Introduction

Our concept about RTM-Diagnosis is first of all based on our own investigations, which we have conducted over 6 years in five leading Moscow Oncological Centres. Over this period we have performed 3500 RTM-examinations, and 540 women were cancer patients. Also our views were formed by investigations of Michel Gautherie, a French Scientist in Breast Thermobiology. He worked in this field for over 16 years. His data published in [1] is based on investigation of 85,000 patients. In 247 patients he measured temperature invasively with the help of fine-needle thermoelectric probes. This unique set experimental data form the basis of our modern concepts about temperature distribution in the breast.

Content

Basis of Microwave Radiometry

1. Problems of Breast Cancer Detection at an Earlier Stage

Breast cancer is a common disease and about 1 in 11 women in Australia will develop breast cancer by the age of 75. One in every 9 women in the United States will experience breast cancer during her lifetime. The early detection of breast cancer is thus currently one of our most important clinical challenges.

Specialists say that detection of the breast cancer by the clinical methods detects tumours at a later stage. Once a tumour is palpable and clinically evident it has usually been present for about 10 years. Screening once in 12-24 months is not enough to detect fast growing breast tumours. Note that patients with "fast growing breast cancer" forms a quarter of all breast cancer patients. …So it is expedient to use screening in conjunction with other non-invasive investigative methods [1, 2].

The microwave radiometry [3-5, 7, 10] is based on measuring the intensity of natural electromagnetic radiation from a patient's tissue. This intensity is proportional to temperature of tissue. The change of the temperature (thermal abnormality), that is a basis of the earlier detection of breast cancer, may be caused by higher metabolic activity of tumours.

It should be noted that thermal changes proceed to the anatomical changes that can be detected by traditional methods such as ultrasound, mammography and palpation. Thus microwave radiometry is a very promising method for breast cancer detection at an earlier stage.

2. Basic Concept of Microwave Radiometry

Microwave radiometry measures natural electromagnetic radiation from a patient's internal tissue at microwave frequencies.

The intensity of the radiation is proportional to the temperature of tissue. So we can say that microwave radiometry allows us to measure internal temperature of tissue and display it on the monitor of a personal computer.

3. Difference between Microwave Radiometry and Infrared Thermography

The main difference between well-known infrared thermography and microwave radiometry is that the former allows the reading and displaying of skin temperature only, and the latter shows internal temperature changes in addition.

4. Breast Cancer Detection Methods

The main diagnostic means used for detection of oncological disease may be divided into three groups that are shown in ***Fig.1***.

The first group includes physical examination methods. These methods are effective when the tumour is formed, and when it has a well-delineated boundary.

Unfortunately in this phase, when tumours can be detected by physical methods (e.g. in average the tumour only of 1-2 cm can be detected by mammography) metastasis may have occurred.

The inevitable radiation load, used for mammography, does not allow one to conduct screening more than once every six months.

Physical methods have other features that restrict their abilities. For instance, in mammography, X-ray examination is not effective enough for young women as breast tissues are too dense and so X-ray images have insufficient contrast.

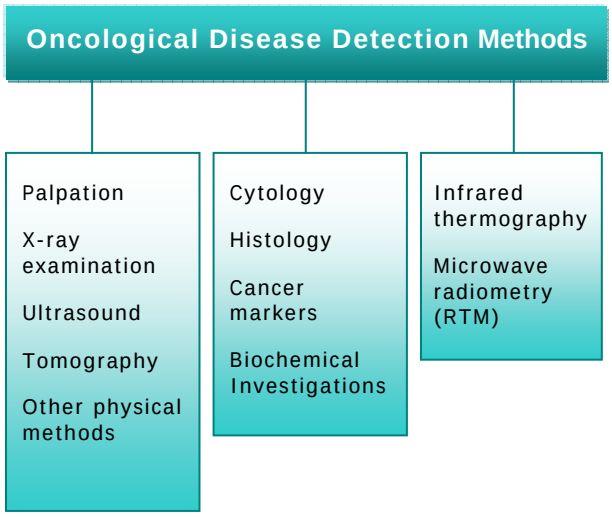

Fig. 1

In the second group the most reliable method is histology. However it is applied during or after the operation.

Applying cancer markers is developing, however they are best designed for monitoring of oncological diseases, and they are not always accurate.

5. Advantages of Microwave Radiometry

- ***Non-hazardous***

Microwave radiometry is non-hazardous both to the patients and to the personnel taking the thermograms, as during the examination the intensity of natural electromagnetic radiation from the patient's tissue is measured only.

- ***Non-invasive***

Temperature is measured non-invasively.

- ***Earlier detection of diseases***

It should be noted that thermal changes proceed to the anatomical changes that can be detected by traditional methods such as ultrasound, mammography and palpation. Thus microwave radiometry is a very promising method for earlier detection of breast cancer, and other conditions such as inflammation, hormonal imbalance, fibroadenomas and cysts.

Detection of fast growing tumours

The specific heat generation in the tumour is proportional to grow rate of the tumour. So fast growing tumours are "hotter" and are more contrasting in thermograms. Thus microwave radiometry is a unique method that may allow the earlier detection of most fast growing tumours. Using microwave radiometry (RTM-Diagnosis) in conjunction with other traditional methods allows the detection of patients with fast growing tumours [12].

Ability to detect patient with increased proliferative activity of cells

An important feature of Microwave Radiometry is that it can distinguish mastopathy and fibroadenoma with proliferation from mastopathy and fibroadenoma without proliferation. So the method allows us to detect patients who are at the greatest risk of having breast cancer.

Ability to monitor treatment

Microwave radiometry is non-hazardous to both the patients and to the personnel taking the thermal measurements, so it can be safely used for the monitoring of treatment including surgery, chemotherapy, radiotherapy, leptin resistance diet, detoxification and hormone balancing etc.

6. Historical Reference

The temperature of the human body (oral temperature) was measured for the first time with the help of a mercurial thermometer (which had been just developed) in Germany in 1851. Since then temperature and its dynamic analysis has become one of the traditional diagnostic methods. Non-invasive measurement of internal organ temperatures began one hundred years later due to the development of night vision equipment during the Second World War.

By this method the skin temperature was measured. The skin temperature partially reflects internal organ temperature, due to heat transfer. 20 years later (1972) the first investigation of measuring internal tissue temperature (tumours of mammary gland) were held. The measurement was based on receiving natural electromagnetic radiation at microwave frequencies. These studies were successful, as tissue is transparent enough for waves of this frequency range.

The first work that recognized microwave radiometry as a method for detecting breast cancer was published in 1977. Later this subject was discussed in literature [4, 6, 8, 10]. However to this present day the method has not been used widely in medical practice.

7. Thermal Diagnostic Methods and Tumour Growth

The tumour growth dynamics is characterized by the doubling time of a tumour (mass or the number of cells). The doubling time (DT) is a constant for a specific patient in spite of the fact that it varies widely

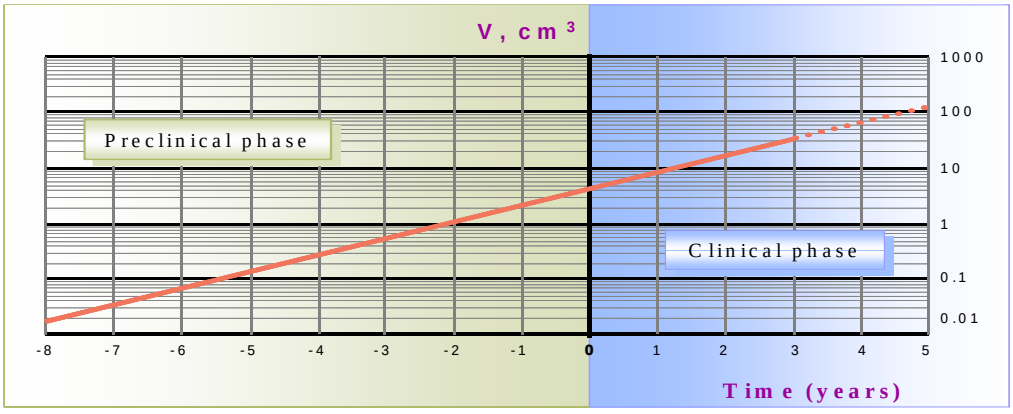

Fig. 2

(from 3 days to hundreds of days for different patients). Biological history of tumour growth may be divided into preclinical and clinical phases. The border between these phases is relative as it is determined by diagnostic equipment abilities. Therefore it is natural to apply the tumour growth behaviour studied for the clinical phase to the preclinical phase (doubling time is constant for a specific patient). The tumour growth is shown in ***Fig. 2.***

When the doubling time is constant the tumour growth is represented by the exponential curve. It should be noted when the tumour mass doubles the tumour diameter increases $\sqrt[3]{2}$ times. Also tumours with short doubling time have a high specific heat generation (Watt/cm^3). As when the tumour grows rapidly, energy consumption increases and so heat generation rises. This relationship is shown in ***Fig. 3***.

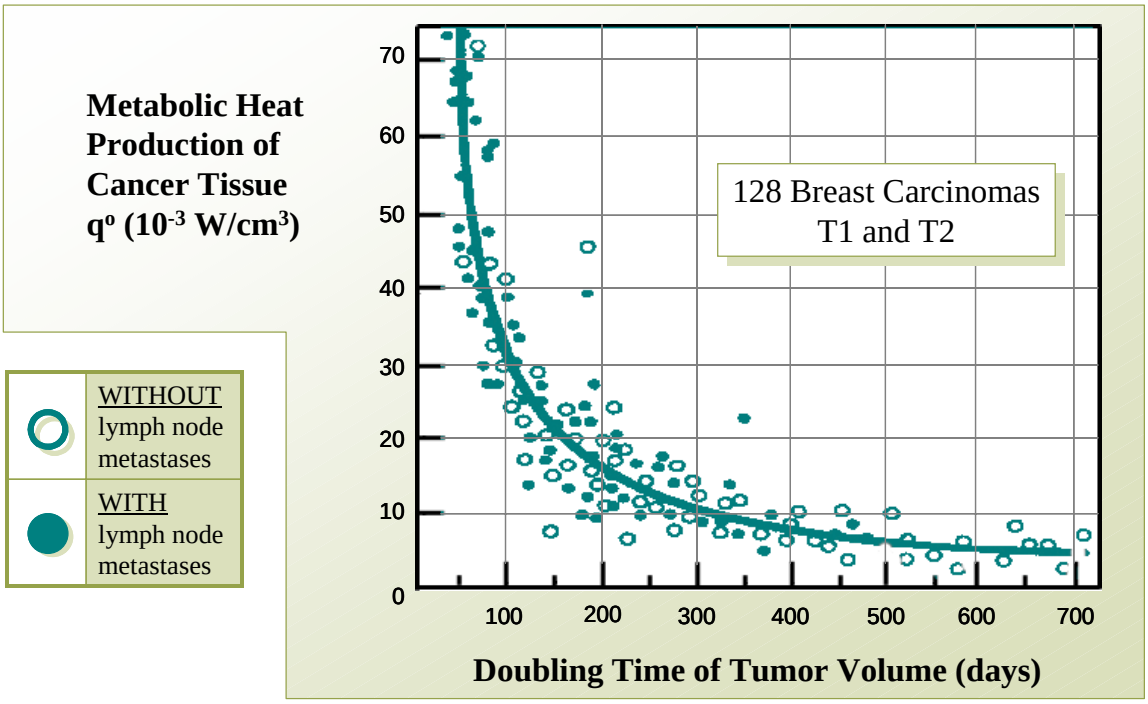

Fig. 3

Therefore most of dangerous tumours (tumours with short DT) can be detected by thermal methods first of all. It means that the thermal method allows the detection of patients with rapidly growing tumours. According to current data these patients are a quarter of all breast cancer patients.

8. Heat Transferring in the Bio-object

Gautherie made the best explanation of heat transfer within breast tissues. Therefore I will quote his work [1]. In according to M. Gautherie "temperature and blood flow pattern in cancerous mammary tissues," result from two phenomena: heat transfer from the cancer into the surrounding tissues, and vascular reactions.

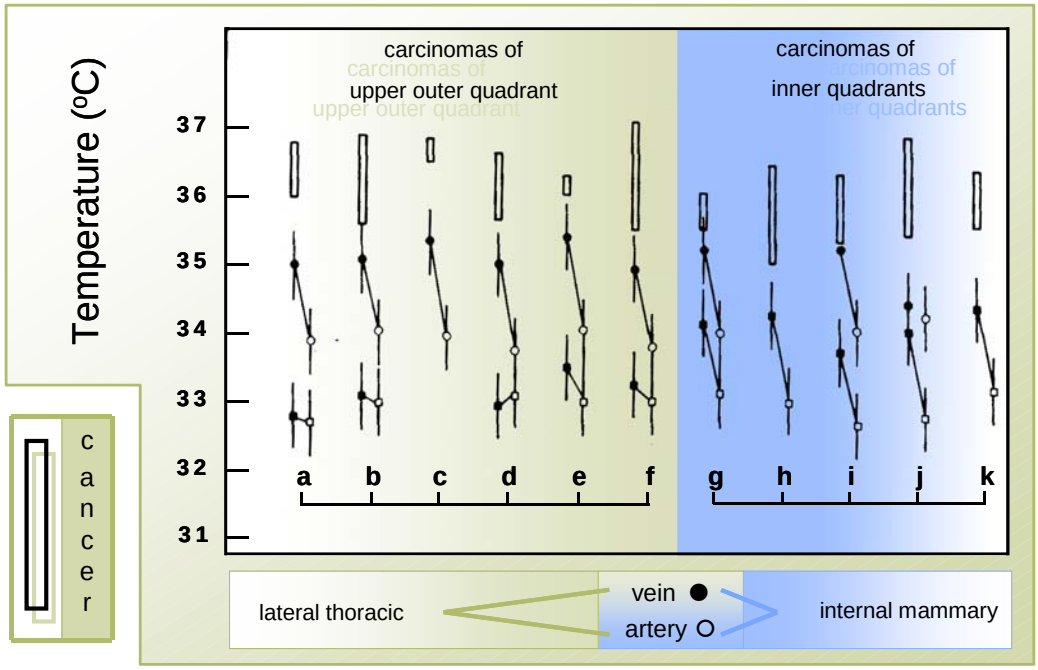

Fig. 4 *Tumour and blood temperature in breast carcinomas. An example of a series of measurements of tumour temperature and venous and arterial blood temperature taken during surgical management (mastectomy) of mammary carcinomas with various localizations. Measurements were carried out by means of thermometric fine-needle probes; five times for each temperature (the vertical segment indicates standard deviation from the mean value). In all cases investigated, tumour temperature was significantly higher than blood temperature, and venous blood temperature was higher than arterial blood temperature.*

Heat transfer occurs by tissue conduction as well as blood convection. However, from the physiologic viewpoint, it seems to be more appropriate to distinguish between the two following processes (***Fig. 5***):

1) "Effective" conduction, including conduction in the physical sense (Fourier's law) and convection by the capillary vessels assumed to be distributed isotropically (see above);

2) Convection through the relatively large vessels, the veins essentially, according to Newton's law. It is noteworthy that maximal capacity of heat transfer by convection through large vessels is much higher than by tissue conduction and capillary convection, up to 100 times, approximately. Nevertheless, the relative contribution of the various processes depends on the actual vascularisation, which is largely different from one breast to the other, particularly under malignant conditions. Furthermore, conduction of heat is easier along the galactophorous ducts as was demonstrated by intramammary measurements. This anisotropy of thermal conductivity may explain the relative hyperthermia of the nipple observed in some carcinomas, depending on tumour localization.

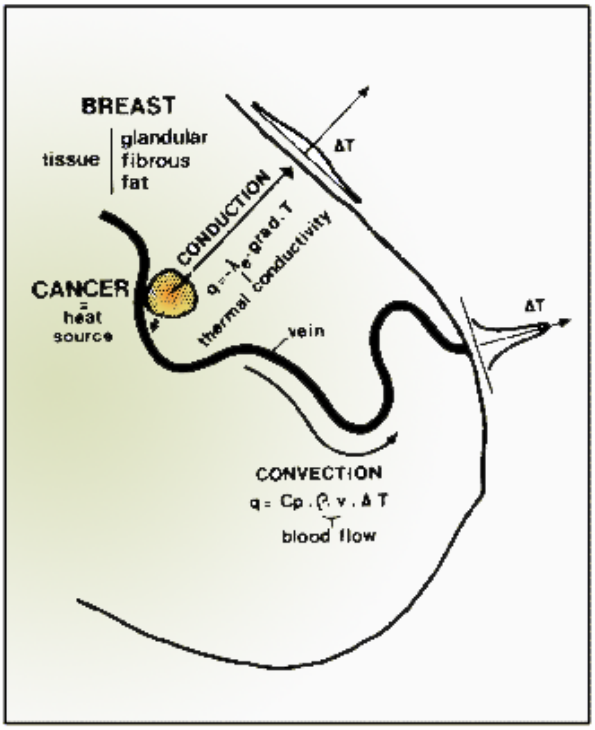

Fig. 5.

Breast thermokinetics. The metabolic heat produced by the tumour is transferred to the surroundings tissues, particularly towards the skin, through two pathways:

1) *by conduction and capillary convection according to Fourier's law (the quantity of heat transported is a function of the thermal conductivity (λ_e), which depends on the type of mammary tissue either glandular, fibrous or adipose);*

2) *by convection by large vessels according to Newton's law (the quantity of heat transported is a function of the blood flow; Cp., heat capacity; P, density; v, rate of blood). Through these processes of heat transfer, as well as from vascular reactions, increase in skin temperature (ΔT) is generally associated with cancer.*

9. Temperature Pattern in Human Tissue

In some parts of a human body the temperature is constant due to homeostasis. This temperature is approximately equal to the temperature measured in axial, oral and rectal areas (36.5°C – 37.0°C). The central nervous system, thoracic organs, the abdominal area, all has a constant temperature.

When the room temperature is 20 – 25°C the skin temperature lowers to 32 – 33°C so there is a temperature gradient between the skin temperature and the internal temperature.

This temperature gradient and its dynamics, depending on room temperature, are shown in ***Fig. 6***.

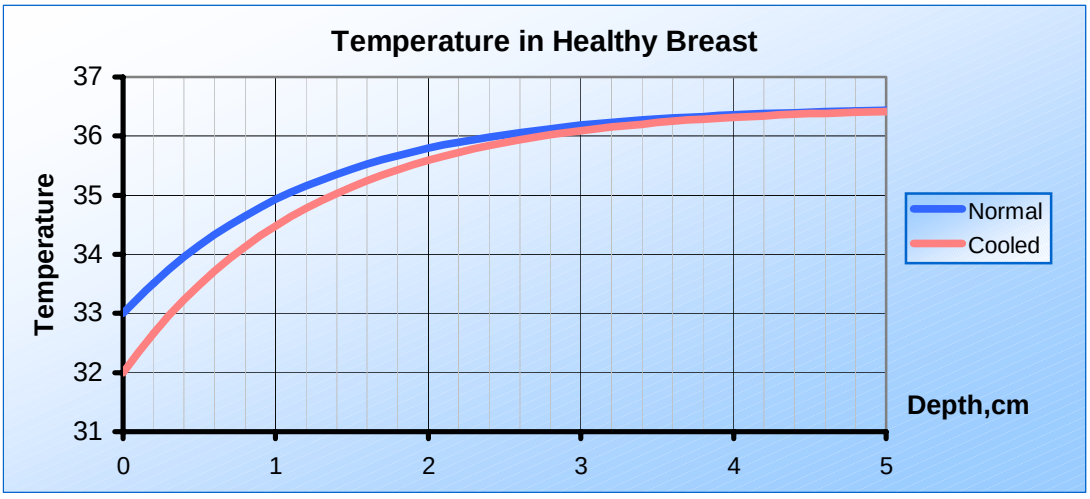

Fig. 6

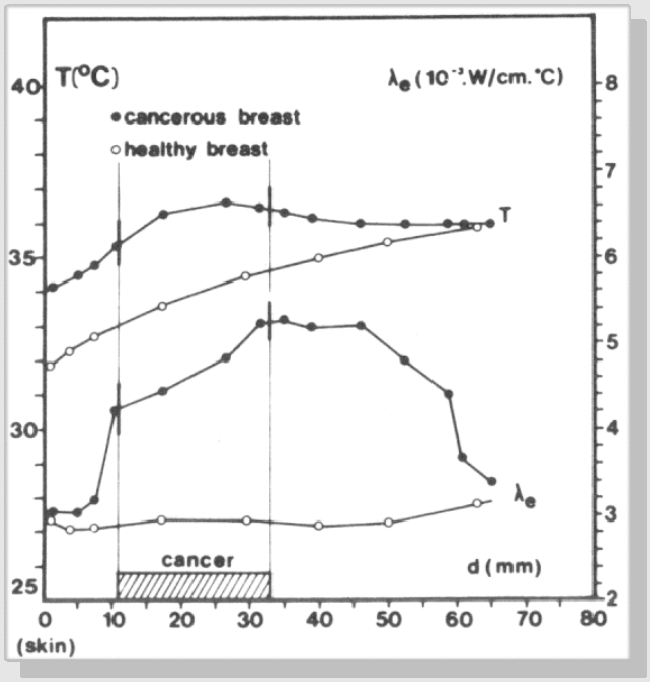

Fig. 7

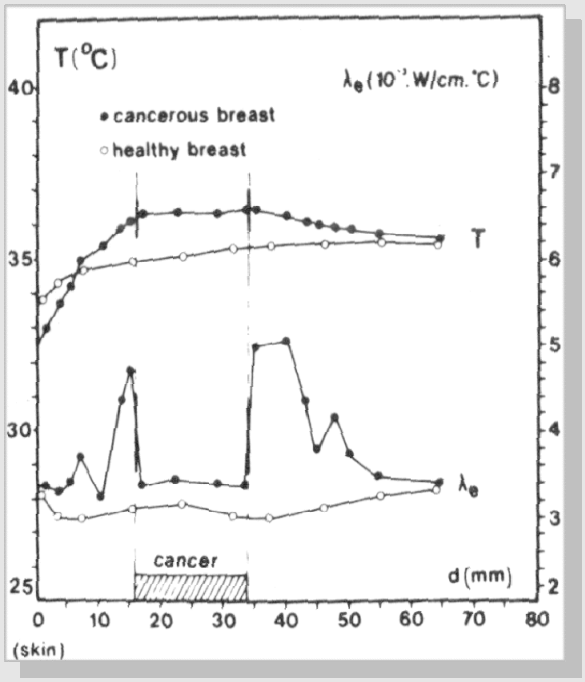

Fig. 8

Fig.7 shows results obtained by Gautherie [1] with the help of fine-needles.

We can see that the temperature in cancer is three degree higher than the temperature in the healthy breast. In this example the skin temperature near the tumour is 2 degree higher than the skin temperature in the healthy breast too.

Also, Gautherie published the diagram, when the skin temperature near the tumour is less than it is in the healthy breast ***(Fig. 8)***.

10. Cancer tumour temperature.

Gautherie in [13] published his data of the cancer. These data you can see in ***Fig.9***.

On the base of these data we have written a very simple equation of the tumour temperature.

$$T = k \cdot \frac{R^2}{D_T} \cdot B \text{, where}$$

k – constant;

R – tumour radius;

D_T – doubling time of the tumour;

B - BIOT'S number.

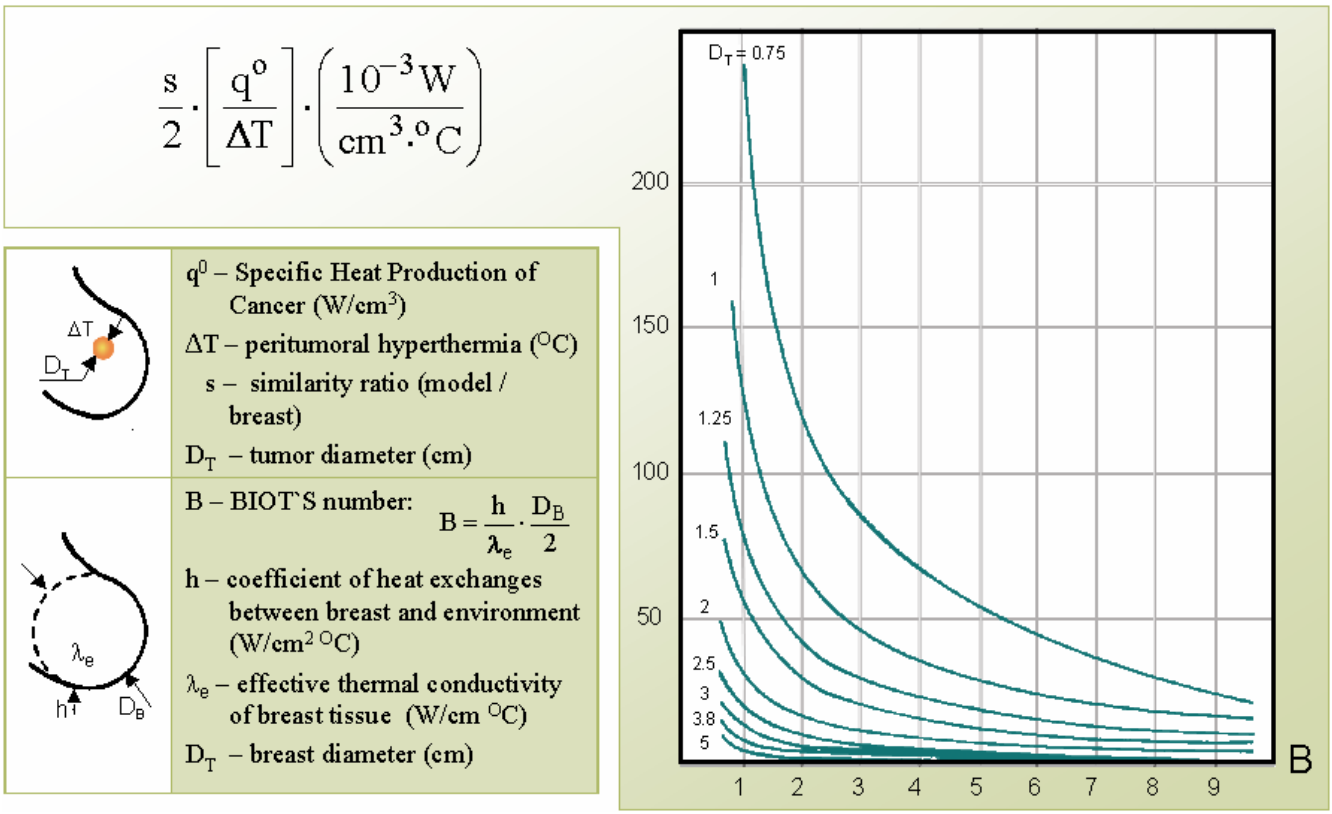

Fig. 9 *Rheoelectric simulation of heat transfer conditions in cancerous breasts: Experimental chart giving the specific heat production of cancer tissue (q^0) versus peritumoral hyperthermia (ΔT = temperature difference between the periphery of the tumour and the symmetrical area on the contralateral healthy breast), Biot's number (B), and tumour diameter (D_T). These curves, fitted by hand from the analogue model of heat transfer, allow direct evaluation of q^0 from measurements of geometric parameters on mammography (s, D_T, and D_B), and thermal parameters (ΔT and λ_e). On account of the ranges of variations of λ_e and D_B, q^0 does not depend on tumour depth. The coefficient h may be assumed to be constant and equal to 1 x 10^{-3} $W/cm^2/^oC$ under controlled conditions (room temperature at 21 ± 1°C, no air draughts).*

11. Electromagnetic Radiation from Heated Objects

According to the law of physics, any object above zero degrees Celsius emits radiation at all frequencies and, in particular, in the microwave region, that is used in microwave radiometry.

This feature of heated objects is used for measuring averaged internal tissue temperature and detecting thermal abnormalities (higher or lower temperature of internal tissue).

The noise power received by the antenna contacted an evenly heated absorbing object is:

$$P = kT\Delta f \text{ , where}$$

k - Boltzmann's constant (1.38 x 10^{-23} Dg/°K)

Δf – System bandwidth,

T – Temperature of the biologic object

Therefore the power noise received by the antenna is proportional to the tissue temperature.

When the object temperature is 309°K, i.e. 36°C the noise power received by the antenna is $3x10^{-13}$ Watt. This value corresponds with the noise generated by the antenna. Special methods are applied for receiving and processing signals.

12. Propagation of Electromagnetic Waves in the Body

Bio-objects usually examined consist of several layers (e.g. skin – fat – muscle). Each layer has different absorption of electromagnetic wave and different depth penetration of electromagnetic wave in the tissue. Depth penetration it is the depth in which the energy decreases in **e –** times. ***Fig.10*** demonstrates the depth of penetration for plane wave in the body for different tissues.

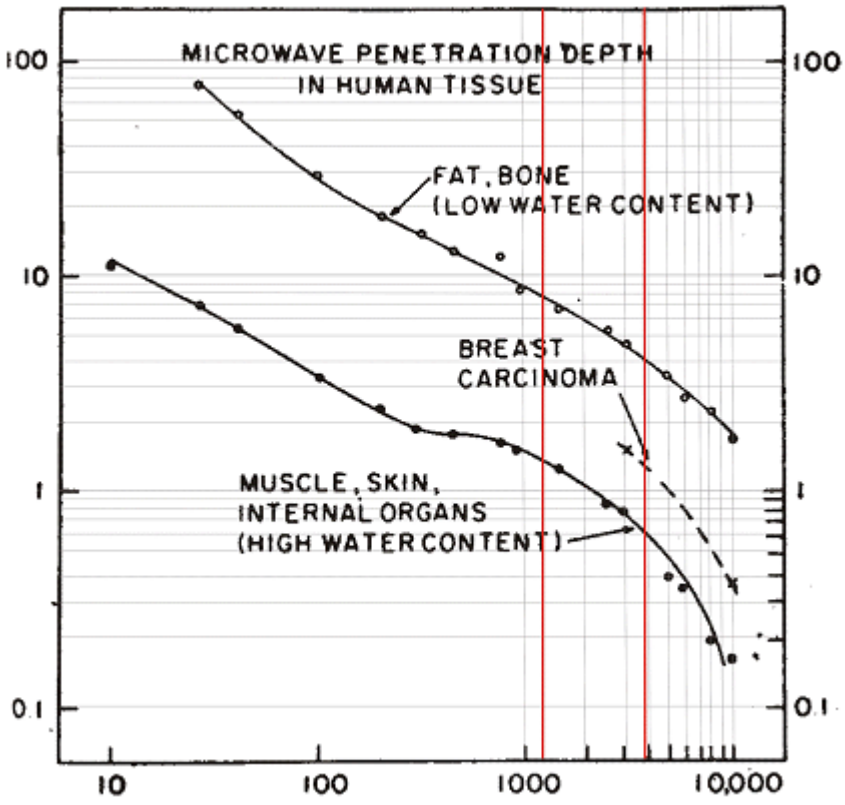

Fig.10

The radiation power passes through all parts of tissue with different losses and different temperatures, so the temperature measured by the antenna is not equal to the physical temperature of the examined organ, but depends on the temperature of other parties of the body and losses in these parts.

The exponential law of distribution describes propagation of plane waves in the body.

$$P = P_0 \cdot \exp^{-G \cdot z}, G = i\beta + \alpha \text{ , where}$$

α – attenuation per unit in environment

β – propagation factor of electromagnetic wave;

P_0 – input power

The attenuation per unit in tissue depends on the water content of tissues. The tissues may be divided into two groups. The first group includes low water content tissue, which is represented by fat and bone. The attenuation per unit of the tissue is low. It is 20-30% (0.5-0.7dB/cm).

The attenuation per unit of skin and muscle (high water content tissue) is greater. It is about 50% (3dB/cm).

For infrared, bio-tissue is not transparent thus radiation attenuates at a depth of several microns.

13. Brightness Temperature

The power of radiation from all tissues passes through layers with different losses and different temperatures, so the temperature measured at the output of the antenna is not equal to the physical temperature of the investigated organ. This temperature depends on temperature of several layers of the body and losses in these layers.

This measured temperature is called brightness temperature and

$$T_{br} = \int_v T(r) * P(r) dV \text{ , where}$$

T(r) – temperature in the tissue;

P(r) – Radiometric Weighting Function and

$$P(r) = \frac{\sigma |E(r)|^2}{\int_v \sigma |E(r)|^2 dV},$$

where

σ – conductivity of the tissue;

$|E(r)|$ - Electromagnetic field of the Antenna in the tissue.

The conductivity of normal tissue and malignant tissue is shown in ***Fig.11*** [10].

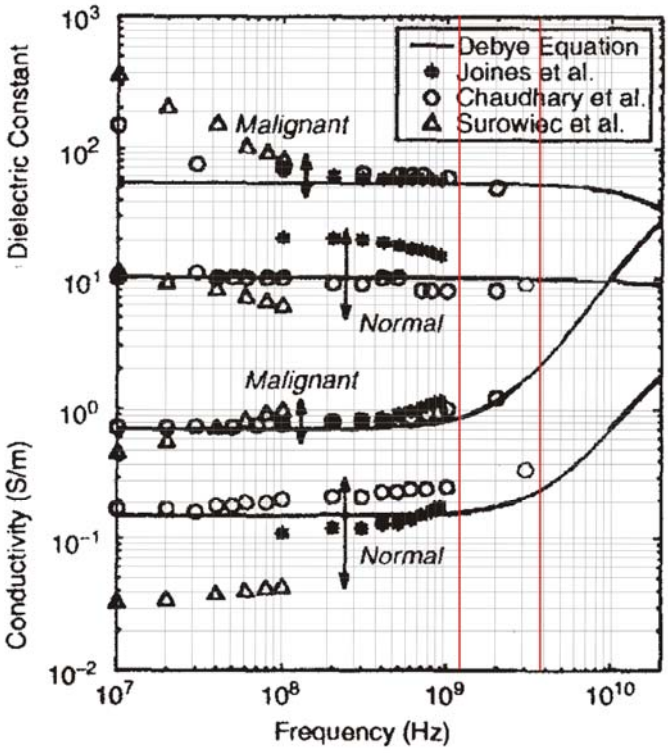

Fig.11

The brightness temperature is the averaged temperature in volume (cylinder) under the antenna. The diameter of the cylinder is 4 cm; the depth is 3-7 cm, depending of water content.

Fig.12 shows the area in which RTM measured the temperature.

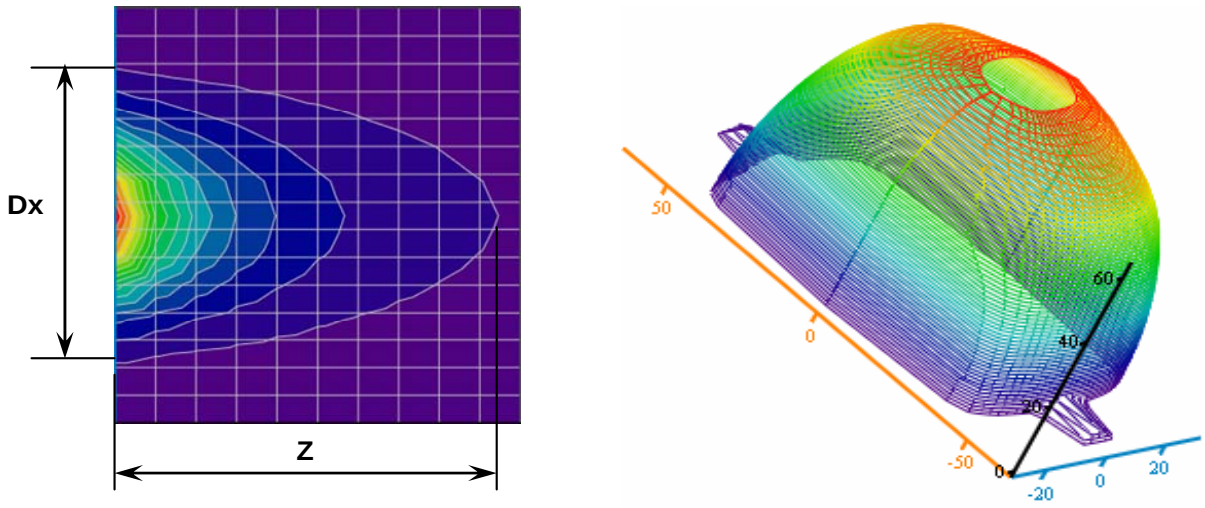

Fig.12 *Energy distribution*

We can see that 80% of energy is placed in the volume 43cm^3 and the size of the area is 3.8 x 3.2 x 4.3 cm.

Widths of Antennas

Table 1

ENERGY	Dx, cm	Dy, cm	Z, cm	V, cm^3
20	1.45	1.2	0.8	1.4
30	1.7	1.6	1.2	2.6
40	2.1	2	1.6	4.5
50	2.5	2	2	7.1
60	3	2.4	2.4	10.6
70	3.4	2.8	3.2	21.2
80	3.8	3.2	4.3	43
90	4.2	4	6.2	112.3
95	4.5	4.8	8.4	273.7

Also, ***Fig.12*** shows that the measured volume is rather large. That's why breast RTM-examination very often reflects lung inflammation (especially if the breast is small).

14. Device Structure

Fig.13 *RTM-01-RES microwave computer based system*

In 1997 RES Ltd. developed the RTM-01-RES computer based microwave radiometer. The system is shown in ***Fig.13***.

RTM-01-RES is safe and simple in operation. It does not require a calibration procedure and is always ready for measurements.

The system consists of the following items:

- Internal Temperature Sensor (ITS) with the antenna;
- Skin Temperature Sensor (STS);
- Data Processing Unit (DPU).

The system includes a personal computer and a printer. The device is connected to a PC through a serial port. The results of the investigated organ are shown on the monitor of the computer or printed as a thermogram and temperature field.

The advantage of the method is the expert system for breast cancer detection. The expert system analyses several parameters, including thermal asymmetry, dispersion of the temperature within the breast, etc.

15. Technical Specifications of RTM-01-RES

The technical specifications of the RTM-01-RES are the following:

Table 2

Items	Specifications
Depth of detection of a thermal abnormality (higher or lower temperature)	**3 –7 (depending on water content)**
Accuracy of measuring the internal temperature, when the temperature range is 32 - 38°C, seconds	**± 0.2°C**
Time of measuring internal temperature at one point, second	**8**
Applicator diameter, mm	**39**
Accuracy of skin temperature measurement, °C	**±0.2**
Time of measuring skin temperature at one point, second, when the temperature range is 32 - 38°C, seconds	**1**
DPU weight, kg	**4**
Power supply	**230 ± 23 Volt, 50-60 Hz**

The device complies with the requirements of the European standards EN 60601-1-2:2003, class 1, type B.

16. Functional Scheme of RTM-01-RES

The device is a modulated null-radiometer with a slipping circuit for compensating reflection between the biological object and the antenna. The used wavelength is 26 cm. The scheme of the device is protected by the patent of the Russian Federation [11]. The functional scheme is illustrated in ***Fig.12***.

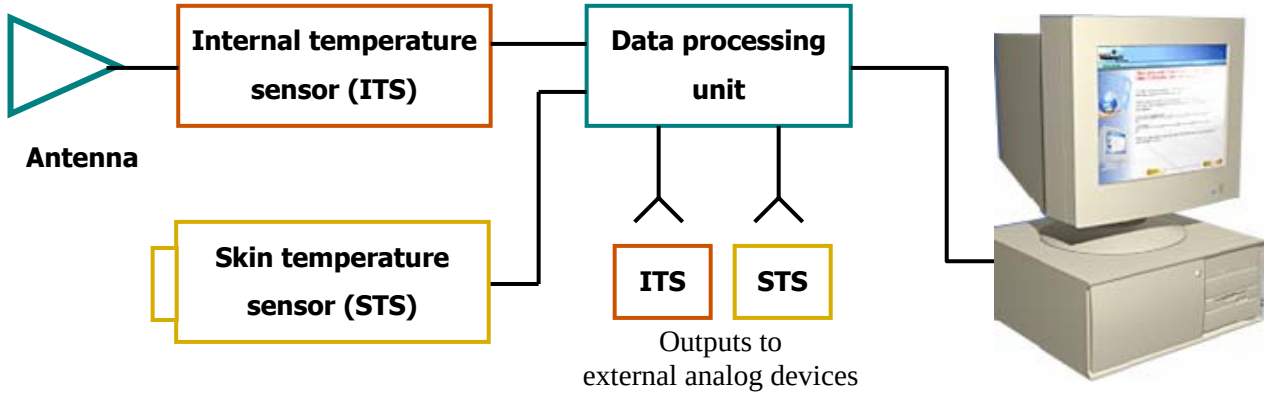

Fig. 14 *Functional scheme of RTM-01-RES*

When the temperature is measured, the antenna's position on the patient's skin is in accordance with the computer diagram of the examined organ. The antenna receives microwave radiation from the examined organ as noise at microwave frequencies and the signal is amplified in the Internal Temperature Sensor (ITS).

The signal amplified in the ITS is transmitted to the Data Processing Unit (DPU), where it is processed.

The voltage from the Skin Temperature Sensor (STS) is transmitted to the DPU too. The skin temperature sensor is non-contact infrared frequencies receiver.

The buttons located on the front cover of the data processing unit switches the modes. The internal and skin temperature values are displayed on the 3-digit temperature indicator as degrees Celsius with an accuracy of 0.1.

The Data processing unit produces a series of digital signals for interfacing with the PC.

On the front cover there are a temperature indicator, INTERNAL TEMPERATURE SENSOR and SKIN TEMPERATURE SENSOR button, and POWER) power indicator. On the rear panel of the DPU there are connectors for connecting with the Internal Temperature Sensor (15-pin and coaxial connectors), as well as a PC 9-pin connector, and 9-pin connector for the Skin Temperature Sensor (analogue signals that are on this connector has positive polarity with scale factor of 0.01V/degree). Also the power switch and fuses are on the rear panel.

17. Visualization of Internal Temperature Fields

In some works discussing microwave radiometry temperature data is displayed as a diagram ***(Fig.15)***, when the names of the measured points go along the horizontal axis and the internal temperature values are along the vertical axis.

This method allows analysis of temperature differential between corresponding points on the left and right breasts. However it is difficult to analyse the temperature at various locations on one entire breast by this method.

Therefore the temperature data are also displayed as a temperature field that is used in infrared thermography ***(Fig.16)***.

In the temperature field, cool areas of the breast are displayed by "cold" colours (i.e. blue) and hot ones are reflected by "warm" colours (red and orange).

Internal temperature fields show temperature abnormalities, in particular, corresponding to the location of a cancer.

Note that for medical personnel it is easier to analyse temperature data displayed as a thermogram or temperature field, than numerical values of measured temperature.

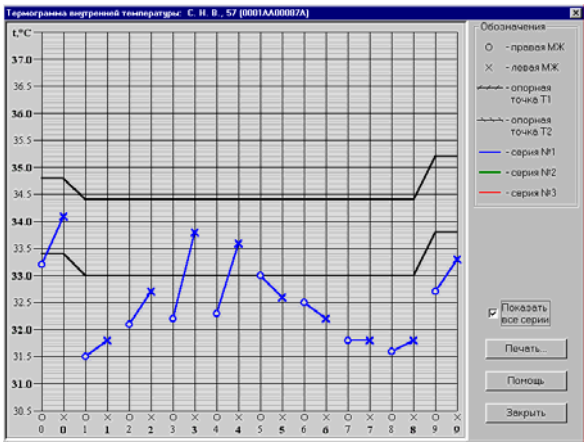

Fig.15

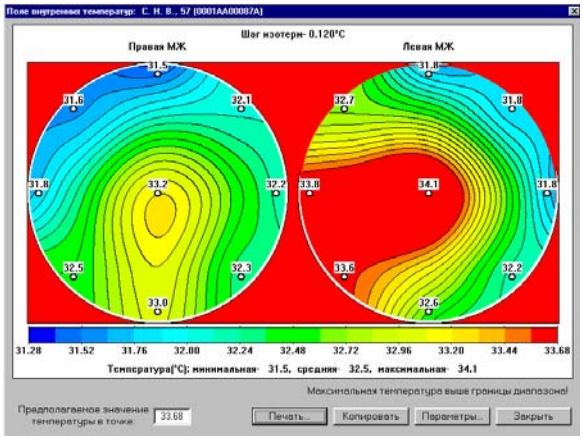

Fig.16

18. Clinical Trials of RTM-01

The clinical trials were held under the direction of leader Russian specialists at five Moscow medical centres [12-15]. As follows:

- Branch #1 of the Mammology Health Centre;
- Municipal Clinical Hospital #40;
- The Research Institute of Clinical Oncology of the Oncological Scientific Centre under the Russian Academy of Medicine Sciences (RAMS);
- The Oncological Health Centre of the Moscow Health Care Committee;
- The Main Military Clinical Burdenko Hospital of the Defense Ministry of the Russian Federation.

The purpose of the clinical trials was to estimate the ability of the RTM-01-RES system to detect breast cancer and monitor the treatment of benign tumours. At the Oncology Health Centre of the Moscow Committee of Health, specialists estimated the ability of the RTM-01-RES to select high-risk patients. The high-risk patients are patient that should undergo complex diagnostic investigation. The results of RTM-diagnosis were compared with ultrasound and mammography.

RTM-diagnosis was carried out independently from clinical, x-ray and other examinations. The results of RTM-diagnosis were compared with results reported by histology. They were blind clinical trials (a doctor did not know results reported by other methods).

The results of the clinical trials [12-15] are displayed in ***Fig.17***.

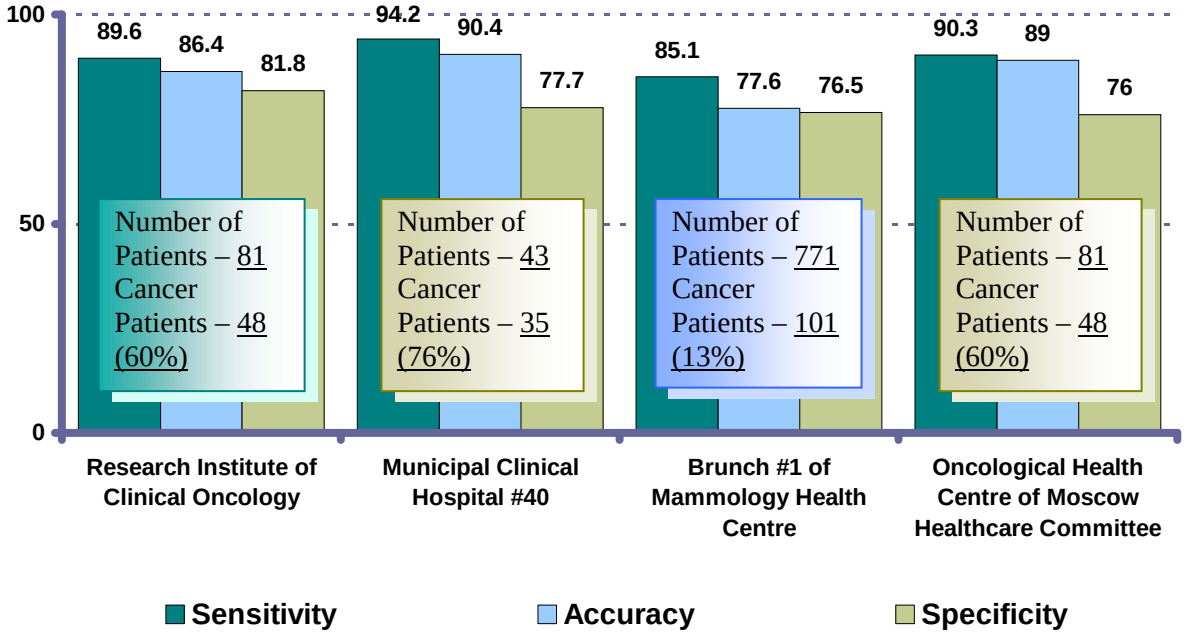

Fig. 17

The ***Fig.17*** shows that all data are coordinated. The sensitivity of the method is 85-94%, the specificity is 75-80%, and the accuracy is 77-90%. These results are comparable with results of mammography.

Within the framework of the investigation the results of RTM-diagnosis, mammography and ultrasound were compared with histology results.

The results of breast cancer detection for various diameters of tumour are shown in the ***Table 3*** [12-15].

Table 3

№	Tumor Diamter (cm) According to Mammography	Num.	%	Thermo-positive		Thermo-negative		Risk Group		Uncertain Conclusions	
				Number	%	Number	%	Number	%	Number	%
1	Mammography does not see any tumors	29	9,2	19	65,5	6	20,7	4	13,8	0	0
2	Less 1,3 cm	19	6	10	52,6	2	10,5	5	26,3	2	10,5
3	1,3 ≤D< 1,8	45	14,2	26	57,7	6	13,3	12	26,6	1	2,2
4	1,8 ≤D< 2,3	58	18,3	36	62,1	4	6,9	16	27,6	2	3,4
5	2,3 ≤D< 2,6	49	15,5	39	79,6	2	4,1	6	12,2	2	4,1
6	2,6 ≤D< 3,6	42	13,3	37	88,1	3	7,1	2	4,8	No	0
7	3,7 ≤D< 7	37	11,7	33	89,1	1	2,7	3	8,1	N0	0
8	Diffuse-Infiltrative	11	3,5	10	90,9	No	0	No	0	1	9,1
9	No Information	26	8,2	22	84,6	2	7,7	2	7,7	N0	0
10	THE SUM	316	100	232	73,4	2,6	8,2	50	15,8	8	2,5

The results are represented in ***Table 4***.

Table 4

	Ultrasound	Mammography	RTM-*Diagnosis*
Number of breast cancer patients examined	**30**	**31**	**31**
Number of positive results	**25**	**24**	**28**
Number of false results	**1 –** fibroadenoma **4-** mastopathy	**5-** mastopathy **2 –** fibroadenoma	**3**
Detective ability (sensitivity)	**83.3%**	**77.4 %**	**90.3 %**

This table shows that RTM-Diagnosis distinguishes mastopathy and fibroadenoma with proliferation from mastopathy and fibroadenoma without proliferation well. Thus one of the advantages of RTM-Diagnosis is to select patients with proliferative fibroadenoma and mastopathy. Other diagnostic techniques cannot do this as they detect anatomical changes in the breast. RTM-Diagnosis provides a doctor with information on active processes within the breast.

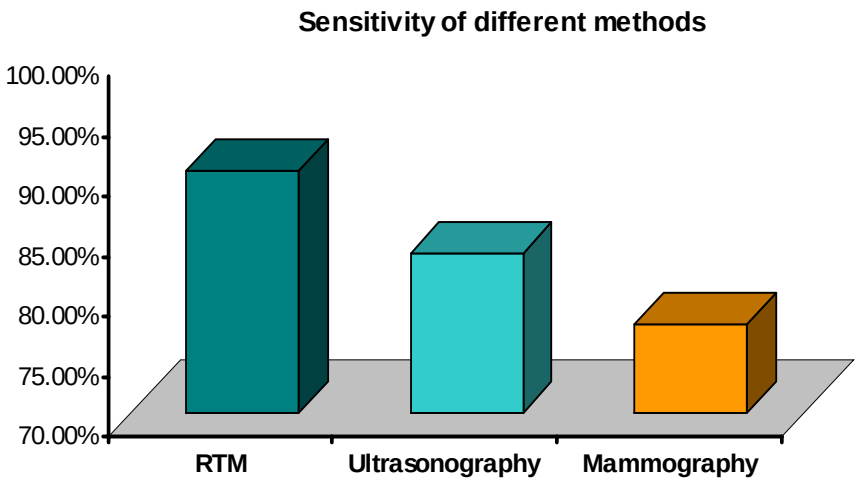

Fig. 18

Thus in 82% of all cases RTM-Diagnosis selected proliferative mastopathy and fibroadenoma as risk group patients correctly. Ultrasound selected 18% and mammography – 36.3%.

Table 5

Disease	Number of examined patients	Ultrasound	Mammography	RTM-Diagnosis
Mastopathy and fibroadenoma with proliferation	11	2 – cancer 4- mastopathy 5- fibroadenoma	4 – cancer 6 – mastopathy 1- fibroadenoma	9- Thermogram shows RTM-features of risk group 2- there are no RTM-features
Mastopathy and fibroadenoma without proliferation	18	12- mastopathy 4- fibroadenoma 2 – not performed	14 – mastopathy 2 – fibroadenoma 1 – cancer 1 – not performed	3 – Thermogram shows RTM-features of risk group 15– there are no RTM-features

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