Approved by
the Chief of Scientific Research
Blokhin Institute of Clinical Oncology,
Doctor of Medical Science,
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14 May, 1998

Clinical Trial Protocol of the RTM-01 Radiometer, Developed by RES Ltd

Over the period from February 10th to May 14th, 1998, the clinical trial of the RTM-01 radiometer, developed by RES, Ltd. was conducted at the Blokhin Scientific Research Institute of Clinical Oncology. The trial was in the diagnostic and surgical department.

1. The Purpose and Methods of the Trial

The purpose of the trial is to estimate the ability to use the RTM-01 radiometer in medical practice. In this case the ability to detect breast cancer was checked.

The RTM-01 №092 radiometer was chosen for the trial. The RTM-01 radiometer is a modulated null-radiometer with a slipping circuit for compensating the reflection between the biological object and the antenna.

The device scheme is protected by the Russia patent #2082118.

The device operation bases on measuring the intensity of natural electromagnetic radiation from a patient's internal tissues at microwave frequencies.

Radiation is received by antenna, which is set on the projection of the organ examined. Diagnostics of disease bases on analyzing a thermal abnormality (increase or fall in temperature of tissues in comparison with the temperature of surrounding tissues).

The cause of the thermal abnormality, in the case of breast cancer, maybe an increase in internal tissue temperature, which accompanies increased cell metabolism in the area of the tumour.

The basic medical and technical parameters of the RTM-01 radiometer are the following:

- Thermal abnormality is detected at the depth - 3….5cm;
- Accuracy of measuring the averaged internal temperature - ± $0{,}2^0$C;
- Time of measuring at a point - 15s;
- Antenna diameter - 39mm;
- Power consumption from 200V 50Hz network – 20Watt;
- Weight of the basic set - 4kg.

Temperature data are displayed as a three-digit number on a panel with discreteness of $0{,}1\ ^0$C.

The radiometer may be connected with PC computer, using serial port, or temperature data may be input into computer manually.

Software for storing data of patients, a brief anamnesis, displaying and processing the results of measurements was supplied.

Patients were examined on 6-9 days from the first day of their menstruation period.

The temperature of the breast was measured according to scheme, which is represented in Appendix. The temperature was measured at nine points and at lymph node points.

Tested patients lay on the back with the hands behind the head in order to normalize the arrangement of the measured points and increase the total accuracy of measurement due to the breast was flattened naturally in this position. Also a physician could measure the temperature at lymph node points in this position.

Radiometric examinations were carried out independently on clinical, x-ray and histological examinations. Diagnostic software was used to analyze the results of measurement and to diagnose. The diagnosis of breast cancer based on the comparison of the internal temperature field of a current tested patient with internal temperature fields of verified breast cancer patients. The average temperature of the breast, temperature diversity within one breast, thermal asymmetry between the breasts and other characteristics (total 6) were under consideration.

Once the trial was complete the radiometric results were compared with the result of histology.

2. Results of the Trial

A total of 81 women were examined with the help of the radiometer.

According to the histology results 48 women were diagnosed with breast cancer.

According to the radiometric results 43 women were diagnosed with breast cancer (true positive diagnosis TP).

Five women diagnosed with breast cancer had no enough radiometric features (RTM-features) of breast cancer (false negative diagnosis FN).

27 women diagnosed with non-oncologic disease had no RTM-features of breast cancer according to radiometric results (true negative diagnosis TN).

Six women diagnosed with non-oncologic disease had RTM-features of breast cancer (false positive diagnosis FP).

3. Resume

1. The RTM-01 radiometer has small dimensions, weight and power consumption. It can be easily transferred within a hospital.
2. It is easy to operate the RTM-01 microwave radiometer. There are no external adjustment elements on the device.
3. The utilization of the device is absolutely harmless for patients of any ages and with any diseases as well as for physicians. So examinations may be repeated to analyze dynamics of disease.
4. The device was used for more than 100 hours. Over this period there was no failures.
5. The sensitivity of the method (detective ability of breast cancer) is:

   TP/(TP+FN) x 100% = 43/(43+5) x 100% = 89,6%

   The accuracy of the method is:

   (TF + TN)/(Studies number) x 100% = (43+27)/81 x 100% = 86,4%

   The specificity of the method is:

   TN/(FP+TN) x 100% = 27/(27+6) x 100% = 81,8%

6. Imaging when temperature values are linked with measured sites and isotherm lines are drown through sites having the same temperature help physicals to diagnose.

4. Conclusion

The RTM-01 radiometer developed by RES, Ltd. can be recommended to be used in medical practice for screening at consulting and oncology rooms and at specialized oncology and mammology centers for detection of breast cancer and monitoring of treatment.

The serial production of the device is recommended.

Signed by:

Head of diagnostic and surgery department

Doctor of Medical Science, Professor, Komov D. V.

Doctor of Medical Science, Professor, Hailenko V. A.

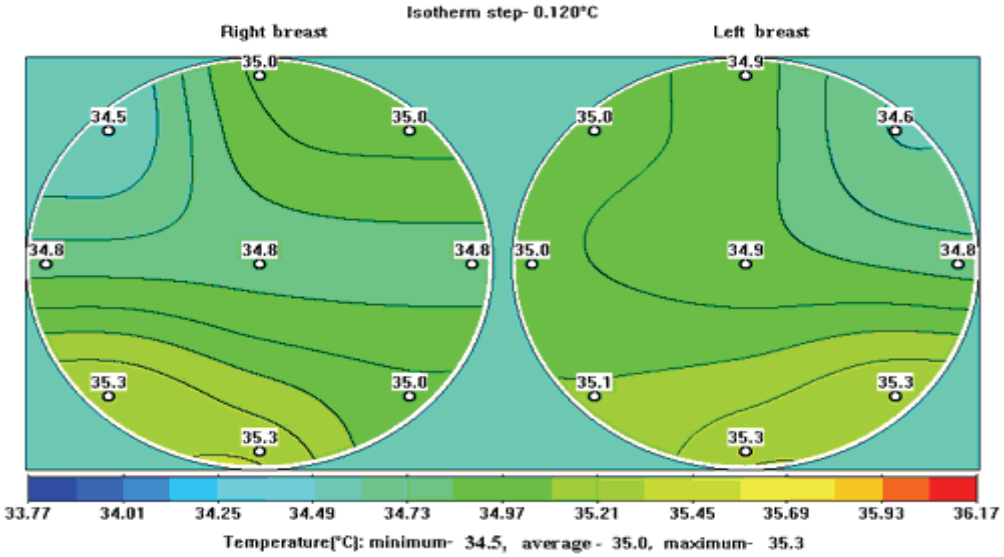
This is a translation, the original is in Russian.

Appendix: Protocols of radiometric examinations (3 protocols).

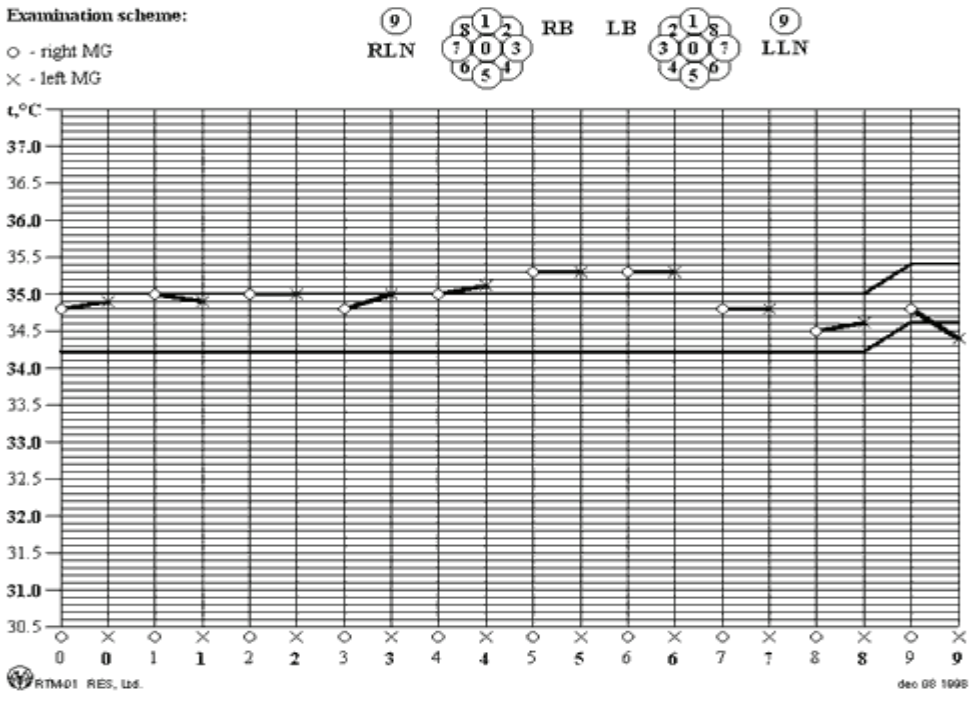
Examination protocol # 001AA00940A

Name:	D.T.Sh.	Age:	21 year old	History#	
Place:		SRI CO		Doctor:	Polykarpova S.B..

INTERNAL TEMPERATURE FIELD



THERMOGRAM



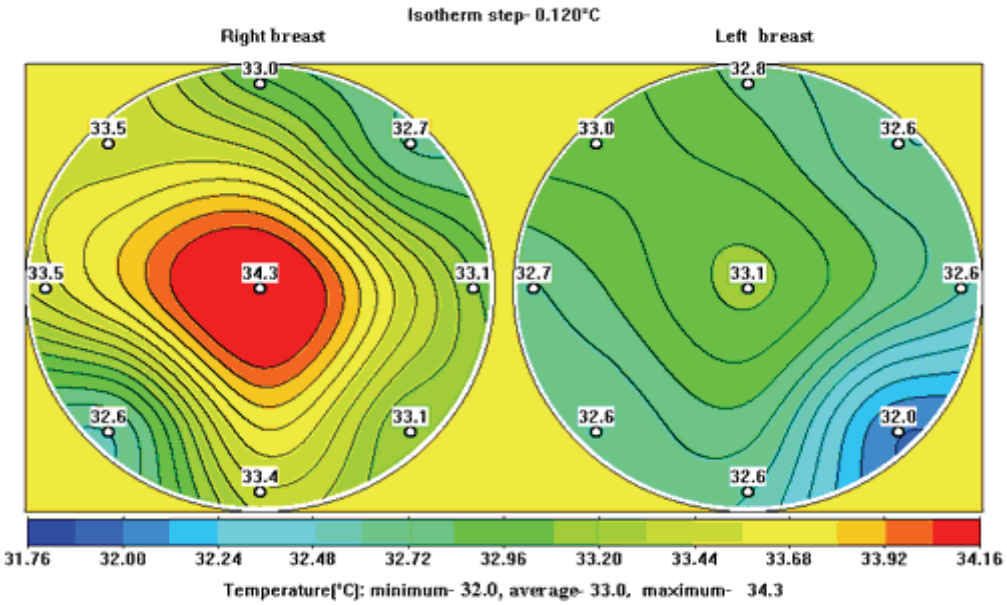
Diagnosis: No RTM-features of breast cancer.

D.T.Sh., 21 year old, had a clinical examination in the Blokhin Scientific Research Institute of Clinical Oncology. Diagnosis - fibrocystic mastopathy.

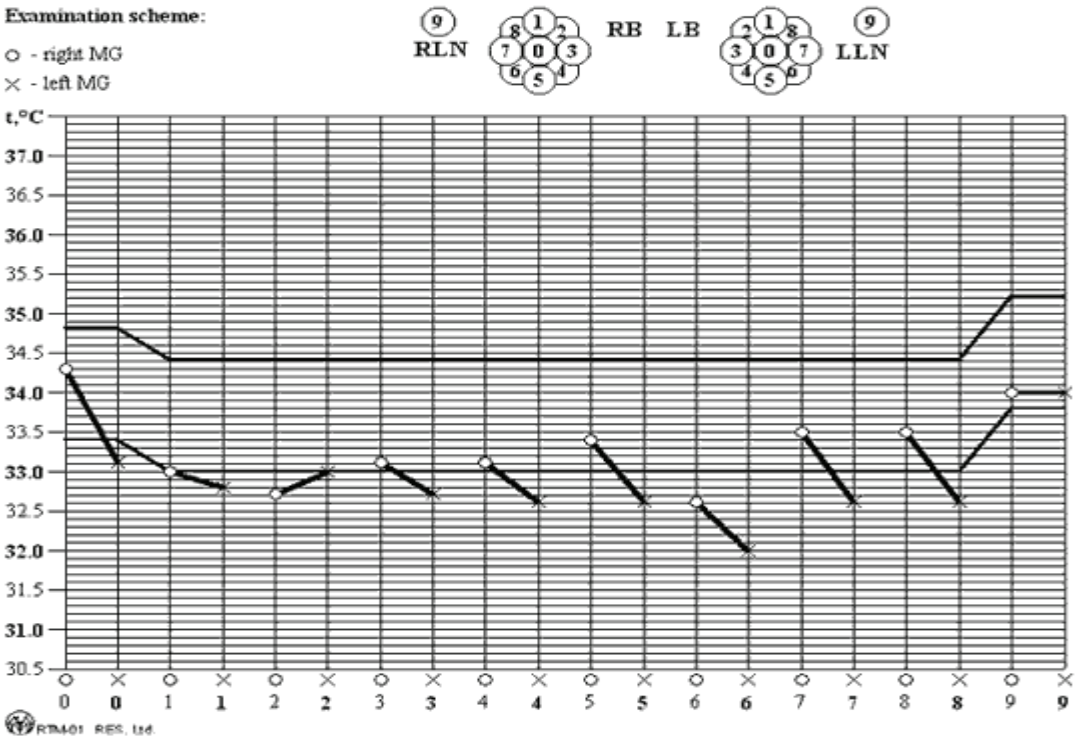
Examination protocol # 001AA00975A

Name.	K.M.G.	Age:	57 year old	History#	98/7792
Place		SRI CO		Doctor:	Polykarpova S.B.

INTERNAL TEMPERATURE FIELD



THERMOGRAM



Diagnosis: The thermogram shows the RTM-features of right breast cancer.

Extract from the history #98/7792

K.M.G., 57 year old, was treated from 1th April to 13th April, 1998. She had been diagnosed with right breast cancer $T_2N_1M_0$ IIA stage. The type of growth is multicentric.

A tumor on the right breast was being observed for two weeks. Cytology 22665-1# - cancer cells. There is a tumor of 3ŕ 2cm in the upper outer quadrant of the right breast. The tumor is solid, not very movable, without a fixed boundary.

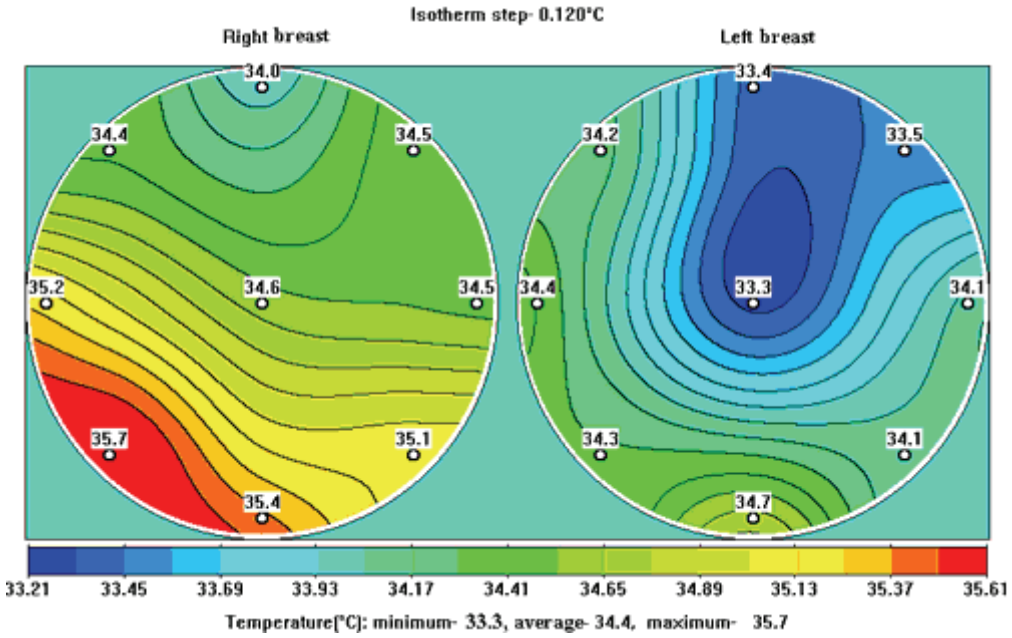
There is a tumor of 1cm diameter in the nipple. There is no cancer cells in the lymph nodes.

Hystology 4037/98# - there are two tumor of 1 and 1,5cm. The type of cancer is inflomantary cancer, there are metastases in one lymph node.

Examination protocol # 001AA00957A

Name:	M.M.I.	Age:	43 year old	History #	98/6609
Place:		SRI CO		Doctor :	Ignatenko M.B.

INTERNAL TEMPERATURE FIELD



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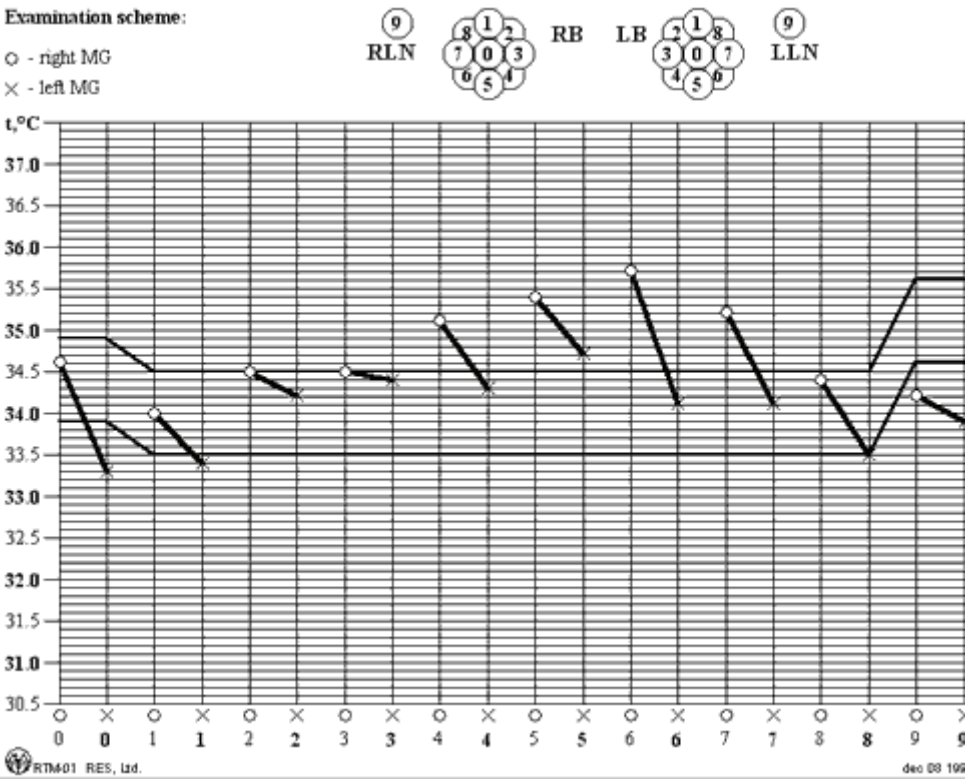

Diagnosis: The thermogram shows the RTM-features of right breast cancer

Extract from the history #98/6609

M.M.I., 43 year old, was treated in the SRI CO from 24thMarch to 17thApril, 1998. She was diagnosed with right breast cancer $T_2N_1M_1$ II b stage.

There is a solid fixed tumor of 4r' 3cm on the border of the upper quadrants.

Hystology 3672# - inflamantary ductal cancer, metastases are in five lymph nodes.

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