(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 February 2017 (02.02.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/017556 A1

(51) International Patent Classification:
A61B 90/00 (2016.01) *A61B 10/02* (2006.01)

(21) International Application Number:
PCT/IB2016/054259

(22) International Filing Date:
18 July 2016 (18.07.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/197,612 28 July 2015 (28.07.2015) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

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

(54) **Title**: WORKFLOW OF NEEDLE TIP IDENTIFICATION FOR BIOPSY DOCUMENTATION

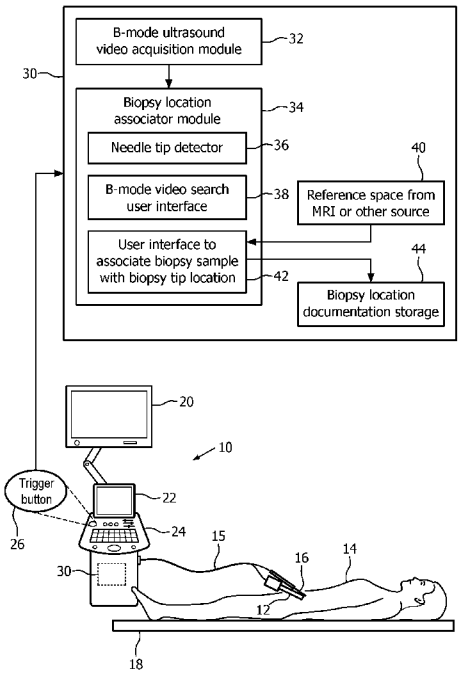

FIG. 1

(57) **Abstract**: An interventional instrument (16) is inserted into a patient (14) to perform an interventional medical procedure guided by a medical imaging device (10). A trigger control (26) is activated. An electronic data processing device (30) is programmed to operate the medical imaging device to: acquire and display video (50) of the interventional instrument (16) inserted into the patient; detect activation of the trigger control; in response to the detecting, process a video segment (54) of the acquired video to identify a trigger image (60) as a frame of the video segment capturing a medical intervention event performed by the interventional instrument and a location (62) of the medical intervention event in the identified trigger image; and display a still image of the identified trigger image with a superimposed marker (102) indicating the identified location of the medical intervention event.

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WORKFLOW OF NEEDLE TIP IDENTIFICATION FOR BIOPSY DOCUMENTATION

FIELD

The following relates generally to the imaging-guided surgical arts such as biopsy arts, brachytherapy arts, and the like.

BACKGROUND

Imaging-guided surgical procedures are used for diverse purposes such as tissue sample extraction (i.e. biopsy) procedures, targeted laser ablation procedures, and brachytherapy procedures (in which radioactive seeds are delivered to targeted locations). An example of such a procedure is a prostate biopsy procedure. Prostate cancer affects one in six men in the United States, and in year 2014 was the second leading cause of cancer death in American men. Prostate biopsy is typically performed under ultrasound imaging guidance, using brightness-mode ("B"-mode) ultrasound video imaging to assist the urologist in targeting known lesions or other suspicious prostate regions for biopsy. A known system for ultrasound-guided prostate biopsy is the UroNav™ system (available from Invivo Corp., Gainsville, Florida, USA), which employs a reference image acquired by magnetic resonance imaging (MRI) and fused (i.e. spatially registered) with the ultrasound imaging. This allows precision-targeting of lesions identified on MRI, without the need for an MRI in-gantry procedure. In addition to the point targets identified through MRI, the UroNav™ system can also be used for guiding systematic sextant biopsies with the predefined prostate zones. In other known ultrasound-guided prostate biopsy systems, the reference frame is provided by an initially acquired three-dimensional ultrasound reference image, or the biopsy samples are referenced to a robotic manipulator reference frame.

Regardless of the choice of reference frame, meticulous documentation of biopsy locations is instrumental in longitudinal management of patients with likely or confirmed prostate cancer. With proper biopsy sample (i.e. core) location documentation, suspicious findings, or findings of low-grade cancer, can be followed up with repeat biopsies in the same locations in regular intervals (e.g. 6 or 12 months) to monitor for potential changes and deterioration of the condition; or, benign findings can be used to deliberately sample new, previously unsampled locations in order to maximize the likelihood of cancer detection on repeat biopsy. Such approaches can help steer away patients from unnecessary

radical therapy and toward "active surveillance" or loco-regional therapy with reduced side-effects, cost, and impact on the quality of life

A key step in accurately documenting a biopsy location is precise identification of an ultrasound video frame that clearly images the biopsy needle tip after firing, and accurate identification of the needle tip in this image. Correlation with the reference MRI image (in the UroNav™ system) or other reference then provides the biopsy location in the reference image space. However, the task of documenting biopsy locations can be tedious, and involves careful coordination between the urologist performing the biopsies and the assistant operating the ultrasound imaging system. As soon as a biopsy needle has been fired to obtain a tissue sample, the ultrasound video acquisition needs to be paused. The ultrasound frame showing the deployed needle is then selected visually, by cycling through the ultrasound video frames until a frame is identified in which the urologist clearly observes the biopsy needle. Thereafter, the needle tip is localized in the selected frame, for example using a mouse or trackball or touchscreen to mark the needle tip in a "frozen" display of the selected frame. Each of these steps slows down the biopsy workflow, requires training, and is operator-dependent and prone to operator error.

While prostate biopsy is described herein as an illustrative example, the skilled artisan will readily appreciate that similar difficulties arise in documenting locations of other image-guided surgical procedures employing medical imaging video guidance. For example, the disclosed techniques are readily applied to biopsy procedures of the prostate, liver, or other organs or tissues, as well as to other image-guided surgical procedures such as brachytherapy procedures.

The following discloses a new and improved systems and methods that address the above referenced issues, and others.

SUMMARY

In one disclosed aspect, a device is configured to operate in conjunction with an interventional instrument inserted into a patient to perform an interventional medical procedure. The device comprises a medical imaging device including a display component, a trigger control, and an electronic data processing device. The electronic data processing device is programmed to operate the medical imaging device to provide image guidance and location documentation for the interventional medical procedure by guidance and location documentation operations including: causing the medical imaging device to acquire and display video of the interventional instrument inserted into the patient; detecting activation of

the trigger control; in response to the detecting, processing a video segment of the acquired video to identify a trigger image as a frame of the video segment capturing a medical intervention event performed by the interventional instrument and a location of the medical intervention event in the identified trigger image; and causing the medical imaging device to display a still image of the identified trigger image with a superimposed marker indicating the identified location of the medical intervention event.

In another disclosed aspect, a biopsy guidance and location documentation device comprises a trigger control and an ultrasound imaging device including a display component and an electronic processor. The ultrasound imaging device is configured to perform a method including: acquiring and displaying video of human anatomy being biopsied; detecting a biopsy trigger signal generated by user activation of the trigger control; processing the acquired video to automatically identify a trigger image as a frame of the video showing a fired biopsy needle tip and a location of the fired biopsy needle tip in the identified trigger image; and displaying the automatically identified trigger image as a still image with a superimposed marker indicating the automatically identified location of the fired biopsy needle tip.

In another disclosed aspect, a biopsy device comprises a biopsy needle assembly configured to fire the biopsy needle to collect a biopsy sample, and the biopsy guidance and location documentation device of the immediately preceding paragraph. In some such biopsy devices, the biopsy device further comprises a transrectal ultrasound probe configured for insertion into the rectum of a patient, with the biopsy needle assembly being secured with the transrectal ultrasound probe for insertion into the rectum of the patient and/or combined with a positioning device such as a transperineal grid plate with the rectal ultrasound probe.

In another disclosed aspect, a biopsy guidance and location documentation method comprises: acquiring and displaying, on a display device, medical imaging video of human anatomy being biopsied; detecting a trigger signal; in response to detecting the trigger signal, processing the acquired medical imaging video to identify a trigger image as a frame of the medical imaging video showing a fired biopsy needle tip and a location of the fired biopsy needle tip in the identified trigger image; and replacing the video displayed on the display device with a still image display of the identified trigger image with a superimposed marker indicating the identified location of the fired biopsy needle tip.

One advantage resides in providing a more efficient biopsy workflow.

Another advantage resides in providing more accurate identification of biopsy locations.

Another advantage resides in providing reduced likelihood of erroneous biopsy location identification.

A given embodiment may provide none, one, two, more, or all of the foregoing advantages, and/or may provide other advantages as will become apparent to one of ordinary skill in the art upon reading and understanding the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

FIGURE 1 diagrammatically illustrates an ultrasound-guided prostate biopsy system providing biopsy location documentation as disclosed herein.

FIGURE 2 diagrammatically illustrates a biopsy sample acquisition method including biopsy location documentation suitably performed using the system of FIGURE 1.

FIGURE 3 diagrammatically illustrates a flow chart of a suitable implementation of the needle tip detection employed in FIGURES 1 and 2.

FIGURE 4 illustrates a trigger frame identified in a phantom using the implementation of FIGURE 3.

FIGURE 5 illustrates the trigger frame of FIGURE 4 with a superimposed linear marker indicating the needle.

DETAILED DESCRIPTION

With reference to FIGURE 1, an illustrative ultrasound-guided prostate biopsy system is shown. An ultrasound imaging system **10** provides image guidance for targeting known lesions or other suspicious prostate regions for biopsy. The ultrasound imaging system **10** may, for example, be an EPIQ™ ultrasound imaging system available from Koninklijke Philips N.V., Eindhoven, the Netherlands, or may be another commercial or custom-built ultrasound imaging system. A rectal ultrasound probe **12** is inserted into the rectum of a patient **14**. (The lower half of the patient is cut away in diagrammatic FIGURE 1 to reveal the inserted probe **12** which would otherwise be occluded from view. Typically, the patient is lying on the side or facing up with the legs lifted up and fixed on a table extension.)

The illustrative ultrasound probe **12** is connected with the ultrasound imaging system **10** via cabling **15**. The illustrative ultrasound probe **12** includes an integrated biopsy needle assembly **16** for collecting biopsy samples. More generally, any type of image-guided biopsy technique may be employed, e.g. a transrectal ultrasound-guided biopsy using the integral probe **12**, **16** as illustrated in which the ultrasound probe is inserted into the rectum and accesses the prostate via the rectal wall; or a transperineal biopsy in which the ultrasound probe is passed into the rectum but the biopsy needle passes through the perineum to access the prostate (optionally using a stereotactic grid plate or the like); or so forth. For the illustrative transrectal prostate biopsy procedure, the patient **14** lies on his side (as diagrammatically indicated in FIGURE 1) on a diagrammatically indicated patient bed or support **18** with suitable pillows or other supports (not shown). The illustrative ultrasound imaging system **10** includes a display component **20** for displaying ultrasound images, and one or more user interfacing components such as a user interface display **22** and user control panel **24** including user input devices such as a keyboard, dedicated buttons, a trackball or mouse or other pointing device, or so forth. Instead of or in addition to a pointing device, one or both display components **20**, **22** may be a touchscreen display enabling user input by pressing a location on the display **20**.

In order to target a lesion or other tissue, the urologist (or, more generally, a medical professional) manipulates the probe assembly **12**, **16** to align it with the target while the ultrasound imaging system **10** operates in a video mode, for example providing brightness mode (B-mode) imaging frames at a high frame rate of, for example, on the order of 15-30 frames per second. The urologist views the ultrasound display **20** showing the B-mode video while manipulating the probe assembly **12**, **16** in order to receive (near) real-time feedback enabling precise targeting of the lesion or other target tissue. When the urologist is satisfied that the target is in proper alignment, the urologist fires the biopsy needle to acquire the biopsy sample. The urologist then immediately withdraws the biopsy needle with the captured biopsy core and stores the core in a biopsy specimen container. As described next, the system of FIGURE 1 provides automated or semi-automated documentation of the biopsy location, so that the urologist can concentrate on performing the biopsy sample recovery and storage actions and then can review the proposed biopsy location association, correct it if necessary, and associate the finally chosen location with the biopsy sample.

The user control panel 24 includes a trigger control **26** for triggering the biopsy location association. The illustrative trigger control **26** is a “biopsy” button **26** diagrammatically shown in enlarged isolation in FIGURE 1 for illustrative purposes. It will

be appreciated that the trigger control **26** could take other forms, such as a handheld remote control in wireless radio or infrared contact with the ultrasound imaging system **10**, a soft key shown in the user interface display **22** (which in this case would be touch-sensitive), or so forth. When the biopsy button **26** is pressed, a biopsy location association operation is performed. To this end, the ultrasound imaging system **10** further includes a microprocessor, microcontroller, or other electronic data processing component **30** which is diagrammatically indicated in FIGURE 1. While the illustrative electronic processor **30** comprises a microprocessor or microcontroller housed inside the ultrasound imaging system **10**, in other embodiments the electronic processor may have another physical architecture, such as being a desktop or notebook computer connected by a video cable with the ultrasound imaging system to receive, process, and display video acquired by the ultrasound imaging system. The illustrative electronic processor **30** is programmed to implement a B-mode ultrasound video acquisition module **32** that causes the ultrasound imaging system **10** to acquire B-mode video and display the acquired B-mode video on the display component **20** for viewing by the urologist or other medical professional. When the urologist presses the trigger button **26**, the electronic processor **30** detects this trigger signal. Upon receipt of the trigger signal, the ultrasound imaging system **10** continues to acquire video content for some predetermined time interval (or, alternatively measured, for some predetermined number of frames at a given frame rate) where the predetermined time interval is sufficiently long to capture the firing of the biopsy needle tip into the tissue being biopsied. Thereafter, a biopsy location associator module **34** processes this video segment acquired after activation of the biopsy button **26** in order to determine a biopsy location. The illustrative biopsy location associator module **34** includes an automatic needle tip detector **36** that processes the frames of the video segment in order to identify a "trigger" frame (or trigger image) that best captures the fired biopsy needle tip, and to identify the biopsy needle tip location in that trigger image. This automatic identification can be done, for example, by matching a linear biopsy needle tip pattern oriented at the appropriate firing angle (known due to the orientation of the rectal ultrasound probe/biopsy needle assembly **12**, **16**) to a most prominent linear feature in each image frame.

The automatically identified trigger frame is displayed on the display component **20** of the ultrasound imaging system **10** as a still image display (also sometimes referred to as a still frame display) – that is, the trigger frame is displayed as a static image. Additionally, a marker indicating the automatically identified needle tip location is superimposed on the still image display of the trigger image. It will be appreciated that since

the needle tip detection process is fast, from the viewpoint of the urologist the B-mode video on the display **20** is replaced by the still image display of the trigger image only a few moments, or even apparently instantaneously, after activating the trigger control **26**. The urologist then reviews the displayed trigger image with the superimposed marker. In one embodiment the superimposed marker is a dotted or dashed line, or is displayed as a translucent or semi-transparent marker, so that the underlying needle tip image can be seen behind it; additionally or alternatively, the urologist can toggle between showing or hiding the superimposed marker using a suitable toggle control or button of the user input panel **24**. If the urologist is satisfied with the displayed result, the urologist can accept it by suitable input via a user input device (e.g. clicking on an "accept" button shown on the display using a mouse or trackball). On the other hand, if the urologist is unsatisfied with the automatically identified trigger image and/or the identified biopsy needle tip location, the urologist may invoke a video search user interface **38** in order to flip through the frames of the video segment acquired after triggering the biopsy needle firing in order to manually find a different trigger image that is preferred by the urologist. This manual search preferably starts with the automatically identified trigger image, which is likely to be at least close in the sequence of frames making up the video segment to the "best" image as judged by the urologist.

In this way, user input is received via a user input component **22**, **24** of the ultrasound imaging device **10** that identifies a documented location of the fired biopsy needle tip as one of (i) the location of the fired biopsy needle tip automatically identified via the needle tip detector **36** or (ii) a manually identified location of the fired biopsy needle tip in a manually identified trigger image identified from the video by the urologist using the search user interface **38**. Thereafter, the documented location of the fired biopsy needle tip in the reference frame of the medical imaging device **10** is transformed to a documentation reference frame or space **40**. This reference space **40** may be variously defined. For example, the reference space **40** may be defined in terms of a reference magnetic resonance image that is fused with the ultrasound images. This choice of reference frame is provided by the UroNav™ system. Advantageously, suspicious lesions may be readily identified in the magnetic resonance image so that the UroNav™ system can superimpose these on the B-mode video during the lesion targeting phase. In another approach, the reference frame **40** is defined in terms of a three-dimensional reference ultrasound image acquired using the ultrasound imaging system **10** before commencing the biopsy procedure. As yet another example, the reference frame **40** may be defined in terms of a mechanical framework of a

robotic manipulator used to position the rectal ultrasound probe/biopsy needle assembly **12**, **16**.

With the documented biopsy location determined in the documentation reference frame, the urologist then uses a user interface **42** to associate the biopsy sample with the documented location, and the documented biopsy location in the documentation reference frame **40** is recorded in a biopsy location documentation storage **44**. The documentation storage **44** may, for example, be a local storage medium such as a hard disk of the ultrasound imaging system **10**, and/or may be network data storage such as an Electronic Medical Record (EMR) or Electronic Health Record (EHR). In making the biopsy sample/documented biopsy location association, the urologist may suitably use a biopsy sample indexing number from the biopsy specimen container or any other auditable biopsy sample identification framework.

In some embodiments, the trigger control **26** solely operates to trigger execution of the fired biopsy needle tip location association processing performed by the electronic processor **30**. In such embodiments, the urologist first operates a separate control (not shown) to fire the biopsy needle tip to acquire a biopsy sample. Immediately thereafter, the urologist (or an assistant) activates the trigger control **26** to execute the biopsy needle tip location association function of the ultrasound imaging system **10**.

In other embodiments, including the illustrative embodiment, the trigger control **26** also triggers the biopsy needle tip assembly **16** to fire the biopsy needle tip to acquire the biopsy sample. In these embodiments, a trigger signal generated by activation of the illustrative trigger control **26** is conveyed via the cabling **15** to the ultrasound probe assembly **12**, or more particularly to the biopsy needle assembly **16**, and triggers the biopsy needle tip assembly **16** to fire a biopsy needle tip into the lesion to acquire a biopsy core (i.e. biopsy sample). Concurrently, the activation of the trigger control **26** also initiates the biopsy tip location association operation. This operation includes, as an initial step, continuing the video collection for a time interval (or, equivalently, number of frames) that is long enough to capture images of the fired biopsy needle tip. This time interval is short, e.g. a fraction of a second to a few seconds, as it merely needs to span the time for the biopsy needle to fire and embed into the target tissue. After activating the trigger control **26** to fire the biopsy needle tip and initiate the tip location association operation, the urologist retrieves the fired needle tip containing or holding the biopsy sample via a biopsy needle guide and places the biopsy sample into a biopsy specimen container.

With continuing reference to FIGURE 1 and with further reference to FIGURE 2, a biopsy guidance and location documentation workflow performed using the system of FIGURE 1 including the ultrasound system **10** and the processor **30** is described. B-mode video **50** is continuously acquired and displayed to provide image guidance for targeting the biopsy needle. After the urologist has aligned the target tissue, the biopsy needle tip is fired, for example using a handheld biopsy gun having a firing button (features not shown). After firing the biopsy needle, the trigger button **26** of the ultrasound device **10** is pressed to generate a trigger signal **52** that starts the biopsy needle tip location and documentation procedure. After trigger signal **52** is output, the video acquisition continues for a time interval Δt (which may be measured in time units or as a number of B-mode video frames based on a frames/second rate). Thus, a video segment **54** is acquired after the trigger signal **52** is detected, which images the previously triggered biopsy needle tip that is now embedded in the target tissue.

In some alternative embodiments, the firing of the biopsy needle tip also triggers the start of the biopsy needle tip location and documentation procedure. In other words, in these embodiments the same trigger control is actuated to simultaneously trigger both the biopsy needle firing and the start of the documentation procedure. In such embodiments, the time interval Δt starts at the same time as the initiation of the biopsy needle firing, and so Δt in these embodiments should be long enough to encompass the firing time and capture the needle tip after it has come to rest embedded into the target tissue.

Regardless of whether the biopsy needle tip is fired by the trigger control **26** or by a separate control, the video segment **54** which images the fired biopsy needle tip is analyzed on a frame-by-frame basis by the needle tip detector **36** to automatically identify a trigger frame **60** showing the fired needle tip, and the needle tip location (i.e. tip) **62** is identified in the trigger frame or image **60**. The needle tip detector **36** suitably leverages a needle tip pattern **64** having a known angle, and optionally further leverages *a priori* knowledge that the needle tip is in a known general region **66**. Such localization to a known region **66** sets the search area within a video frame segment to optimize the performance of the needle tip detector **66**. For example, in embodiments providing guidance and documentation for a transperineal biopsy procedure employing a grid plate, the grid location of the biopsy defines the *a priori* known region **66**. This information **64**, **66** is provided based on the approximately known position and orientation of the rectal probe assembly **12**, **16**. For example, the needle tip pattern **64** can be scanned over each video frame with a suitable

comparison metric (e.g., a sum of |image pixel-pattern pixel|) used to assess whether a match is found.

With continuing reference to FIGURES 1 and 2, in an operation **70** the trigger frame **60** is displayed with a superimposed marker indicating the identified tip **62**. The urologist then makes a decision **72** as to whether to accept this automatically identified biopsy needle tip location **62**. If it is accepted, then in an operation **74** the association user interface **42** is invoked to perform the biopsy sample/biopsy location association, including transforming from the ultrasound image frame space to the reference space **40**, as already described. On the other hand, if the decision **72** is that the automatically identified needle tip location **62** is not satisfactory, then in an operation **76** the video search user interface **38** is invoked via which the urologist manually searches the video segment **54** frame-by-frame to manually choose the documentation trigger frame and then manually identifies the biopsy needle tip location in this frame. The manually identified tip location is then associated to the biopsy sample via operation **74** as already described.

With reference to FIGURE 3, an illustrative needle tip detection approach suitably performed by the needle tip detector **36** is described. In an operation **80**, a first frame is selected from the video segment **54**. A tip detection algorithm **82** is then applied, which in the illustrative example attempts to match the biopsy needle tip pattern **64** at its known angle to a linear feature in the video frame under analysis. In a decision **84** it is determined whether this attempt at finding the needle tip in the image frame was successful. If not, then flow passes to decision **86** where it is determined if there are more frames to analyze in the video segment **54**, and if so a next frame is selected in operation **88**.

If the decision **84** determines that the attempt to identify the tip in the frame currently under analysis was successful, then flow passes to a scoring operation **90** which scores the match using some quantitative metric as to likelihood that the biopsy needle tip location has been accurately identified. For example, the metric may sum the difference, on a pixel-by-pixel basis, between the pixel value of the pattern **64** and the value of the corresponding pixel in the matched linear feature of the frame under analysis. In another approach, the metric may measure aspects of the matched linear feature of the frame under analysis such as its width and length, and compare these with the pattern width and length. After all frames of the video segment **54** have been analyzed, in an operation **92** the highest-scoring frame is identified as the trigger frame or image **60**, and the biopsy needle tip location **62** is identified in this trigger frame **60**.

With reference to FIGURES 4 and 5, an example of a biopsy needle tip identification is shown, for an imaged phantom. FIGURE 4 shows the image including a linear feature **100** that is likely to be the biopsy needle tip. FIGURE 5 shows the same image with a marker **102** superimposed indicating the identified biopsy needle tip location.

In the following, some further illustrative embodiments are described.

In one approach, a user input-triggered needle tip detection is provided. A user (e.g. urologist) determines when to start the automatic needle tip detection. In the illustrative embodiments, this determination is advantageously automatically made by pressing the biopsy button **26** which also triggers the firing of the biopsy needle tip. In other embodiments, separate controls are employed, the first control being activated to fire the biopsy needle tip into the tissue and the second control triggering start of the tip location association procedure. In either case, an image processing-based automatic needle tip detection algorithm is applied to detect needle tips from a set of given image frames (e.g. the video segment **54**) and return the frame number of the needle firing frame (i.e. the trigger frame **60**). If the urologist is unhappy with the automatically selected trigger frame and tip location, then a user interface (UI) **38** enables the operator (e.g. urologist) to manually select the needle firing frame and adjust the needle tip position. A UI **42** enables the operator to associate the biopsy core to the automatically or manually identified tip location.

The needle tip detector **36** receives a group of N ultrasound frames making up the video segment **54**, at least some of which show the fired biopsy needle tip embedded in the tissue from which the biopsy sample is being acquired. Other input data like the biopsy guide line (expected path of the biopsy needle, e.g. the angle or direction of the needle tip pattern **64**) and parameter settings are also optionally provided to the needle tip detector **36**. The output of the needle tip detector **36** includes a needle tip location L_i, $0<i<N+1$ with corresponding needle score S_i, $0<i<N+1$ for each frame in the segment (or at least for each frame in which the tip detection algorithm **82** successfully located the needle tip; in some embodiments any frames in which the tip detection algorithm **82** failed to locate the needle tip are assigned a score of zero). A detected firing frame N_{firing} is identified for the video segment **54**, which is the frame having the highest score value (highest S_i). The score is a metric of how likely it is that the detected signal actually stems from the needle tip. In one suitable approach, the tip detection algorithm **82** first tries to detect the needle in each single frame in a pre-defined region **66**, and the needle score is computed based on the level of confidence in the detection in any given frame. The ultrasound frame most likely showing the actual needle firing is then determined at the end. Once the needle tip is detected, the live

imaging stream is frozen as the firing ultrasound frame of N_{firing} identified by the needle tip detector **36** is displayed as a still frame. (Alternatively, the system may initially display the last frame, i.e. the frame when the urologist manually triggered the algorithm). A visualized needle tip marker, which can be a highlighted graphical object like a yellow bar (optionally translucent or partially transparent, and/or showed as a dashed or dotted line, so as to reveal the underlying image feature that was detected as the needle tip), is displayed at the detected needle tip location L_{firing}. The urologist may then examine the identified firing ultrasound frame and also the marked identified needle tip location. If the result is satisfactory, the urologist accepts the automatically identified tip location L_{firing} and processing moves to the association operation **74**. Otherwise, the urologist can choose to adjust it (i.e. manually identify the tip location) via the search user interfacing operation **76**.

In a suitable embodiment of this tip search user interfacing operation **76**, the first operation to perform is to manually identify the needle firing frame. The search user interface **38** enables the urologist to move from one frame to another. For example, in one specific user device implementation, the urologist can either use a middle wheel of a (not shown) mouse to scroll through the frames, or move a scroll bar displayed at the right side edge of a viewing panel displayed on the display **20**. As the urologist goes through difference frames, the detected needle tip location for each frame is displayed (e.g. output by the pattern matching operations **82**, **84** of FIGURE 3 for each analyzed frame). When the urologist stops at a frame, if the urologist is satisfied with the needle tip position in that frame then the adjustment is finished and the workflow proceeds to the association operation **74**. Otherwise, the user can further choose to adjust the needle tip in the manually identified trigger image.

If the urologist chooses to adjust the marker position in the provided user interface **38** is again used, for example in a specific embodiment the urologist uses the mouse to click at a desired location in the view panel, which will bring the marker to the position. The urologist may also first point the mouse at the biopsy guideline and then scroll the middle wheel, which will move the marker back and forth along the biopsy guide line until it is at the desired position.

In the association operation **74**, the urologist associates the documentation biopsy needle tip location (i.e. the automatically or manually identified biopsy needle tip location) to the aimed target/zone. In one suitable approach, a list of targets or zones identified from the reference MRI image or other reference space **40** is displayed. The association user interface **42** enables the urologist to browse and select the appropriate target for biopsy. When a biopsy sample acquisition is performed and the needle tip has been

labeled, the urologist suitably associates the biopsy with the target or zone. In some embodiments, the urologist also has the option to add a new target label for the biopsy into the record. If the targets are predefined in a desired order, the system can be configured to advance to the next target automatically for the user. The association data are stored in the documentation storage **44**.

An alternative embodiment (not shown) does not include the automatic needle tip detector **36**. In this case, a variant biopsy needle tip location association procedure can be employed. In this variant procedure, the needle tip location L_i is set to a fixed position, for example the mean position of the needle tips from a training data set. The needle score S_i is set to a constant number and then N_{firing} is the last frame in the group.

While the illustrative interventional procedure is a transrectal prostate biopsy procedure, it will be appreciated that the disclosed image guidance and location documentation devices and methods may be readily employed in biopsy procedures for other human anatomy, such as other organs like the liver, and/or using other access pathways such as trans-perineal Bx access.

It will be further appreciated that the disclosed image guidance and location documentation devices and methods may be readily employed in other types of interventional procedures, such as in brachytherapy procedures in which the interventional instrument is a brachytherapy seed delivery instrument and the medical intervention event corresponding to the firing of a biopsy needle tip is the depositing of a radioactive seed by the brachytherapy seed delivery instrument.

It will be further appreciated that the disclosed image guidance and location documentation devices and methods may be readily employed in conjunction with image-guided interventional medical procedures using guidance medical imaging modalities other than ultrasound. For example, the medical imaging modality may be computed tomography (CT) or cone-beam CT or magnetic resonance imaging (MRI).

It will be yet further appreciated that the disclosed processing operations performed by the electronic processor **30** may be embodied by a non-transitory storage medium storing instructions that are readable and executable by the microprocessor, microcontroller, or other electronic data processing component **30** to perform these operations. Such non-transitory storage medium may, by way of non-limiting illustration, include a hard disk drive or other magnetic storage medium, a flash memory, read-only memory (ROM) or other electronic storage medium, an optical disk or other optical storage medium, various combinations thereof, or so forth.

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 construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS:

1. A device configured to operate in conjunction with an interventional instrument (16) inserted into a patient (14) to perform an interventional medical procedure, the device comprising:

a medical imaging device (10) including a display component (20);

a trigger control (26); and

an electronic data processing device (30) programmed to operate the medical imaging device to provide image guidance and location documentation for the interventional medical procedure by guidance and location documentation operations including:

causing the medical imaging device to acquire and display video (50) of the interventional instrument (16) inserted into the patient,

detecting activation of the trigger control;

in response to the detecting, processing a video segment (54) of the acquired video to identify a trigger image (60) as a frame of the video segment capturing a medical intervention event performed by the interventional instrument and a location (62) of the medical intervention event in the identified trigger image, and

causing the medical imaging device to display a still image of the identified trigger image with a superimposed marker (102) indicating the identified location of the medical intervention event.

2. The device of claim 1 wherein one of:

(I) the interventional instrument (16) comprises a biopsy instrument and the medical intervention event comprises firing of a biopsy needle by the biopsy instrument to acquire a biopsy sample; and

(II) the interventional instrument comprises a brachytherapy seed delivery instrument and the medical intervention event comprises depositing a radioactive seed by the brachytherapy seed delivery instrument.

3. The device of any one of claims 1-2 wherein the medical imaging device (10) comprises an ultrasound imaging device.

4. The device of any one of claims 1-3 wherein the guidance and location documentation operations further include:

receiving, via one or more user input devices (22, 24) of the ultrasound imaging device (10), one of:

(i) an indication that the identified location (62) of the medical intervention event is acceptable whereby the identified location of the medical intervention event is designated as the documented location of the medical intervention event in a reference frame of the medical imaging device; or

(ii) an indication that the identified location of the medical intervention event is not acceptable wherein the guidance and location documentation operations further include providing a user interface (38) via which the video segment (54) is browsed and the documented location of the medical intervention event in the reference frame of the medical imaging device is manually chosen.

5. The device of claim 4 wherein the guidance and location documentation operations further include:

transforming the documented location of the medical intervention event in the reference frame of the medical imaging device to a documentation reference frame (40); and

recording the documented location of the medical intervention event in the documentation reference frame.

6. The device of any one of claims 1-5 wherein the still image display of the identified trigger image (60) with the superimposed marker (102) replaces the display of the video (50) on the display component (20) of the medical imaging device (10).

7. The device of any one of claims 1-6 wherein the trigger control (26) is operatively connected (15) with the interventional instrument (16) such that activation of the trigger control triggers the interventional instrument to perform the medical intervention event.

8. The device of claim 7 wherein the guidance and location documentation operations further include:

selecting the video segment (54) as a video segment consisting of a predetermined time interval or number of frames (Δt) starting at the detection of activation of the trigger control (26).

9. A biopsy guidance and location documentation device comprising:

a trigger control (26); and

an ultrasound imaging device (10) including a display component (20) and an electronic processor (30), the ultrasound imaging device configured to perform a method including:

acquiring and displaying video (50) of human anatomy being biopsied,

detecting a biopsy trigger signal generated by user activation of the trigger control,

processing the acquired video to automatically identify a trigger image (60) as a frame of the video showing a fired biopsy needle tip and a location (62) of the fired biopsy needle tip in the identified trigger image, and

displaying the automatically identified trigger image as a still image with a superimposed marker (102) indicating the automatically identified location of the fired biopsy needle tip.

10. The biopsy guidance and location documentation device of claim 9 wherein the method performed by the ultrasound imaging device (10) further includes:

receiving user input via a user input component (22, 24) of the ultrasound imaging device that identifies a documented location of the fired biopsy needle tip as one of (i) the automatically identified location (62) of the fired biopsy needle tip and (ii) a manually identified location of the fired biopsy needle tip in a manually identified trigger image comprising a frame of the video (50);

transforming the documented location of the fired biopsy needle tip to a documentation reference frame (40); and

recording the documented location of the medical intervention event in the documentation reference frame in a biopsy location documentation storage (44).

11. The biopsy guidance and location documentation device of claim 10 wherein the documentation reference frame (40) comprises a reference three-dimensional magnetic resonance image fused with the automatically or manually identified trigger image.

12. The biopsy guidance and location documentation device of any one of claims 9-11 wherein processing the acquired video (50) to automatically identify a trigger image (60) as a frame of the video showing the fired biopsy needle tip includes the operations of:

attempting to identify (82, 84) the biopsy needle tip in each frame of a video segment (54) of the acquired video;

scoring (90) at least each frame in which the biopsy needle tip is successfully identified using a reliability metric for the biopsy needle tip identification; and

identifying the trigger image (60) as the highest-scoring frame.

13. The biopsy guidance and location documentation device of claim 12 wherein attempting to identify (82, 84) the biopsy needle tip in each frame of the video segment (54) comprises attempting to match a linear needle tip image pattern (64) at a known biopsy needle tip angle or direction in each frame of the video segment.

14. The biopsy guidance and location documentation device of any one of claims 9-13 wherein the method further includes:

terminating the acquiring and displaying of video (50) a predetermined time interval or number of frames (Δt) after detecting activation of the biopsy trigger control (26); and

selecting a video segment (54) of the video for processing including the video frames acquired during the predetermined time interval or number of frames (Δt).

15. The biopsy guidance and location documentation device of any one of claims 9-14 wherein the displaying of the automatically identified trigger image (60) replaces the displaying of the video (50).

16. The biopsy guidance and location documentation device of any one of claims 9-15 wherein the trigger control (26) is configured to trigger the firing of the biopsy needle tip to collect a biopsy sample.

17. A biopsy device comprising:

a biopsy needle assembly (16) configured to fire the biopsy needle tip to collect a biopsy sample; and

the biopsy guidance and location documentation device (10, 26, 30) of any one of claims 9-16.

18. The biopsy device of claim 17 wherein the trigger control (26) is a biopsy button that when pressed also triggers the biopsy needle assembly (16) to fire the biopsy needle tip to collect the biopsy sample.

19. The biopsy device of any one of claims 17-18 further comprising:

a transrectal ultrasound probe (12) configured for insertion into the rectum of a patient (14), the biopsy needle assembly (16) being secured with the transrectal ultrasound probe for insertion into the rectum of the patient with the rectal ultrasound probe.

20. A biopsy guidance and location documentation method comprising:

acquiring and displaying, on a display device (22), medical imaging video (50) of human anatomy being biopsied;

detecting a trigger signal;

in response to detecting the trigger signal, processing the acquired medical imaging video to identify a trigger image (60) as a frame of the medical imaging video showing a fired biopsy needle tip and a location (62) of the fired biopsy needle tip in the identified trigger image; and

replacing the video displayed on the display device with a still image display of the identified trigger image with a superimposed marker (102) indicating the identified location of the fired biopsy needle tip.

21. The biopsy guidance and location documentation method of claim 20 further comprising:

firing the biopsy needle tip to collect a biopsy sample in response to the trigger signal.

22. The biopsy guidance and location documentation method of any one of claims 20-21 wherein the human anatomy being biopsied is a prostate.

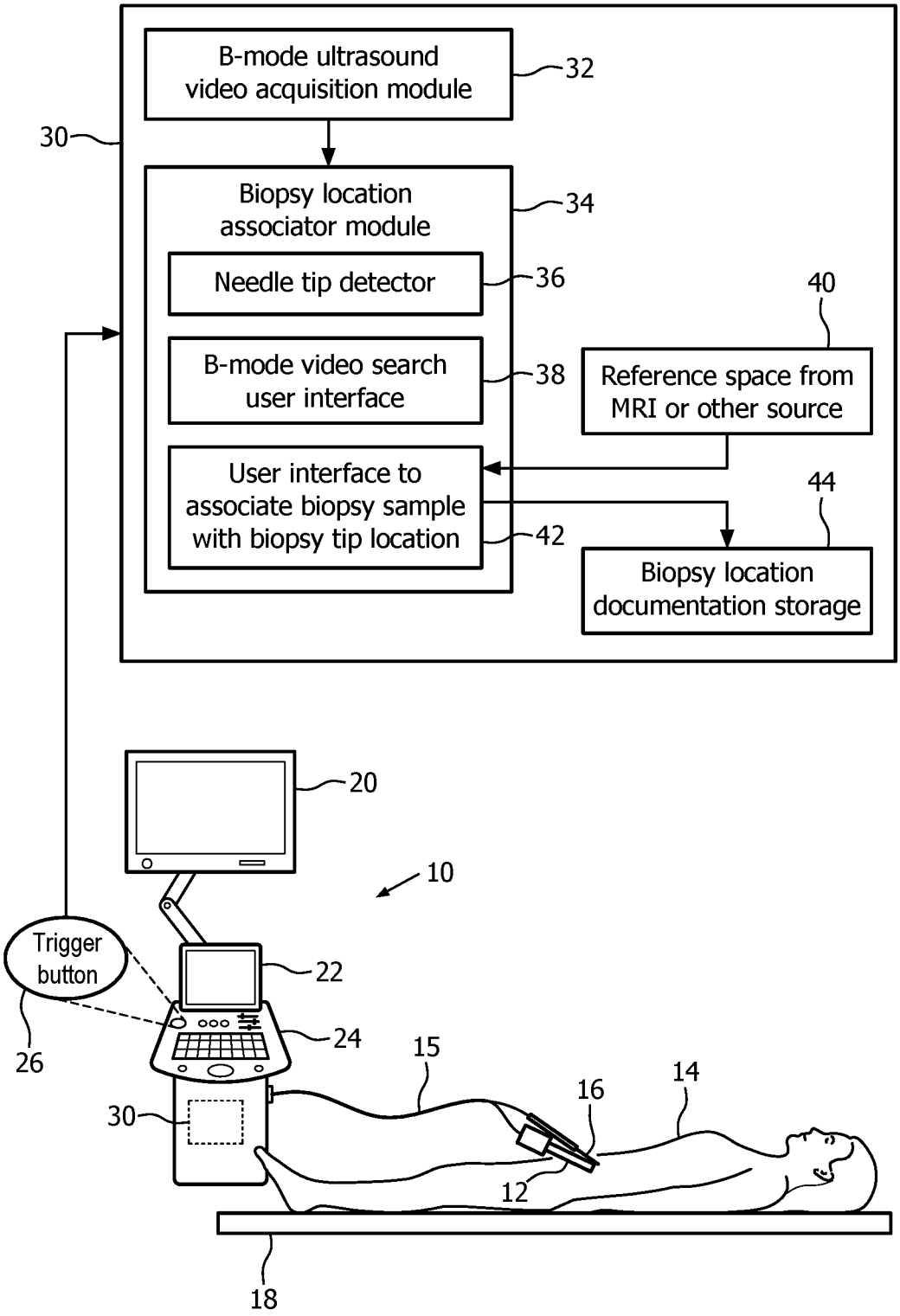
B-mode ultrasound video acquisition module
32
30
Biopsy location associator module
34
Needle tip detector
36
40
B-mode video search user interface
38
Reference space from MRI or other source
User interface to associate biopsy sample with biopsy tip location
42
44
Biopsy location documentation storage
20
10
Trigger button
22
24
26
15
16
14
30
12
18

FIG. 1

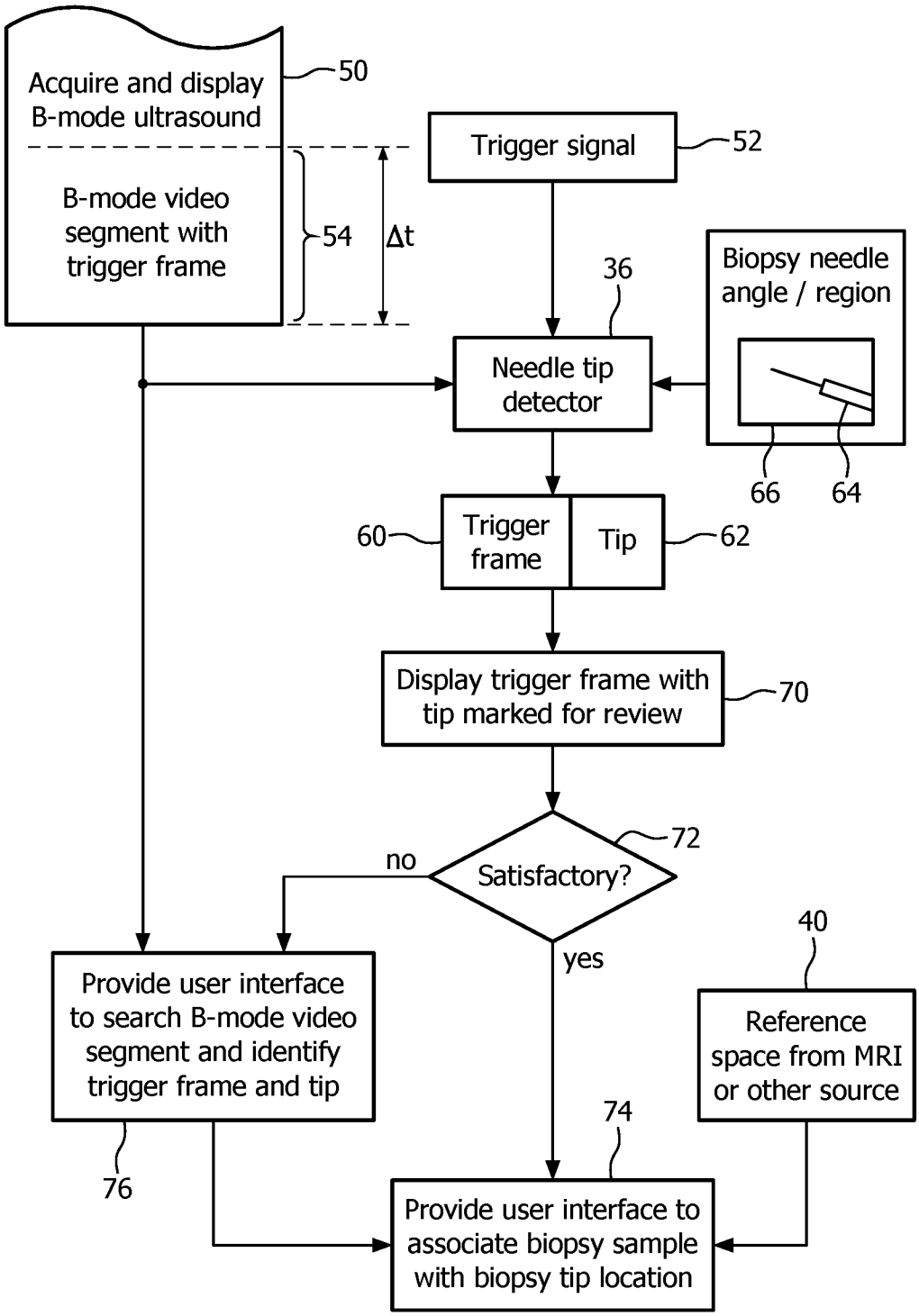
Acquire and display B-mode ultrasound
50
B-mode video segment with trigger frame
54
Δt
Trigger signal
52
36
Biopsy needle angle / region
Needle tip detector
66
64
60
Trigger frame
Tip
62
Display trigger frame with tip marked for review
70
72
Satisfactory?
no
yes
40
Reference space from MRI or other source
Provide user interface to search B-mode video segment and identify trigger frame and tip
76
74
Provide user interface to associate biopsy sample with biopsy tip location

FIG. 2

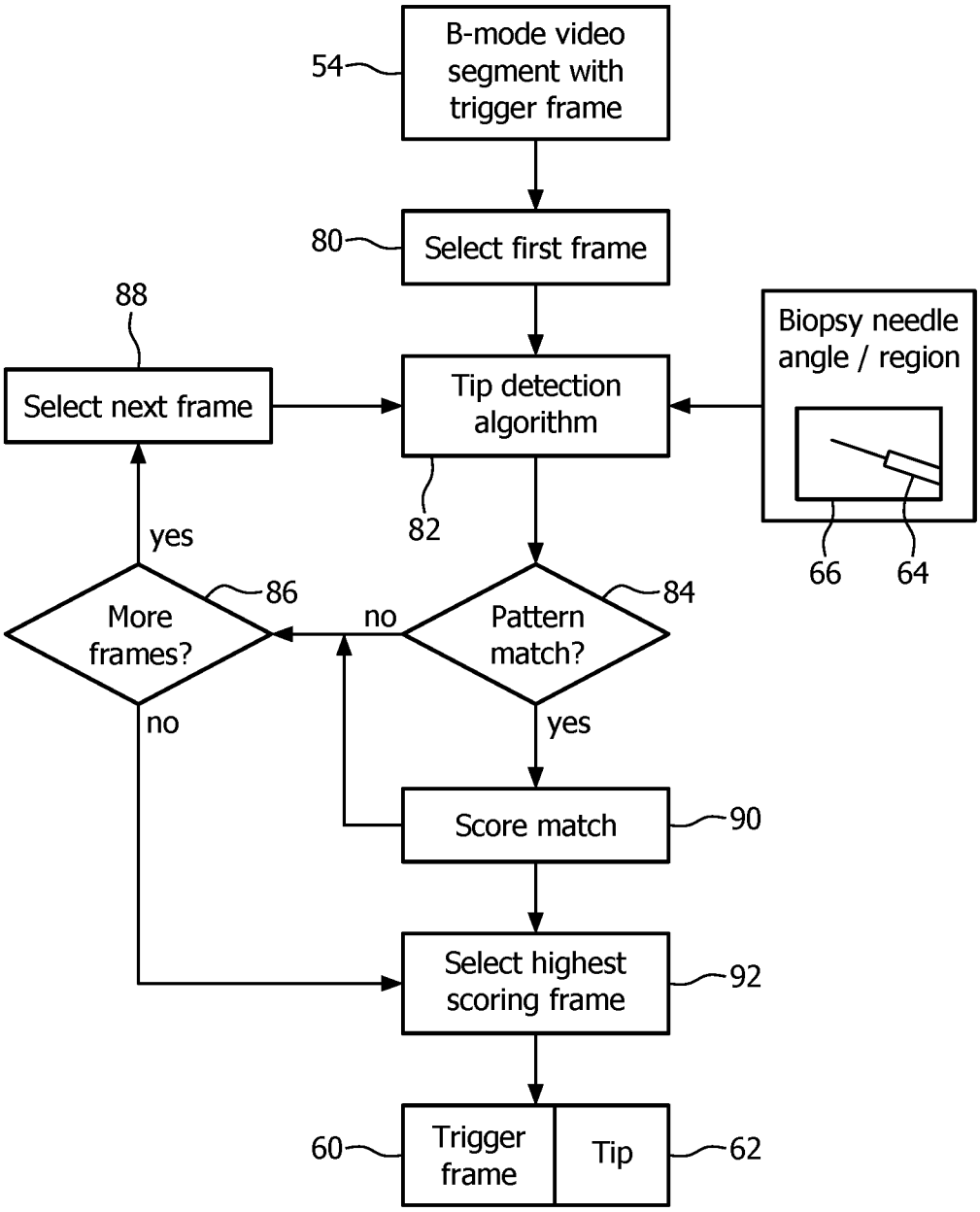
B-mode video segment with trigger frame
54
Select first frame
80
88
Select next frame
Tip detection algorithm
Biopsy needle angle / region
82
66
64
yes
More frames?
86
no
Pattern match?
84
no
yes
Score match
90
Select highest scoring frame
92
60
Trigger frame
Tip
62

FIG. 3

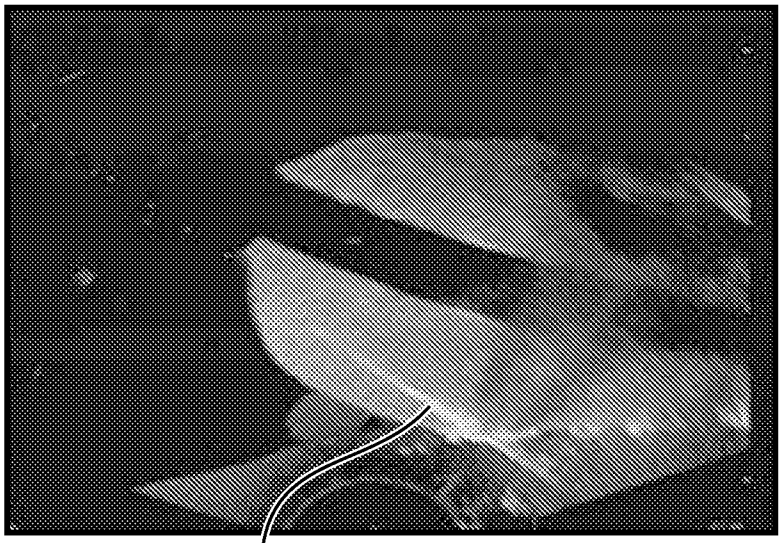

FIG. 4

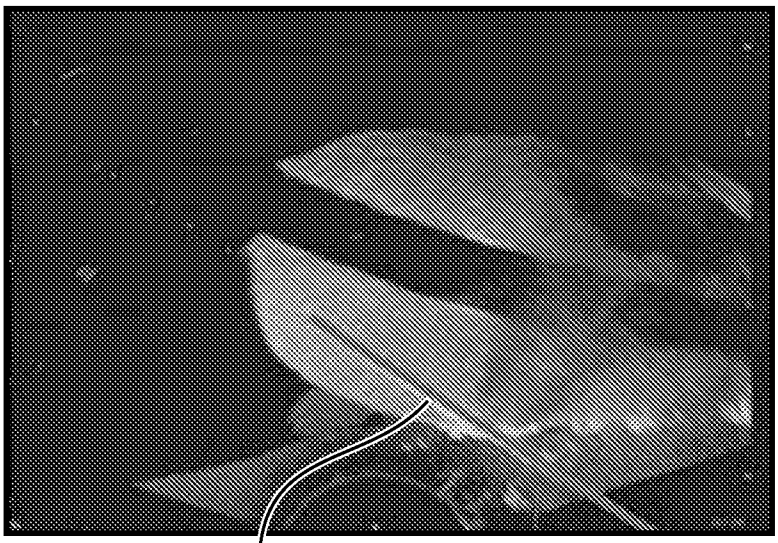

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/054259

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B90/00 A61B10/02
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/338477 A1 (GLOSSOP NEIL [CA] ET AL) 19 December 2013 (2013-12-19)	1-11, 14-19
A	paragraphs [0008] - [0013] paragraphs [0019] - [0021] paragraphs [0028] - [0029] paragraphs [0044] - [0054]; figures 2-3 paragraphs [0058] - [0065]; figures 4-6 paragraphs [0084] - [0086]; figure 11	12,13
A	WO 2012/151073 A2 (ENDOSEE CORP [US]; OUYANG XIAOLONG [US]; INDMAN PAUL D [US]; DECKMAN R) 8 November 2012 (2012-11-08) paragraphs [0047] - [0055]; figures 1-6 paragraphs [0078] - [0087]; figures 40-51	1-19

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"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)

"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

"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

"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

"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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 September 2016	07/10/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schnurbusch, Daniel

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2016/054259

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2004/019799 A2 (COMPUTERIZED MED SYST INC [US]; BURDETTE EVERETTE C [US]; DEARDORFF DA) 11 March 2004 (2004-03-11) page 14, line 5 - page 16, line 27; figures 1-5 page 19, line 8 - page 23, line 34 -----	1-19
A	WO 2014/141262 A1 (UC CARE LTD [IL]) 18 September 2014 (2014-09-18) page 8, line 26 - page 11, line 17; figures 1-3B page 14, line 12 - page 15, line 11; figure 4 page 21, line 11 - page 23, line 13 -----	1-19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2016/054259

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 20-22
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

Continuation of Box II.1

Claims Nos.: 20-22

Method claim 20 defines a method for treatment of the human or animal body by surgery practised on the human or animal body, because "[...] acquiring and displaying [...a...] medical imaging video of human anatomy being biopsied; detecting a trigger signal [...] replacing the video displayed on the display device with a still image display of the identified trigger image [...] indicating the identified location of the fired biopsy needle tip [...]" (claim 20) is seen as a surgical step performed on a patient, because the description only discloses embodiments, where the video display is a live video display and the trigger signal is a signal partly used or connected with a firing signal for the biopsy needle. Hence the video display and the method of replacing the display with a still image of the identified location of the fired biopsy needle is directly linked to the surgical procedure. Therefore no search has been performed for the subject-matter of this claim and the corresponding dependent claims (see Article 17 (2) PCT and Rule 39.1.(iv) PCT) and no written opinion is required for the subject-matter of these method claims (see Rule 43bis.1 and Rule 67.1 (iv) PCT).

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2016/054259

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2013338477 A1	19-12-2013	NONE	
WO 2012151073 A2	08-11-2012	CA 2835081 A1	08-11-2012
		CN 103841880 A	04-06-2014
		EP 2709513 A2	26-03-2014
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		JP 2014521373 A	28-08-2014
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		EP 2967424 A1	20-01-2016
		JP 2016518150 A	23-06-2016
		US 2016030021 A1	04-02-2016
		WO 2014141262 A1	18-09-2014