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(54) **Title**: A DEVICE FOR IMAGING, RECORDING AND SAVING THERMOGRAPHIC IMAGE, A SYSTEM OF THREE LIQUID CRYSTAL MATRICES USED BY THIS DEVICE AND ITS APPLICATION FOR THE DETECTION OF THERMAL ANOMALIES, AND A METHOD OF DIAGNOSING OF THESE ANOMALIES

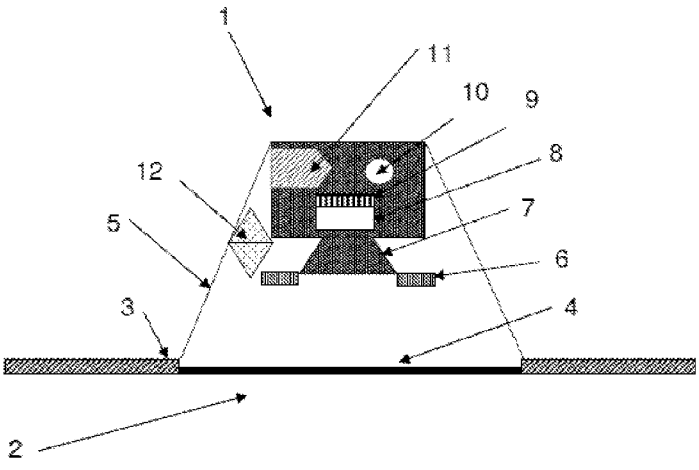

Fig. 1

(57) **Abstract**: The invention relates to a device for imaging, recording and saving a thermographic image of a breast, characterised in that it comprises a video recorder (1) and an infrared mapping liquid crystal matrix (2) working in the temperature range of approximately 1 ° in a range of 31,8 ° C to 34.8 ° C, wherein the recorder (1) preferably includes a housing (5), a light source (6), a camera (7) with an optoelectronic transducer (8), an analog-digital converter (9), a power source (10) and a storage medium (11). The present invention also refers to a method of diagnosing of the breast pathology using that device, a system of the three infrared mapping liquid crystal matrices (2) and its application for the detection of thermal anomalies on the surface of the breast.

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A device for imaging, recording and saving thermographic image, a system of three liquid crystal matrices used by this device and its application for the detection of thermal anomalies, and a method of diagnosing these anomalies

The present invention refers to a device for imaging, recording and saving thermographic image of breast surface in women and a method of diagnosing of thermal anomalies. The present invention refers also to the system of three liquid crystal matrices used by this device and its application for the detection of these thermal anomalies.

The present invention is used for the detection of pathophysiological processes taking place in the breast in women during the periods except the lactation, which have specific and unique thermodynamic characteristics associated with adequate expression of heat. Degenerative processes taking place in the breast, such as fibro-cystic degeneration (*degeneratio fibrocistica*) due to regional restrictions of the blood supply are characterised by reduced temperature in relation to the surrounding tissue, which is associated with the hypothermic expression on the surface of the examined breast. On the other hand, according to the experimental studies [Zhao at al., (Qi Zhao, Jiaming Zhang, Ru Wang, Wei Cong, Use of a Malignant Tumour Thermocouple for detection, IEEE Eng. In Medicine and Biology Mag., January / February 2008)] the proliferative (neoplastic) processes are associated with the neoangiogenesis giving intraorganic hyperthermia focus, which may be monitored and recorded on the surface of the examined breast, as the areas of increased temperature relative to the surrounding tissue. The use of two thermographic matrices instead of one to the observation of the anomalies having the hyperthermic expression, allows for increased precision of the imaging of these anomalies through the prism of their thermal characteristics, because each sensor works only in the range of 1.5 ° C.

Existing solutions, including the reported inventions (Polish patent application No. P.381431 of the present applicant), insufficiently or incorrectly have solved the problem of correct identification of the nature of thermal anomalies, or by assuming too little gradient of the temperature difference (about 0.4 ° C) for recognition of the observed anomalies for forecasting, inconsistently with clinical data, or through the adoption of a faulty temperature point of 36.6 ° C for the division of thermographic scale for imaging of epidermic changes of hypo- and hyperthermic expression, which is in contradiction with the results of empirical measurements in vivo, or generally by not considering the possibility of the preliminary differentiation of that type of thermal anomalies during the test (no clear division of the hypo- and hyperthermic scale), which causes further objective difficulties in the interpretation of thermographic image from the medical point of view and can make the correct determination of

the diagnosis impossible for the sake of the absence of correctly identified thermal range, within which thermographic tumour markers should be sought.

In the above-mentioned Polish patent application No. P.381431 an unsuccessful attempt to eliminate accidental separation of the operating ranges of the temperature was taken, in which the individual double sets of thermographic detectors had to work. However, the assumption in that invention that the separation point of thermographic scale for the detection and identification of pathological changes of the hypo- and hyperthermic nature on the surface of the tested breast, is the point of the physiological temperature of the human body set at 36.6 ° C was incorrect, since in almost all empirical studies involving contact thermomastography or thermography by using infrared cameras, has not been established experimentally that the relatively constant physiological temperature of 36.6 ° C measured under the patient's arm or even intraglandular, was transposed to equally stable and constant physiological temperature recorded on the surface of the examined breast. What's more, in the current research work on the breast thermography, including also the latest studies dedicated to the modelling of thermodynamic aspects of the breast cancer (see L. Jiang at al., Dynamic Characterization for Tumour and Deformation-Induced Thermal Contrasts on Breast Surface: A Simulation Study, Biomedical Applications in Molecular, Structural, and Functional Imaging, 2009), none functional dependence that allows to construct the appropriate functional dependence describing the transformation of the point intraglandular physiological temperature into the corresponding temperature of the breast surface in the conditions of the relative euthermy with the environment, causing no thermoregulatory response was identified. In particular, none of the scientific work stated that the physiological temperature of 36.6 ° C measured under the patient's arm translates to the same standard temperature as measured on the breast surface. This means that indicated in this application and described by the present inventors the point of physiological separation of the detected thermal anomalies on these of the expression of hypo- and hyperthermic nature, was purely theoretical in nature and did not allow for the practical use in the apparatus for thermomastography. In the case of the contact thermography the issue of a distinct separation of thermal anomalies is crucial, because in the course of this study it is not possible to selectively eliminate the specific temperature ranges as passive infrared liquid crystal displays work in the factory established strict range of the temperatures, and therefore, despite the very high-resolution of the study, difficulties may arise in the normal visual evaluation of the characteristics of the observed changes in the temperatures, which as a consequence on that basis makes impossible to uniquely identify if the pathology is called "hot" - associated with the neoplastic processes and the *mastitis* type processes, or "cold" - the processes associated with mild, degenerative processes, especially when one set of displays is used for imaging of the temperature anomalies only in the double wide spectrum below or above 36.6 ° C.

Another known solution disclosed in U.S. patent application No. U.S. 20100312136A1, Ch. Cozzi in 2010, is a system comprising an apparatus and procedure solution, including the method of carrying out a medical diagnosis by means of thermography using the camera working at infrared.

The contact thermographic diagnosis based on the passive liquid crystal infrared displays and the electronic contact sensors for measuring the temperature, is fundamentally different from the remote thermography using the cameras working at infrared, primarily in terms of the physical effects used for obtaining the image of an isotherm distribution on the surface of the examined breast, as the first method is based on the transfer of the heat by conduction to the detector, while the second one is based on the emission. It is therefore not possible to directly compare these two methods, not only because the infrared mapping images generated by the apparatus according to the invention are formed at the passive display and are analogue, and the same testing and reading of the results takes place in real time, while a device according to the U.S. patent application No. U.S. 20100312136A1, Ch. Cozzi, generates the digital images, which are just produced with a small time shift by the computer as a result of the numerical analysis of the data obtained from the optoelectronic transducer receiving an infrared radiation, and the basis for assessing thermogram obtained in this manner is a quantitative analysis. Moreover, a recording of infrared mapping images from the apparatus according to the present invention is carried out by means of a separate, removable recording unit comprising a digital camera with a CCD transducer working in the visible light range of the electromagnetic wavelength range of about 380 to 700 nm, while the operating band of an infrared camera is in the range of so called near infrared from 700 to 1000 nm and it should be noted that an increase of the sensitivity does not apply for the classical cameras, such as those used in the present invention here described, because they have an infrared filter arranged in front of CCD transducer, which almost completely absorbs the radiation in the near-infrared band. Thus, the infrared mapping image coming from the camera of the present invention is the image generated as a result of the projection of a light that is selectively reflected in a thermotropic mesophase contained in the same display in the range of the visible spectrum, whereas the image obtained from the infrared camera is a picture completely reconstructed in a digital manner by a computer, as it is derived from the registration of an electromagnetic radiation invisible to the human eye. These two fundamental differences make both that the same basic mechanism of detection of the surface temperature of the breast for both inventions is different, and further the method of the formation of the infrared mapping image carrying the substantial medical information for the researcher is different, and as a consequence the technique of fixing the two images is different - in the first case there is a digitalisation of the analogue image, and in the other from the very beginning there is a reconstructed digital image.

Additionally, the U.S. patent application 20100312136A1 claims an algorithm comprising the procedure for making the thermographic digital images in two series and their comparison, in

addition to the registration device through the attachable module, optional a network. Moreover, in said application the method of the identification of the locoregional hypo- or hyperthermia recorded on the surface of the examined breast, representing the essence of the intraglandular pathology is not clarified, in other words, Ch. Cozzi, neither in the description of his invention nor in the claims does indicate any specific point or the range of the temperatures that separate the organ normothermy from the thermal anomalies.

The novelty introduced by the present invention is an establishment of a completely different scope of the analysis of the thermal anomalies recordable by the method of the contact thermography on the surface of the examined breast, which is crucial for the medical meaning of such examination, because its purpose is not the multi-point temperature measurement itself, but to separate the anomalous areas with significant distinction of at least 0.5 ° C in order to eliminate the random artefact thermal variations unrelated to the intraorganic hypo- or hyperthermia. Therefore, a new three-interval thermographic range related to the subject of the present invention, comprising in the range from 31.8 ° C to 34.8 ° C, is further separated out into three sub-ranges: the first from 31.8 ° C to 32.8 ° C allowing to reveal the temperature anomalies on the surface of the tested breast showing the hypothermic expression, the second from 32.8 ° C to 33.8 ° C allowing to reveal the temperature anomalies on the surface of the examined breast showing the hyperthermic expression having a lower average temperature, and the third from 33.8 ° C to 34.8 ° C allowing to reveal the temperature anomalies of the surface of the examined breast showing the hyperthermic expression of a higher average temperature, constitutes the diagnostic value of the entire device and is the result of discoveries made by the present inventors by empirical studies in vivo with the patients.

Therefore, the inventors introduce in the present invention specifically defined reference temperature ranges within which the anomalies showing the hypothermic expression and the anomalies showing the hyperthermic expression are separately revealed. Otherwise, Also, these two inventions solve the problem of the calibration of the temperature detectors in completely different way, because in case of the Ch. Cozzi invention it is calibrated before each measurement, and in the case of the present invention, the calibration is done only once, at the stage of production of the liquid crystal infrared mapping displays, through the selection of the appropriate compositions of the mixtures of the chemical compounds selected from the group of chiral and non-chiral nematics to ensure a constant preset thermochromic response.

Another key difference between the present invention and the application cited above by Ch. Cozzi, is a method of reading the results of the thermomastographic examination, where the U.S. patent application No. 20100312136A1 employs the algorithm to automatically perform qualitative and quantitative analysis, and then automatically generate the scoring database separately based on the qualitative and quantitative analysis. The present invention has completely different assumption that thermograms rating is based on the binary criterion - positive-/-negative-result,-including-a-decision-support-system-with-an-artificial-intelligence,

which compares not individual series of the infrared mapping images obtained in the same patient, but the results of the study with other reference images of thermal anomalies collected in the database, resulting in a completely different analytical algorithm.

Thus, the object of the present invention is to provide a device for imaging, recording, and saving the thermographic image that allows correct identification of the nature of the thermal anomalies on the surface of the examined breast.

A further object of the invention is to provide a system of infrared mapping liquid crystal matrices suitable for use with the above-mentioned device to the detection of the pathological changes of hypo- and hyperthermic expression.

Another object of the invention is to provide a method of diagnosing breast pathology using the above equipment together with the infrared mapping liquid crystal matrices.

Thus, the present invention refers to the device for imaging, recording, and saving the thermographic image of the breast, which includes the image recorder and the infrared mapping liquid crystal matrix operated at the temperature range of approximately 1 ° in the range from 31.8 ° C to 34.8 ° C, wherein the recorder preferably includes a housing, a light source, a camera and an optoelectronic transducer, an analog-to-digital converter, a power supply and a storage medium.

Preferably, the device according to the present invention operates on a three-interval thermographic scale comprising a detection range of a surface temperature of the breast from 31.8 ° C to 34.8 ° C, and divided into three sub-ranges:

- a first sub-range from 31.8 ° C to 32.8 ° C with the thermo-optical separation of 0.5 ° C, for the detection of the anomalies of the hypothermic expression,
- a second sub-range from 32.8 ° C to 33.8 ° C with the thermo-optical separation of 0.5 ° C, for the detection of the anomalies of the hyperthermic expression of a lower temperature,
- a third sub-range from 33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C, for the detection of the anomalies of the hyperthermic expression of a higher temperature.

Preferably, the infrared mapping liquid crystal matrix has a hand grip and an infrared mapping display, wherein the hand grip is made of plastic, in particular polypropylene.

Preferably, the infrared mapping matrix liquid crystal is round and has a diameter of at least 140 mm.

Preferably, the infrared mapping matrix liquid crystal operates in the temperature range from 31.8 ° C to 32.8 ° C with the thermo-optical separation of 0.5 ° C.

Preferably, the infrared mapping matrix liquid crystal operates in the temperature range from 32.8 ° C to 33.8 ° C with the thermo-optical separation of 0.5 ° C.

Preferably, the infrared mapping matrix liquid crystal operates in the temperature range from 33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C.

Preferably, the light source is at least one LED diode, especially one that emits a white light.

Preferably, the system of the camera with an optoelectronic transducer constitutes a digital camera with a CCD matrix of 1/3" type with a sensitivity of at least 0.5 lux, a resolution of at least 540 lines / inch, with lens having a maintenance of a brightness at F 1.2 level.

Preferably, the power source is a DC power system having a voltage from 1.5 V to 9 V.

Preferably, the storage medium is selected from the media, such as a hard drive, an optical drive such as CD, CD-R, CD-RW, DVD-type optical disc, Blu-Ray, HD-DVD, a memory card or USB flash drive, and the most preferably the storage medium is a memory card a flash eprom type with a capacity of at least 4 GB.

Preferably, the device according to the present invention further includes an element capable of transferring of the data through a wired or a wireless transmission.

Preferably, the element that makes the data transfer possible is the wireless transmitter using radio wave frequency of 2.5 GHz, working in a Bluetooth standard.

The present invention also provides the system of three infrared mapping liquid crystal matrices comprising

- a first liquid crystal matrix operating in the temperature range from 31.8 ° C to 32.8 ° C with the thermo-optical separation of 0.5 ° C for the detection of the anomalies of the hypothermic expression;
- a second liquid crystal matrix operating in the temperature range from 32.8 ° C to 33.8 ° C with the thermo-optical separation of 0.5 ° C for the detection of the anomalies of the hyperthermic expression;
- a third liquid crystal matrix (of a confirmatory type) operating in the temperature range from 33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C for the detection of the anomalies even warmer showing the hypothermic expression.

The present invention relates to the use of said system of the three infrared mapping liquid crystal matrices for the detection of thermal anomalies on the surface of the breast,

- the first matrix for the detection of the anomalies of the hypothermic expression, preferably related to the intraorganic pathologies of a benign characteristics,
- the second matrix for the detection of the anomalies of the hyperthermic expression, preferably pathologies associated with intraorganic pathologies of a hyperplastic characteristics, and
- the third confirmatory matrix for the detection of the anomalies of hyperthermic expression, preferably intraorganic pathologies associated with the hyperplastic characteristics.

The present invention also provides the method of diagnosing of the thermal anomalies of the breast surface using said device for imaging, recording, and saving the thermographic image of the breast, characterised in that it comprises the sequence of steps of:

- applying the infrared mapping liquid crystal matrix combined in a detachable manner with the recorder, with the infrared mapping display to the examined breast;
- turning on the light source;

- recording the colour image of the isotherms depicted on the infrared mapping matrix using the camera equipped with the optoelectronic transducer and the analog-to-digital converter for a period of up to 20 seconds;
- recording the obtained digital video signal on the storage medium;
- transferring the recorded digital video signal to a computer or a mobile device equipped with a database of thermographic images of the breast and an artificial intelligence system or having established connection with such database and the artificial intelligence system via an intranet or the Internet;
- using the artificial intelligence system to carry out the analysis of the obtained infrared mapping images using the database of the thermographic images of the breast;
- as a result of the analysis, obtaining a guidance as to the most likely outcome of the thermographic examination in a binary system (positive / negative).

Preferably, in the method according to the present invention, said sequence of steps is performed three times, by successively using infrared mapping liquid crystal matrices being comprised in the above mentioned system of the three infrared mapping liquid crystal matrices.

Preferably, in the method according to the present invention, the reading of the thermographic examination results is carried out in the binary system - positive / negative based on the presence or absence in the infrared mapping image of a hypothermia marker visible as a delimited area of a different colour to the dominant colour of the thermal background visible at the working area of the first passive contact infrared mapping liquid crystal display.

Preferably, in the method according the present invention for detection there is used the thermographic three-interval scale comprising the range of the surface temperatures of the breast from 31.8 °C to 34.8 °C, and separated into three sub-ranges:
- the first sub-range from 31.8 °C to 32.8 °C with the thermo-optical separation of 0.5 °C, for the detection of the anomalies of the hypothermic expression,
- the second sub-range from 32.8 °C to 33.8 °C with the thermo-optical separation of 0.5 °C, for the detection of the anomalies of the hyperthermic expression at the lower temperature,
- the third sub-range from 33.8 °C to 34.8 °C with the thermo-optical separation of 0.5 °C, for the detection of the anomalies of the hyperthermic expression of the higher temperature.

The present invention, which is the subject of this application eliminates the shortcomings of the contact thermography of the breast previously used, due to the discovery and use of a new scale of the operating temperature from 31.8 °C to 34.8 °C intended to thermomastographic apparatus according to the present invention, which scale is also separated out to the three sub-ranges: the first from 31.8 °C to 32.8 °C with the thermo-optical separation of 0.5 °C, that allows to reveal the temperature anomalies on the surface of the tested breast showing the hypothermic expression, the second from 32.8 to 33.8 °C with the thermo-optical separation of 0.5 °C that allows to reveal the temperature anomalies on the surface of the examined breast having the hyperthermic expression with the lower average temperature, and the third from

33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C that allows to reveal the temperature anomalies on the surface of the examined breast having the hyperthermic expression with the higher average temperature.

In experimental studies on the breast thermography, the range of the temperatures recorded on the surface of the examined breast rarely was below 31 ° C and above 35 ° C (see JF Head, Determination of mean temperatures of normal breast and breast whole quadrants by infrared imaging and image analysis, IEEE, 2001), and therefore the above-mentioned Polish patent application No. P.381431 did not properly consider the experimentally established upper limit of the hypothermia and lower limit of the hyperthermia of the organs disclosed in the breast thermography as a point of division was there determined theoretically at 36.6 ° C. The consequence of such determination of the reference point of division of the thermographic scale in the above mentioned invention is that none of its two measurement sub-ranges, respectively, for the analysis of the anomalies having the hypothermic expression at the temperatures below 36.6 ° C, nor the anomalies having the hyperthermic expression at the temperatures above 36.6 ° C, do not enter in the appropriate detection ranges of the present invention, because they end for the interval for imaging of the hypothermic changes at 32.8 ° C, and for the range for imaging of the hyperthermic changes said sub-ranges start above 32.8 ° C and end at 34.8 ° C, and are separated from the boundary value of 36.6 ° C of as much as 1.8 ° C.

Thresholds of the temperature ranges determined empirically for the device according to the present invention, are not only a basis for the creation of a new thermographic scale designed exclusively for specialised use in the thermomastographic examination, which is important and critical breakthrough in terms of innovation, because none of the filed inventions so far relating to the devices for contact thermomastography, did not allow to carry out real-time classification of the thermal anomalies visualised in terms of their thermodynamic and pathophysiological characteristics of both, while allowing an initial diagnosis based on the presence of the markers of the hypo- or hyperthermia on the surface of the examined breast, which are predictors of the presence of a specific type of intraglandular pathology. The present invention therefore includes in particular the new thermographic scale, which, in this or a similar temperature range and in a specific, defined and three-interval functional division, has not been disclosed in any other published patent application in the field of thermomastography.

The device according to the present invention does not require the examination of both breasts simultaneously.

The solutions disclosed in the Polish patent application No. P.381431 and in the present description and claims are different in the key aspects, the first invention refers to the dual-band operating temperature scale separated around the point 36.6 ° C, and the other to the three-interval scale separated around points 32.8 ° C and 33.8 ° C. Also in the technical context, the first invention consists of a double detection system comprising two matrices enabling the

parallel differential diagnosis of the both breasts, and the set consists of two kits of differently calibrated matrices, while the apparatus according to the present invention consists of the system of the three passive infrared mapping liquid crystal displays placed in the separate hand grips, applied sequentially, first to one, then the other breast.

In the present invention the use of the thermo-optical separation of 0.5 ° C is consistent with the data obtained from empirical observations [Zhao et al. 2008] and according to the scientific literature is sufficient to consider such temperature difference as significant from the point of view of the diagnostic and prognostic value, because the changes suspected of neoplastic transformation are characterised by the average thermal differentiation of 0.7 ° C in ratio to the surrounding healthy tissue.

It was surprisingly found that the use of a triple set of the infrared mapping matrices, with a total thermal detection range covers an area of the hypo- and hyperthermic anomalies present on the surface of the examined breast, while maintaining the possibility of a separate observation (separation), allows for clear differentiation and thus, to a certain interpretation of the examination from the medical point of view.

The basis of the invention is a new division of the thermographic scale on the three complementary ranges, obtained from carried out empirical measurements. The application of this division makes possible to uniquely identify the thermographic markers of the benign and malignant processes. The observation of the thermographic markers of the benign process takes place on a single infrared mapping matrix, and for the observation of the markers of the malignant processes, the present invention provides two separate matrices, of which the last (third) acts as a confirmatory matrix. The disclosure on the third confirmatory matrix the thermal marker is equal to the confirmation of the presence of the outbreak of the hyperthermia, which is associated with the neoplastic processes. The above-mentioned Zhao at al. [2008] pointed out the statistical association of the thermal differentiation of 0.7 ° C order and more, with the presence of the malignant tumour.

For the device according to the present invention there are programmed during the production of the thermographic matrices, three complementary operating temperature ranges, tailored to the experimentally determined thresholds in relation to the standard surface temperature of the breast of 32.8 ° C. The application of these thresholds allows for the filtration of the thermal background of the examined breast and eliminates the artefact readings, by cutting off, in the case of the first matrix, the thermal background in the lower range of the thermographic scale at 32.8 ° C, which allows for the visualisation of only the changes with the temperature of at least 0.5 ° C, compared to the standard surface temperature of the breast (characterised by the benign pathologies) and respectively for the second matrix, the cutting off the thermal background in the upper range of the thermographic scale at 32.8 ° C, which allows for the observation of the anomalies at the temperature higher by at least 0.5 ° C in relation to the surface temperature of the normal breast (that is significantly warmer - hyperthermic, being

characteristic of the malignant abnormalities), and for the third matrix, cutting off the thermal background was at even higher temperatures, that is above 33.8 ° C, which allows to reveal the anomalies that are significantly warmer of at least 1 ° C, relative to the standard breast surface temperature of 32.8 ° C (obviously related to the thermal characteristics of the tumour with malignant course).

The triple system of the thermographic matrices is in the device of the present invention an unique application of the concept of thermal hardware filtration, not for the purpose of implementing of the technical purposes (to ensure appropriate scope for the thermal detection study of the breast in women), but only for a specific medical purpose, understood as a solution to the initial differentiation by type of the intraorganic pathology through its association with the thermal characteristics, forming specified thermographic marker.

Without determining whether the observed anomaly has the of hypo- or hyperthermic type of expression, no one can talk about the presence of the thermographic markers as the markers are attributed to the thermodynamic model of tumour growth and the formation of cysts.

The binary criterion for the evaluation of the examination result by the contact thermography filtered by using the device according to the present invention, it is possible to use, because each of three passive infrared mapping liquid crystal displays included in the diagnostic kit, works in a strictly defined and programmed at the manufacturing stage temperature range, correlated with the new thermographic scale, so that in given temperature range there is a search of specific types of mammary pathology. This means that the individual passive infrared mapping liquid crystal displays create a set of functional tests aimed at the detection of functional thermodynamic markers specific only for a group of breast pathology and giving a fixed expression of heat, which makes that on the display designed for the imaging of the hyperthermic expression, researcher will not see the signs corresponding to the benign pathologies associated with the degenerative processes, for example fluid cysts, and vice versa. The binary criterion boils simply to identification of the presence of the optically delimited anomaly, determined in relation to dominant thermal background expressed on the display by the predominant colour of the thermo-optical response of the thermotropic mesophase, because each primary colour visible on the display in the RGB system (red-green-blue) corresponds to the difference in temperature of 0.5 ° C order. In order to support this binomial assessment it is also possible to specify the quantitative scope, based on relational, fixing the percentage of the active surface of the infrared mapping imaging display occupied by the given, dominant colour corresponding to the specific temperature of the thermal background of the examined organ in relation to the visualised, demarcated colour anomaly, which should include a minimum surface. It should be noted that the quantitative determinants are not the only criterion of the evaluation and qualification of the contact thermogram as abnormal or normal, because the test is being able to detect even the smallest expressions of the anomalous temperatures on the surface of the tested breast, but can give additional information about the

scale of severity of the pathological process. It was experimentally established that the mere presence of the thermal marker identified on any passive infrared mapping liquid crystal display according to the present invention can classify the whole test by contact thermography as giving positive result, indicating the thermodynamic characteristics of the observed anomaly, hence the quantitative parameters is associated with the marker is not the subject of the claims in the present patent application.

Each of the thermographic matrices in order to act as a fully functional thermographic detector requires being mounted in the hand grip made of a flexible unbreakable plastic, preferably polypropylene.

Each of the matrices is preferably round and has a diameter of at least 140 mm.

In addition, the device according to the present invention is equipped with the optoelectronic recorder of the colour images of the isothermal distribution on the surface of the examined breast being revealed on the passive infrared mapping matrices, consisting of the digital camera system, preferably with the CCD (Charge Coupled Device) matrix, allowing the recording, and then the reading of the electric signal that is proportional to the amount of light falling on it and the electronic system enabling the analog-to-digital conversion of the image and then encoding the video signal, for example, according to the standard ISO / IEC 14496-10:2004 (H.264/AVC), the storage medium, such as flash memory card, allowing for the digital recording of the entire test sequence and preferably a wireless transmitter that contains the stored video image, working, for example, in the standard according to the specification IEEE 802.15.1 that uses radio waves in the 2.4 GHz ISM band (Bluetooth). The recorder dramatically expands the diagnostic potentials of the tester by providing the ability to send the full sequence of the thermographic examination as a digital file to the computer and further by means of the Internet using the analytic centre in order to carry out its thorough analysis with the use of the algorithm based on the artificial intelligence system comparing the normal and the pathological patterns of the thermograms with those actually obtained during a particular test. The support of the thermograms analysis by the artificial intelligence system using different algorithms to compare different images increases the accuracy of the examination, facilitating the identification of the important from a medical point of view the thermal anomalies, which has a significant impact on the confidence of the diagnosis.

The recorder of the present invention is an additional, complete and removable component with its own power supply, which is secured by a system of bolts into the plastic hand grip of the infrared mapping matrix.

The embodiment of the device according to the present invention in shown in the drawings, in which Figure 1 illustrates schematically the construction of the recorder in combination with the infrared mapping liquid crystal matrix display.

In the figure 1 the recorder having the casing 5 is composed of five basic elements, such as:

- the digital micro camera 7 with the optoelectronic transducer 8, which is a part of the CCD matrix having a minimum size of 1/3", with the sensitivity of at least 0.5 lux, the resolution of at least 540 lines / inch, and with lens having a maintenance of a brightness at F 1.2 level;
- the storage medium 11, such as the memory card the flash eprom type with the capacity of at least 4 GB;
- the light source 6, which is a distributed lighting system with LED diodes emitting the white light, arranged around the lens of the camera 7 directed on the infrared mapping display 4 of the liquid crystal matrix 2;
- the own DC power supply system 10, in this case 9V, and
- the component for the data transmission 12, here the wireless transmitter that uses radio waves with a frequency of 2.4 GHz, working in the Bluetooth standard.

The recorder 1 according to the present invention is attached to the hand grip 3 of the infrared mapping liquid crystal matrix 2.

The purpose of the recorder is to carry out the real-time video recording of the full sequence of the thermographic examination of the breast, which takes about 15 seconds from the time of the correct application of the detector to the examined breast. The holding of the detector in one place of the examined breast that lasts longer than 20 seconds, may lead to the equalisation of the infrared mapping matrix 2 temperatures and the examined breast area, leading as a result to the loss or distortion of the thermographic image.

The recorder 1 according to the present invention is activated manually by the person performing the test, and automatically turns off after 15 seconds, which is indicated by turning on the red LED diode on the body 5 and a single beep. The method of diagnosing the breast pathology using this device includes the steps, wherein the infrared mapping liquid crystal matrix display combined in a detachable manner with the recorder 1 is applied with the infrared mapping display 4 to the examined breast, then the light source 6 is automatically turned on and for a period of up to 20 seconds the colour image of the isotherms depicted on the infrared mapping matrix is recorded using the digital micro camera 7 with the CCD matrix 8 and the analog-to-digital converter 9. The resulting digital video signal is then recorded in the flash memory card 11, and said sequence of the image recording and saving is carried out for three times, using sequentially the three infrared mapping liquid crystal matrices 2 operating in the three examined temperature ranges. After the examination is completed, the data stored in the flash memory card 11 are transmitted by pressing a single button by the Bluetooth transmitter 12 to the computer equipped with the Bluetooth receiver, having a connection with the database of the thermographic images of the breast and the artificial intelligence system via the Internet, to analyse the obtained infrared mapping images obtained using the database of the thermographic images of the breast. As a result of the analysis the guidance as to the most likely outcome of the thermographic examination in the binary system (positive / negative) is obtained.

The role of the passive infrared mapping detector in the infrared mapping liquid crystal matrix 2 is performed by the set of the three heat-sensitive matrices 2 containing thermotropic liquid crystals from the group of chiral nematics.

Each of the matrices 2 is cut in a circular shape with a diameter of 140 mm and is mounted in the plastic hand grip 3.

To produce the thermotropic mesophase being a key heat-sensitive element - the infrared mapping display 4 of each of the three thermographic matrices 2, a mixture of liquid crystal compounds according to the invention, which is the subject of the Polish patent application No. P.390320 was used, having the following compositions.

The mixture of the first matrix (composition by weight):

- cholesteryl pelargonate 48.61 %
- cholesteryl oleyl carbonate 50.39 %
- cholesteryl propionate 0.28 %
- cholesteryl chloride 0.20 %
- 4,4'-dipentylazoxybenzene 0.52 %.

For this mixture the mesophase is thermo optically responsive in the temperature range from 31.8 ° C to 32.8 ° C, wherein at the temperature of 31.8 ° C a reflected in the mesophase light of red colour (of wavelength 720 nm) appears and this colour is maintained through 0.5 ° C, then at the temperature of 32.3 ° C a reflected in the mesophase light of green colour (of wavelength 545 nm) appears and this colour is maintained through 0.5 ° C, and at the temperature of 32.8 ° C a reflected in the mesophase light of blue colour (of wavelength 410 nm) appears and this colour is maintained through 0.5 ° C.

The mixture of the second matrix (composition by weight):

- cholesteryl pelargonate 50.28 %
- cholesteryl oleyl carbonate 48.72 %
- cholesteryl propionate 0.24 %
- cholesteryl chloride 0.18 %
- 4,4'-dipentylazoxybenzene 0.58 %

For this mixture the mesophase is thermo optically responsive in the temperature range from 32.8 ° C to 33.8 ° C, wherein at the temperature of 32.8 ° C a reflected in the mesophase light of red colour (of wavelength 720 nm) appears and this colour is maintained through 0.5 ° C, then at the temperature of 33.3 ° C a reflected in the mesophase light of green colour (of wavelength 545 nm) appears and this colour is maintained through 0.5 ° C, and at the

temperature of 33.8 ° C a reflected in the mesophase light of blue colour (of wavelength 410 nm) appears and this colour is maintained through 0.5 ° C.

The mixture for the third matrix (composition by weight):

- cholesteryl pelargonate 52.53 %
- cholesteryl oleyl carbonate 46.47 %
- cholesteryl propionate 0.18 %
- cholesteryl chloride 0.16 %
- 4,4'-dipentylazoxybenzene 0.66 %

For this mixture the mesophase is thermo optically responsive in the temperature range from 33.8 ° C to 34.8 ° C, and at the temperature of 33.8 °C a reflected in the mesophase light of red colour (of wavelength 720 nm) appears and this colour is maintained through 0.5 ° C, then at the temperature of 34.3 ° C a reflected in the mesophase light of green colour (of wavelength 545 nm) appears and this colour is maintained through 0.5 ° C, and at the temperature of 34.8 °C a reflected in the mesophase light of blue colour (of wavelength 410 nm) appears and this colour is maintained through 0.5 ° C.

Then, each of the hand grips 3 containing the infrared mapping matrix 2 is connected in the detachable manner with the real-time optoelectronic recorder of the video image, allowing for the digital recording of the sequence of the thermographic examination of the breast and its transmission by the wireless Bluetooth module to the external device - the computer or other mobile device.

Claims

1. A device for imaging, recording, and saving a thermographic image of a breast, characterised in that it comprises an image recorder (1) and an infrared mapping liquid crystal matrix (2) working in the temperature range of approximately 1 ° in a range from 31.8 ° C to 34.8 ° C, wherein the recorder (1) preferably includes a housing (5), a light source (6), a camera (7) with an optoelectronic transducer (8), an analog-digital converter (9), a power source (10) and a storage medium (11).

2. The device according to claim 1, characterised in that it operates in a three-interval thermographic scale comprising the range of the surface temperature detection of the breast from 31.8 ° C to 34.8 ° C, and is divided into three sub-ranges:

- a first sub-range from 31.8 ° C to 32.8 ° C with a thermo-optical separation of 0.5 ° C, for the detection of anomalies of a hypothermic expression,
- a second sub-range from 32.8 ° C to 33.8 ° C with the thermo-optical separation of 0.5 ° C, for the detection of the anomalies of a hyperthermic expression at a lower temperature, and
- a third sub-range from 33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C, for the detection of the anomalies of the hyperthermic expression of a higher temperature.

3. The device according to claim 1 or 2, characterised in that the infrared mapping liquid crystal matrix (2) has a hand grip (3) and an infrared mapping display (4), wherein the hand grip is made of plastic, preferably of polypropylene.

4. The device according to claim 1, 2 or 3, characterised in that the infrared mapping liquid crystal matrix (2) is circular and has a diameter of at least 140 mm.

5. The device according to any one of claims 1-4, characterised in that the infrared mapping liquid crystal matrix (2) operates in the temperature range from 31.8 ° C to 32.8 ° C with the thermo-optical separation of 0.5 ° C.

6. The device according to any one of claims 1-4, characterised in that the infrared mapping liquid crystal matrix (2) operates in the temperature range from 32.8 ° C to 33.8 ° C with the thermo-optical separation of 0.5 ° C.

7. The device according to any one of claims 1-4, characterised in that the infrared mapping liquid crystal matrix (2) operates in the temperature range from 33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C.

8. The device according to claim 1, characterised in that the light source (6) is at least one LED diode.

9. The device according to claim 8, characterised in that the LED diode emits a white light.

10. The device according to claim 1, characterised in that the camera (7) system with the optoelectronic transducer (8) constitutes a digital camera with a CCD sensor of 1/3" type with a sensitivity of at least 0.5 lux, and a resolution of at least 540 lines / inch, with lens having a maintenance of a brightness at F 1.2 level.

11. The device according to claim 1, wherein said power source (10) is a DC power supply system at a voltage of 1.5 V to 9 V.

12. The device according to claim 1, wherein the storage medium (11) is selected from the hard drive, optical drive such as CD, CD-R, CD-RW, DVD-type optical disc, Blu-Ray, HD-DVD, a memory card, or memory USB type.

13. The device according to claim 1, characterised in that the storage medium (11) is the memory card a flash eprom type having minimum capacity of 4 GB.

14. The device according to claim 1, characterised in that it further comprises a device enabling the transmission of data (12) through a wired or wireless transmission.

15. The device according to claim 14, wherein the element (12) that makes the data transfer possible is a wireless transmitter that uses radio waves of frequency 2.5 GHz, working in the Bluetooth standard.

16. A system of three infrared mapping liquid crystal matrices, characterised in that it comprises

- a first liquid crystal matrix operating in the temperature range from 31.8 ° C to 32.8 ° C with the thermo-optical separation of 0.5 ° C for the detection of the anomalies of the hypothermic expression;
- a second liquid crystal matrix operating in the temperature range from 32.8 ° C to 33.8 ° C with the thermo-optical separation of 0.5 ° C for the detection of the anomalies of the hyperthermic expression;
- a third liquid crystal matrix (of a confirmatory type) operating in the temperature range from 33.8 ° C to 34.8 ° C with the thermo-optical separation of 0.5 ° C for the detection of the even warmer anomalies showing the hypothermic expression.

17. The use of the system of three infrared mapping liquid crystal matrices of claim 15 for the detection of thermal anomalies on the surface of the breast,

- the first matrix for the detection of the anomalies of the hypothermic expression, preferably related to the intraorganic pathologies of a benign characteristics,
- the second matrix for the detection of the anomalies of the hyperthermic expression, preferably the pathologies associated with the intraorganic pathologies of a hyperplastic characteristics, and
- the third confirmatory matrix for the detection of the anomalies of hyperthermic expression, preferably the intraorganic pathologies associated with a proliferative nature.

18. A method of diagnosing of the thermal anomalies of the breast surface using the device for imaging, recording and saving thermographic image of the breast according to the claim 1, characterised in that it comprises a sequence of steps of:

- applying the infrared mapping liquid crystal matrix (2) combined in a detachable manner with the recorder (1), with the infrared mapping display (4) to the examined breast;
- turning on the light source (6);
- recording the colour image of the isotherms depicted on the infrared mapping matrix using the camera (7) equipped with the optoelectronic transducer (8) and the analog-to-digital converter (9) for a period of up to 20 seconds;
- recording the obtained digital video signal on the storage medium (11);
- transferring the recorded digital video signal to a computer or a mobile device equipped with a database of thermographic images of the breast and an artificial intelligence system or having established connection with such database and the artificial intelligence system via an intranet or the Internet;
- using the artificial intelligence system to carry out the analysis of the obtained infrared mapping images using the database of the thermographic images of the breast;
- as a result of the analysis, obtaining a guidance as to the most likely outcome of the thermographic examination in a binary system (positive / negative).

19. The method according to claim 18, characterised in that said sequence of the recording and saving the image is performed three times, by successively using three infrared mapping liquid crystal matrices (2) being comprised in the above mentioned system of the three infrared mapping liquid crystal matrices according to the claim 15.

20. The method according to claims 18 or 19, characterised in that the reading of the thermographic examination result is carried out in the binary system positive / negative based on the presence or absence in the infrared mapping image of a hypothermia marker visible as a delimited area of a different colour in relation to the dominant colour of the thermal background visible at the working area of the first passive contact infrared mapping liquid crystal display.

21. The method according to claims 18 or 19 or 20, characterised in that for detection there is used the thermographic three-interval scale comprising the range of the surface temperatures of the breast from 31.8 °C to 34.8 °C, and separated into three sub-ranges:
- the first sub-range from 31.8 °C to 32.8 °C with the thermo-optical separation of 0.5 °C, for the detection of the anomalies of the hypothermic expression,
- the second sub-range from 32.8 °C to 33.8 °C with the thermo-optical separation of 0.5 °C, for the detection of the anomalies of the hyperthermic expression of the lower temperature,
- the third sub-range from 33.8 °C to 34.8 °C with the thermo-optical separation of 0.5 °C, for the detection of the anomalies of the hyperthermic expression of the higher temperature.

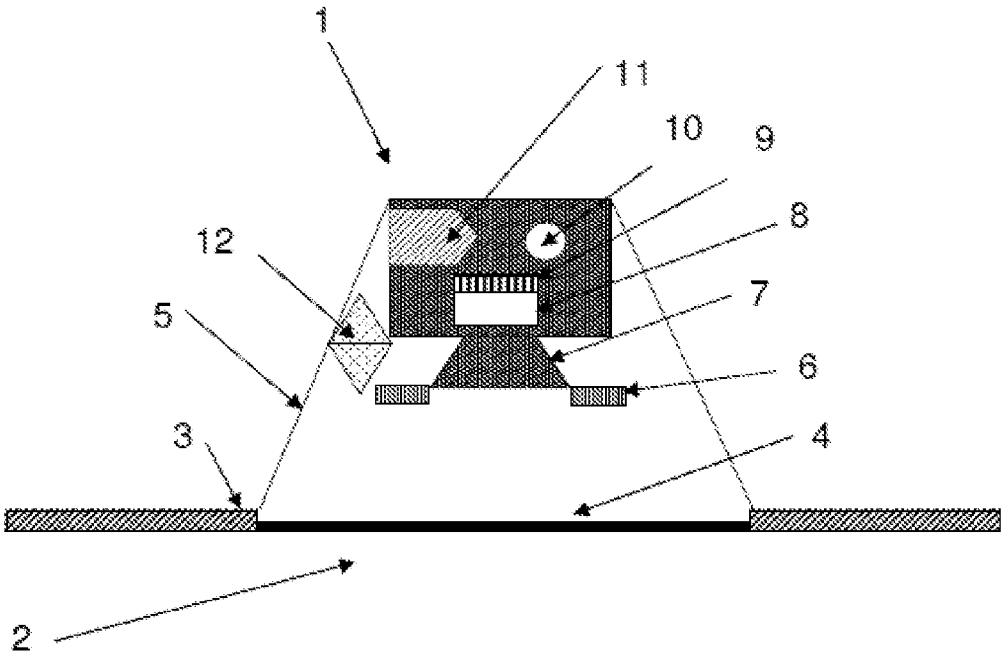

Fig. 1

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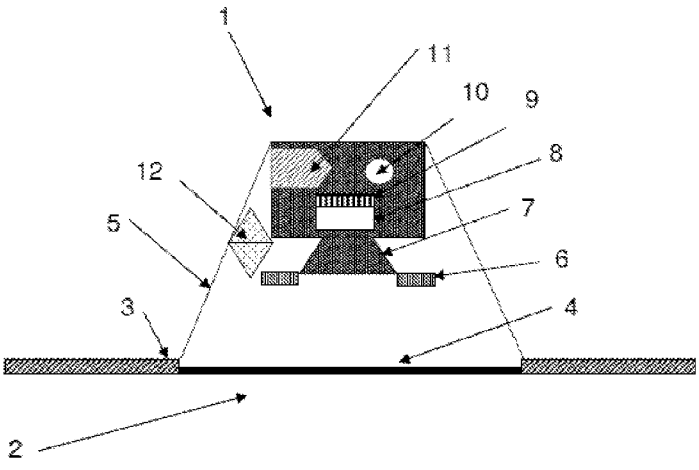

Fig. 1

(57) Abstract: The invention relates to a device for imaging, recording and saving a thermographic image of a breast, characterised in that it comprises a video recorder (1) and an infrared mapping liquid crystal matrix (2) working in the temperature range of approximately 1 ° in a range of 31,8 ° C to 34.8 ° C, wherein the recorder (1) preferably includes a housing (5), a light source (6), a camera (7) with an optoelectronic transducer (8), an analog-digital converter (9), a power source (10) and a storage medium (11). The present invention also refers to a method of diagnosing of the breast pathology using that device, a system of the three infrared mapping liquid crystal matrices (2) and its application for the detection of thermal anomalies on the surface of the breast.

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INTERNATIONAL SEARCH REPORT

International application No
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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.
A	US 2009/259139 A1 (STEPIEN JACEK [PL] ET AL) 15 October 2009 (2009-10-15) cited in the application paragraphs [0002], [0123], [0137]; figure 1; table 1	1,16

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A	column 5, lines 7-26 column 6, lines 25-46 figures 1,2,9	16

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

[X] See patent family annex.

* Special categories of cited documents :

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

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"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

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Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/050990

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2011/093734 A1 (BRASTER SP Z O O [PL]; STEPIEN JACEK BERNARD [PL]; JAREMEK HENRYK [PL]) 4 August 2011 (2011-08-04) cited in the application	16
A	page 1, line 3 - page 3, line 10	1,2,5-7

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X,P	WO 2012/113372 A2 (SALUTOGENESIS GMBH & CO KG [DE]; WEHBERG HEINRICH [DE]) 30 August 2012 (2012-08-30)	1-15
A,P	page 9, line 4 - page 14, line 13	16

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15

A device for imaging, recording and saving a thermographic image of a breast

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2. claim: 16

A system of three infrared mapping liquid crystal matrices

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2013/050990

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.: 17-21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Diagnostic methods practised on the human or animal body

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:

see additional sheet

1. [X] 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.

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IB2013/050990

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A61B 5/01(2006.01)
G01K 11/16(2006.01)

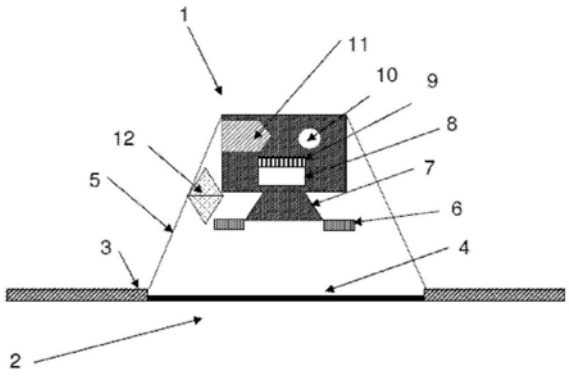
权利要求书3页 说明书10页 附图1页

(54)发明名称

用于成像、记录和储存热像图的装置、使用该装置的三个液晶矩阵的系统及其用于检测热异常的应用以及诊断这些异常的方法

(57)摘要

本发明涉及用于成像、记录和储存乳腺的热像图的装置，其特征在于其包括视频记录仪(1)和在31,8℃至34.8℃范围内以约1°的温度范围中工作的红外测绘液晶矩阵(2)，其中所述记录仪(1)优选包括外壳(5)、光源(6)、具有光电换能器(8)的照相机(7)、模拟数字转换器(9)、电源(10)和存储介质(11)。本发明还涉及使用所述装置、三个红外测绘液晶矩阵(2)的系统来诊断乳腺病理的方法及其用于检测乳腺表面上热异常的应用。



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1. 用于乳腺热像图的成像、记录和储存的装置，特征在于其包括图像记录仪 (1) 和红外测绘液晶矩阵 (2)，所述红外测绘液晶矩阵 (2) 在 31.8℃至 34.8℃的范围内以约 1° 的温度范围工作，其中所述记录仪 (1) 优选地包括外壳 (5)、光源 (6)、具有具有光电换能器 (8) 的照相机 (7)、模拟数字转换器 (9)、电源 (10) 和存储介质 (11)。

2. 如权利要求 1 所述的装置，特征在于其在三间隔热像尺度内运行，所述三间隔热像尺度包括 31.8℃至 34.8℃的乳腺表面温度检测范围并且分为三个子范围：

第一子范围 31.8℃至 32.8℃，其具有 0.5℃的热光间隔并用于检测体温过低表现的异常，

第二子范围 32.8℃至 33.8℃，其具有 0.5℃的热光间隔并用于在较低温度下检测体温过高表现的异常，和

第三子范围 33.8℃至 34.8℃，其具有 0.5℃的热光间隔并用于检测较高温度的体温过高表现的异常。

3. 如权利要求 1 或 2 所述的装置，特征在于所述红外测绘液晶矩阵 (2) 具有手柄 (3) 和红外测绘显示器 (4)，其中所述手柄由塑料制成，优选地由聚丙烯制成。

4. 如权利要求 1、2 或 3 所述的装置，特征在于所述红外测绘液晶矩阵 (2) 是圆形的并且具有至少 140mm 的直径。

5. 如权利要求 1-4 中任一权利要求所述的装置，特征在于所述红外测绘液晶矩阵 (2) 在具有 0.5℃的热光间隔的 31.8℃至 32.8℃的温度范围内运行。

6. 如权利要求 1-4 中任一权利要求所述的装置，特征在于所述红外测绘液晶矩阵 (2) 在具有 0.5℃的热光间隔的 32.8℃至 33.8℃的温度范围内运行。

7. 如权利要求 1-4 中任一权利要求所述的装置，特征在于所述红外测绘液晶矩阵 (2) 在具有 0.5℃的热光间隔的 33.8℃至 34.8℃的温度范围内运行。

8. 如权利要求 1 所述的装置，特征在于所述光源 (6) 为至少一个 LED 二极管。

9. 如权利要求 8 所述的装置，特征在于所述 LED 二极管发射白光。

10. 如权利要求 1 所述的装置，特征在于所述具有光电换能器 (8) 的照相机 (7) 系统构成具有 1/3”类型 CCD 传感器的数字照相机，敏感度为至少 0.5lux 且分辨率为至少 540 行 / 英寸，具有在 F 1.2 水平下的亮度保持的镜头。

11. 如权利要求 1 所述的装置，其中所述电源 (10) 为在 1.5V 至 9V 的电压下的 DC 供电系统。

12. 如权利要求 1 所述的装置，其中所述存储介质 (11) 选自硬盘驱动器、诸如 CD、CD-R、CD-RW、DVD- 型光盘、蓝光光盘、HD-DVD、记忆卡或记忆 USB 型的光盘驱动器。

13. 如权利要求 1 所述的装置，特征在于所述存储介质 (11) 为具有 4GB 的最小容量的快速 EPROM 类型记忆卡。

14. 如权利要求 1 所述的装置，特征在于其还包括通过有线或无线传输实现数据传输 (12) 的装置。

15. 如权利要求 14 所述的装置，其中所述实现数据传输的元件 (12) 是使用 2.5GHz 频率的无线电波并以蓝牙技术标准工作的无线传输器。

16. 三个红外测绘液晶矩阵的系统，特征在于其包括

第一液晶矩阵，其在具有 0.5℃的热光间隔的 31.8℃至 32.8℃的温度范围内运行并用

于检测体温过低表现的异常；

第二液晶矩阵，其在具有 0.5℃的热光间隔的 32.8℃至 32.8℃的温度范围内运行并用于检测体温过高表现的异常；

第三液晶矩阵（验证类型的），其在具有 0.5℃的热光间隔的 33.8℃至 34.8℃的温度范围内运行并用于检测显示体温过低表现的甚至更高的异常。

17. 如权利要求 15 所述的三个红外测绘液晶矩阵的系统用于检测乳腺表面的热异常的用途，

第一矩阵，其用于检测体温过低表现的异常，优选地与良性特征的器官内病理有关，

第二矩阵，其用于检测体温过高表现的异常，优选地与增生特征的器官内病理有关的病理，和

第三验证矩阵，其用于检测体温过高表现的异常，优选地与增殖性质有关的器官内病理。

18. 使用如权利要求 1 所述的用于成像、记录和储存热像图的装置来诊断乳腺表面的热异常的方法，特征在于其包括如下系列步骤：

将所述红外测绘液晶矩阵 (2) 应用于受检查乳腺，所述红外测绘液晶矩阵 (2) 以可拆卸的方式与所述记录仪 (1) 连接并具有红外测绘显示器 (4)；

开启所述光源 (6)；

使用装备有光电换能器 (8) 和模拟数字转换器 (9) 的照相机 (7) 来记录在所述红外测绘矩阵上描绘的等温线的彩色图像，时间长至 20 秒；

记录在所述存储介质 (11) 上获得的数字视频信号；

将记录的数字视频信号传送至计算机或移动装置，所述计算机或移动装置装备有乳腺热像图数据库和人工智能系统或通过局域网或互联网与这种数据库和人工智能系统建立连接；

使用所述人工智能系统以便应用所述乳腺热像图的数据库对所获得的红外测绘成像进行分析；

获得对于二元系统（阳性 / 阴性）中热像检查的最可能结果的指导，作为分析的结果。

19. 如权利要求 18 所述的方法，特征在于，通过相继使用包含在上述如权利要求 15 所述的三个红外测绘液晶矩阵的系统中的三个红外测绘液晶矩阵 (2) 将所述记录和储存图像的系列进行三次。

20. 如权利要求 18 或 19 所述的方法，特征在于，基于作为不同颜色的划界区域可见的体温过低标记的红外测绘图像的存在或不存在，在所述阳性 / 阴性二元系统中进行所述热像检查结果的读取，所述颜色与第一无源接触红外测绘液晶显示器的工作区域可见的热背景的主色相关。

21. 如权利要求 18 或 19 或 20 所述的方法，特征在于，为了检测，存在使用的热像三间隔尺度，所述热像三间隔尺度包括 31.8℃至 34.8℃的乳腺的表面温度范围并且分为三个子范围：

第一子范围 31.8℃至 32.8℃，其具有 0.5℃的热光间隔并用于检测体温过低表现的异常，

第二子范围 32.8℃至 33.8℃，其具有 0.5℃的热光间隔并用于检测较低温度的体温过

高表现的异常，

第三子范围 33.8℃至 34.8℃，其具有 0.5℃的热光间隔并用于检测较高温度的体温过高表现的异常。

用于成像、记录和储存热像图的装置、使用该装置的三个液晶矩阵的系统及其用于检测热异常的应用以及诊断这些异常的方法

[0001] 本发明涉及用于女性乳腺表面的热像图的成像、记录和储存的女性乳腺表面的的装置和诊断热异常的方法。本发明还涉及通过使用该装置使用的三个液晶矩阵的系统及其用于检测热异常的应用。

[0002] 本发明用于检测处于除哺乳期之外的期间的女性乳腺中发生的病理生理学过程，所述哺乳期具有与充分表现的适当热有相关的特殊特异性的和独特的热力学特征。在乳腺中发生的变性变性过程，例如由于血液供应的局部限制产生的纤维－囊性变性（变性纤维囊性），其特征在于与周围组织有关的低温，其与受检查乳腺表面上的体温过低表现有关。另一方面，根据实验研究[Zhao 等人，(Qi Zhao，Jiaming Zhang，Ru Wang，Wei Cong，Use of a Malignant Tumour Thermocouple for detection(用于检测的恶性肿瘤热电偶的使用)，IEEE Eng.In Medicine and Biology Mag.(在医学和生物学期刊中)，一月／二月2008)]，增殖（肿瘤）过程与产生器官内体温过高病灶的血管生成有关，其可在受检查乳腺的表面上被检测并记录，如相对于周围组织的体温升高区域。使用两个热像图矩阵而非一个以观察具有体温过高表现的异常允许通过其热特征的棱镜增加这些异常的成像的精度，因为各个传感器仅在1.5℃范围内工作。

[0003] 现有解决方案包括报道的发明（本申请的第P.381431号波兰专利申请）不充分或不正确解决热异常形式的纠正鉴别的问题，或者通过假设太小的温差梯度（约0.4℃）用于识别预测的观察到的异常，与临床数据不一致，或者通过采用36.6℃的错误温度点用于划分体温过低和体温过高表现的表皮变化的成像的热像尺度，其与体内经验检测的结果不一致，或者通常通过不考虑试验期间热异常类型的初步区别的可能性（没有体温过低和体温过高范围的清楚划分），从医学角度来判断其导致热像图的解释的进一步客观难题并且为了没有正确鉴定的热范围，使得无法正确确定诊断，在其范围内应该寻找热像肿瘤标记。

[0004] 在上述第P.381431号波兰专利申请中，进行了消除温度运行范围的偶然分离的不成功尝试，其中热像检测器的单独双重设置必需工作。然而，所述发明中假设用于检测和鉴别测试乳腺表面上的体温过低和体温过高性质的病理变化的热像尺度的分离点是设置在36.6℃的人体生理学温度点是不正确的，因为通过使用红外照相机在包括接触温度记录法或热像图的几乎所有经验研究中并未实验确定在患者的手臂下或甚至腺内检测的36.6℃的相对恒定生理学温度转置成在受检查乳腺的表面上的记录的同样稳定和恒定的生理学温度。更重要地，在目前对乳腺热像图的研究工作还包括致力于模拟乳腺癌的热力学方面的最新研究（参见L.Jiang 等，Dynamic Characterization for Tumour and Deformation-Induced Thermal Contrasts on Breast Surface:A Simulation Study,Biomedical Applications in Molecular,Structural,and Functional Imaging(乳腺表面上的肿瘤和形变诱导的热对比的动态特征：分子、结构和功能成像的模拟研究、生物医学应用)，2009)中，没有允许构建描述在随环境的相对正常体温的条件下腺内生理学温度点转化为乳腺表面相应温度的合适函数相关的函数相关，导致未能识别体

温调节反应。特别地，没有科学工作表明在患者手臂下检测的36.6℃的生理学温度转化为在乳腺表面上检测的相同标准温度。这表明在本申请中指出并且由本发明人描述的，在这些体温过低和体温过高性质表现上检测的热异常的生理学分离点在性质上是纯理论的并且不允许在温度记录设备中实际使用。在接触热像图的情况下，热异常的明显分离问题是重要的，因为在该研究过程中，不可能选择性消除特殊温度范围，因为无源红外液晶显示器在建立的严格温度范围的工厂中工作，因此尽管研究的非常高的分辨率，但在温度的观察到的变化的特征的正常视觉评价中可能出现难题，因此基于此其使得特异性鉴别不可能，如果病理被称为“热”—与瘤过程和乳腺炎类型过程有关，或者“冷”—与轻微、变性过程有关的过程，特别是当一组显示器用于仅在低于或高于36.6℃的双宽光谱中的温度异常的成像时。

[0005] 在Ch.Cozzi的2010年的第U.S.20100312136A1号美国专利申请中公开的另一已知解决方案是包括装置和步骤解决方案的系统，包括通过使用在红外区工作的照相机的热像图进行医学诊断的方法。

[0006] 基于无源液晶红外显示器和用于检测温度的电子接触传感器的接触热像诊断根本不同于使用在红外区工作的照相机的远程热成像，主要根据用于在受检查乳腺表面上的获得等温线分布的图像的物理效应，因为第一方法基于通过传导至检测器的热的传递，而第二种基于发射。因此，不可能直接比较这两种方法，不仅因为通过本发明的设备产生的红外测绘成像在无源显示器处形成并且是类似物，而且因为相同的结果的试验和读数实时发生，尽管Ch.Cozzi的第U.S.20100312136A1号美国专利申请的装置产生数字图像，但其仅通过从接受红外辐射的光电换能器获得的数据的数值分析产生的计算机的小的时间迁移产生，并且用于评价以该方式获得的热图谱的基础是定量分析。此外，通过包括在约380至700nm的电磁波长范围的可见光工作的具有CCD传感器的数字照相机的单独、可移动记录单元进行来自本发明设备的红外测绘成像的记录，尽管红外照相机的运行波段在所谓700至1000nm的近红外范围内并且应当注意敏感度的增加不适用于诸如可用于在此描述的本发明的那些的传统照相机，因为它们具有安装在CCD传感器前面的红外滤波器，其几乎完全吸收近红外波段的辐射。因此，源自本发明照相机的红外测绘图像是由于在包含在可见光谱范围的相同显示器中的热致中间相中选择性反射的光投影产生的图像，而从红外照相机获得的图是通过计算机以数字方式完全重新构建的图片，因为它衍生自人眼不可见的电磁辐射的配准。这两个根本差别使得二者的两项发明的乳腺表面温度的检测的相同基本机理不同，并且进一步使携带研究者的大量医学信息的红外测绘图像的形成方法不同，因此，固定两个成像的技术不同—在第一种情况下，有类似图像的数字化，并且在刚开始的另一种情况下存在重建数字图像。

[0007] 此外，美国专利申请20100312136A1要求保护包括用于制备两个系列的热像图数字图像的步骤以及它们的比较的算法，除了通过可连接模块配准装置之外，还可选择网络。此外，在所述申请中，没有阐述代表腺内病理实质的在受检查乳腺的表面上记录的限于局部的体温过低或体温过高的鉴别方法，换言之，Ch.Cozzi既没有在他的发明说明书中也没有在权利要求中指出从热异常的温度中区分器官正常体温(normothermy)的任何具体点或范围。

[0008] 本发明介绍的新颖性是可通过在受检查乳腺的表面上的接触热像图的方法记录

的热异常分析的完全不同范围的确定，其对于这类检查的医学意义是重要的，因为它的目的本身不是多点温度检测，但是分离具有至少 0.5℃的显著区别的异常区域以消除与器官内体温过低或体温过高无关的随机人为现象热变化。因此，包括 31.8℃至 34.8℃的范围的与本发明主题有关的新的三间隔热像尺度被进一步分开为三个子范围：第一为允许表明显示体温过低表现的测试乳腺表面上的温度异常的 31.8℃至 32.8℃、第二为允许表明显示具有较低平均温度的体温过高表现的受检查乳腺表面上的温度异常的 32.8℃至 33.8℃和第三为允许表明显示较高平均温度的体温过高表现的受检查乳腺表面的温度异常的 33.8℃至 34.8℃，构成整个装置的诊断值并且是本发明人通过使用患者的体内经验研究进行的发现的结果。

[0009] 因此，发明人在本发明中介绍具体定义的参考温度范围，在其范围内分别表明显示体温过低表现的异常和显示体温过高表现的异常。否则，此外，这两项发明解决了以完全不同方式的温度检测器校准的问题，因为在 Ch.Cozzi 发明的情况下，在各个检测之前将其校准，并且在本发明的情况下，通过选择化合物的混合物的合适组成仅在液晶红外测绘显示器的产生阶段进行一次校准，所述化合物选自手性和非手性向列相以确保恒定预设的热变色反应。

[0010] 本发明和 Ch.Cozzi 的上述引用的申请之间的另一关键区别是读取热像图检查结果的方法，其中第 20100312136A1 号美国专利申请使用自动进行定性和定量分析的算法，然后分别基于定性和定量分析自动产生得分数据库。本发明具有完全不同的假设，即温谱图评级基于二元标准—阳性 / 阴性结果，其包括具有人工智能的决策支持系统，其比较的并非是在相同患者中获得的红外测绘成像的单独系列，而是研究结果与数据库中收集的热异常的其他参考成像，产生完全不同的分析算法。

[0011] 因此，本发明的目的是提供用于成像、记录和储存允许正确鉴别受检查乳腺表面上的热异常性质的热像图的装置。

[0012] 本发明的另外目的是提供适于与上述装置一起使用以检测体温过低和体温过高表现的病理变化的红外测绘液晶矩阵的系统。

[0013] 本发明的另一目的是提供使用上述设备连同红外测绘液晶矩阵来诊断乳腺病理的方法。

[0014] 因此，本发明涉及用于乳腺的热像图的成像、记录和储存的装置，其包括图像记录仪和红外测绘液晶矩阵，所述红外测绘液晶矩阵在 31.8℃至 34.8℃的范围内以约 1° 的温度范围运行，其中记录仪优选包括外壳、光源、照相机和光电换能器、模拟数字转换器、供电和存储介质。

[0015] 优选地，本发明的装置在包括 31.8℃至 34.8℃的乳腺表面温度检测范围内的三间隔热像尺度内运行并且三间隔热像尺度分为三个子范围：

[0016] 第一子范围 31.8℃至 32.8℃，其具有 0.5℃的热光间隔并用于检测体温过低表现的异常，

[0017] 第二子范围 32.8℃至 33.8℃，其具有 0.5℃的热光间隔并用于检测较低温度的体温过高表现的异常，和

[0018] 第三子范围 33.8℃至 34.8℃，其具有 0.5℃的热光间隔并用于检测较高温度的体温过高表现的异常。

[0019] 优选地，红外测绘液晶矩阵具有手柄和红外测绘显示器，其中所述手柄由塑料制成，特别地由聚丙烯制成。

[0020] 优选地，红外测绘矩阵液晶为圆形的并且具有至少 140mm 的直径。

[0021] 优选地，红外测绘矩阵液晶在具有 0.5℃的热光间隔的 31.8℃至 32.8℃的温度范围内运行。

[0022] 优选地，红外测绘矩阵液晶在具有 0.5℃的热光间隔的 32.8℃至 33.8℃的温度范围内运行。

[0023] 优选地，红外测绘矩阵液晶在具有 0.5℃的热光间隔的 33.8℃至 34.8℃的温度范围内运行。

[0024] 优选地，光源为至少一个 LED 二极管，特别地是发射白光的 LED 二极管。

[0025] 优选地，具有光电换能器的照相机系统构成数字照相机，其具有敏感度为至少 0.5lux、分辨率为至少 540 行 / 英寸、镜头在 F 1.2 水平下具有亮度保持的 1/3”类型的 CCD 矩阵。

[0026] 优选地，电源为具有 1.5V 至 9V 的电压的 DC 电源系统。

[0027] 优选地，存储介质选自诸如硬盘驱动器、诸如 CD、CD-R、CD-RW、DVD- 型光盘、蓝光光盘、HD-DVD、记忆卡或 USB 闪存盘的光盘驱动器的介质，并且最优选存储介质为至少 4GB 的容量的记忆卡快速 EPROM 类型记忆卡。

[0028] 优选地，本发明的装置还包括通过有线或无线传输传送数据的元件。

[0029] 优选地，实现数据传输的元件是使用以蓝牙技术标准工作、频率为 2.5GHz 的无线电波的无线传输器。

[0030] 本发明还提供了三个红外测绘液晶矩阵的系统，其包括 ：

[0031] 第一液晶矩阵，其在具有 0.5℃的热光间隔的 31.8℃至 32.8℃的温度范围内运行并用于检测体温过低表现的异常 ；

[0032] 第二液晶矩阵，其在具有 0.5℃的热光间隔的 32.8℃至 32.8℃的温度范围内运行并用于检测体温过高表现的异常 ；

[0033] 第三液晶矩阵（验证类型的），其在具有 0.5℃的热光间隔的 33.8℃至 34.8℃的温度范围内运行并用于检测显示体温过低表现的甚至更高的异常。

[0034] 本发明涉及所述三个红外测绘液晶矩阵的系统用于检测乳腺表面的热异常的用途，

[0035] 第一矩阵，其用于检测体温过低表现的异常，优选地与良性特征的器官内病理有关，

[0036] 第二矩阵，其用于检测体温过高表现的异常，优选地与增生特征的器官内病理有关的病理，和

[0037] 第三验证矩阵，其用于检测体温过高表现的异常，优选地与增殖性质有关的器官内病理。

[0038] 本发明还提供了使用所述用于成像、记录和储存乳腺的热像图的装置来诊断乳腺表面的热异常的方法，特征在于它其包括如下系列步骤 ：

[0039] 将所述红外测绘液晶矩阵应用于受检查乳腺，所述红外测绘液晶矩阵以可拆卸的方式与所述记录仪连接并具有红外测绘显示器 ；

[0040] 开启光源；

[0041] 使用装备有光电换能器和模拟数字转换器的照相机来记录在红外测绘矩阵上描绘的等温线的彩色图像，时间长至 20 秒；

[0042] 记录在存储介质上获得的数字视频信号；

[0043] 将记录的数字视频信号传送至计算机或移动装置，所述计算机或移动装置装备有乳腺热像图数据库和人工智能系统或通过局域网或互联网与这种数据库和人工智能系统建立连接；

[0044] - 使用人工智能系统以便应应用所述乳腺热像图的数据库对进行所获得的红外测绘成像进行的分析；

[0045] 获得对于二元系统（阳性 / 阴性）中热像检查的最可能结果的指导，作为分析的结果。

[0046] 优选地，在本发明的方法中，通过相继使用包含在上述三个红外测绘液晶矩阵的系统中的红外测绘液晶矩阵将所述步骤的系列进行三次。

[0047] 优选地，在本发明的方法中，基于作为不同颜色的划界区域可见的体温过低标记的红外测绘图像的存在或不存在，在所述阳性 / 阴性二元系统中进行所述热像检查结果的读取，所述颜色与第一无源接触红外测绘液晶显示器的工作区域可见的热背景的主色不同。

[0048] 优选地，在本发明的方法中，为了检测，存在使用的热像三间隔尺度，所述热像三间隔尺度包括 31.8℃至 34.8℃的乳腺的表面温度范围并且分为三个子范围：

[0049] 第一子范围 31.8℃至 32.8℃，其具有 0.5℃的热光间隔并并用于检测体温过低表现的异常，

[0050] 第二子范围 32.8℃至 33.8℃，其具有 0.5℃的热光间隔并用于检测在较低温度下的体温过高表现的异常，

[0051] 第三子范围 33.8℃至 34.8℃，其具有 0.5℃的热光间隔并用于检测较高温度的体温过高表现的异常。

[0052] 本申请主题的本发明消除了先前使用的接触式乳腺热像图的缺点，由于意图本发明的热乳腺成像 (thermomastographic) 设备的 31.8℃至 34.8℃的运行温度的新范围的发现和使用，该范围还被分开为三个子范围：第一为允许表明显示体温过低表现的测试乳腺表面上的温度异常的具有 0.5℃的热光间隔的 31.8℃至 32.8℃、第二为允许表明显示具有较低平均温度的体温过高表现的受检查乳腺表面上的温度异常的具有 0.5℃的热光间隔的 32.8℃至 33.8℃和第三为允许表明显示较高平均温度的体温过高表现的受检查乳腺表面的温度异常的具有 0.5℃的热光间隔的 33.8℃至 34.8℃。

[0053] 在对乳腺热像图的实验研究中，在受检查乳腺表面上记录的温度范围很少低于 31℃并且高于 35℃（参见 JF Head，Determination of mean temperatures of normal breast and breast whole quadrants by infrared imaging and image analysis（通过红外成像和图像分析确定正常乳腺和乳腺整个象限的平均温度），IEEE，2001），因此上述第 P.381431 号波兰专利申请没有适当考虑实验确定的乳腺热像图中公开的器官的体温过低的上限和体温过高的下限，因为分割点理论上确定为 36.6℃。上述发明中的热像尺度的参考分割点的这种确定的结果在于分别用于分析在低于 36.6℃的温度下具有体温过低表现

的异常，而非在高于 36.6℃的温度下具有体温过高表现的异常的它的两个检测子范围都没有进入本发明的合适检测范围，因为它们目的为了 32.8℃处的体温过低变化的成像的间隔并且为了所述高于 32.8℃并不高于 34.8℃的子范围的体温过高变化成像的范围并且从多达 1.8℃的 36.6℃的边界值分开。

[0054] 本发明装置的凭经验确定的温度范围的阈值不仅用于创建仅用于热像检查中专门使用而设计的新热像尺度的基础，其鉴于创造性是重要和关键突破，因为目前所提交的发明没有与用于接触温度记录法的装置有关，不允许进行依据它们二者的热力学和病理生理学特征可见的热异常的实时分类，尽管允许基于存在受检查乳腺表面上的体温过低或体温过高标记的最初诊断，其为存在特殊类型的腺内病理的预测。因此，本发明特别地包括以该温度范围或相似温度范围并且以具体定义和三间隔功能划分的新热像尺度，其未在温度记录法领域中任何其他公开的专利申请中公开。

[0055] 本发明的装置不需要同时对两个乳腺进行检查。

[0056] 在第 P.381431 号波兰专利申请和本说明书和权利要求中公开的解决方案在关键方面是不同的，第一个发明涉及在点 36.6℃周围分开的双波段运行温度范围，另一个涉及在点 32.8℃至 33.8℃周围分开的三间隔尺度。此外在技术背景下，第一个发明由包括能实现两个乳腺的平行鉴别诊断的两个矩阵的双检测系统组成，并且装置由两个不同校准的矩阵的盒组成，尽管本发明的设备由相继地首先应用于一个，然后另一个乳腺的放置在单独手柄中的三个无源红外测绘液晶显示器的系统组成。

[0057] 在本发明中，0.5℃的热光间隔的使用与从经验观察值获得的数据一致 [Zhao 等人，2008] 并且从诊断和预测值的角度出发，根据科学文献足以认为这样的温度差是显著的，因为疑似肿瘤性转化的变化特征在于相对于周围健康组织的 0.7℃的平均热差。

[0058] 出乎意料地发现红外测绘矩阵的三重设置的使用，总热检测范围包括受检查乳腺表面上存在的体温过低和体温过高异常区域，尽管保持单独观察值（分离）的可能性允许明显区分，因此从医学观点来看检查的一些解释。

[0059] 本发明的基础是从进行的经验检测获得的三个补充范围上的热像尺度的新划分。该划分的应用使唯一鉴别良性和恶性过程的热像标记成为可能。在单一红外测绘矩阵上发生良性过程的热像标记的观察，并且为了恶性过程标记的观察，本发明提供了两个单独的矩阵，其最后（第三）充当验证矩阵。关于第三验证矩阵的公开，热标记等同于出现体温过高的爆发的确认，其与肿瘤过程有关。上述 Zhao 等人 [2008] 指出在存在恶性肿瘤情况下，约 0.7℃和更多的热差的统计学联系。

[0060] 对于本发明的装置，在热像矩阵的产生过程中有程序化的三个补充运行温度范围，其相对于 32.8℃的乳腺标准表面温度调整以适应实验测定的阈值。这些阈值的应用允许受检查乳腺热背景的过滤和消除人为现象读数，在第一矩阵的情况下，通过切断 32.8℃下热像尺度的较低范围中的热背景，其允许仅具有至少 0.5℃的温度变化的可视化，与乳腺的标准表面温度（特征在于良性病理）相比并且分别用于第二矩阵，切断 32.8℃处的热像尺度的上限中的热背景，其允许相对于正常乳腺的表面温度观察温度高至少 0.5℃的异常（即显著更热—体温过高，是恶性异常的特征），并且对于第三矩阵，切断热背景在甚至更高的温度下即高于 33.8℃，其允许显示相对于 32.8℃的标准乳腺表面温度的至少 1℃显著的更热的异常（明显与具有恶性过程的肿瘤的热特征有关）。

[0061] 热像矩阵的三重系统是在本发明的装置中，热硬件过滤概念的独特应用，不是为了技术用途的目的（以确保用于女性乳腺的热检测研究的合适范围），而仅为了特殊医学用途的目的，理解为通过它与热特征的联系，形成特殊的热像标记的器官内病理类型的初步分化的解决方案。

[0062] 如果不确定观察到的异常是否具有体温过低或体温过高表现类型，没有人能讨论热像标记的存在，这是因为标记归因于肿瘤生长和囊肿形成的热力学模型。

[0063] 能够使用用于通过使用本发明装置过滤的接触热像图评价检查结果的二元标准，因为包含在诊断试剂盒中的各个三个无源红外测绘液晶显示器在制造阶段温度范围下以严格定义和程序化形式工作，与新热像尺度关联使得在给定温度范围下有特殊类型的乳腺病理的探测。这意味各个无源红外测绘液晶显示器建立旨在特异性仅用于一组乳腺病理的功能热力学标记的检测和提供固定的热表现的一组功能试验，其才会使设计用于体温过高表现的成像在显示器上，研究者看不到相应于与变性过程有关的良性病理的迹象，例如，液囊肿，并且反之亦然。二元标准仅爆发光学界定的异常的存在的鉴别，相对于通过热致中间相的热光反应的主色在显示器上表示的优势热背景确定，因为在 RGB 系统（红－绿－蓝）中的显示器上可见的各个原色相应于约 0.5℃温度的差别。为了支持该二项式评价，还可以规定定量范围，基于相关的、固定相对于可见、界定颜色异常由给出、优势颜色相应于受检查器官热背景的特殊温度占据的红外测绘成像显示器的活性表面百分比，其应包括最小表面。应当注意，定量决定因素不是评价和异常或正常形式的接触热谱图的定性的唯一标准，因为试验能够检测甚至测试的乳腺表面上的异常温度的最小表现，但能提供关于病理过程严重程度的范围的另外信息。实验确定仅存在在本发明的任何无源红外测绘液晶显示器上鉴别的热标记能通过如同提供阳性结果的接触热像图分类整个试验，表明观察到的异常的热力学特征，因此定量参数与标记有关，不是本专利申请中权利要求的主题。

[0064] 为了充当全功能热像检测器，各个热像矩阵需要被安装在由柔韧不易破损的塑料优选聚丙烯制成的手柄中。

[0065] 各个矩阵优选为圆形的并且具有至少 140mm 的直径。

[0066] 此外，本发明的装置装备有在受检查乳腺表面上的等温分布的彩色成像的光电记录仪，所述受检查乳腺在由优选具有 CCD（电荷耦合器件）矩阵的数字照相机系统组成的无源红外测绘矩阵上显示，允许记录，然后是与落在它上面的光的量成正比的电信号的读数并且电子系统能实现图像的模拟数字转换，然后编码视频信号，例如根据标准 ISO/IEC 14496-10:2004(H.264/AVC)，诸如闪存卡的存储介质允许整个试验系列的数字记录并且优选为包含储存的视频图像的无线传输器，例如使用 2.4GHz ISM 波段（蓝牙技术）的无线电波，根据规范 IEEE802.15.1 的标准工作。记录仪通过提供发送数字文件形式的完整系列的热像检查至计算机的能力显著扩大测试仪的诊断潜力并且进一步通过使用分析中心的互联网以使用基于人工智能系统的算法进行其彻底分析，比较温谱图的正常图和病理图与实际上在特殊试验中获得的那些。通过使用不同算法的人工智能系统支持温谱图分析以比较不同成像提高了检查的准确性、从医学角度出发促进重要的热异常的鉴定，其对诊断置信度具有显著影响。

[0067] 本发明的记录仪是具有它自己的供电的附加的、完整的和可拆卸的组件，其由进入红外测绘矩阵的塑料手柄的螺栓系统固定。

[0068] 本发明装置的实施方案在附图中示出，其中图 1 示意地例示了连接红外测绘液晶矩阵显示器的记录仪的结构。

[0069] 在图 1 中，具有外壳 5 的记录仪由五个基础元件组成，例如，

[0070] - 具有光电换能器 8 的数码微型照相机 7，其为具有 1/3”的最小尺寸的的 CCD 矩阵的一部分，敏感度为至少 0.5lux，分辨率为至少 540 行 / 英寸，并且具有在 F 1.2 水平下具有亮度保持的镜头 ；

[0071] - 存储介质 11，例如容量为至少 4GB 的记忆卡、快速 EPROM 类型 ；

[0072] - 光源 6，其为具有 LED 二极管的分散式照明系统，所述 LED 二极管发射白光、排列在定向在液晶矩阵 2 的红外测绘显示器 4 上的照相机 7 的镜头周围 ；

[0073] - 自己的 DC 供电系统 10，在该情况下 9V，和

[0074] - 用于数据传输 12 的组件，此处使用频率为 2.4GHz，以蓝牙技术标准工作的无线电波的无线传输器。

[0075] 将本发明的记录仪 1 与红外测绘液晶矩阵 2 的手柄 3 连接。

[0076] 记录仪的目的是进行乳腺的全系列热像检查的实时视频记录，其从正确应用检测器至受检查乳腺的时间花费约 15 秒。保持检测器在受检查乳腺的一个位置持续大于 20 秒可能导致红外测绘矩阵 2 温度和受检查乳腺区域的平衡，结果导致热像图丢失或失真。

[0077] 本发明的记录仪 1 由进行试验的人员手动激活并且在 15 秒后自动关闭，其由开启主体 5 上的红色 LED 二极管和单一蜂鸣声指示。使用该装置诊断乳腺病理的方法包括步骤，其中以可拆卸方式与记录仪 1 连接的红外测绘液晶矩阵显示器与红外测绘显示器 4 一起应用于受检查乳腺，然后光源 6 自动开启并且持续多达 20 秒时间，使用具有 CCD 矩阵 8 和模拟数字转换器 9 的数码微型照相机 7 记录在红外测绘矩阵上绘制的等温线的彩色图像。然后，在闪存卡 11 中记录产生的数字视频信号，并且连续使用在三个检查温度范围中运行的三个红外测绘液晶矩阵 2 将所述图像记录和储存的系列进行三次。在完成检查后，通过按压单个按钮通过蓝牙发射器 12 将在闪存卡 11 中储存的数据传输至装备有蓝牙接收器的计算机，通过互联网使乳腺热像图的数据库与人工智能系统连接以分析使用乳腺热像图数据库获得的红外测绘成像。作为分析的结果，获得二元系统（阳性 / 阴性）中热像检查的最可能结果的指导。

[0078] 红外测绘液晶矩阵 2 中无源红外测绘检测器的作用是通过包含来自手性相列相组的热致液晶的三个热敏矩阵 2 的装置进行。

[0079] 将各个矩阵 2 切割成直径为 140mm 的圆形并且安装在塑料手柄 3 中。

[0080] 为了产生作为关键热敏元件的热致中间相—使用各个三个热像矩阵 2 的红外测绘显示器 4，本发明液晶化合物的混合体，其为第 P.390320 号波兰专利申请的主题，具有下列组成的。

[0081] 第一矩阵的混合物（以重量计的组成）：

[0082]

胆固醇壬酸酯	48.61%
胆固醇油醇碳酸酯	50.39%
胆固醇丙酸酯	0.28%
氯化胆固醇	0.20%
4,4'-二戊基氧化偶氮苯	0.52%。

[0083] 对于该混合物，中间相为在 31.8℃至 32.8℃的温度范围内的热光反应，其中在 31.8℃的温度下，出现在中间相中反射红色的光（波长为 720nm）并且该颜色以 0.5℃保持直，然后在 32.3℃的温度下出现在中间相中反射绿色的光（波长为 545nm）并且该颜色以 0.5℃保持，并且在 32.8℃的温度下，出现在中间相中反射蓝色的光（波长为 410nm）并且该颜色以 0.5℃保持。

[0084] 第二矩阵的混合物（以重量计的组成）：

[0085]

胆固醇壬酸酯	50.28%
胆固醇油醇碳酸酯	48.72%
胆固醇丙酸酯	0.24%
氯化胆固醇	0.18%
4,4'-二戊基氧化偶氮苯	0.58%。

[0086] 对于该混合物，中间相为在 32.8℃至 33.8℃的温度范围内的热光反应，其中在 32.8℃的温度下，出现在中间相中反射红色的光（波长为 720nm）并且该颜色以 0.5℃保持，然后在 33.3℃的温度下出现在中间相中反射绿色的光（波长为 545nm）并且该颜色保持以 0.5℃，并且在 33.8℃的温度下，出现在中间相中反射蓝色的光（波长为 410nm）并且该颜色以 0.5℃保持。

[0087] 第三矩阵的混合物（以重量计的组成）：

[0088]

胆固醇壬酸酯	52.53%
胆固醇油醇碳酸酯	46.47%
胆固醇丙酸酯	0.18%
氯化胆固醇	0.16%
4,4'-二戊基氧化偶氮苯	0.66%。

[0089] 对于该混合物，中间相为在 33.8℃至 34.8℃的温度范围内的热光反应，其中在 33.8℃的温度下，出现在中间相中反射红色的光（波长为 720nm）并且该颜色以 0.5℃保持，然后在 34.3℃的温度下出现在中间相中反射绿色的光（波长为 545nm）并且该颜色以 0.5℃保持，并且在 34.8℃的温度下，出现在中间相中反射蓝色的光（波长为 410nm）并且该颜色以 0.5℃保持。

[0090] 然后，以可拆卸方式将各个包括红外测绘矩阵 2 的手柄 3 与视频图像的实时光电

记录仪连接，允许乳腺热像检查系列的数字记录及其通过无线蓝牙技术模块传输至外部装置—计算机或其他移动设备。

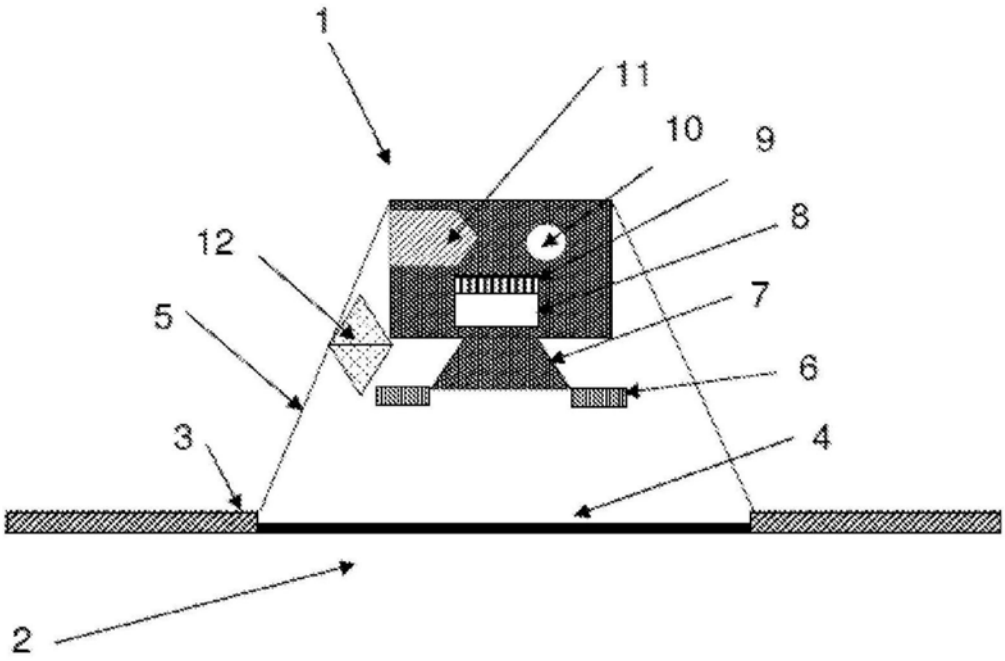

图 1

Abstract

The invention relates to a device for imaging, recording and saving a thermographic image of a breast, characterised in that it comprises a video recorder (1) and an infrared mapping liquid crystal matrix (2) working in the temperature range of approximately 1 ° in a range of 31,8 ° C to 34.8 ° C, wherein the recorder (1) preferably includes a housing (5), a light source (6), a camera (7) with an optoelectronic transducer (8), an analog-digital converter (9), a power source (10) and a storage medium (11). The present invention also refers to a method of diagnosing of the breast pathology using that device, a system of the three infrared mapping liquid crystal matrices (2) and its application for the detection of thermal anomalies on the surface of the breast.