

(51) International Patent Classification:
A61B 10/00 (2006.01) *G06Q 50/00* (2012.01)(21) International Application Number:
PCT/IN2016/000275(22) International Filing Date:
18 November 2016 (18.11.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
5663/CHE/2015 21 November 2015 (21.11.2015) IN

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(54) Title: SYSTEM AND METHOD FOR AUTOMATED GROSS EXAMINATION OF TISSUES

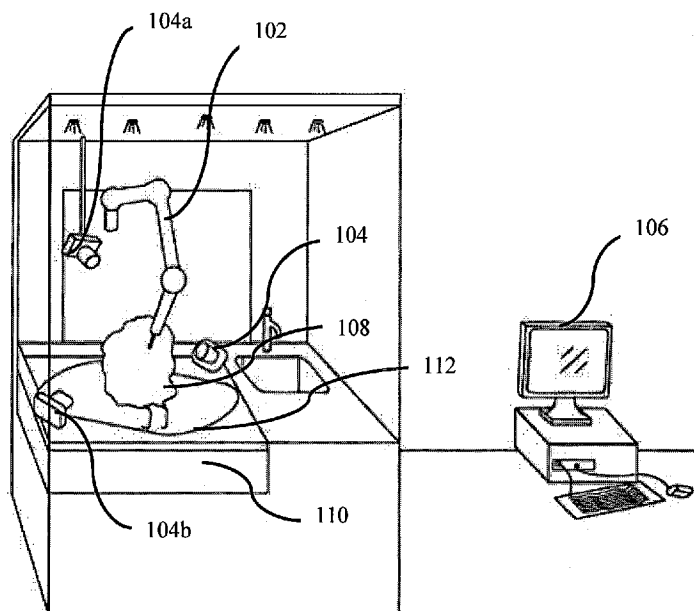


FIG. 1

(57) Abstract: The various embodiments herein provide a system and method for automatic gross-examination of tissue samples. The apparatus is of cubicle shape comprising a bed where the specimen is placed, an ultrasound equipment mounted on top of cubicle box, a robotic arm mounted with a plurality of surgical blades, and a camera. The ultrasound technology is used to accurately understand the specimen, size and dimensions of a tumor that is studied. The robotic arm assisted surgical blades receive ultrasound output or camera output and accurately slice the specimen for further analysis. The information pertaining to gross-examination is stored in an external server connected to the apparatus and analyzed using artificial intelligence algorithms.



Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

SYSTEM AND METHOD FOR AUTOMATED GROSS EXAMINATION OF TISSUES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The embodiments herein claims the priority of the Indian Provisional Patent Application filed on October 21, 2015 and subsequently postdated by 1 months to November 21, 2015 with the number 5663/CHE/2015 and entitled, "AN AUTOMATED APPARATUS AND METHOD FOR GROSS EXAMINATION OF TISSUES", and the contents of which are included in entirety as reference herein.

BACKGROUND

Technical Field

[0002] The embodiments herein are generally related to pathology grossing. The embodiments herein are particularly related to objective and reproducible inspection, image analysis and automated processing of pathological specimens. The embodiments herein are more particularly related to a completely automated apparatus with provision for human, technical, expert interface and a method for gross examination of tissue samples using image analysis techniques and artificial intelligence.

Description of the Related Art

[0003] To accurately diagnose various diseases and conditions, medical personnel remove one or more samples of tissue from the body of a patient. This process of harvesting tissue from the body is known as a biopsy. Once the tissue

sample or samples are removed and sent to a pathological laboratory, the tissue is passed/processed through a series of procedures performed by a histo-technician and, ultimately, a pathologist, in order to diagnose the tissue. Once a tissue sample is removed from the body of a patient, the sample is typically placed into a specimen container containing a tissue fixative solution and then the container is transported to a pathological laboratory. The tissue undergoes a process known as "grossing-in" in the pathological lab during which a histo-technician retrieves the tissue sample from the container, typically cuts the tissue sample into appropriate sizes for tissue processing, places individual samples into the appropriate sized small plastic tissue cassettes and assigns tracking numbers to each cassette. These tracking numbers are then logged into a tracking system used in the laboratory.

[0004] However, there is an immense need for the focus on grossing as grossing is a key step from where the entire story of pathological specimen processing begins. Grossing-in being the first step and most critical step involving histotechnicians/ pathologists expertise and experience, any error at this stage severely and adversely affect the entire process of pathological testing and reporting.

[0005] All the current innovations till date have been dealing with post grossed specimen. The identification of key suspected or pathological areas is a crucial step in grossing; and this step is not currently standardized as it relies on visual inspection and palpation of specimen, both of which are highly subjective. Any error in identification of "accurate/relevant area" will lead to a completely

erroneous report, which endangers the “pathological quality” there by affecting clinical decision-making for patient care.

[0006] Currently used innovations deal with post-grossed specimen. The grossing-in step is currently not standardized and largely relies on visual inspection and palpation of specimen, both of which are highly subjective. Any error in identification of accurate or relevant area leads to a completely erroneous report, which endangers the pathological quality there by effecting clinical decision making for patient care.

[0007] The current methods of pathological grossing are not effective for deeply embedded tumors in view of limitation of visual inspection and palpation. The current method also poses a risk of accidental injury and/or infection to pathologist.

[0008] The average number of pathological specimens grossed globally is close to 50 Million with a huge deficiency of the trained histo-technicians, thereby making the step of Grossing highly vulnerable. The average time taken for the expert technician to gross the specimen is approximately thirty minutes. With this big gap of time, expertise and the quality of reporting, only a compromised report is expected to get.

[0009] Hence there is a need for a more objective, accurate, reproducible and automated way, which is driven by artificial intelligence technology and endorsed by trained pathologist before proceeding- using double check mechanism, for a gross

examination of the tissue samples. There is also an immense need for the high speed and automated Grossing-in of specimens; a lymph node harvesting technology which is addressed with a help of imaging and robotics, as lymph node harvesting technology is an important event in the grossing in and as majority technicians are under-trained; reproducibility of results with minimum human interface and maximum accuracy; ability to serve the remote areas, which largely depend of tele-pathology, where grossing in errors lead to major misdiagnosis; ability to gross high volumes of specimens in limited time, with limited resources; accurate measures for preventing cross contamination with the help of automated and standardized procedures; digital documentation of the grossing process for review and corrections; and for better and uniform reporting with help of artificial intelligence.

[0010] Hence there is a need for an automated apparatus and method for gross examination of tissue samples. Further there is a need for an automated apparatus and method linked with Artificial Intelligence Engine for classification, probabilistic modelling, and advanced image analysis (image mining, speech recognition) processes. Still further there is a need for an automated apparatus and method provided with ultrasound technology and standardized imaging techniques for the gross examination of tissue samples method and to accurately understand the specimen, size and dimensions of the tumor. Yet there is a need for an automated apparatus and method for gross examination of tissue samples, to reduce a risk of accidental infection to pathologist/technicians during grossing, and to reduce a skin

and eye infection due to exposure to formalin. Yet there is a need for an automated apparatus and method for grossly reducing the time with help of robotics, in view of the high volumes of the specimen loads.

[0011] The above mentioned shortcomings, disadvantages and problems are addressed herein, which will be understood by reading and studying the following specification.

OBJECTS OF THE EMBODIMENTS

[0012] The primary object of the embodiments herein is to provide an automated apparatus and method for gross examination of tissue samples.

[0013] Another object of the embodiments herein is to provide an automated apparatus and method connected to an artificial intelligence engine for classification, probabilistic modeling, advanced image analysis such as image mining and speech recognition processes during the gross examination of tissue samples.

[0014] Yet another object of the embodiments herein is to provide an automated apparatus and method with ultrasound or other imaging techniques for the gross examination of tissue samples to accurately understand the specimen, size, texture, margins, character, nodal status, and dimensions of the tumor.

[0015] Yet another object of the embodiments herein is to provide an automated apparatus and method that reduces a risk of accidental infection to pathologist or technicians during grossing, and reduces a skin and eye infection due to exposure to formalin.

[0016] Yet another object of the embodiments herein is to provide an automated apparatus and method with the ultrasound equipment and other imaging techniques to automate the process of cutting the specimen by providing output from ultrasound equipment and other imaging techniques to the robotic surgical blades to accurately slice a specimen for further analysis.

[0017] Yet another object of the embodiments herein is to provide an automated apparatus and method for more accurate pathological dissection, to get the samples of ideal/ relevant areas for processing.

[0018] Yet another object of the embodiments herein is to provide an automated apparatus and method to increase accuracy and to reduce false-positive and false-negatives.

[0019] Yet another object of the embodiments herein is to provide an automated apparatus and method to help the pathologist to navigate to accurate and relevant zones in the specimen.

[0020] Yet another object of the embodiments herein is to harvest a maximum number of nodes.

[0021] Yet another object of the embodiments herein is to reduce a time taken for grossing process.

[0022] Yet another object of the embodiments herein is to provide an automated apparatus and method with a robotic arm, which has three dimensional blades for precise detection and dissection of the specimen of cubes.

[0023] Yet another object of the embodiments herein is to provide an automated apparatus and method for processing tissue before performing an automated slide review.

[0024] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing of tissue with the help of robotics and artificial intelligence.

[0025] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing of tissue in an enclosed atmosphere to prevent an exposure of pathologist to formalin and risk of infections and accidental injuries during “grossing” process.

[0026] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing of tissue with a unique way of capturing and integrating the image coupled with transferring the data uniquely to robot to perform tissue grossing process.

[0027] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing of tissue with an image analysis application and techniques that are applied to objectivize the subjective pathologist reading in a reproducible manner at a stage when a labeled specimen enters grossing-in.

[0028] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing of tissue to perform 3

dimensional mapping and analysis of the images of the tumor tissue, normal tissue, necrotic tissue, and margins with the help of the Image mining algorithms.

[0029] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing, which is involved only in slicing and block preparation (called Grossing).

[0030] Yet another object of the embodiments herein is to provide an ultrasound cleaning mechanism built-in in the automated apparatus and method for gross processing of tissue, to keep the instruments clean for a sequential processing.

[0031] Yet another object of the embodiments herein is to provide an automated apparatus for gross processing with a box like structure having a lock-in mechanism thereby enabling a cleaning of all parts effectively and efficiently.

[0032] Yet another object of the embodiments herein is to provide an automated apparatus for gross processing having Classification (supervised learning) algorithms/ models, and Digital pathology for collaboration.

[0033] Yet another object of the embodiments herein is to provide an automated apparatus for gross processing in which a data mining and analytics are carried out at server level.

[0034] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing in a safe manner to reduce the risk accidental infection to pathologist/ technicians during grossing.

[0035] Yet another object of the embodiments herein is to provide an automated apparatus and method for gross processing in a safe manner to reduce skin and eye infections due to exposure to formalin.

[0036] Yet another object of the embodiments herein is to provide an automated apparatus and method for significantly increasing an accuracy in slicing of the specimen and preserving the integrity of gross specimen.

[0037] Yet another object of the embodiments herein is to provide an automated grossing apparatus and method to avoid a lot of problems in grossing like wrong depth during splicing (errors due to inability in understanding a resistivity and hardness of the specimen).

[0038] Yet another object of the embodiments herein is to provide an automated grossing apparatus and method to increases an ability to reach deep areas such as areas close to vessels, deep lungs, intramural tumors etc. which are otherwise difficult to reach.

[0039] Yet another object of the embodiments herein is to provide an automated grossing apparatus and method integrated with analytic engine, robotic arm, ultrasound mechanism and mobile computing technology.

[0040] Yet another objective of the embodiments herein is to provide a system and method for enabling additional reinforcement of the measurements by the indirect measurement techniques like USG, X-Rays, NMR imaging tools for accurate and automated interpretation of gross-examination.

[0041] Yet another objective of the embodiments herein is to automate the process of gross-examination by employing a combination of a plurality of technologies such as robotics, analytics, ultrasound, mobile computing etc.

[0042] Yet another objective of the embodiments herein is to automate the process of gross-examination by enabling storage of information pertaining to gross-examination on an external server.

[0043] Yet another objective of the embodiments herein is to automate the process of gross-examination through machine learning algorithms and methodologies.

[0044] These and other objects and advantages of the embodiments herein will become readily apparent from the following detailed description taken in conjunction with the accompanying drawings.

SUMMARY

[0045] The various embodiments herein provide system and method for an automated apparatus for the gross examination of tissue sample.

[0046] According to one embodiment herein, an automated apparatus for the gross examination of tissue sample is provided. The apparatus is of cubicle or rectangular shape comprising a bed where the specimen is placed, an ultrasound equipment mounted under the bed, camera mounted on 3-D movable arm for accurately capturing the image for the detailing of the specimen and a robotic arm capable of moving in X-axis, Y-axis and Z- axis, a plurality of surgical blades

housed in the cubicle box and mounted in the robotic arm. A 3D movable camera captures the details of the specimen to be grossed, similar to a naked eye but with objectification. The ultrasound technology is used to accurately understand the specimen, size and dimensions of a tumor that is studied. The ultrasound equipment also assists in the automation of the process of cutting the specimen. The surgical blades receive ultrasound output and accurately slice the specimen for further analysis.

[0047] According to one embodiment herein, a precision instrument, which is linked with an Artificial Intelligence engine for classification, probabilistic modeling and advanced image analysis of gross-examination of tissues, is provided. All these are analytical models that are specific and customized to each type of specimen being handled. Processes such as automated image analysis, remote viewing, pathologists' collaboration, standard image segmentation, storage retrieval etc. are included in the system as a part of the integrated applications.

[0048] According to one embodiment herein, an apparatus for enabling automated gross-examination of tissues is provided. The apparatus comprises stainless steel bed for placing the tissue sample, cubes of multiple sizes to act as the base for the bed, mountable ultrasound equipment and retractable robotic blades are provided. The Stainless steel bed is provided with a disposable cover for each specimen. The Bed is configured to slide out and when bed is outside, to avoid accidental injury. The blades inside robotic are retracted inside. Only on completion

of ultrasound and confirmation by pathologist the blades are extended out of the robotic arm.

[0049] According to one embodiment herein, the apparatus is provided with a built-in ultrasound cleaning mechanism to keep the instruments clean for a sequential processing.

[0050] According to one embodiment herein, the box is formed or fabricated in three sizes of 30/60/90 sqcm with bed arranged at a 2/3rd height from the base. The bed is provided on top with a piezoelectric glass mounted with the ultrasound equipment. The bed is connected with a motor for rotating the bed for assisting the dissection process of grossing-in and enable imaging process. The box has a modular design with lock-in mechanisms to ensure that all the parts are opened and cleaned manually by an operator or a lab technician with a minimal training. The ultrasound equipment is arranged or configured to cover an entire surface area on top of the bed. Alternatively the ultrasound equipment is arranged as an array for covering specimen per sqmm.

[0051] According to one embodiment herein, the robotic arm is mounted with medical grade surgical blades (like scalpel) with a retractable mechanism for safety. The 3 blades are configured to cover X-Y-Z axes As soon as the specimen is sliced, the blades are cleaned with an ultrasound mechanism. The equipment is provided with an automatic cleaning facility arranged inside and is cleaned later manually. An output of ultrasound is input to robotic arm, based on the command

issued from the server after the analysis by the pathologist and analytics from server to cut and slice the sample for analysis. The output of ultrasound is input to robotic arm, for precise detection and dissection of specimen into cubes of preset sizes using the medical grade blades. The cubes are transferred with help of robotic arm into automatic wax block for preparation, which are then subjected to analysis.

[0052] According to one embodiment herein, any analytics on AI and Machine learning is carried out in the server and the results are communicated the apparatus from the server. A plurality of classification (supervised learning) algorithms/ models, and Digital pathology for collaboration are employed in the analysis of the samples.

[0053] According to one embodiment herein, the apparatus is configured to perform automatic process of grossing of tissues by integrating the technologies of data mining, analytics, robotics, ultrasound and mobile computing.

[0054] According to one embodiment herein, the apparatus is configured to storage data/information related to gross-examination of tissue samples on an external server.

[0055] According to one embodiment herein, a method is provided with the steps involved in a preliminary identification and recording information about a gross-examination sample. The method comprises the following steps: Identification of the nomenclature and taxonomy of a specimen; Placement of the specimen is on the ultrasound bed laterally depending on the size of the specimen; The specimen is

stabilized with a robotic arm and the measurements of the specimen are captured by ultrasound technique; The specimen is video graphed and contour shape is recorded; and, Measurements are analyzed by pathologists; when the pathologists approve the measurements, the measurements and shape of the specimen are recorded in the database. When the pathologists do not approve the measurements, the pathologist modifies the measurements and the measurements and shape of the specimen are recorded in the database.

[0056] According to one embodiment herein, a method is provided with the steps involved in an image analysis of a gross-examination sample. The method comprises the following steps: The analysis of the specimen is carried out by the ultrasound waves and the waves are converted into co-ordinates by a computer algorithm; An image is captured by a piezoelectric device with the help of ultrasound waves and the image is sent to the image analysis algorithm for further analysis; The total size of the tumor versus the total size of the specimen is identified from the sonic imaging and the location of the tumor is identified with respect to its boundaries from left to right; The size of the tumor as per general slicing is also captured and stored for further use and the lymph nodes are counted from the image analysis and are mapped to the co-ordinates and nodal dissection takes place; and, The specimen is sliced from left to right while enabling more slicing at the boundaries of the tumor and while slicing the tumor, the grittiness and the texture of the tumor are captured.

[0057] According to one embodiment herein, a method is provided with the steps involved in generating an analysis report of a gross-examination sample after conducting an image analysis on the sample, according to one embodiment herein. The method comprises the following steps: Once the slicing is done the robotic arm disengages and the tumor is held for further clinical purposes; The tumor is then dissected to obtain a block of tumor by the robotic arm as per the grossing principles; A predefined full report is generated with all the necessary information; and, The report and the block are sent for further clinical purposes.

[0058] According to one embodiment herein, a system is provided to enable texture and consistency analysis and reporting of a sample. The system comprises an automated/manual robotic arm with 3D control, a module with pressure/time /power gradient control coupled with movement measurement technology and a module for measurement of resistance / movement traversed with outputs based on programmed calculator for consistency. The embodiment also comprises a module with a standardized scale with a validated score system to objectively document the consistency and texture, that is reported automatically with a pathologist/ a technical expert interface to minimize false negatives and errors. The embodiment also comprises an artificial intelligence module that comprises: input capturing in terms of force vs. movement vs. time vs. texture and coupling with graded output for dissecting to robotic arm; data integration with image [Visual/optical] vs. Scan [electromagnetic/ piezoelectric/ texture/tensile and other properties; artificial

intelligence based algorithm for the forward and backward integration; and, automated typing into the pre-formatted texting taking inputs specific to organ.

[0059] According to one embodiment herein, a system is provided to enable sensor-blade technology in the robotic arm in the apparatus. The system comprises a module with an intact tissue sliced and the scanner integrated with blade, a module with a feedback loop from the technical interface/ historical control / machine learning controls the dissecting pressure and distance to be traversed, a module with a pressure too low that undercuts and be augmented by positive feedback loop, a module with a pressure too high that overcuts and be inhibited by negative feedback loop; and a module with an accurate dissection with texture/ consistency oriented outputs, which are objective and quantifiable.

[0060] According to one embodiment herein, a system is provided to enable Lymph-node plucking with the present apparatus. The system comprises a Lymph-node sample, a module with a 3D controlled human interface enabled arm having inputs from the Imaging and Scanning integrated with pathologist inputs, a module with a plurality of outputs to a plucker/ rotator blade [not slicing, which is unique] that plucks without damaging the surrounding tissues, a module with image based mapping of the spherico ovaoidal structures, having high probabilistic chances of being Lymph nodes and coordinates to be sent to the robotic arm and a final feedback loop coupled with artificial intelligence makes the prediction better with

machine learning and technical interface for better nodal yield. The plucking/circular cutting minimizes damage to surroundings of the sample.

[0061] According to one embodiment herein, a system is provided to enable a development of predicting modeling tool for malignant potential based on the final HPE to integrate for a routine imaging with artificial intelligence. The system comprises a module with grossing results coupled with final HPE from the master database/computer, which are specific to the tissues and organ, a module with results of imaging / scanning from the database corresponding to the specimen, a module comprising artificial intelligence based algorithm for machine learning to predict the characters unique for malignant vs. benign tissues and final software that predicts malignant potential at the scanning level itself in the live organisms/ humans.

[0062] According to one embodiment herein, a system is provided for transferring information from an ultrasonic generator to correlating software for pathology image. The system comprises a cloud module with data from USG and final pathology from automated grossing machine, a module for analysis of textures as measured with resistivity index, a module for analysis of image textures from camera and ultrasound, a module to send for the artificial algorithm for correlation to HPE, a module to send for artificial intelligence platform for pattern recognition and validated outputs and an image-pathological correlating software.

[0063] These and other aspects of the embodiments herein will be better appreciated and understood when considered in conjunction with the following

description and the accompanying drawings. It should be understood, however, that the following descriptions, while indicating preferred embodiments and numerous specific details thereof, are given by way of illustration and not of limitation. Many changes and modifications may be made within the scope of the embodiments herein without departing from the spirit thereof, and the embodiments herein include all such modifications.

BRIEF DESCRIPTION OF THE DRAWINGS

[0064] The other objects, features and advantages will occur to those skilled in the art from the following description of the preferred embodiment and the accompanying drawings in which:

[0065] **FIG. 1** illustrates a perspective view of an apparatus for automatic gross-examination of tissue samples, according to one embodiment herein.

[0066] **FIG. 2** illustrates a flow diagram that provides the steps involved in a preliminary identification and recording information about a gross-examination sample, according to one embodiment herein.

[0067] **FIG. 3** illustrates a flow diagram that provides the steps involved in an image analysis of a gross-examination sample, according to one embodiment herein.

[0068] **FIG. 4** illustrates a flow diagram that provides the steps involved in generating an analysis report of a gross-examination sample after conducting an image analysis on the sample, according to one embodiment herein.

[0069] **FIG. 5** illustrates a system that enables texture and consistency analysis and reporting of a sample, according to one embodiment herein.

[0070] **FIG. 6** illustrates a system that enables the sensor-blade technology in the robotic arm in the apparatus, according to one embodiment herein.

[0071] **FIG. 7** illustrates a system that enables Lymph-node plucking with the present apparatus, according to one embodiment herein.

[0072] **FIG. 8** illustrates a system that enables a development of predicting modeling tool for malignant potential based on the final HPE to integrate for a routine imaging with artificial intelligence, according to one embodiment herein.

[0073] **FIG. 9** illustrates a system for transferring information from an ultrasonic generator to correlating software for pathology image, according to one embodiment herein.

[0074] Although the specific features herein are shown in some drawings and not in others. This is done for convenience only as each feature may be combined with any or all of the other features in accordance with the embodiments herein.

DETAILED DESCRIPTION OF THE INVENTION

[0075] In the following detailed description, a reference is made to the accompanying drawings that form a part hereof, and in which the specific embodiments that may be practiced is shown by way of illustration. These embodiments are described in sufficient detail to enable those skilled in the art to practice the embodiments and it is to be understood that other changes may be made

without departing from the scope of the embodiments. The following detailed description is therefore not to be taken in a limiting sense.

[0076] The various embodiments herein provide system and method for an automated apparatus for the gross examination of tissue sample.

[0077] According to one embodiment herein, an automated apparatus for the gross examination of tissue sample is provided. The apparatus is of cubicle or rectangular shape or other suitable shape comprising a bed where the specimen is placed, an ultrasound equipment mounted under the bed, camera mounted on a 3D movable arm for accurately capturing the image for the detailing of the specimen and a robotic arm capable of moving in X-axis, Y-axis and Z- axis, a plurality of surgical blades housed in the cubicle box and mounted in the robotic arm. A 3D movable camera captures the details of the specimen to be grossed, similar to naked eye but with objectification. The ultrasound technology is used to accurately understand the specimen, size and dimensions of a tumor that is studied. The ultrasound equipment also assists in the automation of the process of cutting the specimen. The surgical blades receive the output from the ultrasound equipment or other imaging devices to accurately slice the specimen for further analysis.

[0078] According to one embodiment herein, a precision instrument, which is linked with an Artificial Intelligence engine for classification, probabilistic modeling and advanced image analysis of gross-examination of tissues, is provided. All these are analytical models that are specific and customized to each type of

specimen being handled. Processes such as automated image analysis, remote viewing, pathologists' collaboration, standard image segmentation, storage retrieval etc. are included in the system as a part of the integrated applications.

[0079] According to one embodiment herein, an apparatus for enabling automated gross-examination of tissues is provided. The apparatus comprises stainless steel bed for placing the tissue sample, cubes of multiple sizes to act as the base for the bed, mountable ultrasound equipment and retractable robotic blades are provided. The piezo-electric compatible bed fixed on stainless steel based motor enabled plate is provided with a disposable cover for each specimen. The Bed is configured to slide out and when bed is outside, to avoid accidental injury. The blades inside robotic are retracted inside. Only on completion of ultrasound and confirmation by pathologist the blades are extended out of the robotic arm.

[0080] According to one embodiment herein, the apparatus is provided with a built-in ultrasound cleaning mechanism to keep the instruments clean for a sequential processing.

[0081] According to one embodiment herein, the box is formed or fabricated in three sizes of 30/60/90 sqcm with bed arranged at a 2/3rd height from the base. The bed is provided on top with a piezoelectric glass mounted with the ultrasound equipment. The bed is connected to a motor for rotating the bed for assisting the dissection process of grossing-in and imaging operations. The box has a modular design with lock-in mechanisms to ensure that all the parts are opened and cleaned

manually by an operator or a lab technician with a minimal training. The ultrasound equipment is arranged or configured to cover an entire surface area on top of the bed. Alternatively the ultrasound equipment is arranged as an array for covering specimen per sqmm.

[0082] According to one embodiment herein, the robotic arm is mounted with medical grade surgical blades (like scalpel) with a retractable mechanism for safety. The 3 blades are configured to cover X-Y-Z axes As soon as the specimen is sliced, the blades are cleaned with an ultrasound mechanism. The equipment is provided with an automatic cleaning facility arranged inside and is cleaned later manually. An output of ultrasound is input to robotic arm, based on the command issued from the server after the analysis by the pathologist and analytics from server to cut and slice the sample for analysis. The output of ultrasound is input to robotic arm, for precise detection and dissection of specimen into cubes of preset sizes using the medical grade blades. The cubes are transferred with help of robotic arm into automatic wax block for preparation, which are then subjected to analysis.

[0083] According to one embodiment herein, any analytics on AI and Machine learning is carried out in the server and the results are communicated the apparatus from the server. A plurality of classification (supervised learning) algorithms/ models, and Digital pathology for collaboration are employed in the analysis of the samples.

[0084] According to one embodiment herein, the apparatus is configured to perform automatic process of grossing of tissues by integrating the technologies of data mining, analytics, robotics, ultrasound and mobile computing.

[0085] According to one embodiment herein, the apparatus is configured to storage data/information related to gross-examination of tissue samples on an external server.

[0086] **FIG. 1** illustrates a perspective view of an apparatus for automatic gross-examination of tissue samples, according to an embodiment herein.

[0087] With respect to **FIG.1**, an automated apparatus for the gross examination of tissue sample is provided. The apparatus is of cubicle shaped box comprising a bed 110 where the specimen 108 is placed. An ultrasound equipment is mounted on top of the bed 110 and a robotic arm 102 capable of moving in X-axis, Y-axis and Z- axis is fixed to the top of the box. A plurality of surgical blades is mounted in the robotic arm 102. The blades are configured to extend out during a dissection process and are retracted back inside the arm 102 when not in use. The ultrasound technology is used to accurately understand/detect the specimen, size and dimensions of a tumor that is studied. The ultrasound equipment also automates the process of cutting the specimen 108. The surgical blades receive ultrasound output and accurately slice the specimen for further analysis. A camera 104a, is mounted on 3 D movable arm for accurate capturing of the image for the detailing of the specimen. A plurality of 3D movable cameras 104,104a, 104b is provided to capture

the details of the specimen to be grossed, similar to naked eye but with objectification.

[0088] According to one embodiment herein, a precision instrument, which is linked with an Artificial Intelligence engine for classification, probabilistic modeling and advanced image analysis of gross-examination of tissues, is provided. All these are analytical models that are specific and customized to each type of specimen being handled. Processes such as automated image analysis, remote viewing, pathologists' collaboration, standard image segmentation, storage retrieval etc. are included in the system as a part of the integrated applications.

[0089] According to one embodiment herein, the apparatus comprises stainless steel bed 110 for placing the tissue sample. The bed is mounted with a piezo electric glass 112 on top. A ultrasound equipment is mounted on the bed. The retractable robotic blades are provided. The Stainless steel bed 110 is provided with a disposable cover for each specimen. The Bed 110 is configured to slide out and when bed is outside, to avoid accidental injury. The blades are retracted inside robotic arm, when not in use. Only on completion of ultrasound and confirmation by pathologist, the blades are extended out of the robotic arm.

[0090] According to one embodiment herein, the apparatus is provided with a built-in ultrasound cleaning mechanism to keep the instruments clean for a sequential processing.

[0091] According to one embodiment herein, the box is formed or fabricated in three sizes of 30/60/90 sqcm with bed arranged at a 2/3rd height from the base. The box has a modular design with lock-in mechanisms to ensure that all the parts are opened and cleaned manually by an operator or a lab technician with a minimal training. The ultrasound equipment is arranged or configured to cover an entire surface area on top of the bed. Alternatively the ultrasound equipment is arranged as an array for covering specimen per sqmm.

[0092] According to one embodiment herein, the robotic arm is mounted 102 with medical grade surgical blades (like scalpel) with a retractable mechanism for safety. The 3 blades are configured to cover X-Y-Z axes As soon as the specimen is sliced, the blades are cleaned with an ultrasound mechanism. The equipment is provided with an automatic cleaning facility arranged inside and is cleaned later manually. An output of ultrasound is input to robotic arm, based on the command issued from the server after the analysis by the pathologist and analytics from server to cut and slice the sample for analysis. The output of ultrasound is input to robotic arm, for precise detection and dissection of specimen into cubes of preset sizes using the medical grade blades. The cubes are transferred with help of robotic arm into automatic wax block for preparation, which are then subjected to analysis.

[0093] According to one embodiment herein, any analytics on AI and Machine learning is carried out in the server 106 and the results are communicated the apparatus from the server 106. A plurality of classification (supervised learning)

algorithms/ models, and Digital pathology for collaboration are employed in the analysis of the samples.

[0094] **FIG. 2** illustrates a flow diagram that provides the steps involved in a preliminary identification and recording information about a gross-examination sample, according to one embodiment herein. The method comprises the following steps: Identification of the nomenclature and taxonomy of a specimen (201); Placement of the specimen is on the ultrasound bed laterally depending on the size of the specimen (202); The specimen is stabilized with a robotic arm and the measurements of the specimen are captured by ultrasound technique (203); The specimen is videographed and contour shape is recorded (204); and, Measurements are analyzed by pathologists; when the pathologists approve the measurements, the measurements and shape of the specimen are recorded in the database. When the pathologists do not approve the measurements, the pathologist modifies the measurements and the measurements and shape of the specimen are recorded in the database (205).

[0095] **FIG. 3** illustrates a flow diagram that provides the steps involved in an image analysis of a gross-examination sample, according to one embodiment herein. The method comprises the following steps: The analysis of the specimen is carried out by the ultrasound waves and the waves are converted into co-ordinates by a computer algorithm (301); An image is captured by a piezoelectric device with the help of ultrasound waves and the image is sent to the image analysis algorithm for

further analysis (302); The total size of the tumor versus the total size of the specimen is identified from the sonic imaging and the location of the tumor is identified with respect to its boundaries from left to right (303); The size of the tumor as per general slicing is also captured and stored for further use and the lymph nodes are counted from the image analysis and are mapped to the co-ordinates and nodal dissection takes place (304); and, The specimen is sliced from left to right while enabling more slicing at the boundaries of the tumor and while slicing the tumor, the grittiness and the texture of the tumor are captured (305).

[0096] **FIG. 4** illustrates a flow diagram that provides the steps involved in generating an analysis report of a gross-examination sample after conducting an image analysis on the sample, according to one embodiment herein. The method comprises the following steps: Once the slicing is done the robotic arm disengages and the tumor is held for further clinical purposes (401); The tumor is then dissected to obtain a block of tumor by the robotic arm as per the grossing principles (402); A predefined full report is generated with all the necessary information (403); and, The report and the block are sent for further clinical purposes (404).

[0097] **FIG. 5** illustrates a system that enables texture and consistency analysis and reporting of a sample, according to one embodiment herein. The system comprises an automated/manual robotic arm with 3D control 501, a module with pressure/time /power gradient control coupled with movement measurement technology 502 and a module for measurement of resistance / movement traversed

with outputs based on programmed calculator for consistency. The embodiment also comprises a module 504 with a standardized scale with a validated score system to objectively document the consistency and texture, that is reported automatically with a pathologist/ a technical expert interface to minimize false negatives and errors. The embodiment also comprises an artificial intelligence module 505 that comprises: input capturing in terms of force vs. movement vs. time vs. texture and coupling with graded output for dissecting to robotic arm; data integration with image [Visual/optical] vs. Scan [electromagnetic/ piezoelectric/ texture/tensile and other properties; artificial intelligence based algorithm for the forward and backward integration; and, automated typing into the pre-formatted texting taking inputs specific to organ.

[0098] FIG. 6 illustrates a system that enables the sensor-blade technology in the robotic arm in the apparatus, according to one embodiment herein. The system comprises a module with an intact tissue sliced and the scanner integrated with blade 601, a module with a feedback loop from the technical interface/ historical control / machine learning controls the dissecting pressure and distance to be traversed 602, a module with a pressure too low that undercuts and be augmented by positive feedback loop 603, a module with a pressure too high that overcuts and be inhibited by negative feedback loop 604; and a module with an accurate dissection with texture/ consistency oriented outputs, which are objective and quantifiable 605.

[0099] **FIG. 7** illustrates a system that enables Lymph-node plucking with the present apparatus, according to one embodiment herein. The system comprises a Lymph-node sample 701, a module with a 3D controlled human interface enabled arm having inputs from the Imaging and Scanning integrated with pathologist inputs 702, a module with a plurality of outputs to a plucker/ rotator blade [not slicing, which is unique] that plucks without damaging the surrounding tissues 703, a module with image based mapping of the spherico ovaoidal structures, having high probabilistic chances of being Lymph nodes and coordinates to be sent to the robotic arm 704 and a final feedback loop coupled with artificial intelligence makes the prediction better with machine learning and technical interface for better nodal yield 705. The plucking/ circular cutting minimizes damage to surroundings of the sample.

[00100] **FIG. 8** illustrates a system that enables a development of predicting modeling tool for malignant potential based on the final HPE to integrate for a routine imaging with artificial intelligence, according to one embodiment herein. The system comprises a module with grossing results coupled with final HPE from the master database/computer, which are specific to the tissues and organ 801, a module with results of imaging / scanning from the database corresponding to the specimen 802, a module comprising artificial intelligence based algorithm for machine learning to predict the characters unique for malignant vs. benign tissues 803 and final software that predicts malignant potential at the scanning level itself in the live organisms/ humans 804.

[00101] FIG. 9 illustrates a system for transferring information from an ultrasonic generator to correlating software for pathology image, according to one embodiment herein. The system comprises a cloud module with data from USG and final pathology from automated grossing machine 901, a module for analysis of textures as measured with resistivity index 902, a module for analysis of image textures from camera and ultrasound 903, a module to send for the artificial algorithm for correlation to HPE 904, a module to send for artificial intelligence platform for pattern recognition and validated outputs 905 and an image-pathological correlating software.

[00102] The foregoing description of the specific embodiments will so fully reveal the general nature of the embodiments herein that others can, by applying current knowledge, readily modify and/or adapt for various applications such as specific embodiments without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiments. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation. Therefore, while the embodiments herein have been described in terms of preferred embodiments, those skilled in the art will recognize that the embodiments herein can be practiced with modifications. However, all such modifications are deemed to be within the scope of the claims.

[00103] The embodiments herein provide a system and method for an automated apparatus for the gross examination of tissue sample. The embodiments herein enable an accurate pathological dissection to obtain the samples of ideal and relevant areas for processing. The automated apparatus also increases accuracy and reduces false-positive and false-negative results.

[00104] The automated apparatus helps a pathologist to navigate to accurate and relevant zones in the specimen. The output of present embodiment's analysis is fed to a robotic arm, which has three-dimensional blades for precise detection and dissection of the specimen to required sizes.

[00105] The embodiments herein provide a system for high speed and automated Grossing-in of specimens, to reduce the turn-around time.

[00106] The embodiments herein provide a system and method to enable better lymph node harvesting technology, which is an important event in the grossing in as the majority of the technicians are semi-skilled and under trained. The embodiments herein also assist the pathologists to enable better lymph node harvesting technology with the help of imaging and robotics techniques.

[00107] The embodiments herein provide a system and method to provide reproducible results, with objective parameters and objectification of currently subjective issues with minimum human interface and maximum accuracy.

[00108] The embodiments herein provides access to technologically qualified inputs to serve the remote areas, which largely depend on tele-pathology and where grossing in errors lead to major misdiagnosis.

[00109] The embodiments herein provide a system to enable grossing of high volumes of specimens in limited time with limited resources.

[00110] The embodiments herein provide a system and method to enable accurate measurement and to prevent cross contamination with help of automated and standardized procedures.

[00111] The embodiments herein provide system and method to enable digital documentation of the grossing process for review and corrections.

[00112] The embodiments herein provide system and method to enable better and uniform reporting of grossing-in processes and results through artificial intelligence techniques.

[00113] The embodiments herein reduce the risk accidental infection to pathologist/ technicians during grossing. The embodiments herein further reduce skin and eye infections due to exposure to formalin.

[00114] The apparatus herein is configured to significantly increase accuracy in slicing the specimen and preserve the integrity of gross specimen. The apparatus is configured to avoid a lot of problems in grossing like wrong depth during splicing, which are errors due inability to understand resistivity and hardness of the specimen,

and increase the ability to reach deep areas which are otherwise difficult to reach such as areas close to vessels, deep lungs, intramural tumors etc.

[00115] It is also to be understood that the following claims are intended to cover all of the generic and specific features of the embodiments described herein and all the statements of the scope of the embodiments which as a matter of language might be said to fall there between.

Claims

What is claimed is:

1. A system for automatic gross-examination of tissue samples, the system comprising:
 - a stainless steel bed;
 - a piezoelectric glass lid;
 - a robotic arm;
 - a plurality of cameras;
 - an ultrasound cleaning mechanism; and
 - a server.
2. The system according to claim 1, wherein the system comprises a stainless steel bed for placing a tissue sample, and wherein the bed is mounted with a piezoelectric glass on top, and wherein the stainless steel bed is provided with a disposable cover for each specimen, and wherein the bed is configured to slide out to avoid accidental injury, and wherein a box with a modular design is provided to cover the bed and wherein the box is provided with lock-in mechanisms to ensure that all the parts are opened and cleaned manually by an operator or a lab technician with a minimal training.
3. The system according to claim 1, wherein a robotic arm capable of moving in X-axis, Y-axis and Z- axis is fixed to the top of the box, and wherein a

plurality of surgical blades is mounted in the robotic arm, and wherein the blades are configured to extend out during a dissection process and are retracted back inside the arm when not in use, and wherein a camera is mounted on a 3D movable arm for accurate capturing of the image for the detailing of the specimen, and wherein a plurality of 3D movable cameras is provided to capture the details of the specimen to be grossed, and wherein the cameras are similar to naked eye but with objectification.

4. The system according to claim 1, wherein a built-in ultrasound cleaning mechanism is provided to keep the instruments clean for a sequential processing, and wherein the ultrasound equipment is mounted on top of the bed and the ultrasound technology is used to accurately understand and detect the size and dimensions of a tumor specimen that is studied, and wherein the ultrasound equipment also automates the process of cutting the specimen, wherein the surgical blades on the robotic arm receive ultrasound output and accurately slice the specimen for further analysis.
5. The system according to claim 1, wherein an output of ultrasound equipment is input to robotic arm, based on the command issued from the server after the analysis by the pathologist and analytics from server to cut and slice the sample for analysis, and wherein the output of ultrasound is input to robotic arm, for precise detection and dissection of specimen into cubes of preset

sizes using the medical grade blades, and wherein the cubes are transferred with help of robotic arm into automatic wax block for preparation, which are then subjected to analysis.

6. The system according to claim 1, wherein analytics based on artificial intelligence and machine learning technologies are carried out in the server and the results are communicated the apparatus from the server, and wherein a plurality of classification and supervised learning algorithms or models and digital pathology for collaboration are employed in the analysis of the samples, and wherein an artificial intelligence engine is provided in the server for classification, probabilistic modeling and advanced image analysis of gross-examination of tissues, and wherein the analytical models are specific and customized to each type of specimen being handled, and wherein processes such as automated image analysis, remote viewing, pathologists' collaboration, standard image segmentation and storage retrieval are included in the system as a part of integrated applications.

7. A method for automatic gross-examination of tissue samples, the method comprising:

a preliminary method for identification and recording information about a gross-examination sample;

an image analysis of a gross-examination sample; and,

generating an analysis report of a gross-examination sample after conducting an image analysis on the sample.

8. The method according to claim 1, wherein a preliminary method for identification and recording information about a gross-examination sample comprises the following steps: identification of the nomenclature and taxonomy of a specimen; placement of the specimen is on the ultrasound bed laterally depending on the size of the specimen; the specimen is stabilized with a robotic arm and the measurements of the specimen are captured by ultrasound technique; the specimen is videographed and contour shape is recorded; and, measurements are analyzed by pathologists; when the pathologists approve the measurements, the measurements and shape of the specimen are recorded in the database, and wherein When the pathologists do not approve the measurements, the pathologist modifies the measurements and the measurements and shape of the specimen are recorded in the database.
9. The system according to claim 1, wherein an image analysis of a gross-examination sample comprises the following steps: an analysis of the specimen is carried out by the ultrasound waves and the waves are converted into co-ordinates by a computer algorithm; an image is captured by a piezoelectric device with the help of ultrasound waves and the image is sent to the image analysis algorithm for further analysis; a total size of the tumor

versus the total size of the specimen is identified from the sonic imaging and the location of the tumor is identified with respect to its boundaries from left to right; a size of the tumor as per general slicing is also captured and stored for further use and the lymph nodes are counted from the image analysis and are mapped to the co-ordinates and nodal dissection takes place; and, the specimen is sliced from left to right while enabling more slicing at the boundaries of the tumor and while slicing the tumor, the grittiness and the texture of the tumor are captured.

10. The system according to claim 1, wherein generating an analysis report of a gross-examination sample after conducting an image analysis on the sample comprises the following steps: once the slicing is done, the robotic arm disengages and the tumor is held for further clinical purposes; the tumor is then dissected to obtain a block of tumor by the robotic arm as per the grossing principles; a predefined full report is generated with all the necessary information; and, the report and the block are sent for further clinical purposes.

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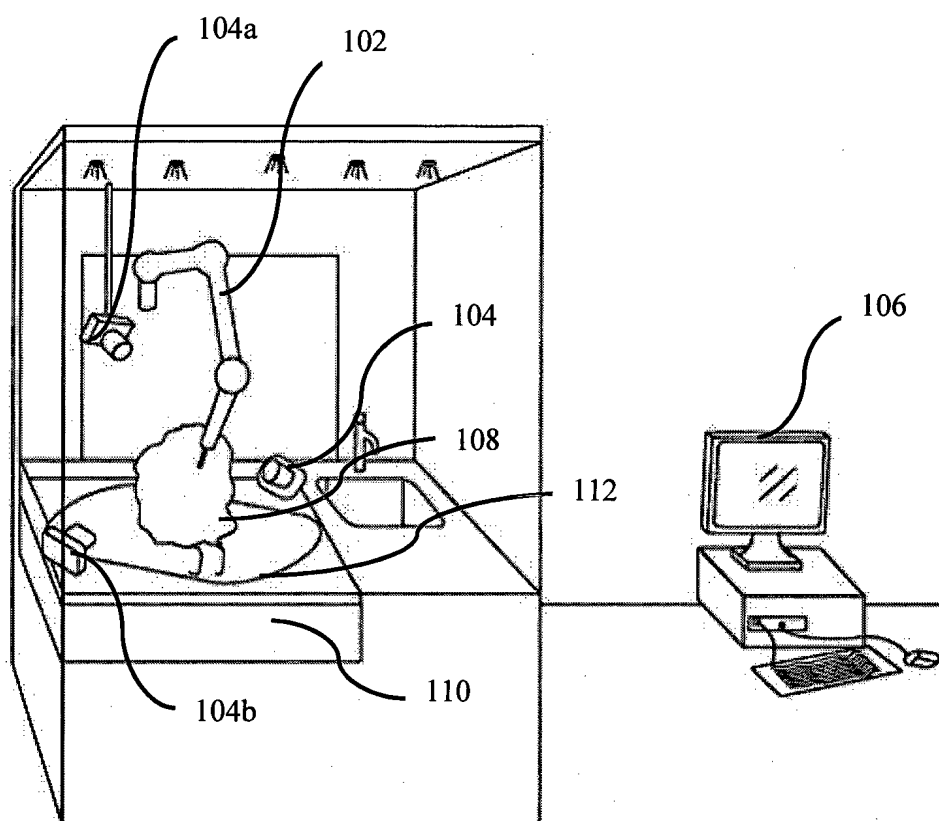


FIG. 1

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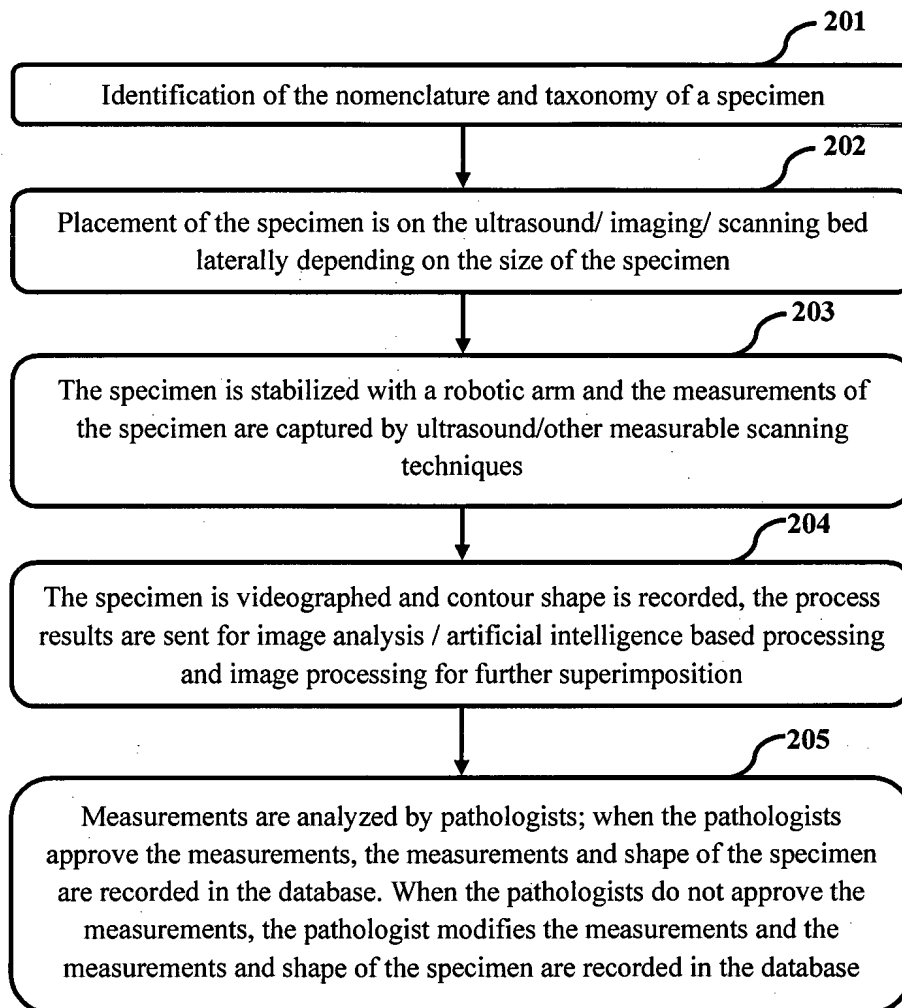


FIG. 2

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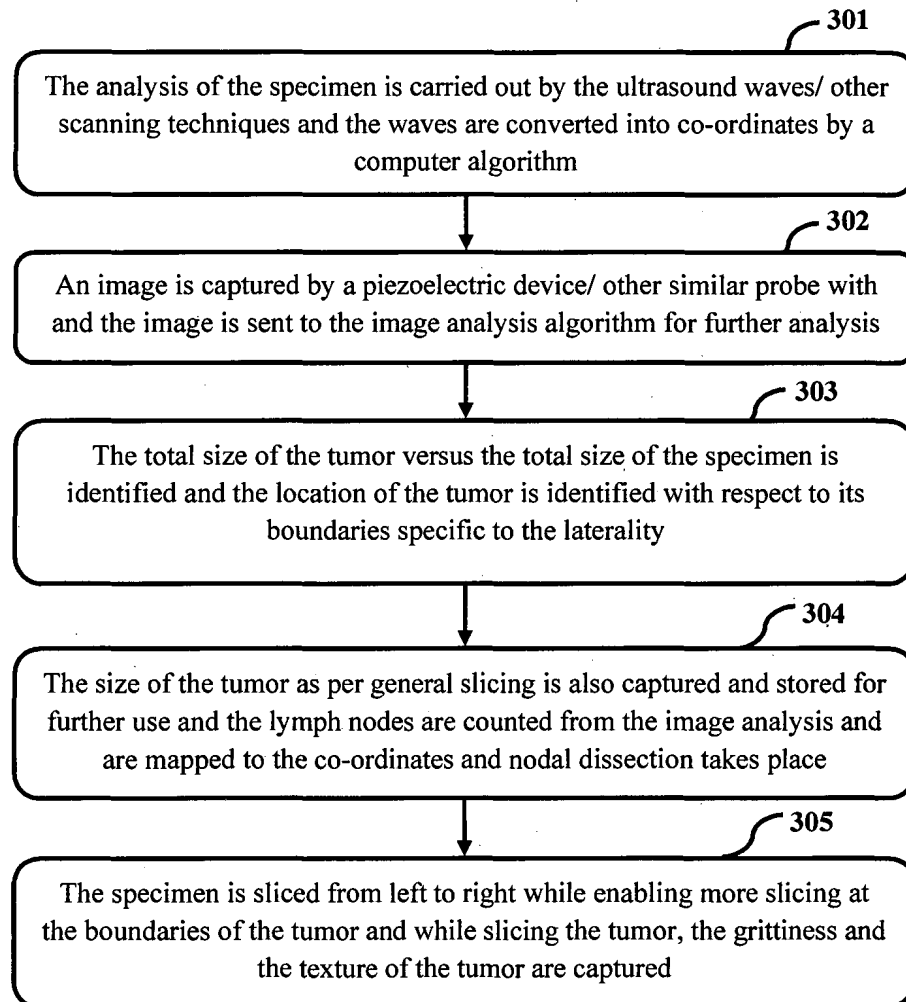


FIG. 3

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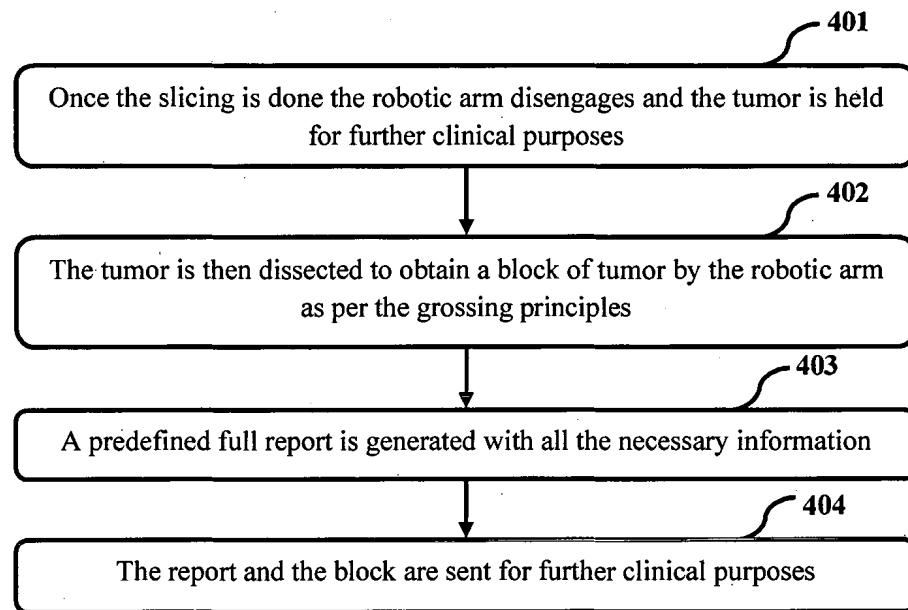


FIG. 4

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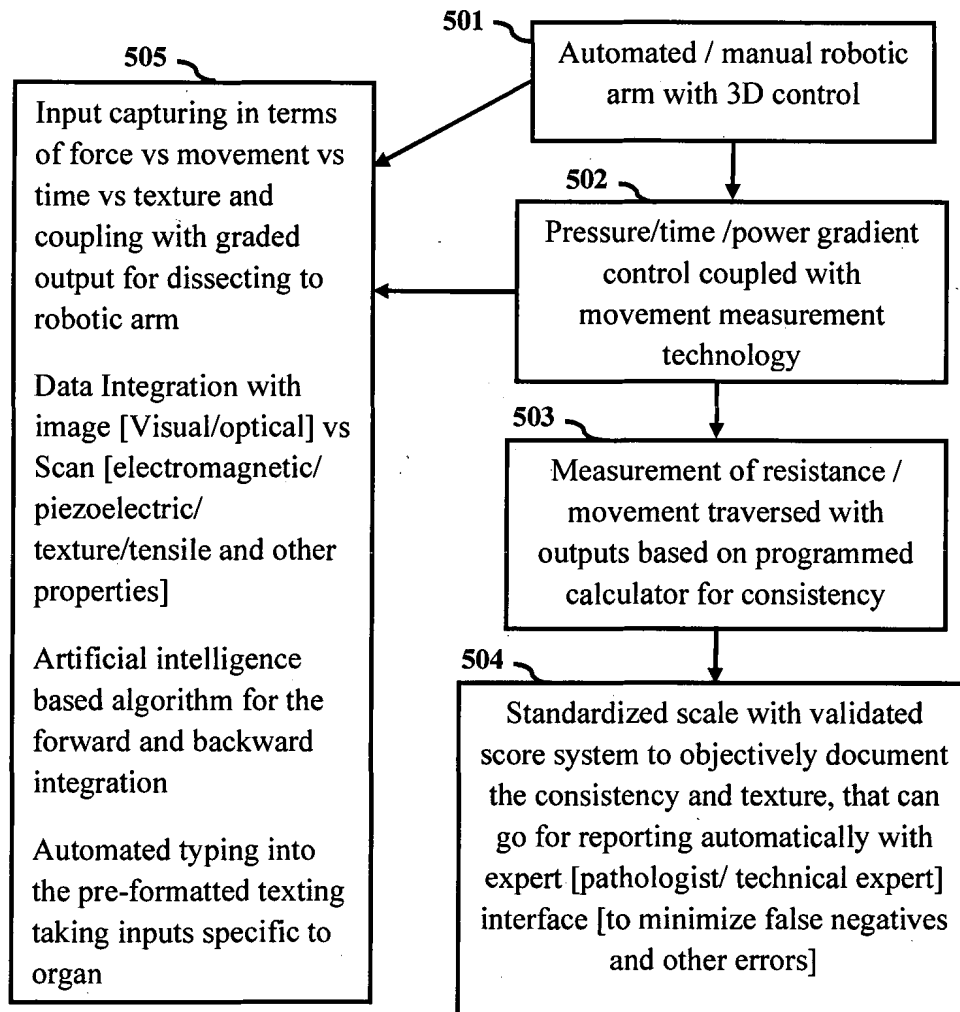


FIG. 5

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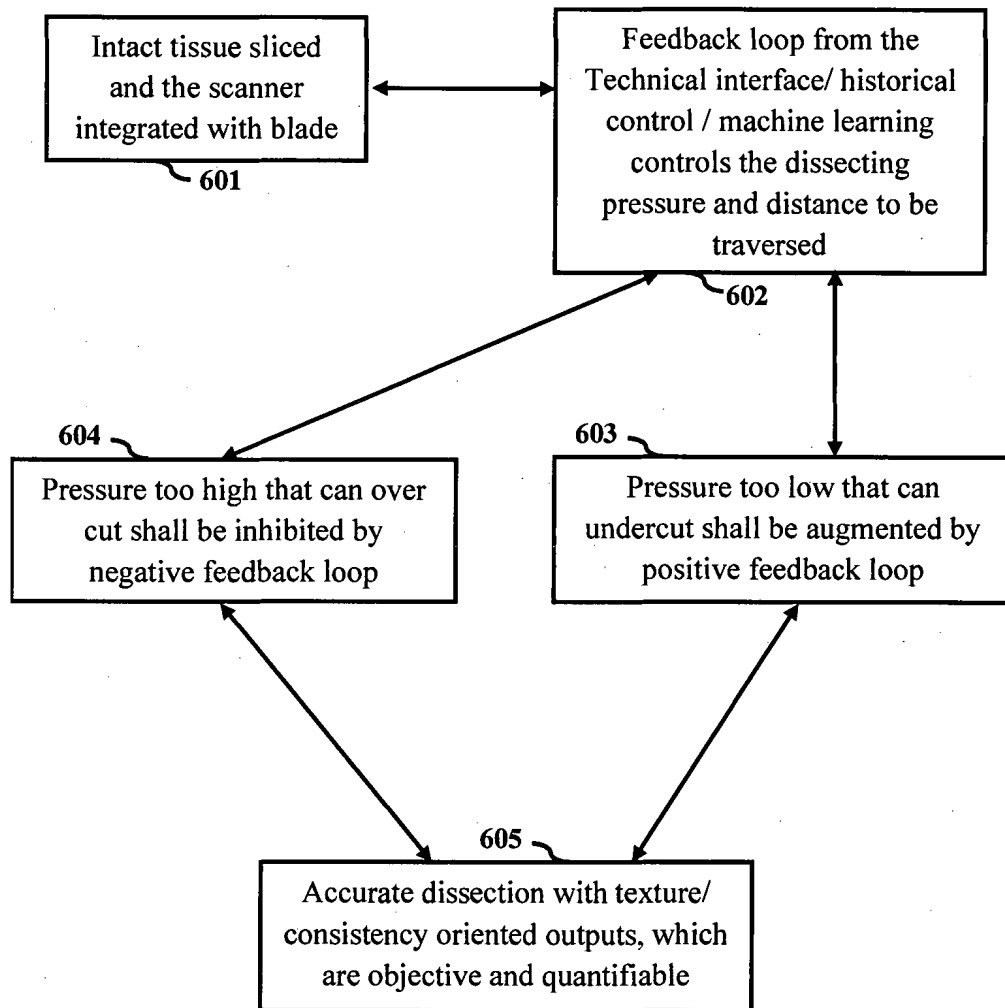


FIG. 6

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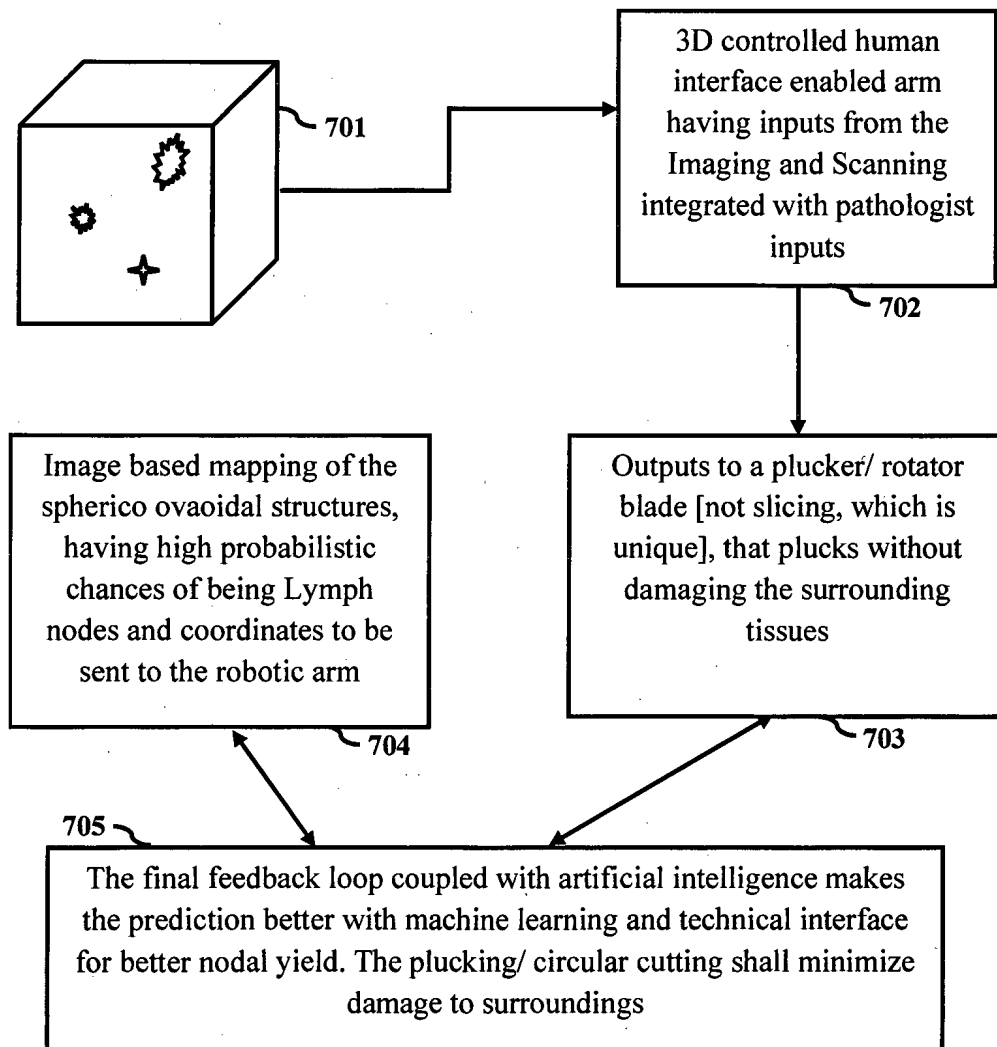


FIG. 7

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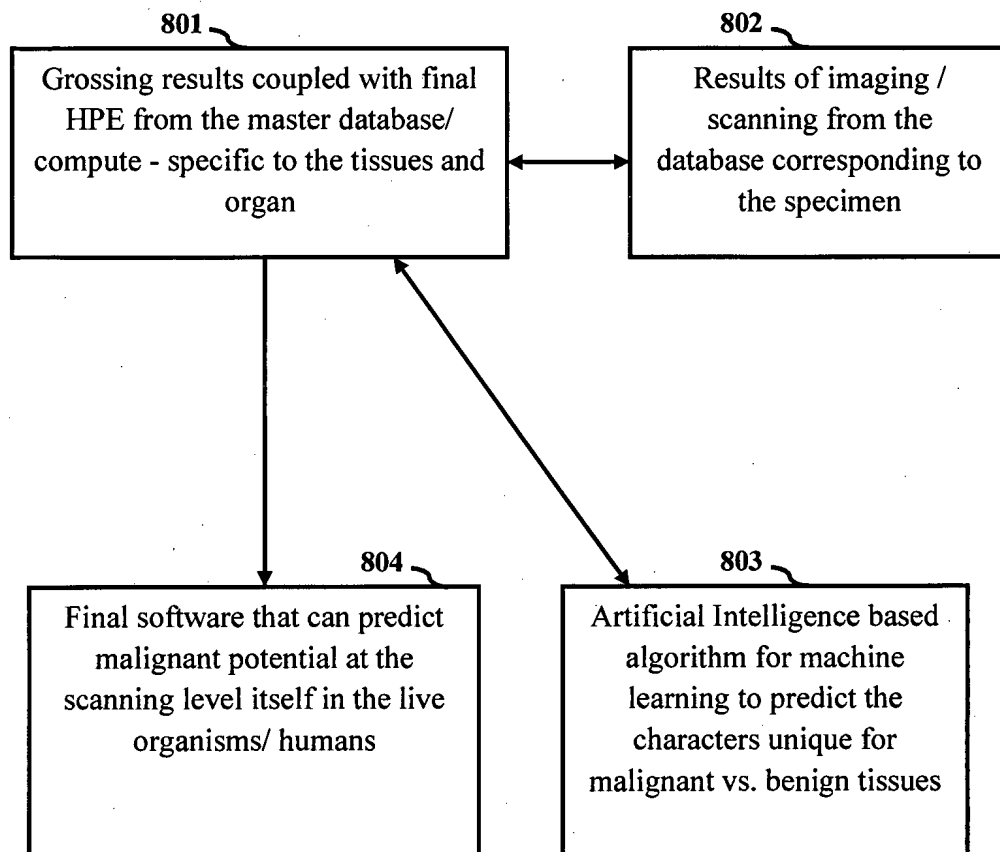


FIG. 8

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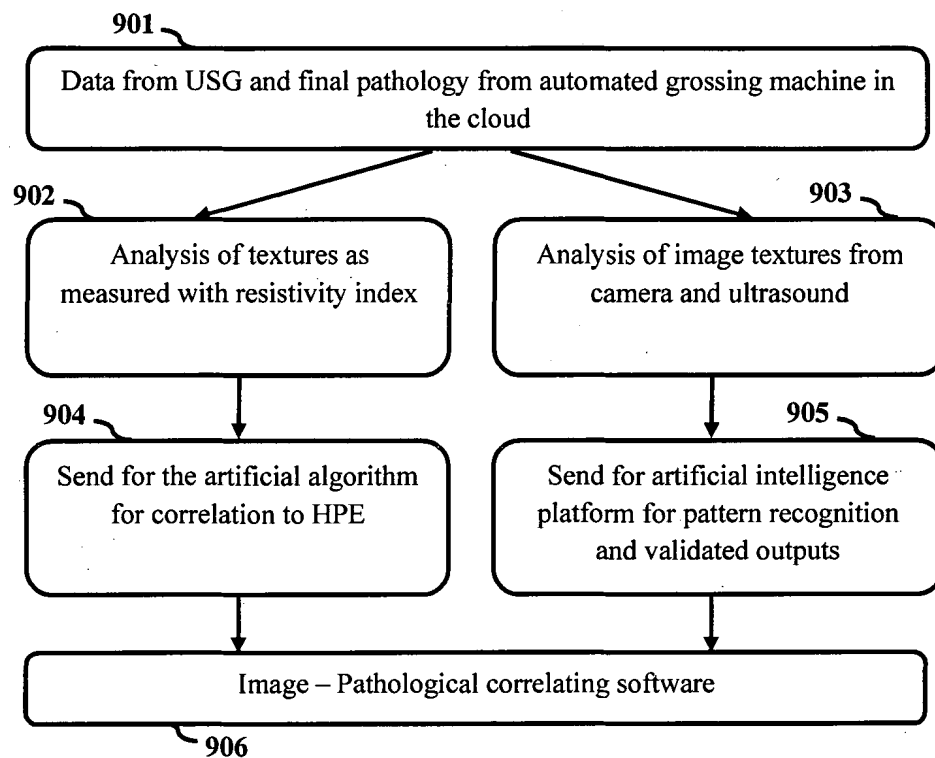


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2016/000275

A. CLASSIFICATION OF SUBJECT MATTER
A61B10/00, G06Q50/00 Version=2017.01

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B, B25J, G01N, G02B, G06T, G06F

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

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

Databases: Patseer, IPO Internal Database

Keywords: robotic arm, ultrasound, imaging, microtome, gross examine, biopsy

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US8771978B2 (RAGAN TIMOTHY (US), TISSUEVISION INC (US)) 08 JULY 2014(08-07-2014) ABSTRACT; FIGURES 1B-1H, 3, 6; COMPONENTS 62, 64, 66; COLUMN 5, LINES 1-5; COLUMN 6, LINES 8-35; CLAIMS 1, 2	1-10
Y	US2013303895A1 (DELPHINUS MEDICAL TECHNOLOGIES INC (US)) 14 NOVEMBER 2013(14-11-2013) FIGURES 8-10; PARAGRAPHS [0003], [0040-0052]	1-10
A	US2007089557A1 (INTUITIVE SURGICAL INC) 26 APRIL 2007(26-04-2007) PARAGRAPHS [0031], [0032], [0046]; FIGURE 1	1, 3-5, 8, 10
A	US7941275B2 (VENTANA MED SYST INC (US)) 10 MAY 2011(10-05-2011) FIGURES 1, 2, 5, 15, 1; COLUMN 6, LINES 52-57, COLUMN 25, LINE 10-25; CLAIMS 1, 2	1, 3, 6-10

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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

Date of the actual completion of the international search

09-02-2017

Date of mailing of the international search report

09-02-2017

Name and mailing address of the ISA/

Indian Patent Office
Plot No.32, Sector 14, Dwarka, New Delhi-110075
Facsimile No.

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IN2016/000275

Citation	Pub.Date	Family	Pub.Date
US 8771978 B2	08-07-2014	EP 2641079 A2	25-09-2013
US 2013303895 A1	14-11-2013	EP 1690154 A4	09-09-2009
US 2007089557 A1	26-04-2007	WO 2007120350 A3	18-09-2008
US 7941275 B2	10-05-2011	WO 2005027015 A3	16-06-2005

专利名称(译)	用于组织的自动粗略检查的系统和方法		
公开(公告)号	EP3376961A4	公开(公告)日	2019-08-14
申请号	EP2016865896	申请日	2016-11-18
[标]发明人	SURESH ATTILI VENKATA SATYA VUTUKURU ANURADHA SAMPARA SRIKANTH SUNDARA		
发明人	SURESH, ATTILI VENKATA SATYA VUTUKURU, ANURADHA SAMPARA, SRIKANTH SUNDARA		
IPC分类号	A61B10/00 G06Q50/00		
CPC分类号	A61B8/08 A61B10/02 A61B2090/3612 A61B34/10 A61B34/30 G01N1/06 G16H10/40		
代理机构(译)	HELLMICH , WOLFGANG		
优先权	5663CHE2015 2015-11-21 IN		
其他公开文献	EP3376961A1		
外部链接	Espacenet		

摘要(译)

本文的各种实施方案提供了用于组织样品的自动粗略检查的系统和方法。该装置具有隔间形状，包括放置样本的床，安装在隔间盒顶部的超声设备，安装有多个手术刀片的机器人臂和摄像机。超声技术用于准确地理解所研究的肿瘤的样本，大小和尺寸。机器人手臂辅助手术刀片接收超声输出或相机输出，并准确切片样本以进行进一步分析。与粗略检查有关的信息存储在连接到设备的外部服务器中，并使用人工智能算法进行分析。