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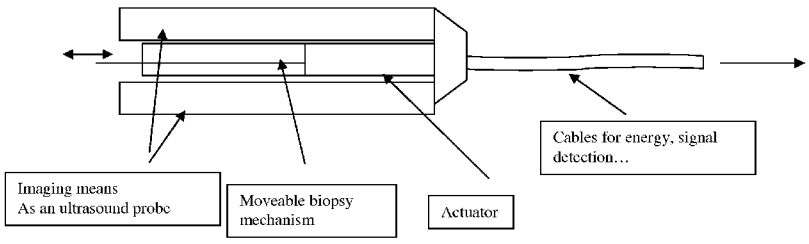
(54) Title: HANDHELD IMAGING GUIDED BIOPSY DEVICE

FIG 1: The device showing in one housing the imaging means and a biopsy mechanism



(57) Abstract: The invention relates to a biopsy device integrating imaging means and moveable biopsy mechanism in one hand-held housing in order to position automatically the biopsy mechanism with a high accuracy in a patient's body for obtaining relevant tissue samples. One embodiment of the invention is that the biopsy mechanism is a part of the imaging means especially to generate adapted mechanical waves during its insertion in the patient' s body in order to perform elasticity imaging and improve the image quality.

Handheld imaging guided biopsy Device

Field of the Invention

The present invention relates in general to biopsy devices, and more particularly to biopsy devices having two functions, imaging monitoring and automated biopsy mechanism for tissue sampling in one handheld housing

Definitions

Imaging means:

It comprises, not exclusively, ultrasound imaging means (with Doppler capabilities or not) and/or microwave imaging means and/or elasticity imaging means and/or magnetic resonance imaging means and/or Optical imaging means and/or photo-acoustic imaging means, and/or electric impedance imaging, and/or electric resistance imaging, and/or electric capacitance imaging and/or terahertz imaging and/or molecular imaging or a combination of them

Biopsy: It means biopsy or cyto-punction or macro-biopsy or micro-biopsy

Description of Related Art

When a suspicious tissue mass is discovered in a patient's body through examination, ultrasound, MRI, X-ray imaging or the like, it is often necessary to perform a biopsy procedure to remove one or more samples of that tissue in order to determine whether

the mass contains cancerous cells. A biopsy may be performed using an open or percutaneous method.

An open biopsy is a surgical procedure that is usually done as an outpatient procedure in a hospital or a surgical center, involving both high cost and a high level of trauma to the patient. Open biopsy carries a relatively higher risk of infection and bleeding than does percutaneous biopsy. The latter comprising :

Fine needle aspiration process (FNA), a very thin needle is used to withdraw fluid and cells from the suspicious tissue mass. This method has an advantage in that it is very low-pain, so low-pain that local anesthetic is not always used because the application of it may be more painful than the FNA itself. However, a shortcoming of FNA is that only a small number of cells are obtained through the procedure, rendering it relatively less useful in analyzing the suspicious tissue and making an assessment of the progression of the cancer less simple if the sample is found to be malignant.

During a core needle biopsy, a small tissue sample is removed allowing for a pathological assessment of the tissue, including an assessment of the progression of any cancerous cells that are found. The core needle biopsy needle also has a special cutting edge.

Several devices are already marketed (see www.bostonscientific.com , www.bardnordic.com , www.breastbiopsy.com, www.senorx.com) and the trends are clearly towards a full automatization for a better biopsy quality. This translates in two key features:

- Comfort, Manipulation and accuracy availability for the practitioner

- Tissue sampling quality: relevant part of the tissue, no contamination during the extraction, sample protection up to its analysis.

A standard procedure in the previous biopsy types using imaging assistance (especially ultrasound techniques) is the following: the physician uses one hand to guide the needle, while the other holds the ultrasound probe. An assistant is often necessary on instruction. This is still the standard in spite of the automatization of various marketed devices.

Moreover, during a biopsy, the current imaging technique used (ultrasound) shows limitations about large suspicious tissue mass; the latter can be heterogeneous and that requires specific biopsy procedures. Often several acts are needed.

We propose a handheld biopsy device which integrates in one housing imaging capabilities to visualize tissue environment and a biopsy mechanism which must be placed automatically to capture the relevant tissue. The biopsy mechanism can be exploited in order to optimize in real time the image quality and the biopsy monitoring, thanks to elasticity imaging

Moreover, such device gives to practitioner the possibility to perform several manipulations in parallel.

Features and advantages of the invention will become readily apparent from the following detailed description with reference to the accompanying drawings which show, diagrammatically and by way of example

only, preferred but still illustrative embodiments of the invention.

Brief Description of the Drawings

Fig 1 is a schematic representation of the device showing in one housing the imaging means and a biopsy mechanism;

Fig 2: is a schematic representation of the device of fig 1, strap preferentially fixed to the practitioner's wrist.

Description

A handheld biopsy device according to the present invention includes at least one biopsy mechanism, at least one actuator and imaging means, the whole integrated in one housing. The actuator can be an electrical motor. The device is such that it is possible to visualize with accuracy the complete process of tissue sampling and to determine the position(s) to extract relevant tissue(s), in particular for large tissue mass with heterogeneities.

A preferred form of the invention is that the imaging means use ultrasound imaging technology (in particular transducer(s)). A rough description would be an ultrasound probe where, inside it, according to its longitudinal axis, is integrated a moveable biopsy mechanism. The practitioner uses only one device during the biopsy; he has more degrees of freedom for manipulation than a current biopsy. He can execute

palpations during the biopsy to allow real time elasticity imaging.

The imaging means are designed such that it is possible to follow on the visualization the biopsy mechanism inside the patient's body. In the case of an ultrasound technology, a part of transducers are tilted in regard to the others in order to detect the biopsy mechanism.

Another embodiment of the present invention is that a part or the whole of transducers are adaptative: in real time it optimize the signal and image quality by controlling its position and angles.

Another embodiment of the present invention is the following: the global integration of these technologies can be made by considering a strap preferentially fixed on the practitioner's wrist: we can find, on one hand, inside the housing, for example transducers as a part of the imaging means, and the required electronics in proximity for signal treatment, the biopsy mechanism comprising for example, a needle and a cannula with cutting means, and, on the other hand, embedded in the strap, we can find as example, actuator(s), user interface to select operational functions, and/or visualization of the relevant tissue for needle positioning, and/or battery, and/or data acquisition means to manage the signals from transducers…

Another feature of the present invention resides in the combination of needle component and transducers such that said needle component can also be used as a complementary transducer a mechanical emitter by apply mechanical pulses of needle and said transducers used

to detect themechanical response of tissue such as in elasticity imaging or the needle is used as an electrode for electrical impedance sensing or electromyography component.

Another feature of the present invention resides in the fact that the device is cordless. The required battery is either inside the housing or embedded in the strap, or in the both.

Another feature of the present invention resides in the monitoring of the current intensity from the actuator measuring indirectly the hardness of the relevant tissue and its environment. This can be complementary information to perform better biopsy.

Another embodiment of the present invention is that the moveable biopsy mechanism integrates at least one sensor, used for tissue characterization as an example, during the biopsy

Another embodiment of the present invention is that the biopsy mechanism is a part of the imaging means. In the case of ultrasound technology used as imaging means, the biopsy mechanism integrates function(s) to generate adapted mechanical waves for real time elasticity imaging.

Another embodiment of the present invention is that the moveable biopsy mechanism comprises at least one moveable cutting cannula and at least one moveable needle. It could further comprise cryogenic and/or vacuum means to execute the tissue sampling.

Another embodiment of the present invention is that the biopsy mechanism comprises one or a plurality of (micro)-structured surfaces and/or one or a

plurality of chemically functionalized zones to capture tissue(s) with one or different specificity during biopsy. These surfaces and/or zones are implemented on at least one element which could be directly compatible with analytical instrumentation(s).

Another embodiment of the present invention is that the device transmits data wirelessly by means of transmit and receive modules so that the said data may be transferred to a network, and/or a PC, and or a PDA, and/or a screen, and/or a screen embedded in the said strap. The said data also may be transmitted from the said network, and/or the said PC, and/or the said PDA and/or a means embedded in the said strap wirelessly through the said modules to the said device in order to control the system.

Another embodiment of the present invention is that the moveable biopsy mechanism comprises at least one adhesive material to capture the relevant tissue. This material is on a protected area up to be exposed when the biopsy mechanism is at the convenient position. After the adhesion of the relevant tissue, this part (area and captured tissue) is protected.

Another embodiment of the present invention is that the moveable biopsy mechanism comprises at least one electrode to capture the relevant tissue. This electrode is on a protected area up to be exposed when the biopsy mechanism is at the convenient position. After the capture of the relevant tissue, this part (area and captured tissue) is protected. The said electrodes can be micro-structured to facilitate the capture.

Another embodiment of the present invention is that the moveable biopsy mechanism comprises at least one electrode to perform dielectrophoresis on relevant tissue and/or by polarizing the tissue and/or cell under electrostatic field(s).

Another embodiment of the present invention is that the device is an elasticity imaging probe comprising imaging means as at least one transducer, at least one moveable actuator generating mechanical waves, at least one electrical driver of the said actuator and one handheld housing integrating all previous elements. This device can be directly connected to a PC or alike, or can be cordless and/or wireless

While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the spirit and scope of the appended claims. Additionally, each element described in relation to the invention can be alternatively described as a means for performing that element's function.

CLAIMS

1. A biopsy device comprising :
   a. a housing
   b. at least one biopsy mechanism moveably connected to said housing
   c. at least one imaging means connected to said housing
   d. at least one actuator for moving said biopsy mechanism outward relative to said housing and for operating said biopsy mechanism

   such that the said imaging means allow the monitoring, control and visualization of the said biopsy mechanism for a relevant and accurate at least one tissue sampling.

2. The biopsy device of claim 1, wherein the said biopsy device is cordless.

3. The biopsy device according to any one of previous claims further comprising a strap, preferentially placed around the wrist of the practitioner, linked to the said housing, integrating a part of the said imaging means and/or an user interface (allowing to the said practitioner to define operating modes and/or to control the said tissue sampling) and/or a part of the said biopsy mechanism and/or a part of the said actuator.

4. The biopsy device according to any one of previous claims, wherein the said biopsy mechanism

integrates at least one sensor and/or at least one actuator, the said sensor being used in a preferred form(s) for said tissue characterization and/or recognition, and/or environment characterization in the proximity of the said tissue (by electrical impedance for example).

5. The biopsy device according to any one of previous claims, wherein the said imaging means comprises an ultrasound probe integrating at least an array of ultrasound transducers capable of transforming ultrasound waves impinging on them in electric signals and/or generating ultrasound waves by electric excitation.

6. The biopsy device according to any one of previous claims, characterised in that a part or the whole of the said array of transducers is designed to optimize the visualization of the said biopsy mechanism during the said tissue sampling.

7. The biopsy device according to any one of previous claims, characterised in that a part or the whole of the said transducer is adaptative to optimize the imaging quality.

8. The biopsy device according to any one of previous claims, characterised in that the said biopsy mechanism is a part of the imaging means.

9. The biopsy device of claim 8, characterised in that the said biopsy mechanism generates adapted mechanical waves for real time elasticity imaging.

10. The biopsy device according to any one of previous claims, characterised in that the said biopsy mechanism comprises at least one moveable cutting cannula and at least one moveable needle.

11. The biopsy device according to any one of the previous claims, characterised in that the said biopsy mechanism comprises a part allowing incision(s) in the patient's body.

12. The biopsy device according to any one of previous claims, characterised in that the said biopsy mechanism integrates cryogenic means.

13. The biopsy device according to any one of previous claims, characterised in that the said biopsy mechanism integrates vacuum means for improving the said tissue sampling.

14. The biopsy device according to any one of previous claims wherein the current intensity from the said actuator is monitored to characterize the said tissue and its environment and participate as a complementary measurement for a better quality of biopsy.

15. The biopsy device according to any of previous claims, wherein the said biopsy mechanism comprises at least one microstructured surface and/or at least one dedicated chemically functionalized zones in order to increase the said tissue sampling yield and specificity during tissue apposition.

16. The biopsy device according to any of previous claims, wherein the said biopsy mechanism comprises a serie of different microstructured surfaces and/or a serie of different dedicated chemically functionalized zones in order to capture tissue with different specificity during at least one penetration in the patient's body.

17. The biopsy device according to the claim 14, wherein the said microstructured surfaces and/or the said dedicated chemically functionalized zones are dismantled and directly compatible with mass spectrometer and/or other relevant analytical instrumentation.

18. The biopsy device according to any of the previous claims, wherein a dedicated analytical instrumentation allows the relevant analysis from the said tissue sampling.

19. The biopsy device according to any one of previous claims further comprising integrated anaesthesia means for anaesthesia product delivery

before the said biopsy mechanism penetration in the patient's body.

20. The biopsy device according to any one of the previous claims further comprising a sterile chamber receiving tissue from the said tissue sampling.

21. The biopsy device according to any one of the previous claims, wherein the said device transmits data wirelessly by means of transmit and receive modules so that the said data may be transferred to a network, and/or a PC, and or a PDA, and/or a screen, and/or a screen embedded in the said strap, the said data also may be transmitted from the said network, and/or the said PC, and/or the said PDA and/or a means embedded in the said strap wirelessly through the said modules to the said device in order to control the system.

22. The biopsy device according to any one of the previous claims, characterized in that the said biopsy mechanism is a needle assembly.

23. The biopsy device according to any one of the previous claims, characterized in that the said biopsy mechanism has a surface coating to increase its visibility with the said imaging means.

24. The biopsy device according to any one of the previous claims, wherein the said imaging means

comprises at least optical transducer to perform photo-acoustic imaging

25. A method of performing a biopsy comprising: providing imaging means and biopsy mechanism in one handheld housing allowing the monitoring, control and visualization in real time of the said biopsy mechanism for a relevant and accurate tissue sampling.

26. The method of claim 25 wherein an actuator drives automatically the biopsy mechanism to move toward said tissue and to remove a biopsy sample from said tissue.

27. The method of claims 25 and 26 wherein the practitioner undertakes palpations to provide to said imaging means information for elastography imaging improving the said monitoring, control and visualization of the said tissue sampling.

28. The method of claims 25 and 26 wherein the said biopsy mechanism generates adapted mechanical waves in order to perform elasticity imaging thanks to the said imaging means.

29. A method and device of performing a biopsy, comprising:
abiopsy device integrating a biopsy mechanism, the latter comprises means to perform

elasticity imaging to guide in real time the said biopsy : the said means generates mechanical waves outside and/or inside the patient's body in order to be capture by at least one transducer integrated in the said device

30. A medical device comprising :
   a. an ultrasound probe
   b. at least one moveable actuator
   c. a housing integrating the said actuator and the said ultrasound probe

such that the said actuator generates specific mechanical waves once it is in a patient's body, the said waves interact with tissues and the resulting mechanical deformations can be treated by the said ultrasound probe to optimize in real time the resulting elasticity imaging.

31. The medical device according to the claim 30, wherein the said actuator generates mechanical waves in function of time and/or position relative to the said ultrasound probe.

32. The device according to claims 30 or 31, wherein further comprising biopsy means for tissue or cell sampling.

33. The device according to claims 30 or 31, wherein further comprising injection means (as an needle assembly and chamber where is placed a product to inject) especially for pain management,

orthopaedic applications, spinal and epidural injections.

34. The device according to any one of the previous claims wherein the biopsy mechanism comprises at least one electrode for the said tissue sampling.

35. The device according to the claim 34, wherein the said electrodes are designed such that to perform dielectrophoretic tissue and/or cell capturing.

36. The device according to the claim 34 or claim 35, wherein the said electrodes (or a part) are moveable by actuators.

37. The device according to the claim 34 or claim 35 or claim 36 further comprising electrophoresis means in view of controlling and/or capturing tissue(s) and/or cell(s).

38. The device according to any one of the previous claims, wherein the biopsy mechanism comprises at least one adhesive material used to extract tissue or cell during the said tissue sampling

39. A method and a biopsy device comprising a moveable biopsy mechanism and at least one

electrode to perform dielectrophoretic tissue capturing.

40. A method and a biopsy device according to the claim 38, further comprising an actuator for automatically drive the said biopsy mechanism.

41. A method and a biopsy device according to the claim 38 or 39, wherein the said electrodes are moveable.

42. A method and biopsy device according to the claim 38 or claim 39 or claim 40, wherein a part of said electrodes perform positive dielectrophoresis and another part of said electrodes perform negative dielectrophoresis

43. A method and biopsy device according to the claim 38 or claim 39 or claim 40, wherein electrophoresis means are used to control and/or capture tissue(s) and/or cell(s).

FIG 1: The device showing in one housing the imaging means and a biopsy mechanism

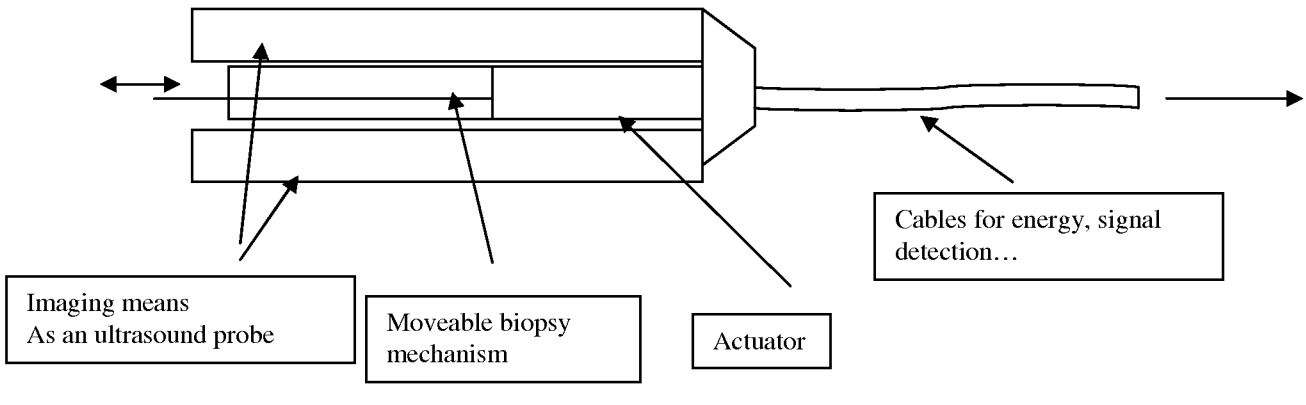


FIG 2: The device with strap preferentially fixed to the practitioner's wrist