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(54) **A LOCATION HEAD FOR AN APPARATUS FOR DETECTING VERY SMALL BREAST ANOMALIES**

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(57) **ABSTRACT**

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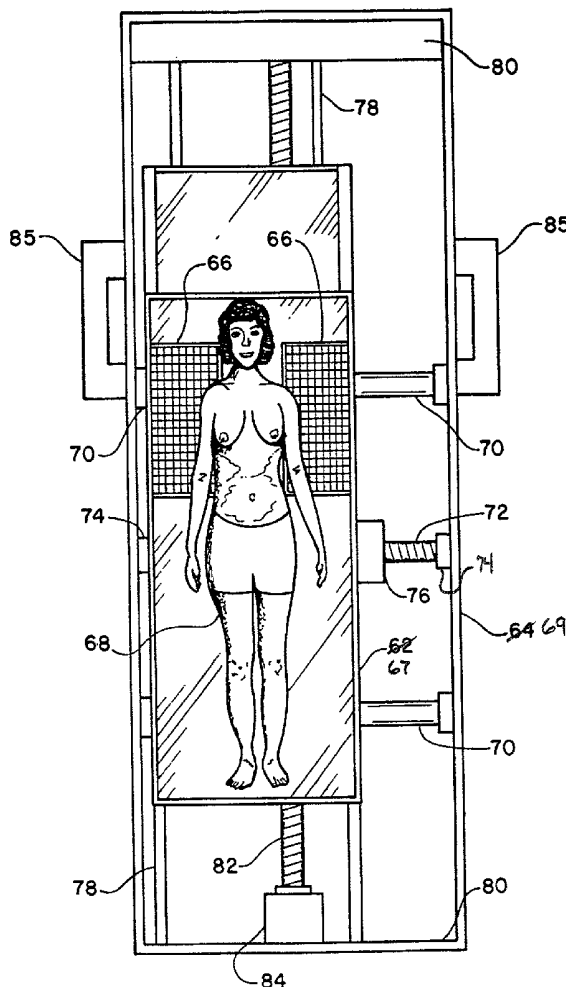
A computer controlled apparatus for detecting breast tumors by mechanically palpating a breast in a full scan manner to detect even very small lumps or other anomalies. The patient is positioned on a fully adjustable bed and oriented relative the apparatus. A detection head mounted for movement in three dimensions is positioned above the bed. A palpation finger is brought into pressure contact with a sequence of small areas across the entire breast, palpating each area to measure tissue density. Concurrent with the palpation scan, a scan of breast color and temperature is conducted. A locator head positions the detector for the scan in a manner that assures repeatability of the palpation scan during each of a series of periodic examinations. This system detects very small lumps and allows easy, accurate, monitoring of suspicious areas over an extended time period. Several different embodiments of the detection head and location head are described.

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Related U.S. Application Data

(63) **Continuation of application No. 09/241,193, filed on Feb. 1, 1999, which is a continuation-in-part of application No. 08/957,648, filed on Oct. 24, 1997, now Pat. No. 6,192,143.**



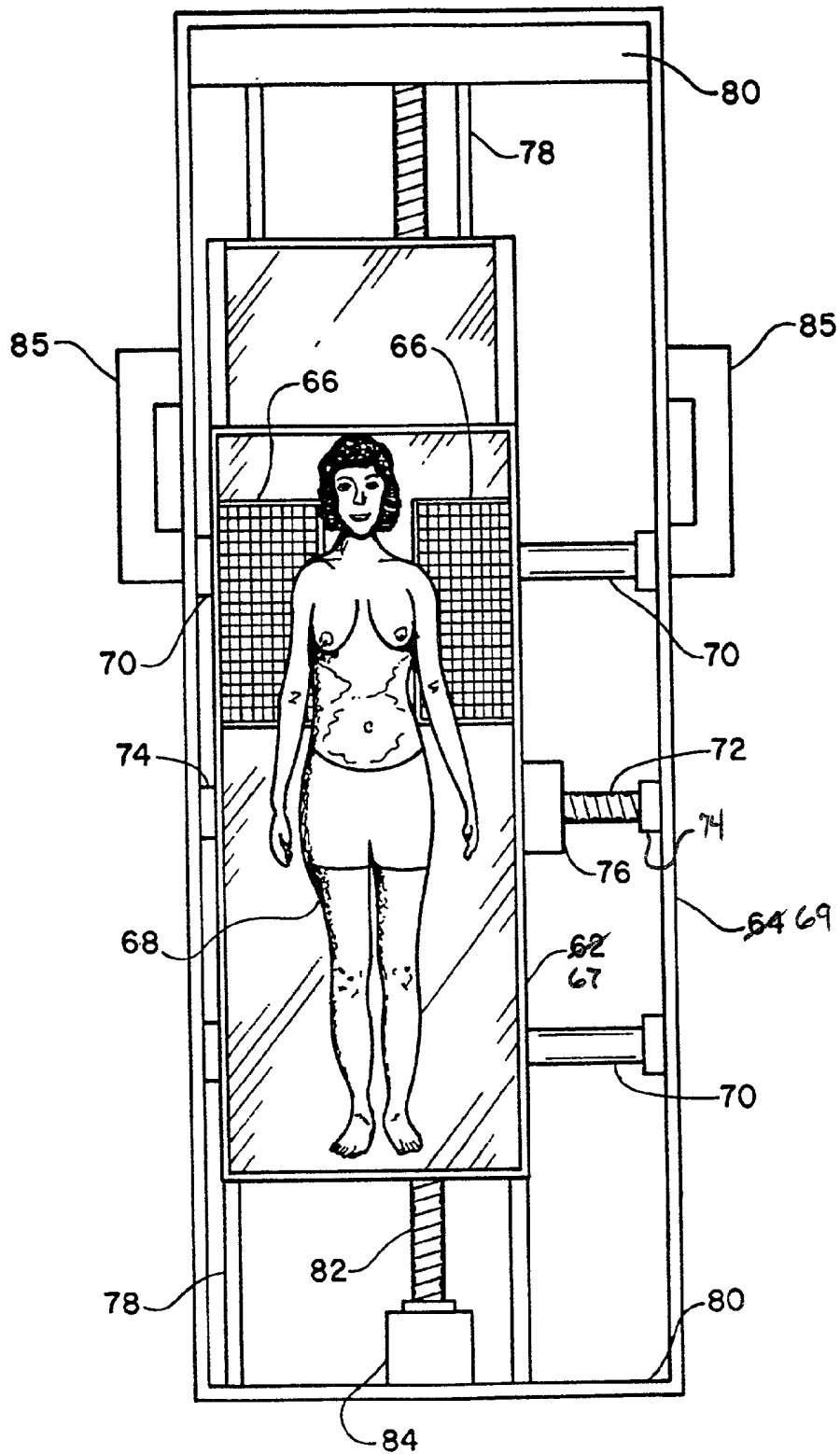


FIGURE 2

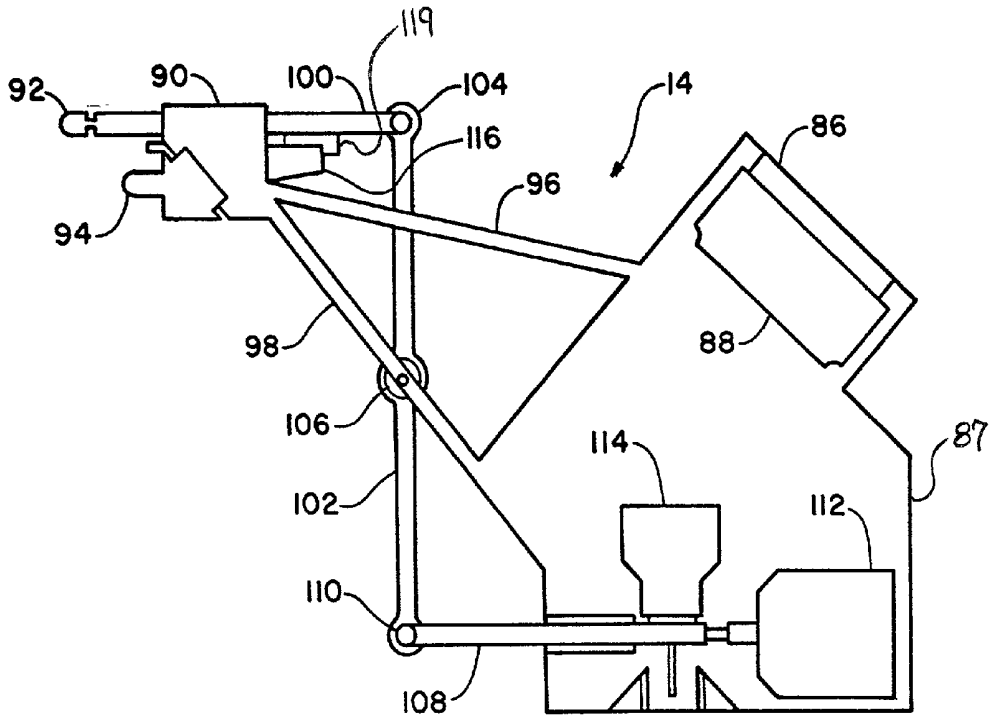


FIGURE 3

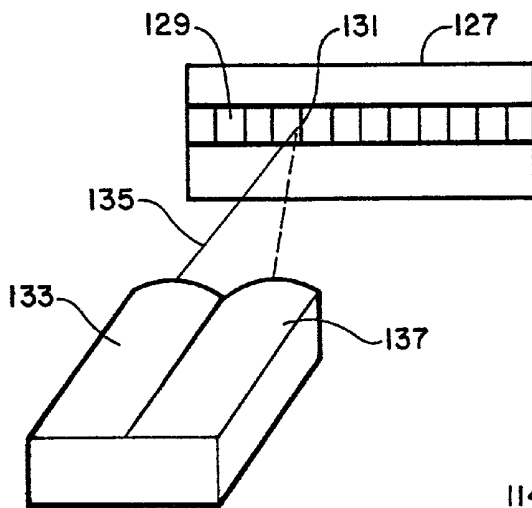


FIGURE 4A

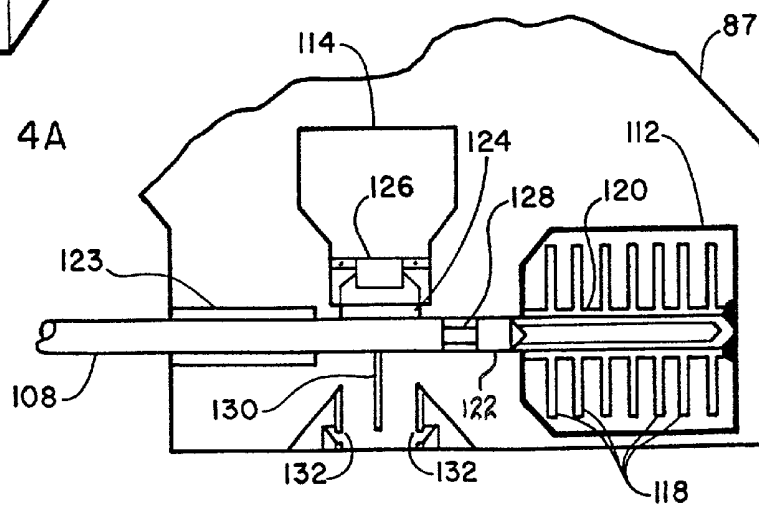


FIGURE 4

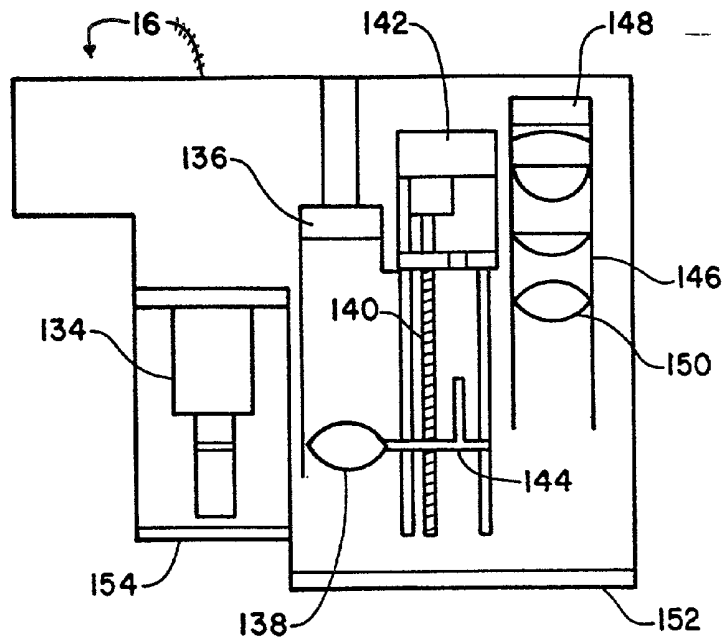


FIGURE 5

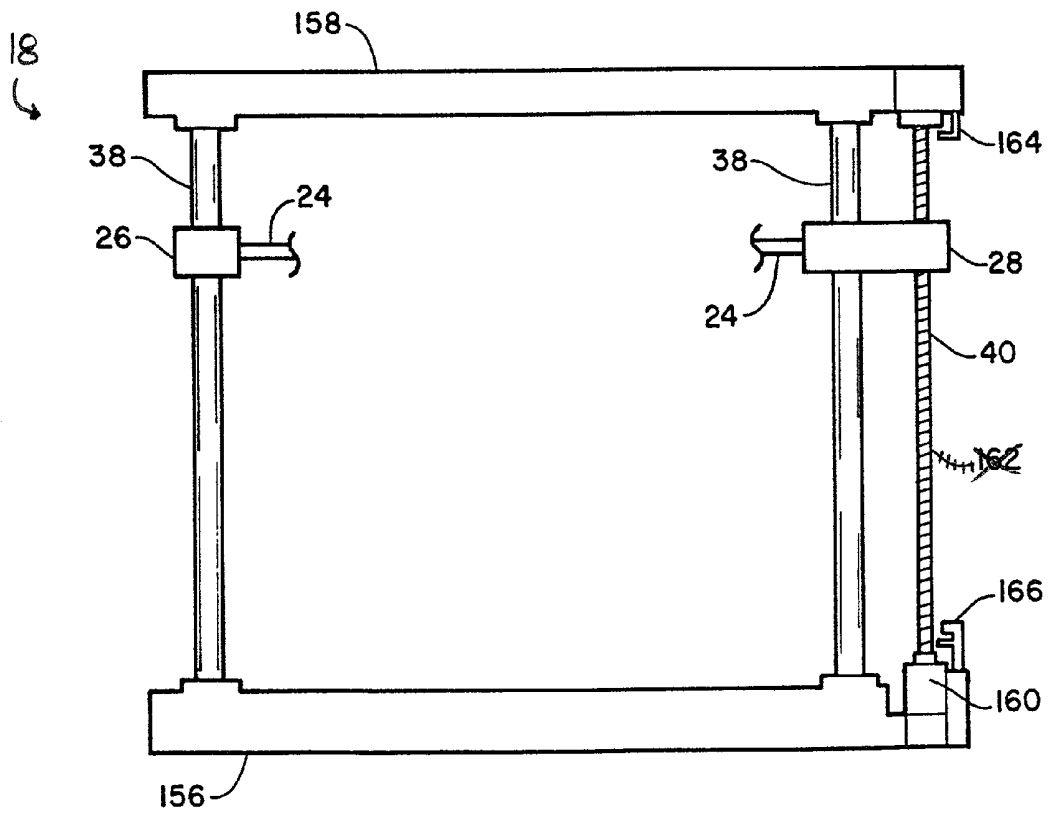
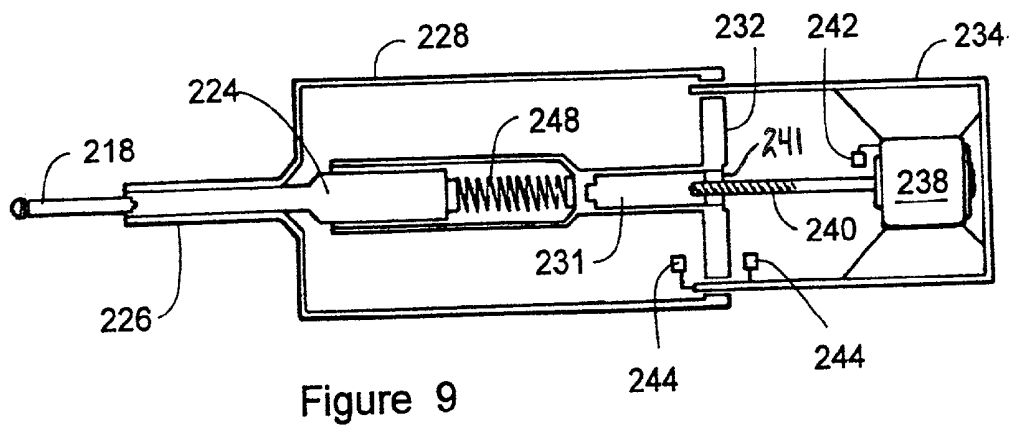
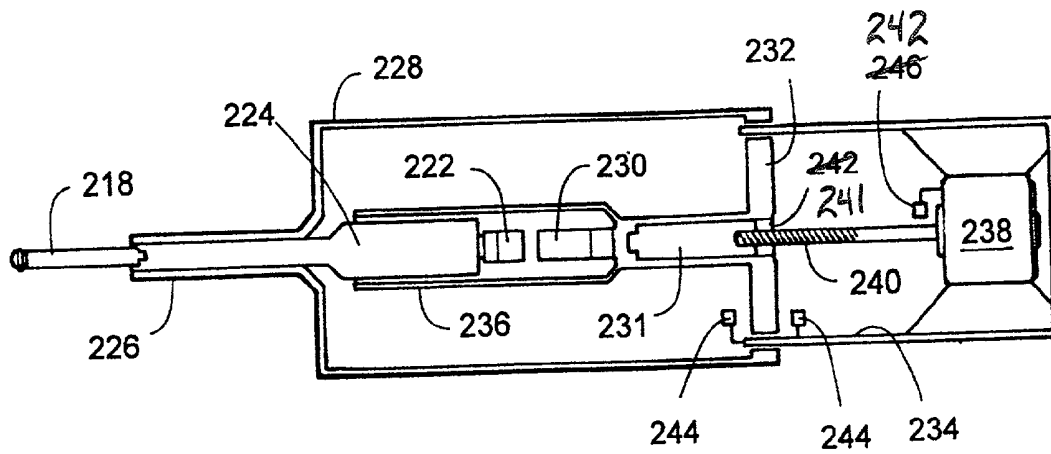
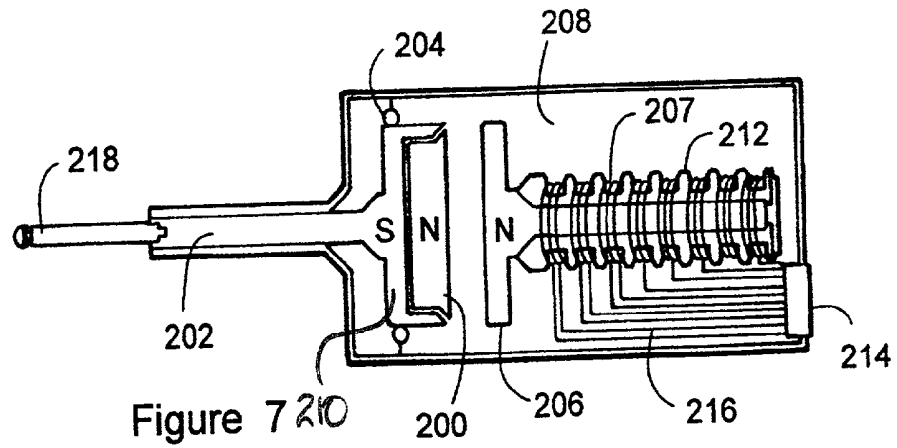


FIGURE 6



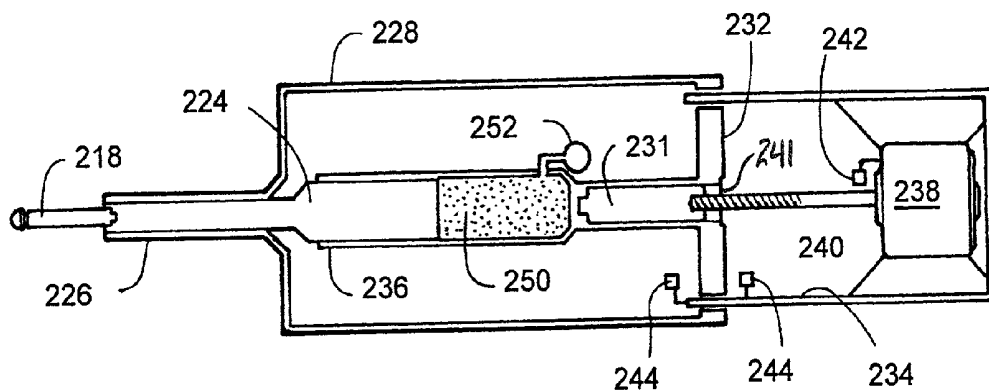


Figure 10

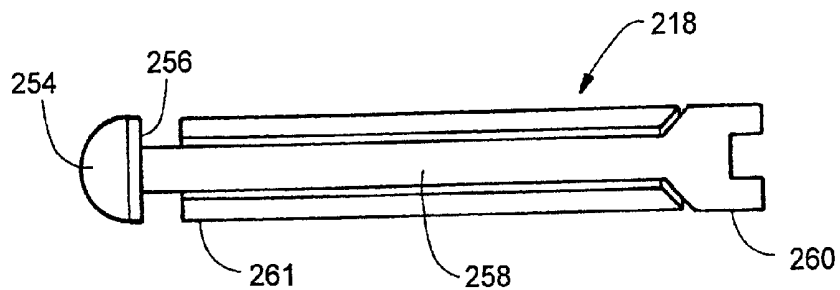


Figure 11

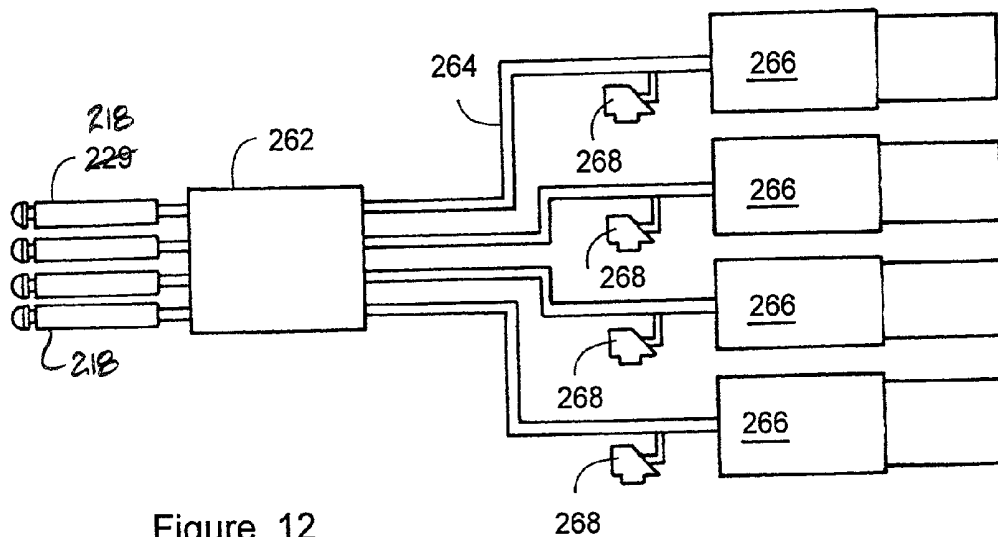
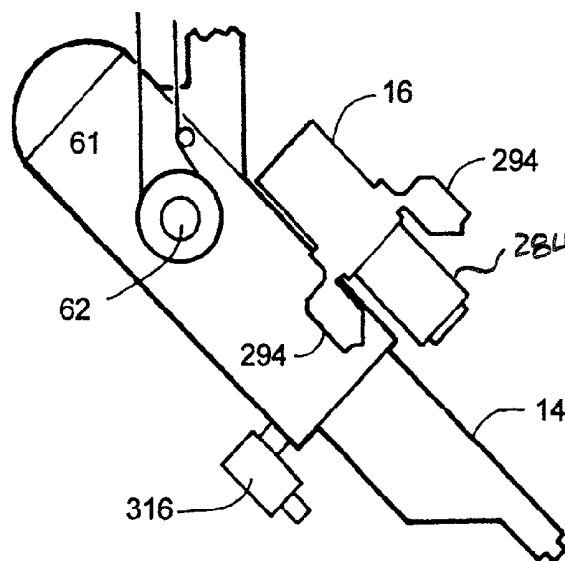
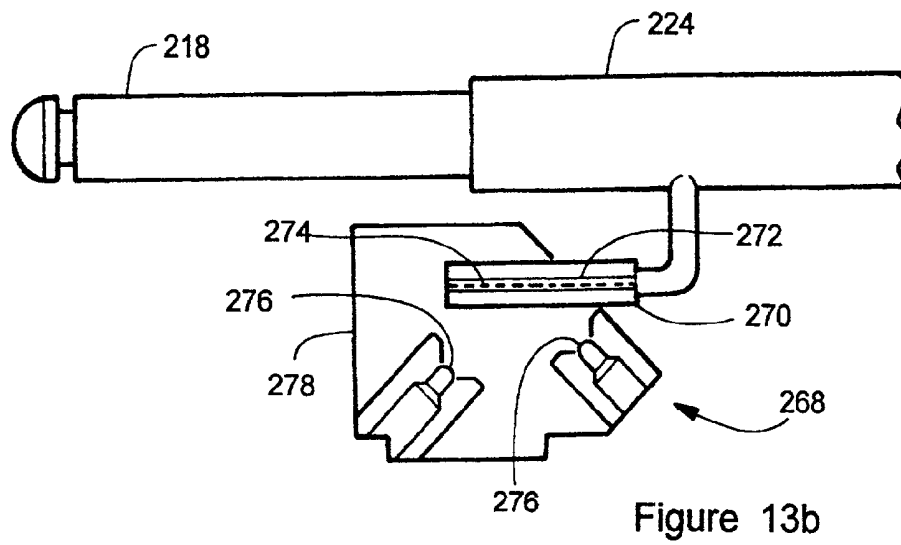
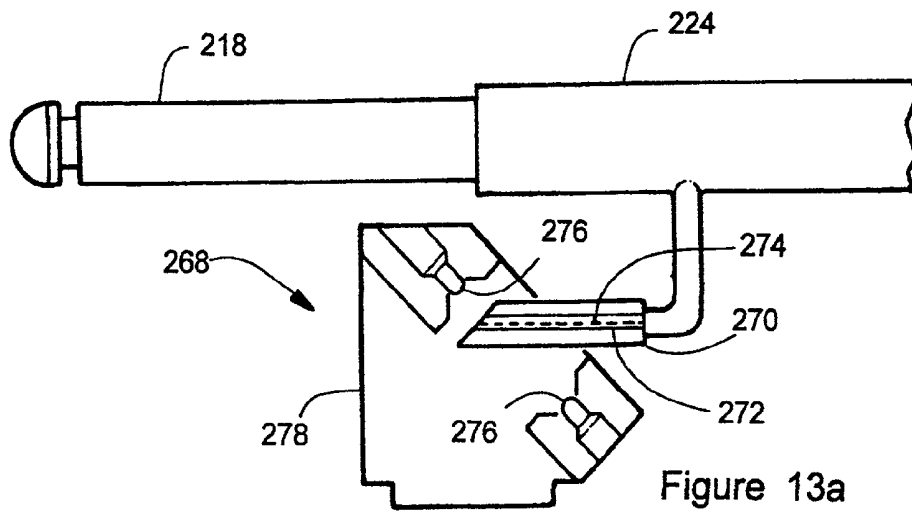
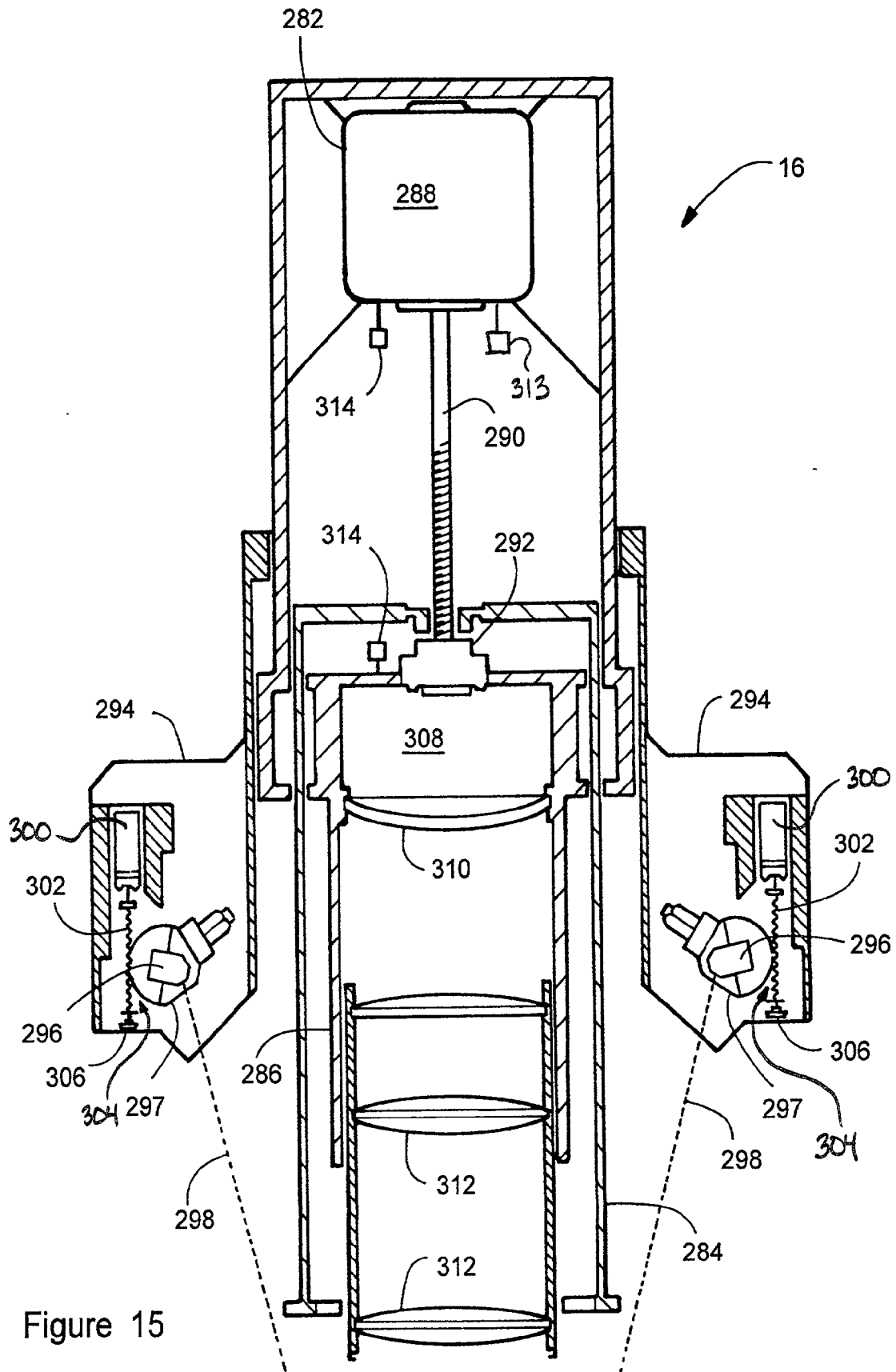


Figure 12





A LOCATION HEAD FOR AN APPARATUS FOR DETECTING VERY SMALL BREAST ANOMALIES

FIELD OF THE INVENTION

[0001] This invention relates to apparatus and methods for detecting very small anomalous masses, in particular tumors, in the human breast. In particular, this invention relates to detection heads for physically detecting breast anomalies and generating an electrical signal corresponding to changes in breast characteristics due to such anomalies.

BACKGROUND OF THE INVENTION

[0002] Recent findings indicate that one of eight women will develop breast cancer, the second leading cause of cancer death in women. Unopposed estrogen activity is an important pathogenic factor, with other risk factors including nulliparity, early menarche, late menopause, a family history of breast cancer, middle age and prior breast cancer.

[0003] The earliest indication of breast cancer generally is the occurrence of a painless lump, sometimes associated with nipple discharge and skin retraction. Later symptoms are generally due to metastases to bone, brain, lungs and liver. Early diagnosis may be possible through monthly self-examinations. Mammography has proven beneficial in early detection.

[0004] When a very small lump, <2 cm, is detected, a biopsy is generally performed, followed by treatment when the lump is found to be malignant. This can range from a lumpectomy with possible radiation treatment of axillary nodes to a modified radical mastectomy with axillary node dissection. With early treatment, the five-year survival rate is about 85%. Without early detection, if distant metastasis occur, the survival rate may drop to 10% or less.

[0005] Early detection of lumps is thus essential. Monthly self-examinations are very desirable, followed by examination by a physician if any suspicious areas are detected. It is, however, difficult for an unskilled person to detect very small lumps or to do a thorough examination.

[0006] Periodic palpation of the breasts by a physician and mammography will often detect very small tumors. These examinations should be reasonably frequent, particularly in older women, in order to detect tumors before they can metastasize. However the cost of frequent examinations, plus the accumulated radiation exposure from frequent mammograms tend to limit frequency. In addition, mammography may miss very small tumors, especially in the dense breasts of younger women. Further, pregnant women should avoid exposure to radiation.

[0007] Palpation of breasts will not detect very small changes and anomalies of the breast until the changes are so large or hard compared to the normal breast tissue that the difference can be detected by a touch of a finger. Generally, palpation is only capable of detecting changes where the anomalous tissue is relatively hard, has a diameter of at least about one centimeter and is close to the surface of the skin. Deeper anomalies, particular in large breasts, are difficult to detect by palpation. Since the characteristics of anomalies are not quantifiable, detecting changes in anomalies from one examination to another is difficult.

[0008] Thus, there is a continuing need for improved methods and apparatus for very early detection of very small breast anomalies that could be malignant, while avoiding radiation exposure.

SUMMARY OF THE INVENTION

[0009] The above-noted problems, and others, are overcome in accordance with this invention by an anomalies detection apparatus for thoroughly palpating entire breasts in a continuous, automatic scanning manner, to detect changes in breast tissue physical characteristics. In particular density is measured across the entire breast and, where anomalies are detected, mobility and size of the anomaly are measured.

[0010] The overall system in which this detection apparatus includes a bed upon which the patient lies face up and which includes means for precisely positioning the patient in the same position for each of a series of periodic examinations. The detection head is mounted on a carriage for movement in three dimensions adjacent to a patient on the bed. A locator head associated with the detection head controls the bed positioning means to position the breasts in precisely the same position as for prior examinations. A palpation means on the detection head includes at least one finger-like palpation end movable toward and away from the breast surface to palpate the breast in the same general manner as a physician. The palpation device is preferably mounted so as to be movable across the entire breast surface sequentially while maintaining the finger generally perpendicular to the breast surface.

[0011] Information sensed by the palpation device is collected, stored and displayed in a conventional manner, such as is done with information from other systems such as computerized tomography and magnetic resonance imaging. The display will reveal, and show details of, any anomalies detected, so that further testing, such as through a biopsy, can be done.

BRIEF DESCRIPTION OF THE DRAWING

[0012] Details of the invention, and of preferred embodiments thereof, will be further understood upon reference to the drawing, wherein:

[0013] FIG. 1 is a schematic elevation view of the entire anomaly detection apparatus;

[0014] FIG. 2 is a schematic plan view showing a patient positioned on the patient positioning bed;

[0015] FIG. 3 is a schematic elevation view of the detection head and actuator;

[0016] FIG. 4 is a schematic elevation view of the detection head and actuator positioning means;

[0017] FIG. 5 is a schematic diagram of a first embodiment of a locator head assembly;

[0018] FIG. 6 is a schematic elevation view of the vertical positioning mechanism of the anomaly detection apparatus;

[0019] FIG. 7 is a schematic representation of the internal components of a first detection head embodiment;

[0020] FIG. 8 is a schematic representation of the internal components of a second detection head embodiment;

[0021] FIG. 9 is a schematic representation of the internal components of a third detection head embodiment;

[0022] FIG. 10 is a schematic representation of the internal components of a fourth detection head embodiment;

[0023] FIG. 11 is a schematic representation of a palpation tip for a detection head;

[0024] FIG. 12 is a schematic representation of a detection head having a plurality of parallel palpation tips;

[0025] FIG. 13 is a schematic representation of an actuator connector for use with a single tip arrangement or a multi-tip arrangement as seen in FIG. 12;

[0026] FIG. 14 is a schematic elevation view of a second embodiment of the robot arm system; and

[0027] FIG. 15 is a schematic representation of the internal components of a second embodiment of a locator head assembly.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0028] Referring to FIG. 1 there is seen a carriage 10 mounted at a proximal end on a horizontal support 12 for movement therealong a detection head 14 (as detailed in FIGS. 3 and 4) is mounted at the distal end of carriage 10. A locator head 16 (detailed in FIG. 5) is mounted to detection head 14 for movement therewith. Digital information from and to detection head 14, locator head 16 and control commands to the various motors, limit switches and the like is passed between a computer center 17 as schematically indicated. Information will be received, stored, interpreted and displayed in the same manner as other medical scanning devices, such as CAT scans, MRI scans, etc. Three dimensional images can be viewed on a conventional computer monitor.

[0029] If desired, images may be shown with different tissue density areas shown in different colors. Artificial intelligence techniques may be used to improve system performance. The combination of tissue density information as developed by palpation and the ancillary local color and temperature information results in detection of much smaller tumors and the ability to easily track changes in discrete tissue areas.

[0030] Horizontal support 12 is mounted on a vertical support mechanism 18 (as detailed in FIG. 6) along which support 12 can move in a vertical direction. Horizontal support includes a traveler 20 that rides in bearings 22 along rods or tubes 24 that are secured at their ends to end blocks 26 and 28. A lead screw extends from a bearing 32 at end block 26 to a drive motor 34 at end block 28. Lead screw 30 extends through correspondingly threaded openings in walls 36 of traveler 20 so that traveler 20 will move to the right or left as the lead screw is rotated in one direction or the other. Conventional limit switches 37 prevent overtravel of traveler 20.

[0031] Guide rods 38 extend vertically through end blocks 26 and 28 and a lead screw 40 extends vertically through end block 28. These components are shown completely and discussed in conjunction with the discussion of FIG. 6, below.

[0032] Carriage 10 includes a base 42 secured to traveler 20. A motor 44 within base 42 rotates a screw 46 that is threaded into an intermediate body 48 to raise and lower that body as the screw is rotated one way or the other. A pair of guide rods 50 extend through brackets 52 to guide movement of body 48. A lower body 54 is secured to intermediate

body 48 for rotation relative thereto. A motor 56 is mounted on intermediate body 48 with lower body 54 mounted on the motor shaft 56 for rotation with the shaft.

[0033] An arm 61 is pivotally mounted at pivot 62 on bracket 64 mounted on the distal end of lower body 54. A motor 60 on lower body 54 drives a pulley 62 on arm 61 through a jackshaft 64.

[0034] Thus, the entire carriage can be moved horizontally by horizontal support 12 and vertically by the vertical support of FIG. 6. Lower body 54 of the carriage can be rotated through a full circle. Arm 61 carrying detection head 14 can be pivoted through at least 180°. This combination of movements permits detection head to be positioned in any desired position relative to any portion of a breast surface.

[0035] In order to perform a complete breast examination, a person lies face-up on a bed 62 mounted on a position adjusting assembly 64 as seen in FIG. 2. The bed will be positioned generally below detection head 14 of FIG. 1.

[0036] Bed 62 has a comfortably padded upper surface, with matrix boards 66 adjacent to the shoulders of person 68. Conventional optical measuring means (not shown) can be provided to locate the exact position of arms, shoulders and neck relative to the matrix board pattern during a first examination. Then, when the person 68 is again positioned on the bed 62 for a later examination, the optical system in conjunction with conventional software can again determine the person's position relative to matrix boards 66 and the position of the bed can be adjusted in accordance with stored location information to place the person in substantially the identical position as for the first examination. Further, if person 68 were to move during the examination, the optical system can detect and correct for the change in position. It is highly desirable that the person be positioned as identically as possible for each of the periodic examinations.

[0037] The underside of bed 62 includes conventional tubular bearings (not seen) through which horizontal guide rods 70 pass. A central threaded rod 72 engages end bearings 74 on assembly and passes through a conventional motor driven nut assembly 76. As the motor driven nut assembly is rotated in one direction or the other, bed 62 will be correspondingly moved sideways. Similarly, a pair of guide rods 78 extend between end walls 80 of assembly 64. Guide rods 70 and 78 are each arranged in a set of at least two parallel guide rods. A central threaded rod 82 passes through a conventional threaded block (not seen) secured to the underside of bed 62. A motor 84 rotates threaded rod 82 to move the bed in either lengthwise direction, as desired. The overhead end blocks 26 and 28 (FIG. 1) are mounted on posts 85, the lower portions of which are seen in FIG. 2.

[0038] The operating structure of detection head 14 is detailed in schematic elevation view in FIG. 3. A removable connection 86 for main housing 87 mounting detection head 14 on arm 61. Preferably, detection head 14 is rotatable relative to arm 61 by a motor 88.

[0039] A detector housing 90 for palpation finger 92 and sensor 94 for sensing distance, color and temperature is mounted on main housing 87 through arms 96 and 98. Finger 92 is designed to act like a physician's palpating finger in a manual breast examination. Typically, finger 92 will be formed from a sturdy, disposable material, such as glass.

[0040] Sensor 94 includes a distance measuring mechanism, of the sort used in cameras and the like, for providing precise distances between the breast surface and the sensor. If desired a plurality of spaced range finders, such as the range finder conventional schematically indicated at 95, may be used to assure that palpation finger 92 is oriented perpendicular to the breast surface.

[0041] A conventional means for measuring the color of the breast surface being examined is included in sensor 94. Typically, this can be a conventional prism for breaking up incoming light and refracting each color of light to an independent photo electric or photo resistive sensor.

[0042] Palpation finger 92 is secured to the distal end of a shaft 100 that is slidable through housing 90 and pivoted at proximal end to the distal end of arm 102 at pivot point 104. Arm 102 is rotatable about an axis 106 centrally located along arm 98. The proximal end of arm 102 is pivotally connected to drive shaft 108 at pivot point 110. When shaft 108 is moved axially by an actuator within actuator housing 112 (as detailed below in conjunction with the description of FIG. 4) shaft 100 and palpation finger move a proportional distance in the opposite direction. As discussed below, a laser reader in reader housing 114 detects movement of shaft 108 and the feedback resistance to movement experienced by palpation finger 92 when pressing against ID breast tissue.

[0043] An error correction sensor 116 is provided on housing 90, cooperating with a member 119 mounted on shaft 108 to detect and correct positioning errors. It is possible that the moving components of the detection head mechanism shown in FIG. 3 may not be positioned correctly any time after coils 118 (FIG. 4) have been activated and repositioned. Resetting the position of the moving parts, e.g., detection head 90, shaft 100, arm 102, and therefore palpation finger 92, is accomplished by the first coil 118 at the left as-seen in FIG. 4. Slight changes in position of the breast skin, due to breathing or the like, is sensed by finger 92 and a corresponding position correction signal is sent to the leftmost coil 118 to correct for that displacement. While this precision is often not required, it is available if needed.

[0044] The internal components within actuator housing 112 and reader housing 114 are schematically illustrated in FIG. 4. A series of electromagnetic coils 118 are arranged in a uniformly spaced relationship along a central tube 120. An end shaft 122 is axially secured to the proximal end of shaft 108 and extends into tube 120. Shaft 108 slides in a sleeve 123.

[0045] End shaft 122 is formed from a magnetic material so that when coils 118 are actuated sequentially, beginning with the coil adjacent to the end of shaft 122 fastened to shaft 108 the magnetic forces will tend to pull end shaft 122 into tube 120. As seen in FIG. 2, this pulls shaft 108, rotating arm 102 and extending shaft 100 and pressing palpation finger 92 toward an adjacent breast.

[0046] The magnetic forces provide a rather "soft" pull so that breast tissue can stop the advance of palpation finger 92 without severe compression. The distance the finger advances will be in proportion to the density of the tissue, with a lump of more dense tissue resisting penetration, so the distance the finger advances will be less. This arrangement of arm 102, shafts 100 and 108 with magnetic coils 118

could be thought of as a weighing scale where breast tissue density corresponds to the object to be weighed and the magnetic actuator is the standard portion of weight placed on the other side of the scale.

[0047] In operation, the first coil 118 will be actuated, moving palpation finger 92 a predetermined distance. Typically the coil is powered up stepwise, at about 250 mv per step up to about 10 volts maximum. The pressure change per step is typically only around about 10 grams per mm² per step. If tissue resistance is low, the second coil 118, and others in sequence, will be similarly actuated, further moving the finger. Eventually, tissue resistance will reach a predetermined level and the distance traveled by the finger will be measured, as detailed below, and the information transferred to conventional information storage means.

[0048] The mechanism for encoding and transmitting the palpation information to the storage and use station is enclosed in reader housing 114. As seen in FIG. 4, a conventional laser optic card 124, using technology as applied in musical compact disks but with a single straight track, is carried by shaft 108. A laser card reader 126 reads the shaft position from the card 124 and transmits the encoded information to the information collection station. There, the information can be converted to machine language or any desired format for interpretation by conventional software systems of the sort used in CAT scan systems or other medical scanning systems. Any error or mechanical tilt is detected in real time by error correction sensor 116 that filters out any mechanical movement other than the desired palpation movement.

[0049] A typical laser card 127 of the sort used in reader 126 is schematically illustrated in FIG. 4a. Card 127 is similar to a compact disk, having a series of reflecting areas 129 separated by non-reflective areas 131. While non-reflecting areas 131 could be light absorbing, generally it is preferred that they be transparent so the impacting light will be passed through. A laser transmitter 133 directs a laser beam 135 against the patterned area of laser card 126. When the laser beam 135 hits a reflecting area, reflected light is picked up by a receiver 137. As card 127 is moved transversely, conventional software can count the pattern of reflection pulses to measure movement of shaft 106 and, ultimately, palpation finger 92. The reflecting areas can be as small as about 0.001 mm for highly precise movement measurement.

[0050] An adjustment mechanism 128, such as a threaded adjustment shaft acting similar to a turnbuckle, is provided to adjust the position of arm 108 relative to the array of electromagnet coils 118. The maximum excursion of arm 108 is limited by pin 130 extending from shaft 108 and limit switches 132

[0051] The unit will thus sequentially test areas to provide a "picture" of the entire breast surface, revealing density changes indicative of tumors on a very fine scale, in a manner similar to the images produced in MRI, CAT and other physical scanning methods.

[0052] To provide the maximum consistency of results from one examination to the next, it is highly desirable that the person and the breasts be positioned as identically as possible for each examination. The movable bed arrangement shown in FIG. 2 aids, in cooperation with. Locator

head **16** schematically illustrated in **FIG. 5**, provide accurate positioning by locating the position of a person on the bed and actuating the various carriage, bed and detection head movement mechanisms under computer control to locate the breast to be examined in substantially the same position it was in at the last prior examination.

[0053] A digital camera **134** provides a digitized image of the breast and patient in a matrix manner to supply sufficient data for the ongoing examination session and the re-positioning of the patient whenever a new image is required. A computer system can compare the original image to a subsequent image at the start of a subsequent examination so that the patient's position can be adjusted until the images match.

[0054] A white light source **136** is provided with a schematically illustrated focussing lens system including lens **138**, a lead screw **140** rotatable by motor **142** and threaded through a lens mount bracket **144** to focus a light spot on the breast surface. As the spot of light is moved transversely and focussed at different depths along the breast, the scan can be saved in computer memory in a conventional manner to produce a three-dimensional image of the breast.

[0055] In addition, a laser scanner **146**, including a laser emitter **148** and a focussing system **150** for producing a small spot on the breast being examined may be used in the same way as the white light spot to create a three-dimensional image. Typically, a 680-820 nm, 0.0095 mW laser may be used, since that laser has sufficient power for imaging without damaging the skin.

[0056] A window **152** of glass or plastic that is transparent to the white light and laser light closes the bottom of locator head **16**. A similar window **154** covers the side of head **16** adjacent to camera **134**.

[0057] The mechanism for raising and lowering the entire carriage as seen in **FIG. 1** is illustrated in **FIG. 6**. Vertical guide rods **38** extend from a sturdy base **156** to a top plate **158**. End blocks **26** and **28** carry horizontal support **12** (**FIG. 1**, omitted from this Figure for clarity) for vertical movement therealong.

[0058] A powerful motor **160** rotates a sturdy lead screw **162** threaded through block **28**. An upper limit switch **164** and a lower limit switch **166** prevent movement of horizontal support beyond desired limits. For a very strong, sturdy assembly, base **156** will rest on the floor or a sub-floor so that bed assembly **64** could be positioned within the frame formed by base **156**, top support **158** and guide rods **38**.

[0059] The image produced by either of these light spots produced at a first examination can be compared to an initial image produced at a later examination to adjust the breast position to substantially match the original position. This will aid in re-examining a suspicious spot or lump found in the initial examination during later examinations.

[0060] The three-dimensional images can be divided into a matrix of cubes or slices with geometric indicia (e.g., a cube might be identified as cube, **2,4,9** on an x-y-z axis basis) and locations can be directly compared between the light spot image and the finger palpation locations.

[0061] A second embodiment of a detection head for detecting changes in density, hardness, and the like in breast tissue in a selected very small area is schematically illustrated in **FIG. 7**.

[0062] A permanent magnet **200** mounted on a non-magnetic rod **202** is movable axial of the rod centerline. Suitable guides **204**, such as rollers, ball bearings, a sleeve or the like, allows smooth, low resistance, axial movement of rod. Permanent magnet **200** faces an electromagnetic coil head **206** mounted on a shaft **207** and fixed to housing **208**. Poles of permanent magnet **200** and electromagnet head **206** (when activated) have the same poles juxtaposed, here having north poles adjacent to each other as indicated, with the electromagnet south pole at **210**. Electromagnet head **206** is powered by any suitable number of powered coils **212**, connected at terminal **214** to a power source via wires **216**.

[0063] Since the magnets have the same poles opposite each other, the arrangement will tend to "push" the magnets apart as soon as electromagnet coils **212** are activated. The intensity of this "pushing" force can be varied in accordance with the number of turns in coil **212** and the power provided thereto.

[0064] A palpation tip **218**, as detailed in **FIG. 11**, is mounted on the distal end of rod **202**. Tip **218** is brought into contact with (or to a predetermined distance from) the breast surface by arm as described above. Coil **212** is energized to increase the field around shaft **207** to increase the field at head **206** and force permanent magnet **200** further away from head **206**, which moves tip **218** against the breast. The breast tissue is depressed at the point of contact, with tissue elasticity pressing tip and **218** and rod **4** back toward coil **206** in accordance with tissue elasticity and hardness at the contact point.

[0065] Variations in this back pressure as represented by the extent to which the tip presses into the breast tissue are transmitted to the recording instrumentation by any suitable means for measuring the movement of tip **218**. Typically, the position of tip **218** may be measured by the mechanism shown in **FIGS. 4 and 4a**, as discussed above. Another embodiment of a tip position measuring system is shown in **FIG. 13**, described below.

[0066] The resilient mounting of permanent magnet **200** resulting from the field between the two magnets will permit the permanent magnet should it strike a breast or other surface during positioning of detection head **14** to provide sufficient "give" to prevent injury or damage to the breast or other surface.

[0067] Another embodiment of the detection head is illustrated in **FIG. 8**. A permanent magnet **222** is mounted on the proximal end of an actuator rod **224** which is slidable along a sleeve **226** mounted on housing **228** a tip **218** of the sort detailed in **FIG. 11** is secured to the distal end of rod **224**.

[0068] A second permanent magnet **230** is mounted on a holder **231** coaxial with rod **224**. Same poles (north to north or south to south) on each of magnets **222** and **230** face, and repel, each other. Holder **231** is supported on a disk **232** slidable within housing **234** coaxial with rod **224**. A sleeve **236** is preferably mounted on holder **231** to aid in guiding movement of rod **224**.

[0069] Detection head is moved as discussed above to bring tip **218** into proximity with a selected location along the breast surface. When tip **218** is initially brought into proximity to the breast surface, rod **224** will hang down and

the force of gravity will cause the rod to move to a point where the gap between magnets **222** and **230** will increase.

[0070] A motor **238** mounted in housing **234** drives a lead screw **240** which is treaded through a corresponding female thread **242** in disk **232**. Motor **238** may be any suitable motor, such as a low rpm DC motor or a stepper motor. Rotation of lead screw will move magnet **230** toward from magnet **222** decreasing the intermagnet gap until breast resistance to penetration of tip will return the intermagnet gap to a predetermined distance. The distance that holder **231** and disk **232** move is representative of breast density characteristics at the contact point. A conventional sensor **247** counts the revolutions of motor **238** to measure the corresponding degree of penetration of tip **218** into the breast.

[0071] Conventional safety sensors **244** may be provided to limit maximum movement of disk **232** (and movement of tip **218** in accordance with disk position) to prevent damage to the breast. As mentioned above, the magnetic field between magnets **222** and **230** will act as a resilient mount for tip **218**, limiting an damage or injury should the tip strike a breast or other surface.

[0072] FIG. 9 is a schematic diagram of another embodiment of detection head **14**. Here, housings **228** and **234**, actuator rod **224**, sleeves **226** and **236**, tip **218**, holder **231**, disk **232**, motor **238** and sensors **242** and **244** are the same as shown in FIG. 9 and discussed above.

[0073] Instead of the spaced permanent magnets **222** and **236** used in the FIG. 7 embodiment, a spring **248** is fastened between the proximal end of rod **224** and holder **231**. Spring **248** is selected to bias the two juxtaposed ends to a particular, predetermined spacing. As discussed in conjunction with FIG. 8, above, when the detection head is positioned over a breast, tip **218** extends downwardly under the force of gravity. Motor **238** rotates to move disk **232** and holder **231** toward rod **224** until the gap between the distal end of holder **231** and the proximal end of rod **224** is at the original predetermined distance. The total movement of holder **231** is indicated by the number of revolutions of lead screw **240** as measured by counting sensor **242**, which is indicative of breast tissue physical parameters.

[0074] Another embodiment of a detection head **14** is schematically illustrated in FIG. 10. Most components are the same as in the embodiments of FIGS. 9 and 10. However, here in place of a magnetic field or spring between the proximal end of rod **224** and the distal end of holder **231**, a gas **250** is enclosed within sleeve **236** at the proximal end of rod **224**. Sleeve **236** fits over rod **224** in a sealing arrangement to prevent pressurized gas **250** from escaping. Any suitable conventional seals may be used between rod **224** and sleeve **236**.

[0075] Any axial physical force applied to rod **224** will change the gas pressure within sleeve **236** which will be measured by a conventional pressure sensor capable of providing an electronic read-out. As before, when the tip **218** is aligned downwardly in contact with breast tissue, the pressure sensed will be lower. Lead screw **240** will be rotated by motor **238** to move holder toward sleeve **236** to slide the sleeve over rod **224**, decreasing the volume and increasing pressure. The number of motor rotations, as counted by sensor **242**, required to bring pressure up to a

predetermined level is indicative of breast physical parameters, such as hardness and density.

[0076] A preferred palpation tip configuration is schematically illustrated in FIG. 11. Tip assembly **218** includes a rounded endpiece **254** which touches the breast surface. Any suitable material may be used, which should be disposable or washable. An end isolator **256**, made up of a soft electrically insulating material prevents any static electricity discharge from the body from effecting the readings. A core member **258** connects endpiece **254** to base **260** which is secured in any suitable manner, such as threads, to rod **224**. Side isolator **258** is generally tubular and is mounted on base and spaced from core **258** to absorb and side impacts or sudden shakes.

[0077] FIG. 12 schematically illustrates a detection head embodiment in which a plurality of tips **218** can be used in a closely spaced parallel array. Here, a plurality of tips **218**, typically of the sort shown in FIG. 11, are mounted on actuator rods **262**, typically rods similar to rods **242** described above, mounted for axial movement. Extension connectors **264**, which may be rigid offset members of the sort schematically shown, inflexible cables, or the like which are capable of transmitting motion from systems **266** of the sort shown in FIGS. 7-10, with the output ends of rods **224** of those systems connected to extension connectors **264** rather than directly to tip actuator rods.

[0078] An encoder slide is preferably included in each connector **264** to provide highly accurate readout of movement of each tip during breast palpation. A preferred encoder slide assembly **268** is detailed in the schematic illustration of FIG. 13. Such an encoder slide assembly **268** may be used with any of the single tip arrangements of FIGS. 7-10.

[0079] As seen in FIG. 13, a preferred encoder slide assembly **268** includes an encoder slide **270** secured to rod **224**, as schematically shown, for movement with that rod. Encoder slide **270** could be secured to any suitable part of rod **224** or to tip **218**, as desired. Encoder slide **270** is transparent and includes a strip **272** bearing reflective dots **274** (or, in the alternative transparent dots in an otherwise opaque strip **272**).

[0080] Decoder sensors **276** are provided on opposite sides of encoder slide **270**, mounted on a housing **278** secured to housing **228** by any suitable mounting means. Decoder sensors **276** are optical or laser sensors and light emitters of the sort used with conventional music or computer compact disks.

[0081] Where dots **274** are reflective against a transparent background, light will pass from a light transmitting decoder sensor **276**—to the other, which is a light detector. As encoder slide **270** moves light will be reflected away when a reflective dot is present between the decoder sensors and will pass to the detector when a space between dots is present in the optical path. Thus, changes between receiving and not receiving light at the second decoder sensor will indicate movement of the slide and the number of pulses of light received during encoder slide **270** movement will indicate distance of movement of rod **228** and tip **229**.

[0082] Where dots **274** are transparent against an opaque background, light pulses received at the detector decoder sensor **276** will indicate movement and distance of movement.

[0083] In the embodiment shown in FIG. 1, the optical locator head 16 is mounted separately from the arm carrying the detection head 14 carrying the palpation finger 92 and sensor 94. FIG. 14 illustrates an alternate embodiment in which the optical locating head 16 and detection head 14 are both mounted at the end of the arm on carriage 10.

[0084] Optical locator head 16 in the FIG. 15 embodiment includes a motor housing 282 secured by any conventional means, such as bolts (not seen) to detection head 16. A lens enclosure 284 is secured to motor housing 282 after precise positioning during manufacture of the assembly. A lens assembly 286 is slidably mounted within lens enclosure 284 for axial movement relative thereto.

[0085] A motor 288 is mounted within motor housing and drives a lead screw 290 which is threaded through a nut 292 secured to lens assembly 286 to move the lens assembly axially within lens enclosure 284.

[0086] Two laser beam positioning enclosures 294 are mounted on opposite sides of motor housing 282. Each enclosure 294 contains a pre-focussed conventional visible light (typically 680 to 850 nanometer) laser diode and light sensor unit 296. A prism 297 refracts light from the laser diode in unit 296 toward the breast being examined, typically along schematically indicated light beams 298. Light reflected from the breast surface passes back through prism 297 to the sensor in unit 296. This diode and sensor unit 296 operates in the same manner as conventional compact disk readers. The sensed returned light will be maximum when the beam from the beam generated by unit 296 is 90° to the breast surface. The mechanism described above for moving palpation tip 218 in three dimensions can thus adjust the tip orientation to provide palpation at 90° to the breast surface. Two enclosures 294 with the components described above are preferably provided, with the first used to palpate one breast and the second used to palpate the second breast, since the size and shape of the two breasts are often somewhat different.

[0087] A motor 300 in each laser beam positioning enclosures 294 drives a lead screw 302 that engages an arcuate gear sector 304 to rotate each unit 296 and prism 297 about the center of rotation 299 of gear sector 304. Prism 297 preferably refracts light from diode 296 at 90°. The laser diode within unit 296 generates a laser beam that produces a red dot on the breast being examined. A conventional sensor 306 within each enclosure 294 counts rotation of lead screw 302 and is calibrated to indicate the exact distance to the surface upon which the dot appears when the beam is at 90° to the surface. The system computer then can conventionally calculate a three dimensional image of the breast surface from a number of these angle readings.

[0088] Lens assembly 286, in conjunction with a light sensor 308, a pre-focussed sensor lens 310 and lenses 312 operate in the same manner as conventional camera automatic focussing systems to bring the breast surface into sharp optical focus by rotating lead screw 290 as necessary. A position sensor 313 counts rotation of lead screw 290 to provide information to the central computer as to the position of focus. Since optical locator head 16 moves in conjunction with palpation head 14, when head 16 is moved to focus on the breast surface, palpation tip 218 will be brought into the predetermined contact with the breast tissue.

[0089] Extreme position sensors 314 are preferably provided to sense movement of lens enclosure 284 to the ends of its desired range of movement and prevent damage which might be caused by movement outside the selected range. Sensors 314 may be any conventional sensors, such as pressure switches, which can turn off motor 288.

[0090] In operation, either of the location head embodiments as shown in FIG. 5 or 15 can be conventionally programmed to map an entire breast step by step. The horizontal and vertical (X and Y) movement of the robot arm 10 takes locator head 16 to all of the selected points across the breast. The focussing mechanism within motor housing 282 and lens enclosure 286 will continually focus sensor 308 to provide the necessary Z direction alignment. The position sensor 313 will count the revolution of motor 288 while the motor is bringing lens assembly 286 to the point of focus to continuously provide lens position information.

[0091] Once locator head 16 has visited all desired points on the breast and has calculated its distance from every visited point, the computer can provide a conventional drawing in three dimensions of the entire breast. During palpation of the breast, location head verifies the address being palpated. Also, location head 16 will automatically compensate for breast movement as the patient breathes. If desired, a video camera 316 may be mounted on locator head 16, as seen in FIG. 14, to provide a general view of the breast during palpation.

[0092] Thus, the apparatus of this invention will provide an accurate map of the breast and will detect any tissue density anomalies and will provide the ability to accurately re examine the breast from time to time to monitor any changes in breast density anomalies.

[0093] While certain specific relationships, materials and other parameters have been detailed in the above description of preferred embodiments, those can be varied, where suitable, with similar results. Other applications, variations and ramifications of the present invention will occur to those skilled in the art upon reading the present disclosure. Those are intended to be included within the scope of this invention as defined in the appended claims.

I Claim:

1. A detection head for use with an apparatus for detecting small breast anomalies, which comprises:

at least one housing,

an elongated rod means having a distal end extending from within said housing to outside said housing and a proximal end within said housing;

sleeve means surrounding a portion of said elongated rod and secured to said housing for guiding movement of said elongated rod means in an axial direction,

a holder means within said housing coaxial with said elongated rod means having a distal end slidable towards and away from said elongated rod means proximal end;

means for resiliently biasing said elongated rod means proximal end and said holder means distal end toward a predetermined spacing;

means for moving said holder means toward and away from said elongated rod means; and

means for measuring holder movement distances.

2. The detection head according to claim 1 wherein said means for moving said holder comprises:

a motor having a rotatable output shaft;

mounting means for said motor movable relative to said housing;

moving means for moving said holder means toward and away from said elongated rod means in accordance with rotation of said output shaft;

and sensor means for counting output shaft rotation.

3. The detection head according to claim 2 wherein said resilient means comprises a first permanent magnet mounted on said elongated rod means proximal end and a second permanent magnet mounted on said holder distal end to bias said holder means distal end and said elongated rod means proximal end toward said predetermined spacing.

4. The detection head according to claim 2 wherein said resilient means comprises a spring connected between said elongated rod means proximal end and said holder distal end to bias said holder means distal end and said elongated rod means proximal end toward said predetermined spacing.

5. The detection head according to claim 2 wherein said resilient means comprises a pressurizable gas compartment between said elongated rod means proximal end and said holder distal end for inflation with a predetermined quantity of gas to bias said holder means distal end and said elongated rod means proximal end toward said predetermined spacing.

6. The detection head according to claim 2 wherein said gas compartment comprises a tubular sleeve having a closed first end and an open second end, said closed first end secured to said holder distal end and said second end sealingly slidably positioned over said elongated rod proximal end.

7. The detection head according to claim 1 wherein said-distal end of said elongated rod includes means for releasably securing a palpation tip thereto.

8. The detection head according to claim 1 further including a palpation tip releasably secured to said distal end of said elongated rod, said palpation tip comprising a proximal base means for releasably securing said palpation tip to said distal end of said elongated rod, an core extending from said base to a distal end, a palpation endpiece secured to said core distal end and a tubular protective core isolator secured to said base and surrounding and spaced from at least a portion of said core.

9. The detection head according to claim 8 further including means for sensing position of said palpation tip relative to said housing.

10. The detection head according to claim 9 wherein said means for sensing position comprises two spaced optical decoder sensors secured to said housing, an encoder slide secured to said elongated rod and having areas of differing light transmission characteristics, said encoder slide movable between said decoder sensors across a line between said decoder sensors in accordance with movement of said rod so that said areas pass across said line.

11. The detection head according to claim 10 wherein said areas of differing light transmission characteristics are selected from spaced light reflecting dots on a light transparent background and spaced transparent dots on an opaque background.

12. The detection head according to claim 1 wherein a plurality of adjacent housings are provided, each having a said elongated rod operatively connected to a palpation tip movable with each said elongated rod, said palpation tips arranged in a parallel array.

13. A detection head for use with an apparatus for detecting small breast anomalies, which comprises:

a housing,

an elongated rod means having a distal end extending from within said housing to outside said housing and a proximal end within said housing;

sleeve means surrounding a portion of said housing and secured to said housing for guiding movement of said elongated rod means in an axial direction,

a holder means within said housing coaxial with said elongated rod means having a distal end slidable towards and away from said elongated rod means proximal end;

a permanent magnet mounted on said proximal end of said elongated rod;

said holder means comprising an electromagnet head mounted on said holder distal end, a shaft connected to said electromagnet head and an electromagnet coil surrounding said shaft; and

adjacent faces of said permanent magnet and said electromagnet head having the same magnetic pole.

14. The detection head according to claim 13 wherein said means for moving said holder comprises:

a motor having a rotatable output shaft;

mounting means for said motor movable relative to said housing;

moving means for moving said holder means toward and away from said elongated rod means in accordance with rotation of said output shaft;

and sensor means for counting output shaft rotation.

15. The detection head according to claim 13 wherein said distal end of said elongated rod includes means for releasably securing a palpation tip thereto.

16. The detection head according to claim 13 further including a palpation tip releasably secured to said distal end of said elongated rod, said palpation tip comprising a proximal base means for releasably securing said palpation tip to said distal end of said elongated rod, an core extending from said base to a distal end, a palpation endpiece secured to said core distal end and a tubular protective core isolator secured to said base and surrounding and spaced from at least a portion of said core.

17. The detection head according to claim 16 further including means for sensing position of said palpation tip relative to said housing.

18. The detection head according to claim 17 wherein said means for sensing position comprises two spaced optical decoder sensors secured to said housing, an encoder slide secured to said elongated rod and having areas of differing light transmission characteristics, said encoder slide movable between said decoder sensors across a line between said decoder sensors in accordance with movement of said rod so that said areas pass across said line.

19. The detection head according to claim 17 wherein said areas of differing light transmission characteristics are selected from spaced light reflecting dots on a light transparent background and spaced transparent dots on an opaque background.

20. The detection head according to claim 13 wherein a plurality of adjacent housings are provided, each having a said elongated rod operatively connected to a palpation tip movable with each said elongated rod, said palpation tips arranged in a parallel array.

21. A detection head for use with an apparatus for detecting small breast anomalies, which comprises:

at least one housing,

an elongated rod having a distal end extending from within said housing to outside said housing and a proximal end within said housing;

a first permanent magnet mounted on said elongated rod proximal end;

sleeve means surrounding a portion of said elongated rod and secured to said housing for guiding movement of said elongated rod in an axial direction,

a holder within said housing coaxial with said elongated rod and having a distal end adjacent to said elongated rod proximal end, said holder slidable towards and away from elongated rod;

a second permanent magnet mounted on said holder distal end;

said first and second permanent magnets having same poles juxtaposed;

means for moving said holder toward and away from said elongated rod; and

means for measuring holder movement distances.

22. The detection head according to claim 21 wherein said distal end of said elongated rod includes means for releasably securing a palpation tip thereto.

23. The detection head according to claim 22 further including a palpation tip releasably secured to said distal end of said elongated rod, said palpation tip comprising a proximal base means for releasably securing said palpation tip to said distal end of said elongated rod, a core extending from said base to a distal end, a palpation endpiece secured to said core distal end and a tubular protective core isolator secured to said base and surrounding and spaced from at least a portion of said core.

24. The detection head according to claim 23 further including means for sensing position of said palpation tip relative to said housing.

25. The detection head according to claim 24 wherein said means for sensing position comprises two spaced optical decoder sensors secured to said housing, an encoder slide secured to said elongated rod and having areas of differing light transmission characteristics, said encoder slide movable between said decoder sensors across a line between said decoder sensors in accordance with movement of said rod so that said areas pass across said line.

26. The detection head according to claim 25 wherein said areas of differing light transmission characteristics are selected from spaced light reflecting dots on a light transparent background and spaced transparent dots on an opaque background.

27. The detection head according to claim 21 wherein a plurality of adjacent housings are provided, each having a said elongated rod operatively connected to a palpation tip movable with each said elongated rod, said palpation tips arranged in a parallel array.

28. The detection head according to claim 21 wherein said means for moving said holder comprises:

a motor having a rotatable output shaft;

mounting means for said motor movable relative to said housing;

moving means for moving said holder means toward and away from said elongated rod means in accordance with rotation of said output shaft;

and sensor means for counting output shaft rotation.

29. A detection head for use with an apparatus for detecting small breast anomalies, which comprises:

at least one housing,

an elongated rod having a distal end extending from within said housing to outside said housing and a proximal end within said housing;

sleeve means surrounding a portion of said elongated rod and secured to said housing for guiding movement of said elongated rod means in an axial direction,

a holder within said housing coaxial with said elongated rod having a distal end slidable towards and away from said elongated rod proximal end;

a spring having a first end secured to said elongated rod proximal end and a second end secured to said holder distal end for biasing said elongated rod proximal end and said holder distal end towards a predetermined relative position;

means for moving said holder toward and away from said elongated rod; and

means for measuring holder movement distances.

30. The detection head according to claim 29 wherein said means for moving said holder comprises:

a motor having a rotatable output shaft;

mounting means for said motor movable relative to said housing;

moving means for moving said holder means toward and away from said elongated rod means in accordance with rotation of said output shaft;

and sensor means for counting output shaft rotation.

31. The detection head according to claim 29 wherein said distal end of said elongated rod includes means for releasably securing a palpation tip thereto.

32. The detection head according to claim 31 further including a palpation tip releasably secured to said distal end of said elongated rod, said palpation tip comprising a proximal base means for releasably securing said palpation tip to said distal end of said elongated rod, a core extending from said base to a distal end, a palpation endpiece secured to said core distal end and a tubular protective core isolator secured to said base and surrounding and spaced from at least a portion of said core.

33. The detection head according to claim 32 further including means for sensing position of said palpation tip relative to said housing.

34. The detection head according to claim 33 wherein said means for sensing position comprises two spaced optical decoder sensors secured to said housing, an encoder slide secured to said elongated rod and having areas of differing light transmission characteristics, said encoder slide movable between said decoder sensors across a line between said decoder sensors in accordance with movement of said rod so that said areas pass across said line.

35. The detection head according to claim 34 wherein said areas of differing light transmission characteristics are selected from spaced light reflecting dots on a light transparent background and spaced transparent dots on an opaque background.

36. The detection head according to claim 29 wherein a plurality of adjacent housings are provided, each having a said elongated rod operatively connected to a palpation tip movable with each said elongated rod, said palpation tips arranged in a parallel array.

37. A detection head for use with an apparatus for detecting small breast anomalies, which comprises:

at least one housing,

an elongated rod having a distal end extending from within said housing to outside said housing and a proximal end within said housing;

sleeve means surrounding a portion of said elongated rod and secured to said housing for guiding movement of said elongated rod means in an axial direction,

a holder means within said housing coaxial with said elongated rod means having a distal end slidable towards and away from said elongated rod means proximal end;

a resilient, expandable, container positioned between said elongated rod proximal end and said holder distal end;

a predetermined quantity of a gas in said container under predetermined pressure to resiliently press said elongated rod proximal end and said holder distal end part a predetermined distance;

means for moving said holder means toward and away from said elongated rod means; and

means for measuring holder movement distances.

38. The detection head according to claim 37 wherein said means for moving said holder comprises:

a motor having a rotatable output shaft;

mounting means for said motor movable relative to said housing;

moving means for moving said holder means toward and away from said elongated rod means in accordance with rotation of said output shaft;

and sensor means for counting output shaft rotation.

39. The detection head according to claim 37 wherein said distal end of said elongated rod includes means for releasably securing a palpation tip thereto.

40. The detection head according to claim 37 further including a palpation tip releasably secured to said distal end of said elongated rod, said palpation tip comprising a

proximal base means for releasably securing said palpation tip to said distal end of said elongated rod, a core extending from said base to a distal end, a palpation endpiece secured to said core distal end and a tubular protective core isolator secured to said base and surrounding and spaced from at least a portion of said core.

41. The detection head according to claim 40 further including means for sensing position of said palpation tip relative to said housing.

42. The detection head according to claim 41 wherein said means for sensing position comprises two spaced optical decoder sensors secured to said housing, an encoder slide secured to said elongated rod and having areas of differing light transmission characteristics, said encoder slide movable between said decoder sensors across a line between said decoder sensors in accordance with movement of said rod so that said areas pass across said-line.

43. The detection head according to claim 42 wherein said areas of differing light transmission characteristics are selected from spaced light reflecting dots on a light transparent background and spaced transparent dots on an opaque background.

44. The detection head according to claim 38 wherein a plurality of adjacent housings are provided, each having a said elongated rod operatively connected to a palpation tip movable with each said elongated rod, said palpation tips arranged in a parallel array.

45. A location head for use with an apparatus for detecting small breast anomalies, which comprises:

a first housing having an open end;

a second housing slidably moveable into and out of said open end;

means for moving said second housing into and out of said open end;

an automatic focussing optical system in said second housing for achieving optical focus at a surface spaced from said optical system;

said automatic focussing optical system comprising means for moving said optical system to achieve said optical focus and means for measuring movement of said optical system;

at least one laser diode unit for projecting a laser beam onto said surface to produce a light dot; and

means for adjusting said laser beam to an angle of about 90° to said surface including means for sensing maximum reflected light intensity.

46. The location head according to claim 45 wherein said means for moving said second housing comprises a motor secured in said first housing, a lead screw rotatable by said motor, and a nut fixed to said second housing for receiving said lead screw and for moving along said lead screw to move said second housing.

47. The location head according to claim 46 further including sensor means for counting revolutions of said lead screw whereby position of said second housing can be continuously monitored.

48. The location head according to claim 46 further including limit switches for detecting movement of said second housing to predetermined maximum movement into and out of said first housing and preventing further such movement.

49. The location head according to claim 45 wherein said means for adjusting said laser dot positions comprises means for mounting said laser diode unit for rotation about a predetermined axis, a rotatable lead screw engaging a gear sector said laser diode unit and means for rotating each lead screw, whereby rotation of each lead screw will rotate said engaged gear sector to move said laser dot position along said surface.

50. The location head according to claim 49 wherein said means for rotation of each said lead screw comprises motor means for rotating said lead screw and means for counting revolutions of said lead screw whereby the position of the laser light dots and the angle between said laser light dots can be determined.

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摘要(译)

一种计算机控制的装置，用于通过以全扫描方式机械地触摸乳房来检测乳房肿瘤，以检测甚至非常小的肿块或其他异常。将患者放置在完全可调节的床上并相对于该装置定向。安装成三维运动的检测头位于床的上方。触诊手指与整个乳房的一系列小区域压力接触，触摸每个区域以测量组织密度。在触诊扫描的同时，进行乳房颜色和温度的扫描。定位器头定位检测器以进行扫描，以确保在一系列定期检查的每一次期间触诊扫描的可重复性。该系统可检测非常小的肿块，并可在较长时间内轻松、准确地监测可疑区域。描述了检测头和定位头的几个不同实施例。

