicting throats with a viral infection and a set of negative images depicting healthy throats;

obtaining labels for each of the plurality of throat image data to label the throat image data as positive or negative;

extracting features from the plurality of throat image data;

applying a machine learning model to learn a mapping between the features and the labels; and

outputting the machine-learned model.

51. The method of claim 50 wherein the viral infection comprises a coronavirus infection.

52. The method of claim 50, wherein the viral infection comprises a COVID-19 infection.

53. A non-transitory computer-readable storage medium storing instructions for predicting viral infections, the instructions when executed by a processor causing the processor to perform any of the methods of claims 50-52.

54. A computer system comprising:

a processor; and

a non-transitory computer-readable storage medium storing instructions for predicting viral infections, the instructions when executed by a processor causing the processor to perform any of the methods of claims 50-52.

55. A non-transitory computer-readable storage medium storing a machine-learned model, the machine-learned model generated according to a process of any one of claims 50-52.

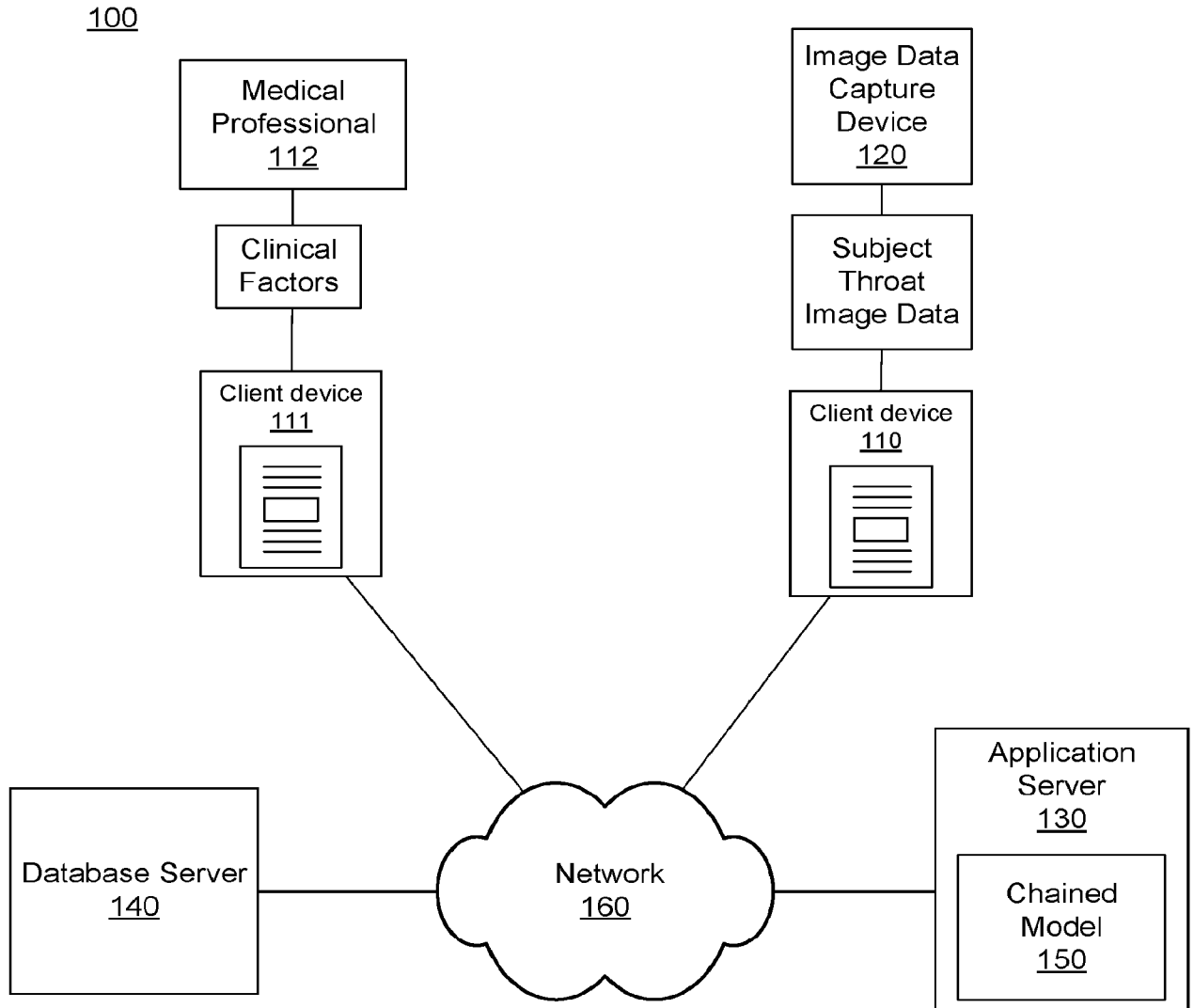


FIG. 1

Detection System
100

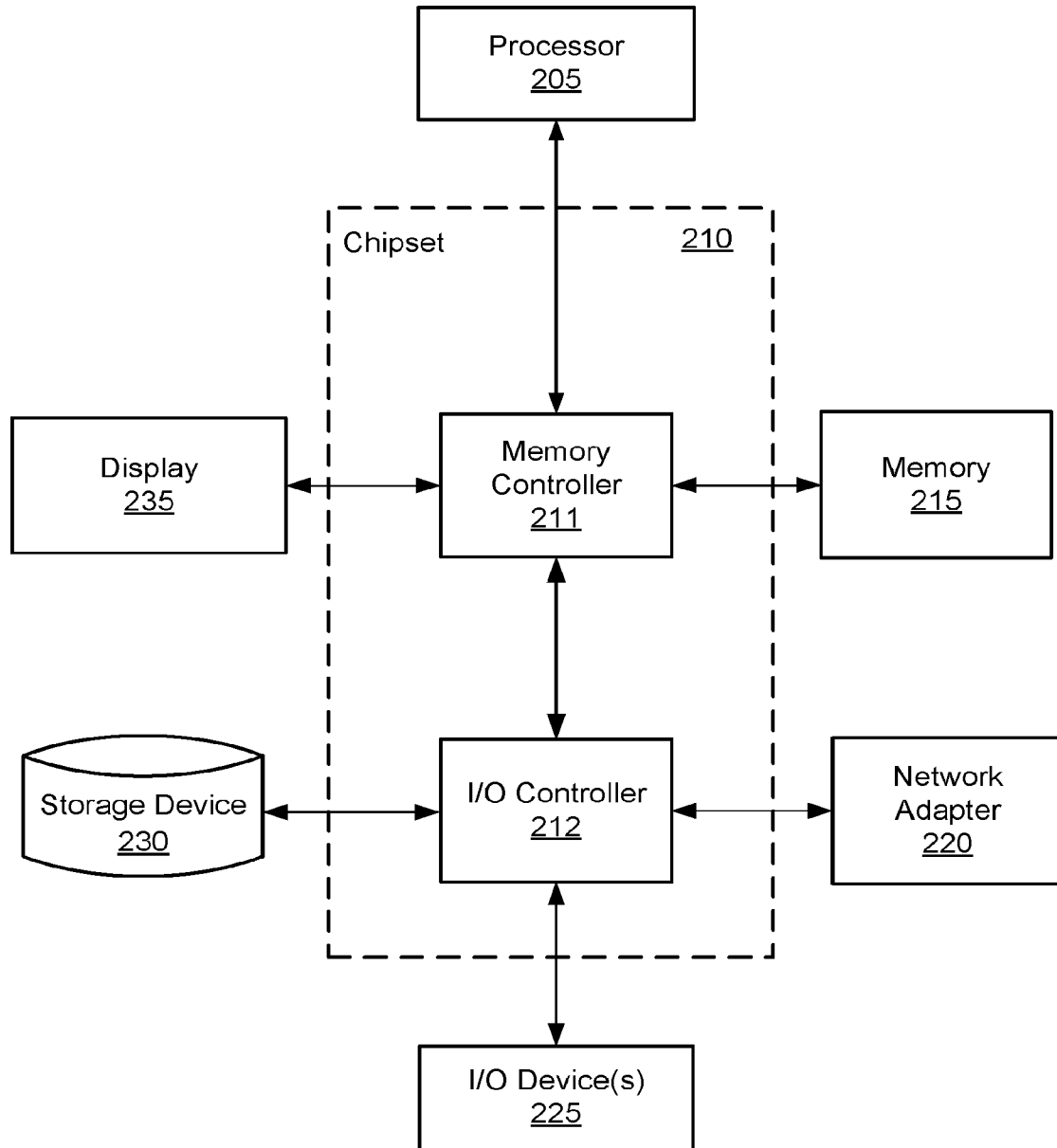


FIG. 2

200

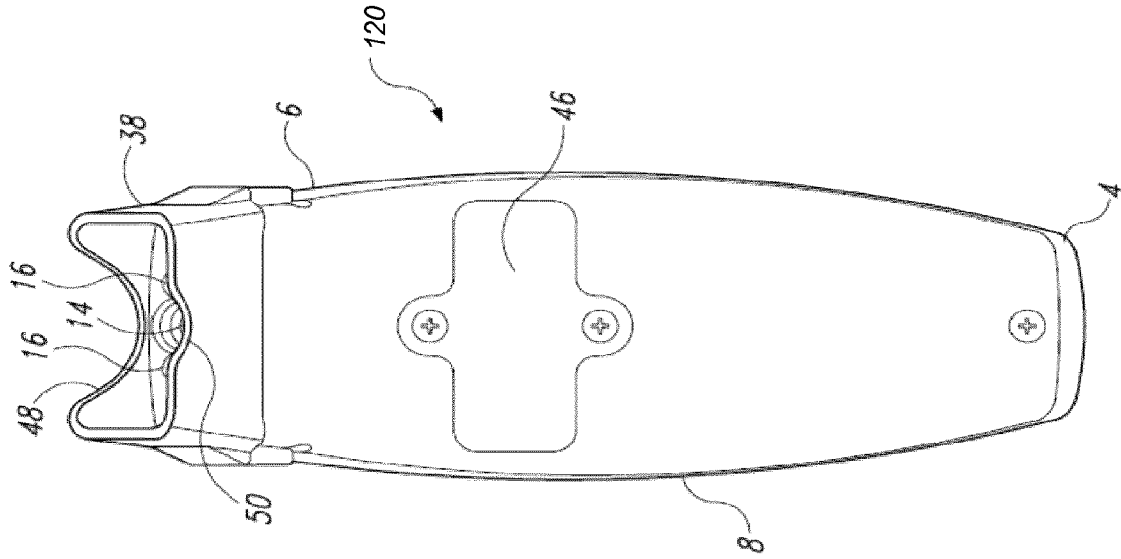


FIG. 3C

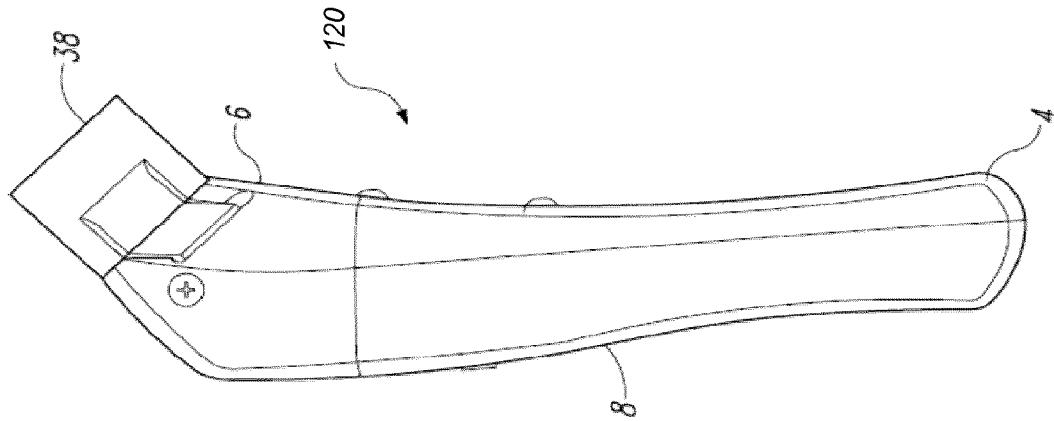


FIG. 3B

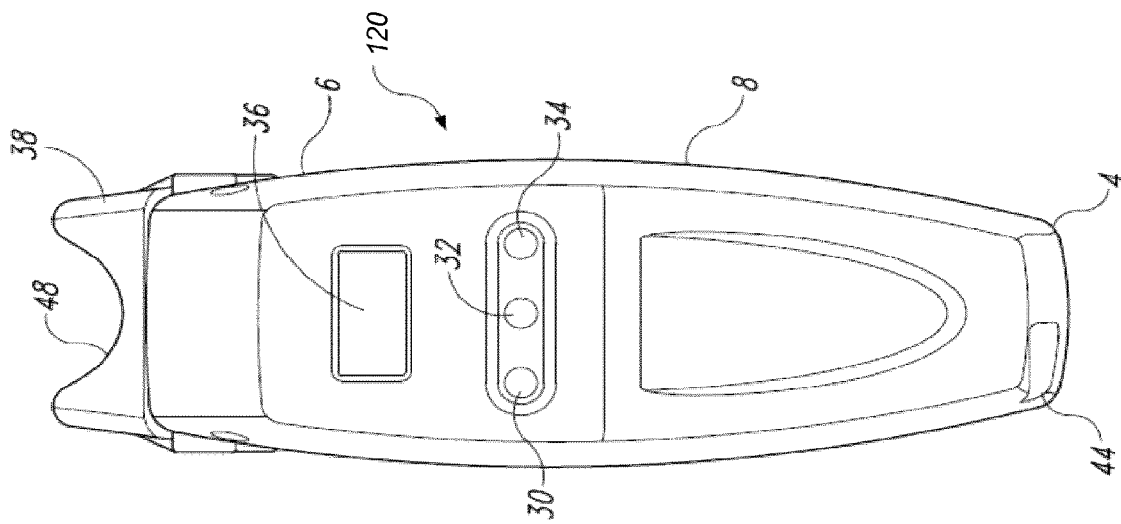


FIG. 3A

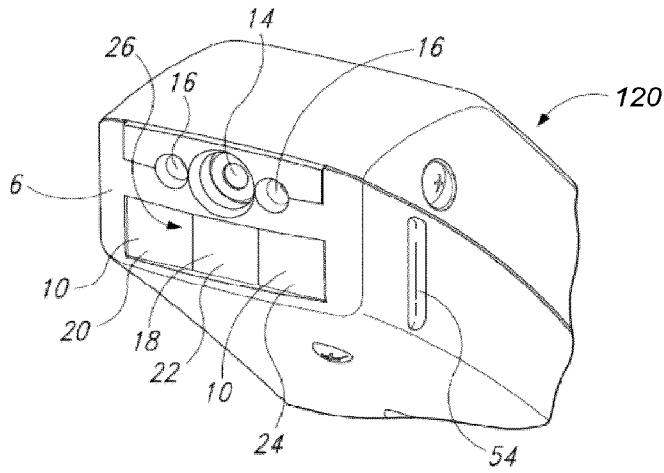


FIG. 3D

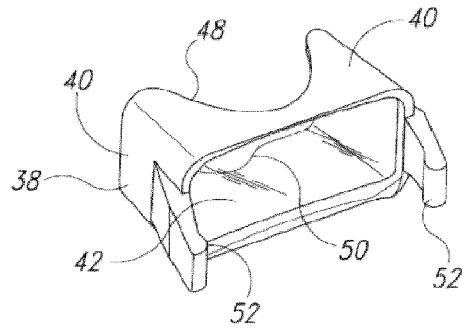


FIG. 3E

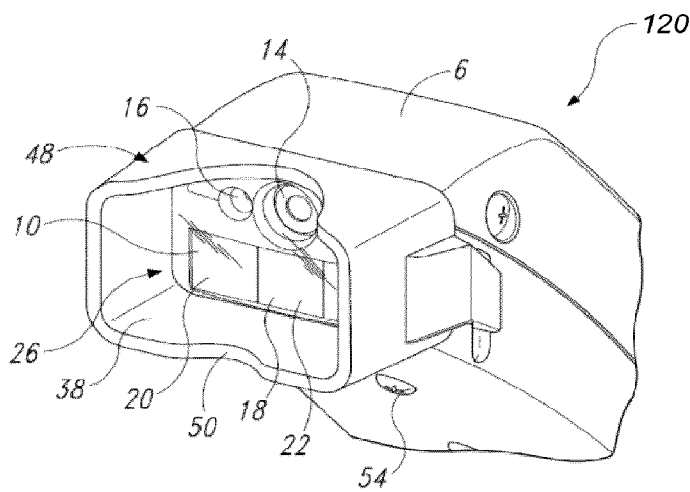


FIG. 3F

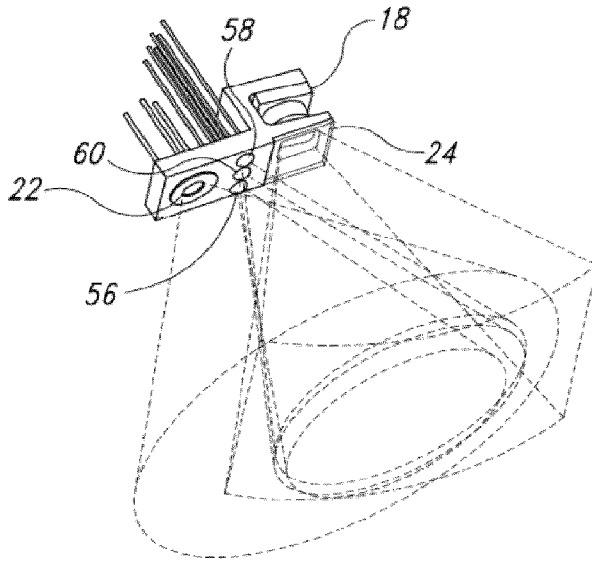


FIG. 3G

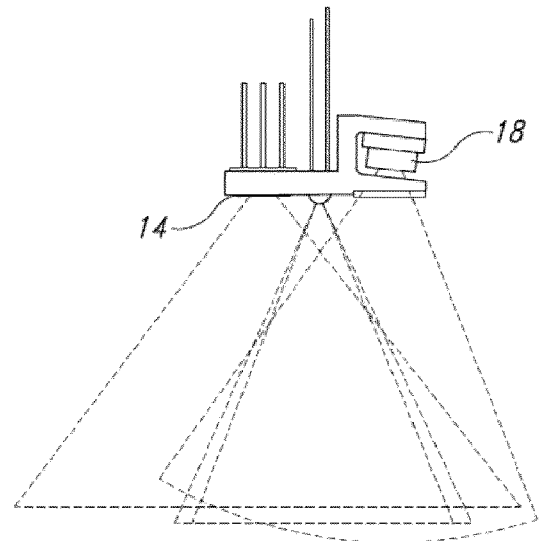


FIG. 3H

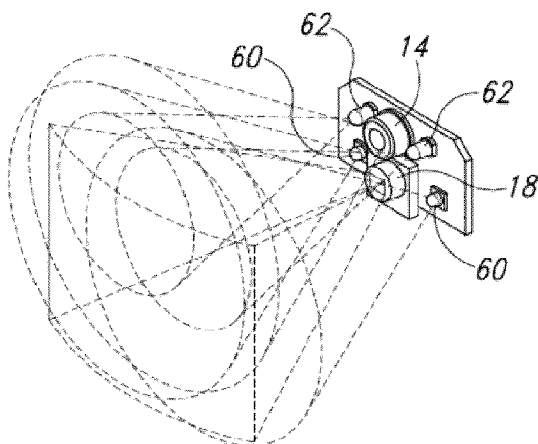


FIG. 3I

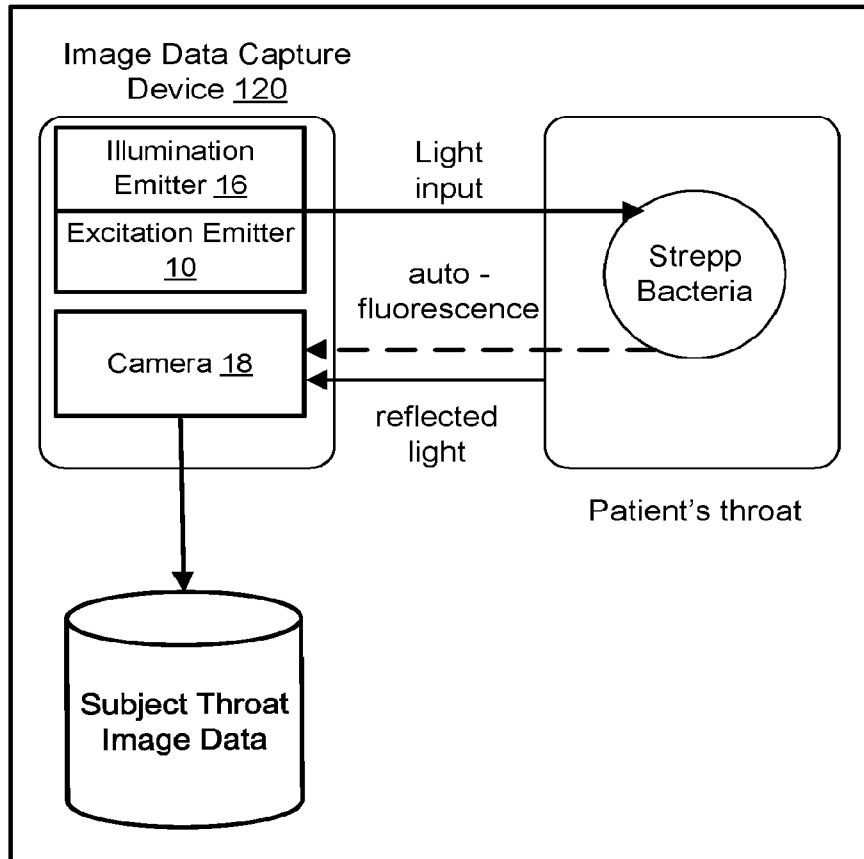


FIG. 3J

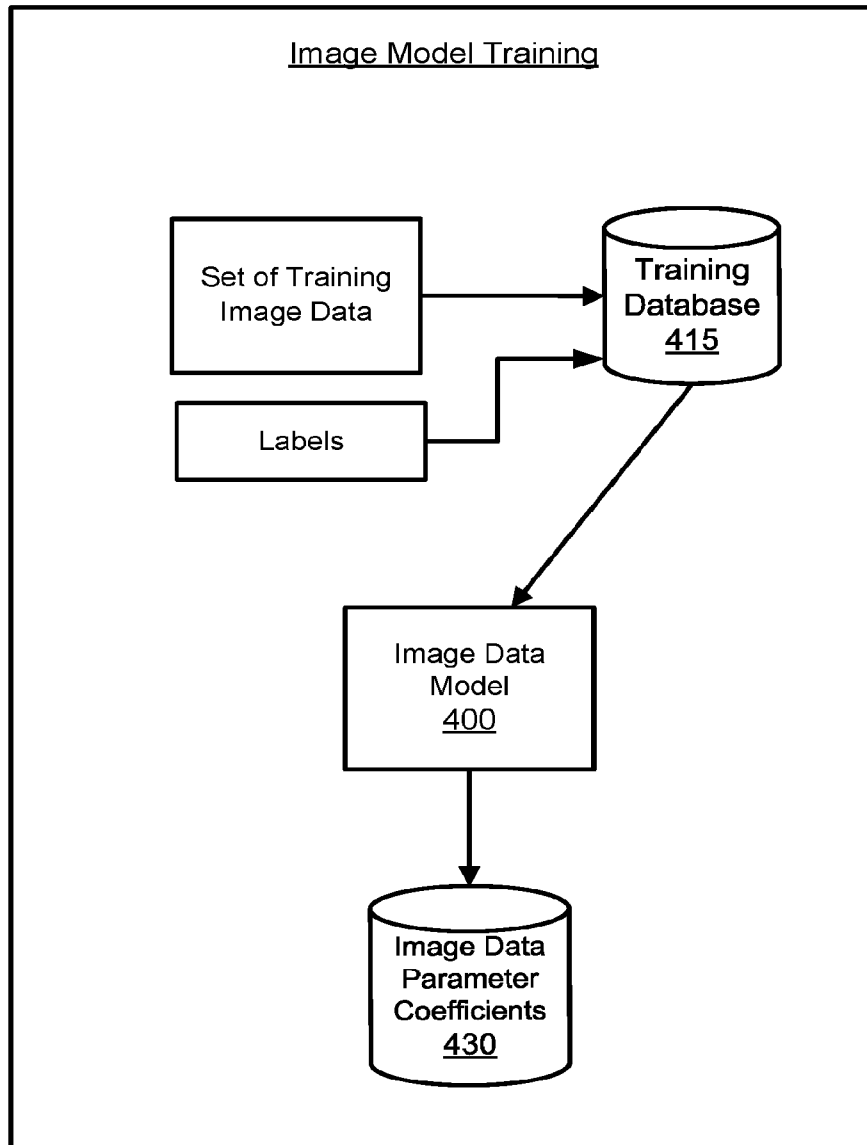


FIG. 4

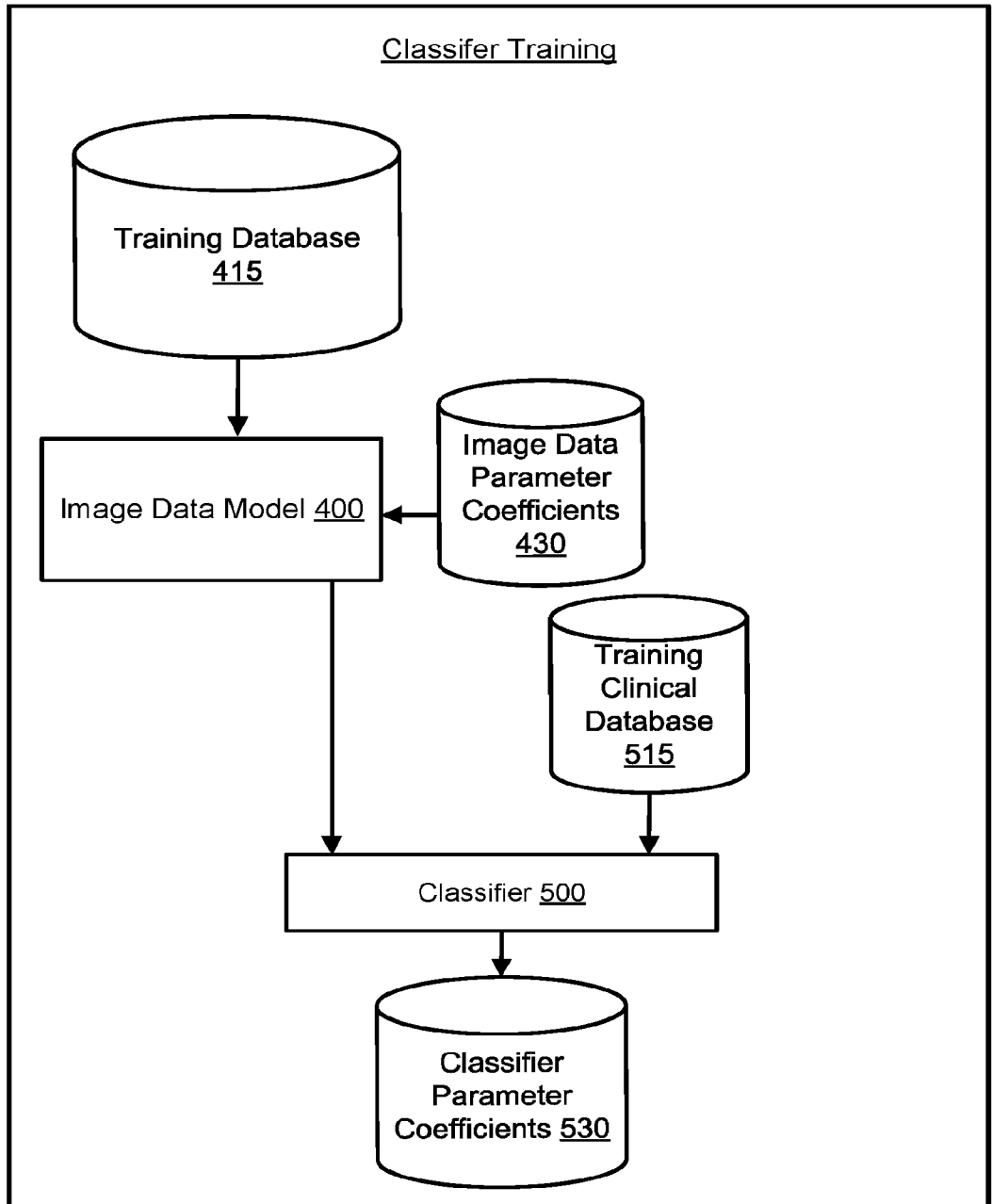


FIG. 5

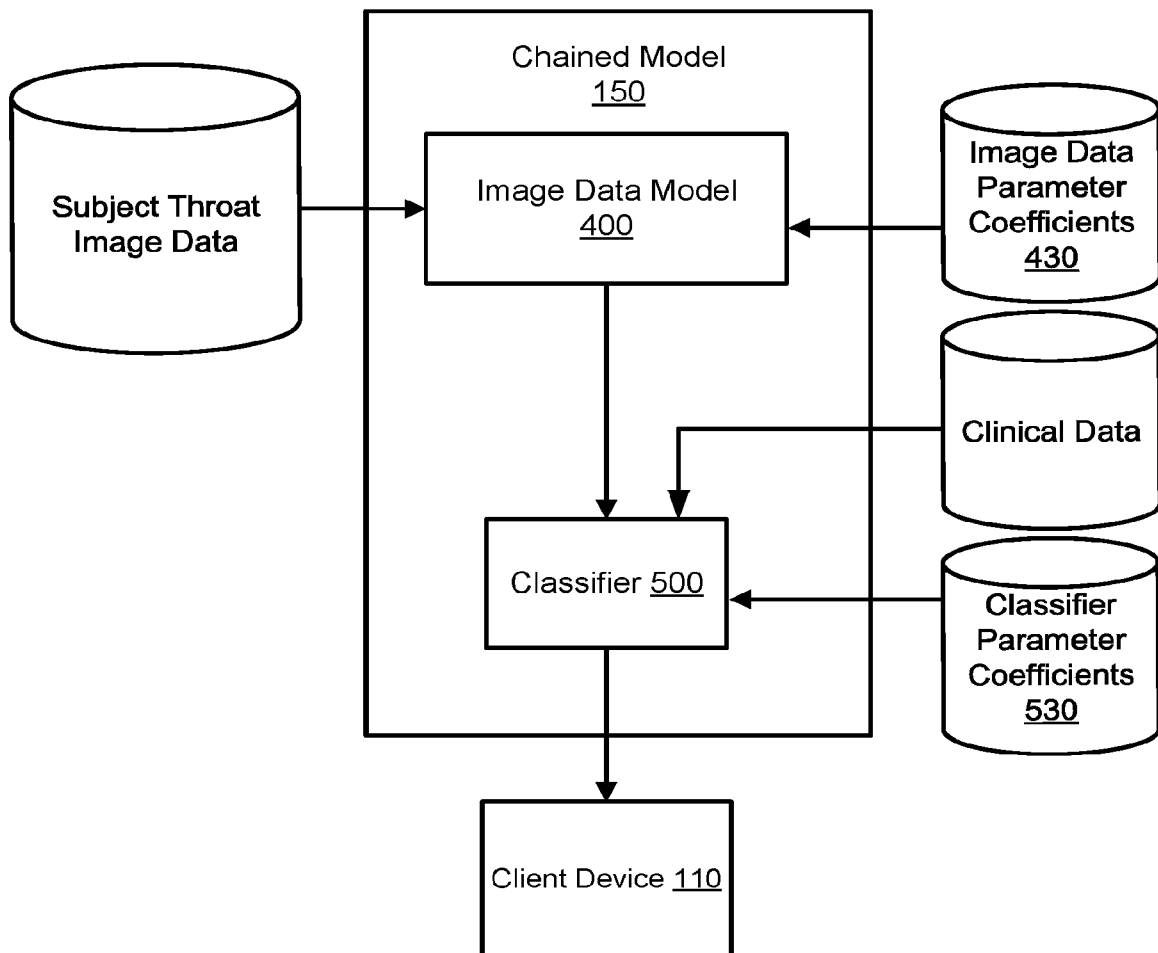


FIG. 6

Output

Inputs

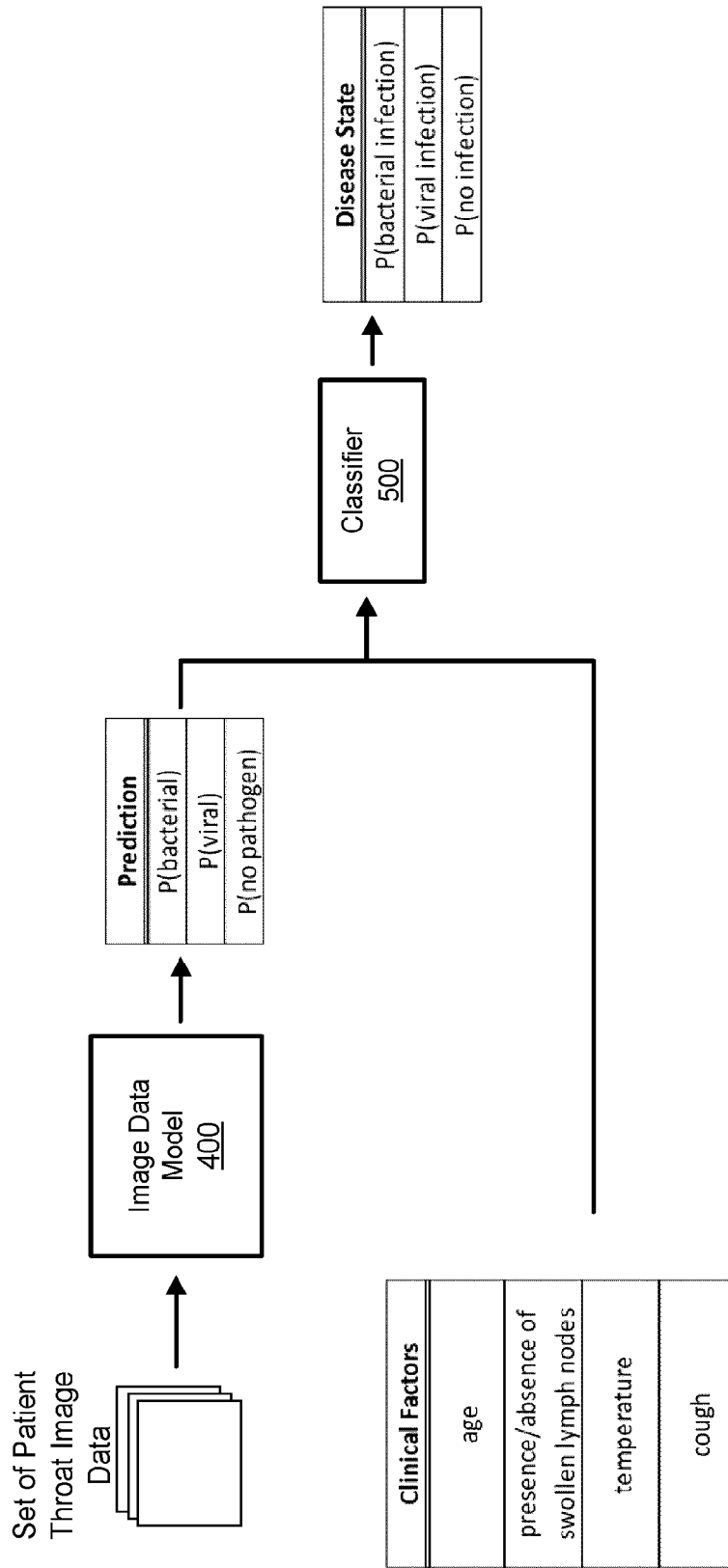
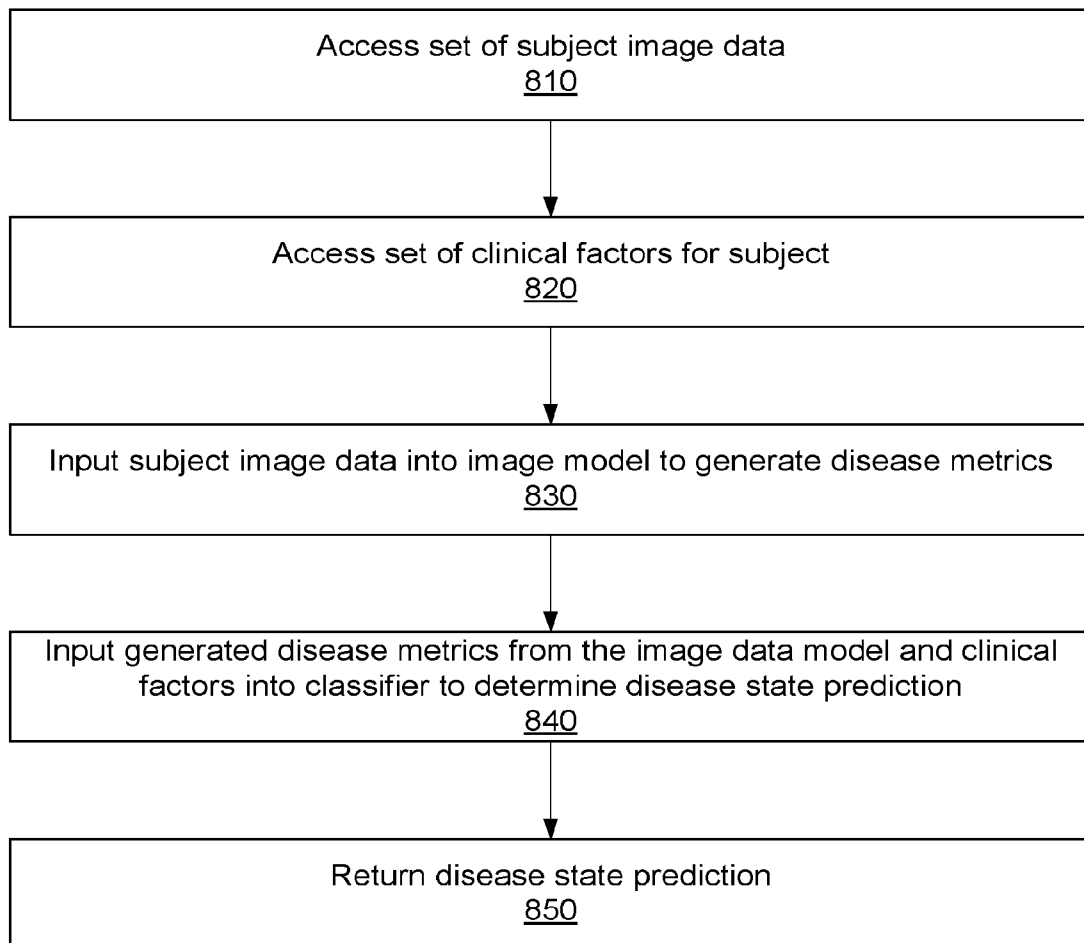


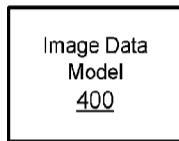
FIG. 7

800**FIG. 8**

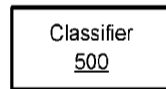
Inputs

Output

Set of Patient
Throat Image
Data



Prediction
P(bacterial)
P(viral)
P(no pathogen)



Disease State
P(bacterial infection)
P(viral infection)
P(no infection)

Clinical Factors
age
presence/absence of swollen lymph nodes
temperature
cough

FIG. 7