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(54) MULTI-MODAL IMAGING SYSTEM AND WORKSTATION WITH SUPPORT FOR STRUCTURED HYPOTHESIS TESTING

MULTIMODALES ABBILDUNGSSYSTEM UND ARBEITSSTATION MIT UNTERSTÜTZUNG FÜR STRUKTURIERTE ÜBERPRÜFUNGEN VON HYPOTHESEN

SYSTÈME D'IMAGERIE MULTIMODAL ET POSTE DE TRAVAIL DOTÉ D'UN SUPPORT POUR LE TEST STRUCTURÉ D'HYPOTHÈSES

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Description

[0001] The present application relates to the in-vivo imaging arts. It finds particular application with workflow and software processing in connection with small animal imaging in a research environment, and will be described with particular reference thereto. It is to be appreciated that the present application also finds use in other clinical and research settings, such as research with human subjects.

[0002] Presently available imaging scanners are not equipped with standardized equipment and techniques that support automated and scientifically rigorous workflow suited to the testing of medical hypotheses. Pre-clinical imaging helps to bridge the gap between medical treatment ideas that have not yet been proven reliable and application in human treatment. Pre-clinical animal imaging research can be used to define the conditions and end points for clinical trials. Specifically, pre-clinical in-vivo small animal imaging provides the capability to visualize and quantify metabolic activity, cell proliferation, apoptosis, receptor status and immunoreactions, angiogenesis, and hypoxia, among other relevant biological processes. This is done by indirectly measuring gene expression, enzyme activity, receptors and transporters, and regional concentrations of molecules through a variety of means, most commonly using emission imaging techniques with radio-labeled tracers.

[0003] This research is characterized by curiosity and/or by hypothesis driven programs often supported by grants to either discover or explore new insights into biological processes. As such, device characteristics such as sensitivity and spatial resolution are at a premium, particularly when viewed against a continual need to visualize smaller and smaller structures and processes. Additionally, the need for quantification of these processes increases as the research moves from describing systems to measuring systems. This work is primarily conducted in academic medical centers. As such, the knowledge of the community advances through literature, conferences, and symposia. Typically, small scale applications are also pursued for promising research findings. Success criteria include the ability to clearly and effectively demonstrate and expand understanding, whether it results in direct commercial activity or not.

[0004] A more specific expression of biological research is the systematic discovery and development of biomarkers, drugs, and therapies that will ultimately be translated from animal models to humans should they prove promising during pre-clinical studies. Distinguishing this area from the more varied general biological area is the need to follow standardized, calibrated processes capable of supporting rigorous regulatory filings. As such, this work is typically (though not exclusively) conducted in commercial pharmaceutical companies and/or instrumentation companies as they seek to discover, develop, and ultimately commercialize drugs and therapies for economic return rather than only build the general knowl-

edge into the processes.

[0005] Quantification is important for reliable evaluation of the acquired data. Without the information on tracer concentration in physical, absolute units, different tracers cannot be compared with each other in an objective manner in the context of tracer development. Also, the quality of diagnostic information extracted from the acquired images depends crucially on the quantifiability of the data. Especially from small animal imaging, a variety of considerations such as, for example, partial volume effects play an important role and should be corrected in order to obtain meaningful concentration values. These effects may be mitigated with single-imaging mode design and/or corrections, or through using complementary modality data such as (but not limited to) anatomical information from a CT scan, which can be helpful in this context.

[0006] Quantification is valuable in the marketplace. Software tools dealing with partial volume and motion correction, and the like are available, and valuable for reliable quantification. Animal imaging plays an important role in the process of tracer development and validation by reducing the amount of time and effort that has to be spent for evaluating tracer properties. With in-vivo imaging, it is possible to perform a serial analysis of the same animal over a period of time and thus study, for example, the biodistribution of the tracer over a long time span. Without imaging, the same study would involve many animals, which would have to be sacrificed at various time points to measure the tracer distribution with in-vitro methods. Moreover, by applying such techniques as pharmacokinetic modeling, it is possible to assess multiple biological parameters at once in one imaging procedure.

[0007] Pharmacokinetic modeling of pharmacodynamics allows the simultaneous assessment of multiple biological and molecular parameters at once. Since the distribution of the tracer in the animal over the course of time is a dynamic process, static imaging only contains limited information compared to the analysis of dynamic sequences, which provides access to the rate constants governing the kinetic processes.

[0008] Pre-clinical applications to support this activity can be summarized as providing users the capability to perform studies of varying scope, each level highlighting requirements or focus areas for the device;

A snapshot measurement on a single subject, e.g., uptake;

Time activity during 1-5 half lives of the radio labeled marker;

A longitudinal study of a single subject across multiple imaging sessions;

A group study with multiple subjects in the same laboratory; and

Population analysis across multiple distributed studies and/or methodologies.

[0009] The levels apply most directly to the discovery and development processes for drugs and biomarkers.

Software applications implementing these study types is important because doing so facilitates standardization leading to higher quality, more reproducible studies that replace time consuming and error prone manual methods or custom programming that is particularly difficult given the data volume associated with this work. Important standardization should be driven by the instrumentation rather than relying on individual principal investigators.

[0010] The present application provides a new and improved small animal handling, imaging, and research data analysis technique that overcomes the above-referenced problems and others.

[0011] Document US 657 430 7 discloses the preamble of independent claim 1.

[0012] The invention is set out in claim 1.

[0013] In accordance with one aspect, an in-vivo imaging system is provided. At least one imaging modality for acquiring in-vivo imaging data of a subject in an imaging region of the imaging device. A reconstruction processor reconstructs raw data into an image representation. A preparation module provides space where subjects are prepared for imaging in the imaging modality. A research workstation provides a user with an electronic interface to the imaging modality.

[0014] In accordance with another aspect, a method of in-vivo imaging is provided. A study is designed for execution on an in-vivo imaging system. Desired data mining and computational bioinformatics activities are selected complement the imaging study. Imaging data is acquired and processed. The processed imaging data is quantified. A statistical analysis is performed on the processed imaging data and/or with results from the computational activities. Then, the statistical analysis is reported in a form that the user chooses.

[0015] In accordance with another aspect, a research workstation for designing an in-vivo imaging study is provided. The workstation includes a study design portal for creating and defining the study. A user can select data pertinent to the study from resources to which the workstation has access at a data mining portal. The user can select available tools from image acquisition, reconstruction, and/or image processing portals. The user can select available tools from a pre-defined set of tools and clinical packages at a quantification portal.

[0016] The user can select at least one of a pre-defined post processing analysis and an ad-hoc post processing analysis at a statistical analysis portal. A reporting portal allows a user to customize a data reporting method.

[0017] In accordance with another aspect, a method of designing a study is provided. A hypothesis capable of being tested in an in-vivo imaging environment is formulated by a user. A study design workflow routine is initiated on a workstation computer. A relationship between imaging and computational methods is specified. Parameters of the study are specified. When the study is designed, a confidence level in the study design is obtained by requesting construction of a model of likely results of the study.

[0018] One advantage lies in improved reproducibility of studies.

[0019] Another advantage lies in greater flexibility for a user to design and execute studies.

5 **[0020]** Another advantage lies in access to existing studies and information databases.

[0021] Another advantage lies in the ability to use standardized protocols for imaging studies.

10 **[0022]** Another advantage lies in the structured post processing of imaging data to maximize the statistical confidence of the results.

[0023] Another advantage lies in the ability to utilize the reported results in regulatory filings that establish the efficacy of novel diagnostics and therapeutics.

15 **[0024]** Still further advantages of the present invention will be appreciated to those of ordinary skill in the art upon reading and understand the following detailed description.

20 **[0025]** The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

25 **FIGURE 1** identifies the context in which the described system and workstation is intended to function;

FIGURE 2 is a diagrammatic illustration of an animal imaging system, in accordance with the present application;

30 **FIGURE 3** depicts several modalities oriented radially about a common center point;

FIGURE 4 depicts a rotating gantry with several modalities;

35 **FIGURE 5** is a profile view of an animal imaging capsule;

FIGURE 6 depicts subsystems of a research workstation available to a user;

40 **FIGURE 7** is a flow diagram that illustrates relationships between components of the system of **FIGURE 2**.

[0026] With reference to **FIGURE 1**, an exemplary context of imaging systems used for diagnostic, therapeutic, and/or research activities is shown.

45 **[0027]** With reference to **FIGURE 2** and continuing reference to **FIGURE 1**, an exemplary imaging system **10** is shown. Optional components to facilitate small animal imaging are included on the figure. The present application contemplates a system with modules for positron emission tomography (PET), Computed Tomography (CT), single photon emission computed tomography (SPECT), animal preparation, a research workstation for visualization, image registration, fusion, and analysis capabilities and other imaging and data handling. The various modules are combined within a cover that allows flexible configurations with various combinations of side-by-side, back to back, distributed, and/or in-line config-

urations, determined by space and throughput issues. A common subject positioner is also contemplated, as well as an animal holder that can be docked and undocked against the positioner. In a side-by-side configuration, as shown in FIGURE 2, accurate image registration is achieved through the docking feature, which provides positional accuracy and repeatability when the animal holder is docked and undocked. Additional image registration can be obtained through the use of fiducial markers.

[0028] With reference to FIGURE 5 and continuing reference to FIGURE 2, an imaging modality **12** is responsible for imaging data acquisition. As mentioned above, the modality **12** can be any imaging modality, including but not limited to one or more of PET, SPECT, CT, and MRI. An animal capsule **14** holds one or more animals during imaging sessions. The capsule **14** typically includes one or more holders, or beds **16**, a cylindrical cover **18**, physiological parameter sensors **20**, provisions for anesthesia **22**, such as a nose cone into which the animal's nose fits, and a holder-side docking interface **24**. Alternately, the cover **18** could include a bag, which can be evacuated to conform to the subject. The docking interface **24** is preferably designed in such way that minimal insert/twist force is applied when the holder is inserted into the imaging modality **12**. It is preferable that the position of an animal is not disturbed when it is transferred from one modality to another. By configuring all the modalities and docking stations with a uniform docking interface **24**, the handler can exchange the holder between different modalities and docking stations. Docking interface functionality includes providing monitoring, heating and anesthesia interface to the handler, and providing support for up to four animals. For safety reasons, the anesthesia valves can be automatically shut off when the capsule **14** is detached and can be reopened when it is attached. The capsules are preferably constructed to withstand many cleanings and sterilizations, e.g., alcohol, steam, radiation, and the like.

[0029] A single animal capsule **14** can support several different bed **16** configurations. One capsule **14** can accommodate up to two (2) rat beds **16**, and alternatively, one capsule **14** can accommodate a larger plurality, e.g. four (4), mouse beds **16**. Apart from a bed mount, each of the capsule interfaces **24** also provides one or more sockets connected with the measurement sensors **20**, a fluid interface for air and anesthesia, and the like. The beds **16** can be either profiled beds or flat pallets. For increasing heating efficiency, it is preferable that separate and as small as possible cylinders **18** be used around each of the animals instead of one large cylinder **18** covering all the animals, although the latter embodiment is by no means unviable. The cylinders **18** are preferably easily removable. Holes are also provided, through which it is possible to insert or pull out catheters for isotope injection and/or optional measurements and physical interactions.

[0030] A flat pallet bed type allows animal technicians

to work with non-standard measurements or with non-commonly used animals or animal configurations. The technicians can freely place different animals of different sizes and weights. The nosecone **22** on the pallet bed **16** preferably is interchangeable to accommodate different sizes of animals. The nosecone **22** is preferably radio-translucent and tightly covers the animal's head. Additionally, the nosecone **22** can be removed, e.g. if an injected anesthesia is used. The pallet bed **16** is equipped with holes at each side for mounting motion restraints.

[0031] In another embodiment, the bed **16** is a form fitting, profiled bed. The profiled bed **16** preferably comes in a few types, each configured to accommodate different animal categories (rats, mice) and sizes (small, medium, large). The bed curves allows for easy and repeatable animal positioning, both with the same subject in temporally remote scans, or with different subjects. Motion restraints are integrated into the bed to prevent rearrangement of the subject during or between scans. Restraints integrated with the bed **16** are also contemplated in lieu of traditional taping and un-taping.

[0032] ECG and respiration probes **20** are preferably integrated with the bed **16**. Alternately, sensors can be applied to the subject manually. SpO₂ and heating elements may also be parts of the bed **16**. Position marks on the bed (i.e. ruler-like markings) assist in reproducing positions when mounting subjects to the bed **16**. Given that exact repositioning is desirable in brain imaging, a stereotactic frame may be included. To allow access to the subject without disturbing the subject's position while it is fixed to the bed **16**, it is preferable to leave the animal's tail, legs, and eyes accessible while the animal is fixed to the bed **16**. It is desirable to autoclave elements that are in contact with animals, so those particular components are preferably resilient to high temperature steam cleaning and disinfection. The beds are independently removable to facilitate access to subjects in multi-animal configurations. With rat and mouse subjects, heated tail holders are preferable because they help prevent tail veins from contracting in a cold environment and altering blood flow rates. Absorbent materials can be included to handle excretion during imaging sessions; the bed design can accommodate disposable materials, or they can be integrated into the bed **16**. The bed **16** can be designed with all or most of desired probes embedded into the bed **16**. Alternately, the bed can be designed with all probes flexible enough to be placed wherever they are required by the operator. The integrated sensors are useful for standard imaging, specifically where throughput is an issue. External probes can be used in, e.g., complex research scenarios, where it is more important to execute given scenario with maximum accuracy. Although the animal preparation and imaging modules are contemplated and shown side by side, animal preparation and imaging may be located in separate rooms.

[0033] With reference again to FIGURE 2, the system **10** also includes a subject positioner **26** capable of receiving and docking the capsule **14**. The positioner **26** is

used to position the animal capsule **14** optimally in an imaging region of the scanner **12** during an imaging session. The capsule **14** has an identifier to provide a unique holder identity to the system. The identity can be read when the holder is connected to the subject positioner **26**, e.g. a bar code that moves past a reader during imaging. Though only two modules are depicted in FIGURE 2, it is contemplated that several more modules could be added to the system as desired, and as space allows. For instance, A PET module could be next to a CT module. Or, because imaging times are typically longer in PET imaging, several PET modules can be provided for each CT module to improve throughput. The positioner **26** has the capability of taking a capsule **14** from one module to the next e.g., between scans. The positioner **26** may also include capsule rollers capable of rolling the capsule **14** about its longitudinal axis, for orienting the capsule **14** differently.

[0034] The modules can be arranged side by side in a parallel fashion, as shown in FIGURE 2, but, for example, can be oriented serially, that is, one behind another, or radially about a common center point, as depicted in FIGURE 3. Another possible orientation of the modalities is a rotating gantry system, as depicted in FIGURE 4. It is preferable that the modules **12** are mobile, allowing one to be switched for another, or oriented differently, depending on the user's needs at the time, but permanent or semi-permanent, wall mounted modules have also been contemplated. Mobile modules preferably come equipped with brakes or other anchoring devices to prevent movement after the user has placed the modules in the desired configuration. A docking station **28** provides anesthesia and monitoring while the animal capsule **14** is attached awaiting a scan. As shown, the docking station may include storage space **31** for storage of additional beds **16** cylinders **18** or other devices when not in use. An induction chamber (not shown) provides an area in which a conscious animal is placed so it can be anesthetized before it is mounted on the animal bed **16**. Like the modalities **12**, it is preferable that the docking station be mobile. This way, the user can move the docking station adjacent to whatever modality **12** with which he or she happens to be working.

[0035] In the embodiment of FIGURE 2, the system **10** includes two modules, namely the acquisition module **12** and the animal preparation module, that is, the docking station **28**. Preferably, the docking station **28** adds several aspects of functionality. These aspects include the induction chamber as previously mentioned, where the subject is brought under anesthesia, a physical workspace **27** to attach the subject to a bed and install the required sensors, docking ports **29** for continuation of life support and anesthesia of the subject between studies, and a "wake up box" that provides life support during wake-up of the subjects (not shown). The preferred method of docking the capsule to the receiving system is through a positive locking mechanism that is engaged through axial force applied by means of an actuator

placed in the positioner **26**. Again, engagement of the actuator should not require disturbance of the animal. The docking interface **24** on each capsule **14** includes leads to engage an animal monitoring and anesthesia (AMA) system **38**, including electrical and gas connections. The anesthesia connection includes an "auto shut-off on disconnection" function to prevent loss of anesthesia to the environment.

[0036] Having thus described hardware and modularity of the system, the application now turns to a typical workflow process of imaging a small animal subject. First, the animal is brought to the facility. In the past, animals involved in a study would typically need to be sacrificed in order to acquire *ex vivo* measurements, essentially freezing uptake characteristics at a point in time. In the present system, such sacrifices are not necessary, so the same animals can be imaged many times over the course of the study. Thus, animals are typically kept on-site, but it is contemplated that they can be brought in from off site. The animal is brought to the scan room and anesthetized. As mentioned previously, this is done with coarse anesthesia in the induction chamber. Once the animal is anesthetized, the animal is positioned and affixed to the imaging bed **16**. In addition to positioning the region of interest of the animal, positioning the animal also includes positioning the animal's head securely in the nosecone **22** for the automatic, continual delivery of anesthesia. At this time the sensors **20** are attached to the subject animal. Once the animal is positioned on the bed **16** the cover **18** is placed over the animal and the capsule **14** is attached to one of the docking ports **29**.

[0037] Next, the user calibrates **40** the system. This involves both a software calibration and a hardware calibration, such as X and Y axis zeroing. Once the scanner is calibrated, the positioner **26** relocates the capsule **14** from the docking port **29** on the preparation module **28** to the docking port **29** on the scanning module **12**. Once the capsule has been properly positioned in the scanning module, the scan is initiated. While the scan is proceeding, the AMA **38** monitors environmental factors of the capsule **14** and vital signs of the subject, and continuously supplies anesthesia to the subject. Subject monitoring allows the user to eliminate physiological variables to the greatest extent possible. By controlling the physiological variables, study design confidence is enhanced as results will be more readily reproducible. Put another way, fluctuations in physiological variables can taint an otherwise sound study, so it is desirable to control these variables as much as possible.

[0038] Once the scan is completed, the animal is removed from the capsule and placed in the post-anesthesia chamber to wake up. Here the AMA **38** monitors the temperature of the chamber. When the animal regains consciousness, it is transferred back to its living environment. The imaging scan can then be processed and integrated into the user's overall clinical study.

[0039] To facilitate creation of a study, the system includes a research workstation **30**. The workstation **30**

includes a computer that controls main system functions and provides an interface for a user to work with the image data. The research workstation **30** includes acquisition control to allow starting, pausing, resuming and stopping an image acquisition and showing status and progress info on the acquisition. The research workstation **30** also interfaces with the AMA **38** in order to display vital signs for multiple animals scanned across several modalities and stages of animal preparation on the workstation. Additionally, acquisition control and a reconstruction user interface may reside in whole or in part on the research workstation **30**. Multimodality function is included on the research workstation **30** such as PET-CT non-rigid registration. In such a situation, interfacing with a CT Acquisition control can be done via the research workstation **30**. It is preferable that the research workstation **30** provides a migration path for all applications of the system **10** to use a common platform for infrastructure services and operation. Naturally, the research workstation **30** can be upgraded as new preparation techniques, scanning techniques, software, hardware, and the like become available.

[0040] Studies conducted for the purpose of research are often hypothesis driven. A technician or clinician may have an idea and run with it. Perhaps results of one study make technicians ask questions they would not have otherwise asked. Other studies may not be researching entirely new ideas, but bolstering the validity of already-existing hypotheses. In either case, it is beneficial for a technician to have the ability to design and modify imaging studies. This includes both developing new aspects of studies and calling upon known methods and techniques to complement new ideas.

[0041] With reference to FIGURE 6, the research workstation **30** includes functionality for subject and study management. The study management component interacts with a protocol setup component for protocol definition. This allows the user to set up and edit parameters. The research workstation **30** interacts with a modality controller **36** to provide information about active studies and to activate a study. A study is activated on request of the modality controller **36**. The research workstation **30** also interacts with the acquisition controller **12**, to pass the protocol to the acquisition controller **12** and to start, pause, stop, or resume acquisitions; it receives progress updates from the acquisition controller **12**, and can then show them to the user and can pass them to the modality controller **36**. Protocol setup in the research workstation **30** preferably allows editing and entry of protocol parameters. The resulting protocol is stored and associated with a study. The research workstation **30** can also receive modification requests from the modality controller **36** and provide protocol info to it. Protocol setup for a study can take place until the moment the study is activated at the modality **12**.

[0042] Further to study design and management, the research workstation **30** provides a visual user study design interface **33** for assessing study approaches, steps,

subject quantities, statistical analysis and other data processing results, and the like. This allows the user to achieve a specified level of confidence given accumulated system accuracies and inaccuracies, as well as specifying a relationship between local imaging and computational methods such as data mining and bioinformatics. The research workstation **30** allows the user to set up complex processes graphically, with the ability to select sequences of steps to conduct a study. The user can designate various widely accepted study types, ranging from loosely structured pilot studies to increasingly rigorous and controlled studies.

[0043] The study design capability works by providing a capability for the user to "drag and drop" blocks that represent the various data import, acquisition, processing, quantification, visualization, analysis, and reporting capabilities onto a palette representing the image and data flow according to their needs. The workstation **30** provides a library of blocks that provide a combination of established and novel steps. Once a block is dragged onto the palette, the user is allowed to set "properties" of the block that configure it for the particular study and account for the user defined interconnections that are desired. Calculators to assess system accuracies and confidence levels are provided by the system, along with means to determine a number of subjects or imaging sessions required to achieve a predictive statistical significance with respect to a hypothesis are provided. Results attained from the studies, settings, indexing, data handling, control, and option settings are all associated with the named study and can be recalled for later use. In this manner, a user can simply have the research workstation **30** recall a study that worked well and adapt selected parameters or blocks to create a new study rather than defining a new study from scratch.

[0044] The research workstation **30** also includes a data mining/bioinformatics design interface, or portal. This subscreen allows the user to access third party search engines **35a** or internal proprietary information applications to access organ models **35b** and disease models **35c**, population databases **35d**, subject specific data **35e**, IP data **35f**, quantification data **35g**, report data **35h**, biobanks **35i**, the electronic patient chart (EPR) **35j** and other knowledge databases **35k**. Such information may include editable templates, STL files, normals, collectives, and the like. This aspect provides a place for commercializing infonnatics research applications that complement standard imaging. Incidentally, after a study has been created and tested, it can be integrated back into the various knowledge databases **35j** for future reference.

[0045] Another design interface or portal available to the user includes choices concerning image acquisition and reconstruction **37**. The research workstation **30** is used to create the study, to register animal data and to invoke a workflow. The research workstation **30** supports the operator workflow in visualizing protocols, providing acquisition control and status and providing images for

reviewing. The research workstation **30** has a large, high resolution display connected. This display supports sensitive subject control and provides easy access to large amounts of information. This includes protocol selection and modification. Additionally, the user is able to manage the Digital Imaging and Communications in Medicine (DICOM) **58** format as well as other native imported image formats. Instrument calibration and accuracy data can be transported in private tags. Outside data that does not have instrument calibration and accuracy tags can be hand entered upon a prompt by the research workstation **30**. Data can then be output to a picture archiving communication system or PACS **60**.

[0046] At an image processing workflow design interface **39** the user can select from a variety of post-acquisition image adjustments and enhancements. In one embodiment, this subscreen presents a graphic user interface for registration of various types, surface and volume rendering, model-based segmentation, visualization, fusion, and the like. Additionally the user has the option to select corrections, such as partial volume correction and local motion correction. Data can be represented as a "transform," from multiple inputs to multiple outputs, including displayable portions (e.g. an image) and non-displayable portions (e.g. a deformation field). Also, the image processing subscreen is a convenient place to include longitudinal and group study protocols **56**.

[0047] The research workstation **30** also includes a quantification design interface **41**. At this point, the user can select standard uptake values (SUVs), pharmacokinetics, tools associated with specific organ systems and/or disease processes such as cardiology, neurology, oncology, bone densitometry, neo-vascularization, as well as other packages. Generally, the user has the option to select existing packages that have been tested and reused often, as well as packages that are less well known but on their way to becoming accepted packages. It is also preferable that the user have the flexibility to create packages, if desired. Some analysis is generally relevant to the preclinical domain whereas in many cases the packages may be early versions that will ultimately be validated for clinical use. In this way, the system aids translation of capability from animal models to human models.

[0048] In a statistical analysis workflow design interface **43**, the user can plan and execute analysis of the study that they have previously designed. Here, the user can, for example, utilize Bayesian confidence calculations for hypothesis evaluation **47**. Hypothesis evaluation **47** includes both study design **33** and statistical analysis **43**. Several automated evaluation frameworks are available in well know study formats, depending on what the user hopes to gain from the data. This subscreen also includes access to statistical calculations for ad-hoc post scan analyses, and is not restricted to pre-designed studies. This way, if the user suspects that there may be some trend or association in the data, they can design their own analyses to investigate it.

[0049] Finally, the user has several options when it comes to reporting data. At a reporting design interface **45**, charts, graphs, literature summaries, standard FDA reports, and the like are available to the user for reporting their study. Of course, the user can also custom design a reporting method that lends itself to illustrating the instant study. Preferably, the workstation **30** also includes hardware modeling functionality that allows a user to design orientations and arrangements of the hardware the user has at their disposal. As each research setting will have different capabilities and constraints (funding, physical space, etc.) each setting will have different hardware available to it. The user can tell the system what hardware it has available and then design an arrangement to aid in workflow and subject processing. With mobile modular modalities, the user has the flexibility to arrange the modalities to best facilitate execution of his or her hypothesis testing. The system can also take the hardware arrangement into account when evaluating the study, such as identifying potential bottlenecks, problems with keeping the subjects under anesthesia too long, and the like.

[0050] Elements of the system and their relationship to each other are shown in FIGURE 7. The imager **12** subsystem includes the detector and the electronics germane to the particular system, whether it be PET, SPECT, CT, MRI, another imaging modality, or a combination thereof. A local user interface **32** provides local user access for instruction entry and status or data read out for the subject positioner **26**, the animal monitoring and anesthesia system **38**, and imager controls for starting or aborting an acquisition sequence. The local user interface depicted in FIGURE 2 is a touch screen, but it could also be a generic detachable control panel that could interface with several different modalities. For modules **12** oriented next to each other, the interface **32** can be mounted on a mobile platform that follows a track along the line of modules, so the interface **32** can be wherever the user happens to be working at the time. In yet another alternate embodiment, the interface **32** could be a wireless device, such as a tablet PC, PDA, or other wireless device that is capable of wireless communication with the system **10**.

[0051] A server **34** processes data gathered by the scanner **12** and also provides control, reconstruction processing, and support for programmatic interfaces to the acquisition system. The modality controller **36** controls local modality functionalities and keeps track of the studies defined for the modality. These include the AMA subsystem **38**, the positioner **26**, docking **29**, the user interface **32**, and a positioning laser **42**. The controller **36** also provides input from the interface **32** of the modality **12** to the research workstation computer **30**. The controller **36** allows selection of a study when a capsule **14** is attached. It retrieves protocol information for the selected study and allows updating of the selected study. When an acquisition screen at the touch screen **32** is chosen, it activates the study at the research workstation **30**, causing the protocol to be loaded into the acquisition

controller **12** by the research workstation **30**.

[0052] The AMA subsystem **38** implements vital signs monitoring (temperature pulse rate, blood pressure, ECG, etc.), anesthesia and waste gas scavenging, and temperature control of the subject or subjects. The AMA subsystem **38** is physically connected to the animal capsule **14** with leads for the monitoring probes **20**, a heater for temperature control, and tubes to carry anesthesia and waste gas.

[0053] A reconstruction processor **44** is used as a compute resource for reconstruction. The reconstruction processor **44** is connected to the server **34** via a network connection, such as a second thin-net connection that supports raw data handling, reconstruction control, and image transfer handling. Additional modalities can be introduced in the system **10**, and in this event, the reconstruction processor **44** can also handle those image formation tasks. In such a case, the reconstruction processor **44** receives raw image data via a proprietary high-speed serial link. The reconstruction processor **44** is connected to the server **34** via a 1 GB thin-net connection, for example, which in turn supports a higher-level programmatic interface for CT reconstruction protocols and image transfer. The server **34** also uses this interface to provide reconstruction control via a programmatic interface to the reconstruction processor unit **44**. Preferably, the reconstruction processor **44** includes five servers, but can include more or less as processing tasks demand. The research workstation **30** includes tools as described herein, and suitable rapid prototyping environment software.

[0054] A positioner control subsystem **46** interfaces to the modality controller **36**, e.g. via an Ethernet connection. Via this connection, movement commands are issued and status and position information is returned. The positioner control **46** is responsible for control of the position of the subject positioner **26**. Motion of the positioner **26** is executed through the modality controller **36** and the position controller **46**. The modality controller **36** implements the interfaces that perform selected bed motions. The positioner controller **46** translates this into servo commands. A high speed router **48** connects the research workstation **30**, the reconstruction processor **44** and the server **34** to the imager **12**. The router **48** is preferably a 1 GB intelligent router that allows isolation of the acquisition sub-net(s) from a department or external network **50**. The imaging modality **12**, research workstation **30**, server **34**, reconstruction processor **44**, and router **48** can be thought of collectively as an acquisition sub-net **51**. Logically, the acquisition sub-net **51** links acquisition control (located within the given modality), the server **34**, the research workstation **30**, and the reconstruction processor **44**. This interface carries acquisition control commands from the research workstation **30** to imaging acquisition **12** and the server, allows the research workstation **30** to request subject positioner **26** motion, and provides the path by which raw imaging data is transferred from acquisition **12** to the server **34** and recon-

struction processor **44**. The intelligent router **48** is used to isolate this logical connection. The connection to the research workstation **30** also supports transfer of minimally processed images to the server platform **34** and to external (i.e. department network) devices **50**.

[0055] A power supply **52** subsystem provides various AC and DC voltages for the components. Emergency shutoff (E-stop) circuitry **54** cuts electrical power when the circuit is interrupted. When the E-stop circuitry **54** is activated, the power supply will switch to a safe mode, e.g., high voltage and motion control power can be switched off, while computing elements may remain operational. The modality controller **36** is able to read and control the status. It is contemplated that the power system **52** can be factory configurable to accept 120V or 230V AC. Additionally, the power supply will contain a power adaptation module. This module will output 230V in order to supply modules that require higher voltages, such as the reconstruction processor **44**.

[0056] The Docking Interface module **29** is responsible for allowing accurate docking of the animal capsule **14** to the positioner **26**. Furthermore, the module **29** is responsible for making robust electrical and pneumatic connections. The docking interface can be electrically controlled by means of an actuator. Generally, the acquisition module **12** and the docking station **28** are encased in a frame that preferably minimizes the weight and maximizes the rigidity of the system. Additionally, the frame should be virtually transparent to radiation events, so it can encase the bore of the imaging device. Fiberglass is an exemplary frame material. Preferably, a touch screen **32** or other local user interface is included for controlling the positioner **26**, displaying AMA data, and to aid in subject positioning. The positioner controller **46** receives motion commands from the touch screen **32** via software also running on the modality controller **36** to perform bed motion. The touch screen **32** provides part of the modality human interfaces. Software for the touch screen **32** runs on the modality controller **36** and interfaces with the AMA **38**, motion control and acquisition info components, also running on the modality controller **36**. The position of the local user interface **32** is dictated by functional considerations, such as objects typically in or around the bore of the device during imaging, and the like. Preferably, the frame is equipped with cover-switches integrated into the E-stop circuitry to switch of power in case the covers are opened.

[0057] The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be constructed as including all such modifications and alterations insofar as they come within the scope of the appended claims.

Claims

1. An in-vivo imaging system comprising:

at least one imaging modality (12) for acquiring in-vivo imaging data of a subject in an imaging region of the modality (12); a reconstruction processor (44) configured to reconstruct raw data into an image representation; a research workstation (30) configured to provide a user with an electronic interface to the imaging modality (12), the workstation including a study design user interface that allows a user to one of create a new study and modify an existing study for use in the in-vivo imaging system; wherein the imaging modality (12), the reconstruction processor (44) and the research workstation (30) are in mutual communication; the workstation further including:

a quantification user interface configured to enable the user to recall existing clinical study packages and allows the user to access at least one of a standardized uptake value tool, a pharmacokinetics tool, a cardiology tool, a neurology tool, an oncology tool, a bone densitometry tool, and a neovascularization tool;

characterised in

the in-vivo imaging system further including: a positioner (26) configured for positioning an animal capsule (14) optimally in the imaging region of the imaging modality (12) during an imaging session; wherein the animal capsule (14) is dockable with at least one of several docking interfaces (29) located at a preparation area (28) and the at least one imaging modality (12) during the imaging session;

the in-vivo imaging system further including:

the animal capsule, the at least one of several docking interfaces and at least one animal monitoring and anesthesia system (38) configured for monitoring vital signs of the subject during a sedation period, and for providing regulated anesthesia to the subject via the at least one of several docking interfaces (29).

2. The in-vivo imaging system as set forth in claim 1, wherein the at least one imaging modality (12) is a small animal imaging modality.

3. The in-vivo imaging system as set forth in claim 1, further including:

at least a second imaging modality (12) that is

mobile relative to the at least one modality (12), the second imaging modality (12) being positionable by a user to facilitate the needs of a hypothesis test of the user, and connectable with the research workstation (30).

4. The in-vivo imaging system as set forth in claim 1, wherein the study design user interface is configured to enable the user to specify a relationship between imaging and computational methods.

5. The in-vivo imaging system as set forth in claim 1, wherein the study design user interface is configured to enable the user to store at least results, indexing settings, data handling settings, control settings, and option settings for later recollection.

6. The in-vivo imaging system as set forth in claim 1, further including:

a data mining user interface configured to enable the user to perform data mining tasks associated with the created or modified study.

7. The in-vivo imaging system as set forth in claim 1, further including:

a statistical analysis user interface which is configured to perform under user control at least one of:

- analyze a previously designed study; utilize Bayesian confidence calculations for hypothesis evaluation; receive automated analyses for more well known studies; analyze a population of a large data set; and an ad-hoc post-study analysis.

8. The in-vivo imaging system as set forth in claim 7, further including a reporting user interface that is configured to enable the user to customize a data reporting method to report the statistical analysis.

9. The in-vivo imaging system as set forth in claim 1, further including an anesthesia control user interface controllable by the user to regulate anesthesia provision via at least one of the preparation area (28) and the imaging modality (12).

10. The in-vivo imaging system as set forth in claim 1, further including:

a touch screen (32) located on the imaging modality (12) through which the user can interface with the research workstation (30).

11. The in-vivo imaging system as set forth in claim 10,

further including:

a modality controller (36) that is configured to control local modality functionalities, keep track of the studies defined for the modality, and provide input from the touch screen (32) of the modality (12) to the research workstation (30).

Patentansprüche

1. In-vivo Bildgebungssystem, das Folgendes umfasst:

mindestens eine Bildgebungsmodalität (12) zum Erfassen von in-vivo Bildgebungsdaten eines Patienten in einer Bildgebungsregion der Modalität (12);

einen Rekonstruktionsprozessor (44), der dafür eingerichtet ist, Rohdaten zu einer Bilddarstellung zu rekonstruieren;

eine Forschungs-Workstation (30), die dafür eingerichtet ist, einem Benutzer eine elektronische Schnittstelle zu der Bildgebungsmodalität (12) bereitzustellen, wobei die Workstation eine Studiendesign-Benutzerschnittstelle umfasst, die es einem Benutzer erlaubt, entweder eine neue Studie zu erstellen oder eine existierende Studie zur Verwendung in dem in-vivo Bildgebungssystem zu modifizieren;

wobei die Bildgebungsmodalität (12), der Rekonstruktionsprozessor (44) und die Forschungs-Workstation (30) in wechselseitiger Kommunikationsverbindung miteinander stehen;

wobei die Workstation weiterhin Folgendes umfasst:

eine Quantifizierungsbenutzerschnittstelle, die dafür eingerichtet ist, dem Benutzer zu ermöglichen, existierende klinische Studienpakete aufzurufen, und dem Benutzer erlaubt, auf mindestens entweder ein standardisiertes Aufnahmewert-Tool, ein Pharmakokinetik-Tool, ein Kardiologie-Tool, ein Neurologie-Tool, ein Onkologie-Tool, ein Knochendichtemessungs-Tool oder ein Neovaskularisations-Tool zuzugreifen; **dadurch gekennzeichnet, dass** das in-vivo Bildgebungssystem weiterhin Folgendes umfasst:

eine Positioniereinheit (26), die dafür eingerichtet ist, eine Tierkapsel (14) während einer Bildgebungssitzung optimal in der Bildgebungsregion der Bildgebungsmodalität (12) zu positionieren;

wobei die Tierkapsel (14) während der Bildgebungssitzung an mindestens eine von mehreren Docking-Schnittstellen (29), die

sich in einem Vorbereitungsbereich (28) befinden, und die mindestens eine Bildgebungsmodalität (12) angedockt werden kann; wobei das in-vivo Bildgebungssystem weiterhin Folgendes umfasst:

die Tierkapsel, die mindestens eine von mehreren Docking-Schnittstellen, mindestens ein Tierüberwachungs- und Anästhesie-System (38), das dafür eingerichtet ist, die Vitalparameter des Patienten während einer Sedierungsdauer zu überwachen, und dem Patienten über die mindestens eine der mehreren Docking-Schnittstellen (29) eine regulierte Anästhesie zu verabreichen.

2. In-vivo Bildgebungssystem nach Anspruch 1, wobei die mindestens eine Bildgebungsmodalität (12) eine Kleintier-Bildgebungsmodalität ist.

3. In-vivo Bildgebungssystem nach Anspruch 1, das weiterhin Folgendes umfasst:

mindestens eine zweite Bildgebungsmodalität (12), die in Bezug auf die mindestens eine Modalität (12) beweglich ist, wobei die zweite Bildgebungsmodalität (12) durch einen Benutzer positioniert werden kann, um die Anforderungen eines Hypothesentests des Benutzers zu erfüllen, und mit der Forschungs-Workstation (30) verbunden werden kann.

4. In-vivo Bildgebungssystem nach Anspruch 1, wobei die Studiendesign-Benutzerschnittstelle dafür eingerichtet ist, dem Benutzer zu ermöglichen, eine Beziehung zwischen Bildgebungs- und Berechnungsverfahren zu spezifizieren.

5. In-vivo Bildgebungssystem nach Anspruch 1, wobei die Studiendesign-Benutzerschnittstelle dafür eingerichtet ist, dem Benutzer zu ermöglichen, mindestens Resultate, Indexierungseinstellungen, Datenhandhabungseinstellungen, Kontrolleinstellungen und Optionseinstellungen zur späteren Abholung zu speichern.

6. In-vivo Bildgebungssystem nach Anspruch 1, das weiterhin Folgendes umfasst:

eine Datengewinnungs-Benutzerschnittstelle, die dafür eingerichtet ist, dem Benutzer das Durchführen von Datengewinnungsaufgaben in Zusammenhang mit der erstellten oder modifizierten Studie zu ermöglichen.

7. In-vivo Bildgebungssystem nach Anspruch 1, das weiterhin Folgendes umfasst:

eine statistische Analyse-Benutzerschnittstelle, die dafür eingerichtet ist, unter der Benutzersteuerung mindestens eine von folgenden Aktionen durchzuführen:

Analysieren einer zuvor konzipierten Studie;
Nutzen von Bayesschen Konfidenzberechnungen zur Hypothesenbewertung;
Empfangen von automatisierten Analysen für bekanntere Studien;
Analysieren einer Population eines großen Datensatzes; und
eine ad-hoc Post-Studien-Analyse.

8. In-vivo Bildgebungssystem nach Anspruch 7, das weiterhin eine Berichterstellungs-Benutzerschnittstelle umfasst, die dafür eingerichtet ist, dem Benutzer zu ermöglichen, eine Datenberichterstellungsmethode an die spezifischen Anforderungen anzupassen, um einen Bericht für die statistische Analyse zu erstellen.

9. In-vivo Bildgebungssystem nach Anspruch 1, das weiterhin eine Anästhesiesteuerungs-Benutzerschnittstelle umfasst, die durch den Benutzer gesteuert werden kann, um die Anästhesie-Bereitstellung über mindestens den Vorbereitungsbereich (28) oder die Bildgebungsmodalität (12) zu regeln.

10. In-vivo Bildgebungssystem nach Anspruch 1, das weiterhin Folgendes umfasst:

einen Berührungsbildschirm (32), der sich an der Bildgebungsmodalität (12) befindet und über den der Benutzer mit der Forschungs-Workstation (30) in Verbindung treten kann.

11. In-vivo Bildgebungssystem nach Anspruch 10, das weiterhin Folgendes umfasst:

eine Modalität-Steuereinheit (36), die dafür eingerichtet ist, die lokalen Modalitätsfunktionen zu steuern, die für die Modalität definierten Studien zu verfolgen und der Forschungs-Workstation (30) eine Eingabe von dem Berührungsbildschirm (32) der Modalität (12) bereitzustellen.

Revendications

1. Système d'imagerie in-vivo comprenant :

au moins une modalité d'imagerie (12) pour acquérir des données d'imagerie in-vivo d'un sujet dans une région d'imagerie de la modalité (12) ; un processeur de reconstruction (44) configuré pour reconstruire des données brutes en une

représentation d'image ;

un poste de travail de recherche (30) configuré pour fournir, à un utilisateur, une interface électronique à la modalité d'imagerie (12), le poste de travail comprenant une interface utilisateur de conception d'étude qui permet à un utilisateur de créer une nouvelle étude ou de modifier une étude existante pour l'utilisation dans le système d'imagerie in-vivo ;

dans lequel la modalité d'imagerie (12), le processeur de reconstruction (44) et le poste de travail de recherche (30) sont en communication mutuelle ;

le poste de travail comprenant en outre :

une interface utilisateur de quantification configurée pour permettre à l'utilisateur de rappeler des ensembles d'étude clinique existante et permet à l'utilisateur d'accéder à au moins un parmi un outil de valeur de détection standardisée, un outil pharmacocinétique, un outil cardiologique, un outil neurologique, un outil oncologique, un outil ostéodensitométrique, et un outil de néovascularisation ;

caractérisées en ce que le système d'imagerie in-vivo comprend en outre :

un positionneur (26) configuré pour positionner une capsule à animal (14) de façon optimale dans la région d'imagerie de la modalité d'imagerie (12) durant une session d'imagerie ;

dans lequel la capsule à animal (14) est raccordable à au moins une parmi plusieurs interfaces de raccordement (29) situées dans une zone de préparation (28) et l'au moins une modalité d'imagerie (12) durant la session d'imagerie ;

le système d'imagerie in-vivo comprenant en outre :

la capsule à animal, l'au moins une parmi plusieurs interfaces de raccordement et au moins un système de surveillance et d'anesthésie pour animale (38) configuré pour surveiller des signes vitaux du sujet durant une période de sédation, et pour fournir une anesthésie régulée au sujet par l'intermédiaire de l'au moins une parmi plusieurs interfaces de raccordement (29).

2. Système d'imagerie in-vivo selon la revendication 1, dans lequel l'au moins une modalité d'imagerie (12) est une modalité d'imagerie pour animal de petite taille.

3. Système d'imagerie in-vivo selon la revendication 1, comprenant en outre :
- au moins une seconde modalité d'imagerie (12) qui est mobile par rapport à l'au moins une modalité (12), la seconde modalité d'imagerie (12) étant positionnable par un utilisateur pour faciliter les besoins d'un test d'hypothèse de l'utilisateur, et raccordable au poste de travail de recherche (30). 5
4. Système d'imagerie in-vivo selon la revendication 1, dans lequel l'interface utilisateur de conception d'étude est configurée pour permettre à l'utilisateur de spécifier une relation entre des procédés d'imagerie et de calcul. 10
5. Système d'imagerie in-vivo selon la revendication 1, dans lequel l'interface utilisateur de conception d'étude est configurée pour permettre à l'utilisateur de stocker au moins des résultats, des réglages d'indexage, des réglages de traitement de données, des réglages de commande, et des réglages d'option pour rappel ultérieur. 20
6. Système d'imagerie in-vivo selon la revendication 1, comprenant en outre :
- une interface utilisateur d'exploration de données configurées pour permettre à l'utilisateur de réaliser des tâches d'exploration de données associées à l'étude créée ou modifiée. 25
7. Système d'imagerie in-vivo selon la revendication 1, comprenant en outre :
- une interface utilisateur d'analyse statistique qui est configurée pour réaliser, sous le contrôle utilisateur, au moins une parmi :
- l'analyse d'une étude conçue auparavant ; 40
- l'utilisation de calculs de confiance bayésienne pour évaluations d'hypothèse ;
- la réception d'analyses automatisées pour des études mieux connues ; 45
- l'analyse d'une charge d'un grand jeu de données ; et
- la réalisation d'une analyse post-étude ad-hoc. 50
8. Système d'imagerie in-vivo selon la revendication 7, comprenant en outre une interface utilisateur de rapport qui est configurée pour permettre à l'utilisateur de personnaliser un procédé de rapport de données pour rapporter l'analyse statistique. 55
9. Système d'imagerie in-vivo selon la revendication 1, comprenant en outre une interface utilisateur de
- commande d'anesthésie pouvant être commandée par l'utilisateur pour réguler la fourniture d'anesthésie par l'intermédiaire d'au moins une parmi la zone de préparation (28) et la modalité d'imagerie (12).
10. Système d'imagerie in-vivo selon la revendication 1, comprenant en outre :
- un écran tactile (32) situé sur la modalité d'imagerie (12) par l'intermédiaire duquel l'utilisateur peut interfacier avec le poste de travail de recherche (30).
11. Système d'imagerie in-vivo selon la revendication 10, comprenant en outre :
- un appareil de commande de modalité (36) qui est configuré pour commander des fonctionnalités de modalité locales, suivre les études définies pour la modalité, et fournir une entrée de l'écran tactile (32) de la modalité (12) au poste de travail de recherche (30).

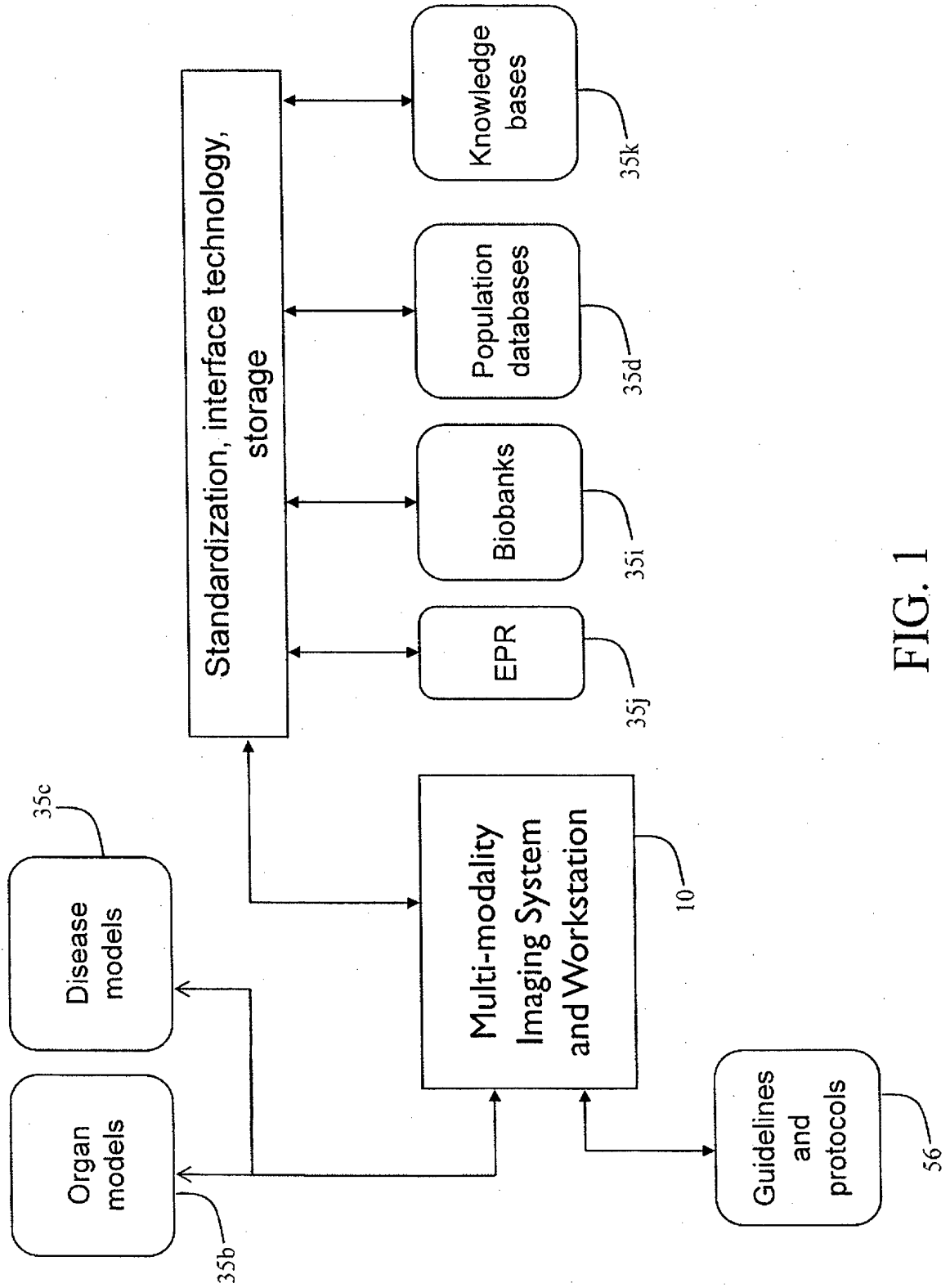


FIG. 1

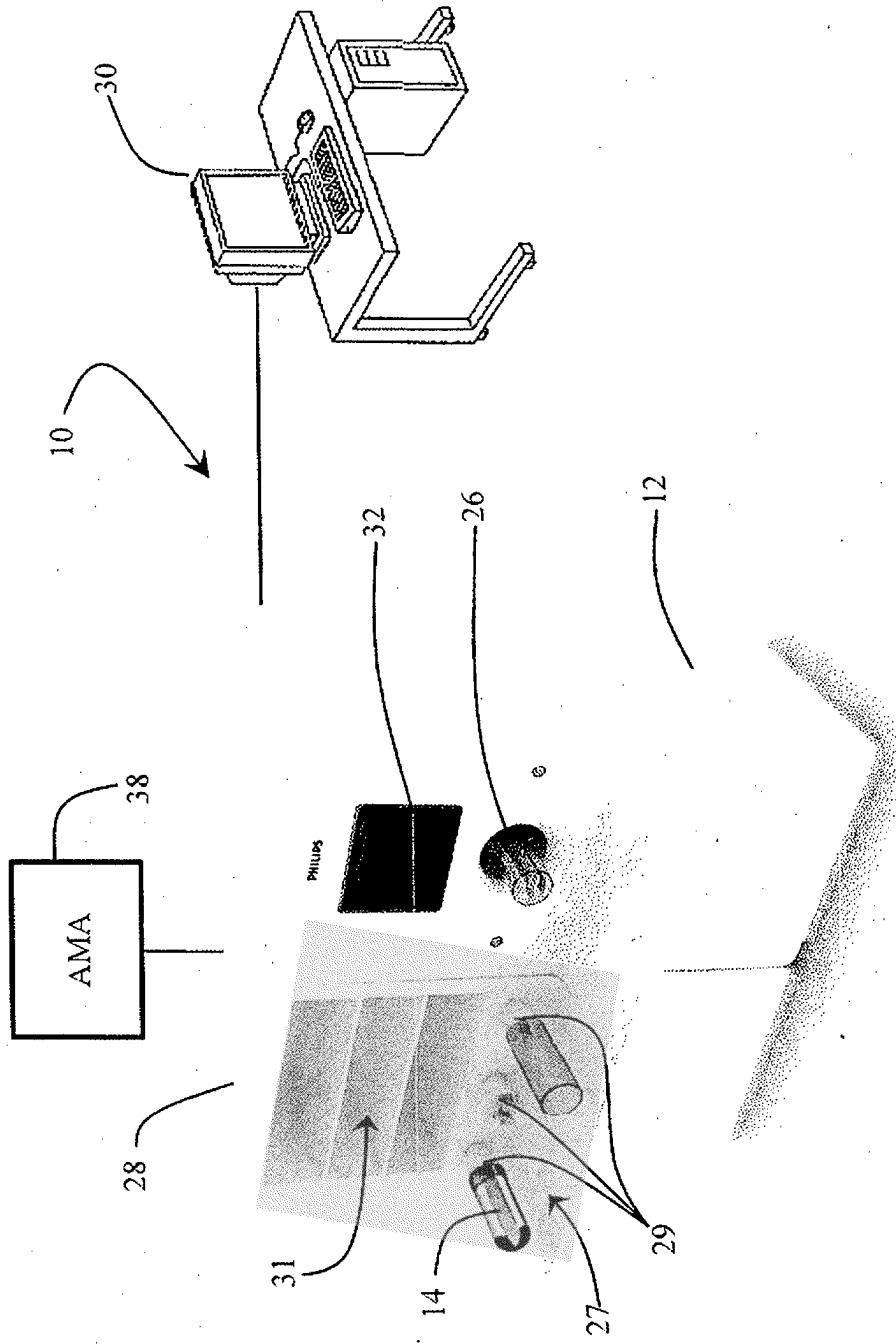


FIG. 2

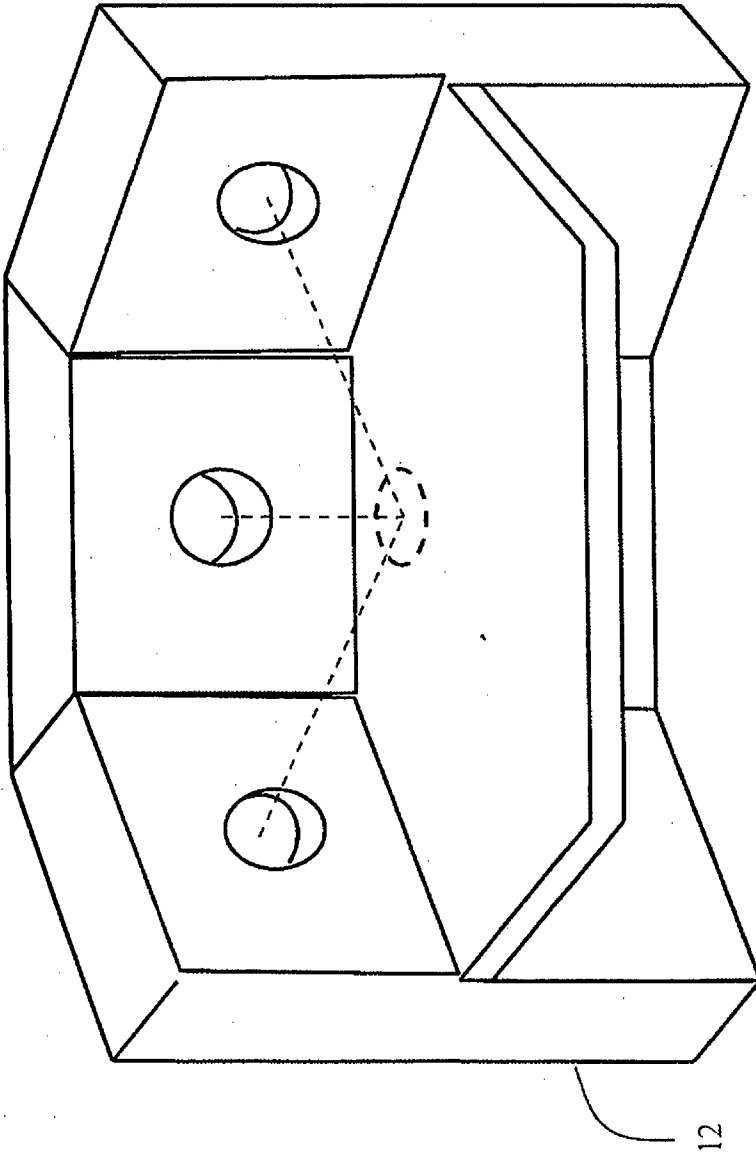


FIG. 3

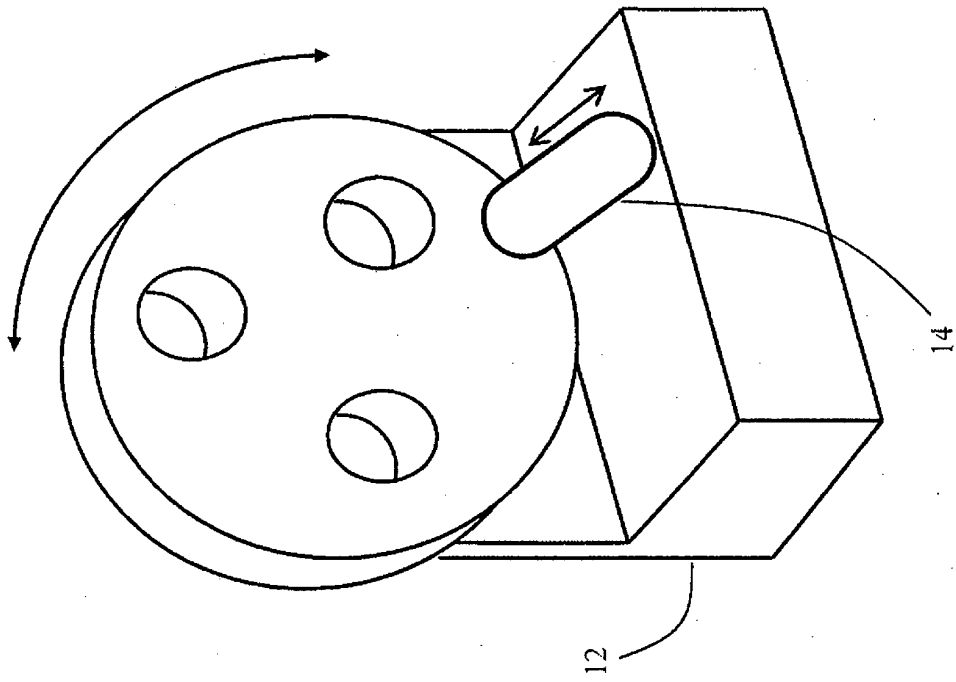


FIG. 4

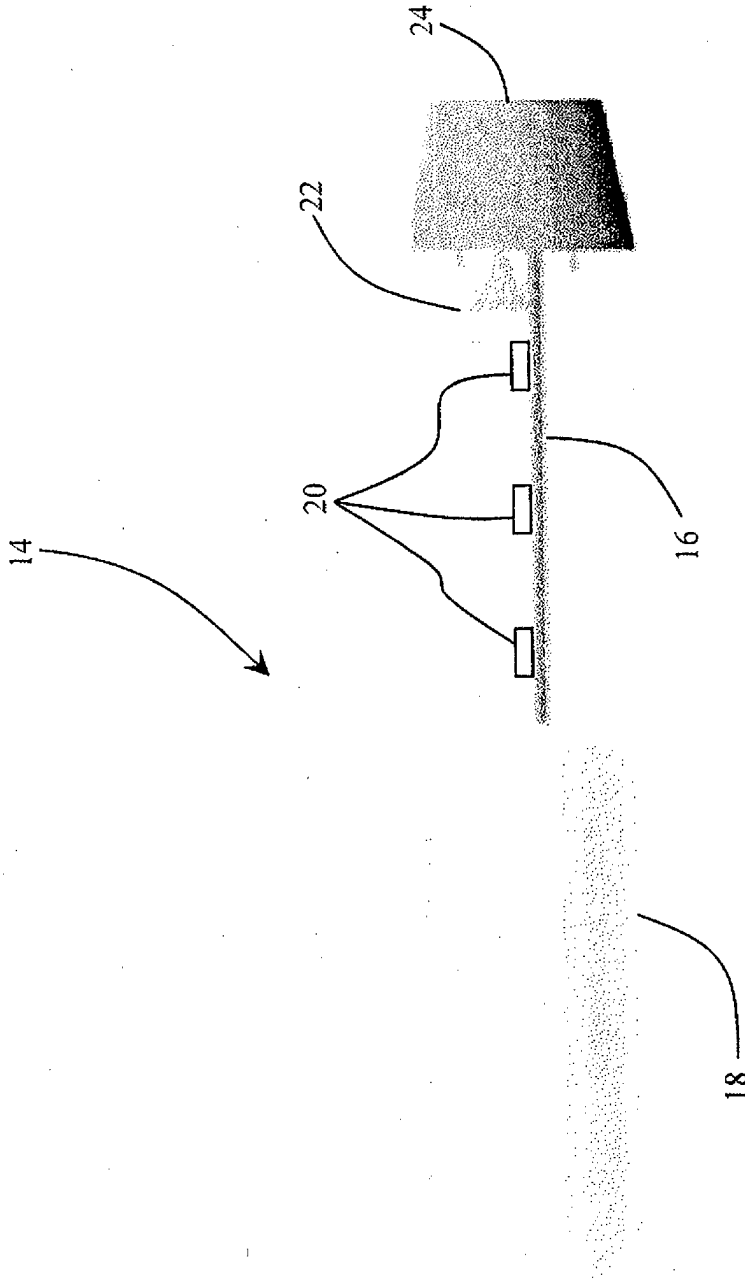


FIG. 5

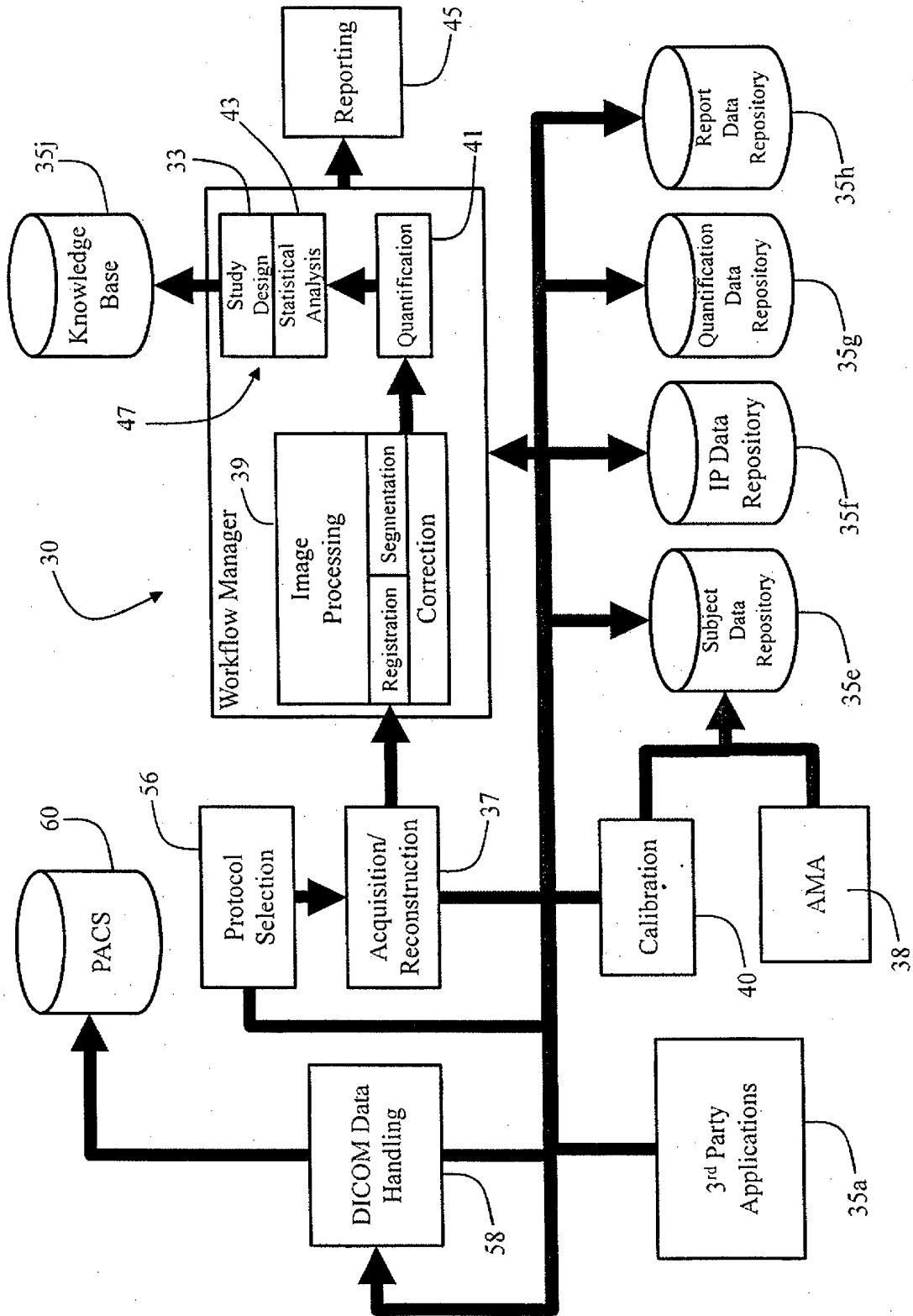


FIG. 6

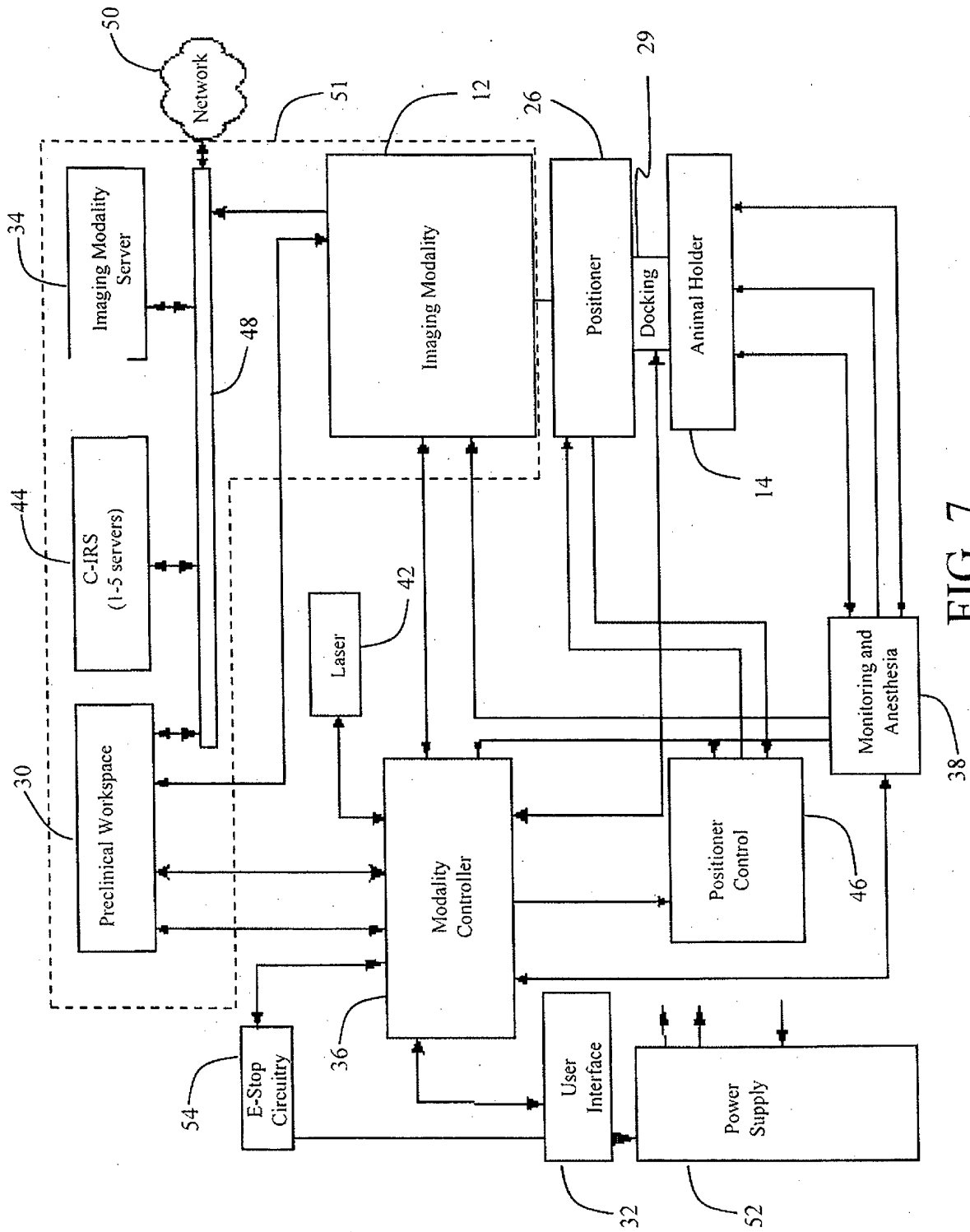


FIG. 7

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6574307 B [0011]

专利名称(译)	多模态成像系统和工作站，支持结构化假设检验		
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[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
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CPC分类号	A61B5/0035 A61B5/4821 A61B6/032 A61B6/0421 A61B6/0442 A61B6/467 A61B6/508 A61B6/5247 A61B2503/40 G06F19/321 G16H30/20		
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外部链接	Espacenet		

摘要(译)

对疾病的体内模型的研究需要在单个成像会话中涉及单个受试者的成像研究，个体或受试者组的连续成像，以及跨多种和异构实验方法的数据整合。每种类型的实验优选地由各种特征集支持，这些特征集可以严格应用以产生定量的，可再现的结果。目前的成像扫描仪没有配备标准化功能，支持适用于假设检验的自动化和科学严谨的工作流程。成像系统 (10) 包括研究工作站 (30)，用户可在其处设计，执行，研究和报告成像计划。系统 (10) 的模块化设计带来的灵活性允许用户定制工作流程参数以进行更稳健的假设测试。

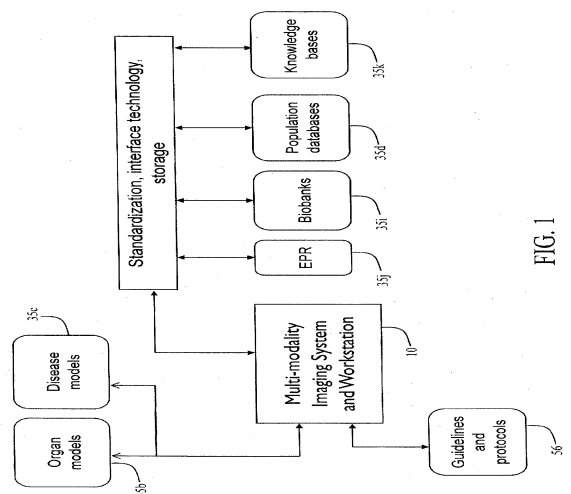


FIG. 1