Medical Radiometer
RTM-01-RES

Clinical trials

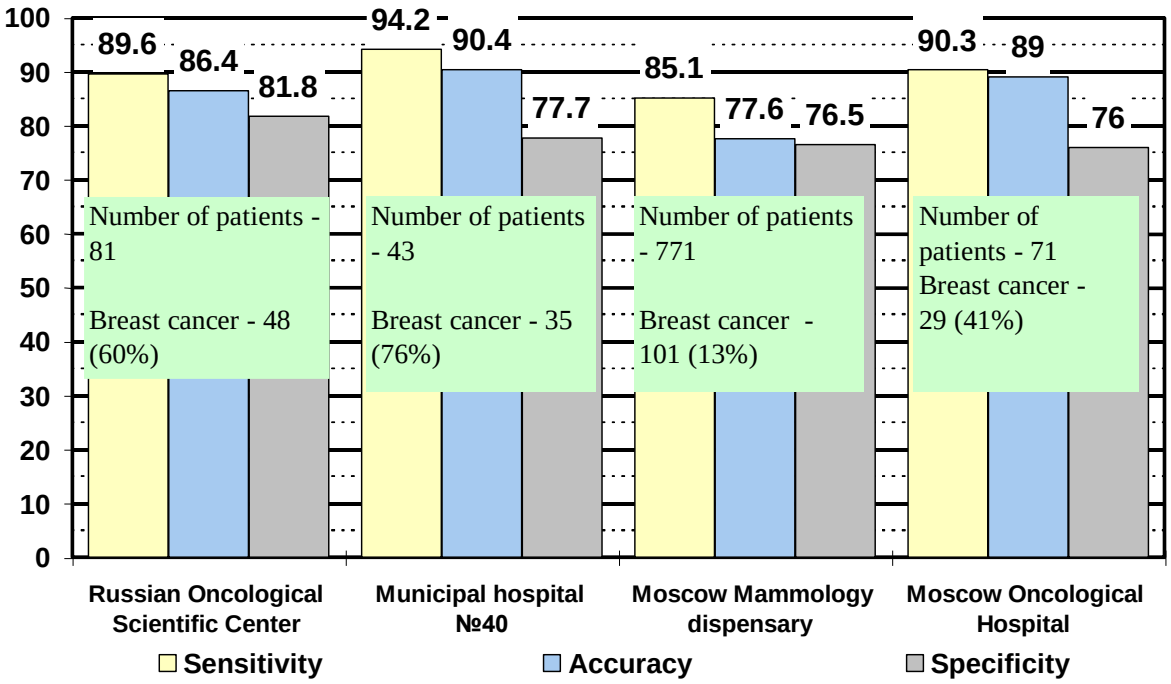
Licences • Certificates

State Clinical Trials of RTM-01-RES

The state clinical trials of RTM-01-RES for evaluating abilities of the System to detect breast cancer were held at five leading Moscow Oncological Centers from 1998 to 2000:

- The Scientific Research Institute of Clinical Oncology of the Russian Oncological Scientific Centre under the RAMS
- Brunch#1 of the Moscow Mammology Health Center
- Municipal Clinical Hospital # 40
- The Oncological Health Centre of the Moscow Health Care Committee
- Burdenko Major Military Clinical Hospital

In the clinical trials 1000 patients took part. The examination results were compared with the results of histology. These investigations have shown that the sensitivity of the method to breast cancer diagnosis is about 90%.



Sensetivity = Ncc/ Nc
Accuracy =(Ncc+Nhh)/Nt
Specificity = Nhh/ Nh
Nc-Number of patients with breast cancer;
Nh- Number of healthy patients;
Ncc-Number of patients with breast cancer, who were diagnosed by RTM-01, and said to have the breast cancer;
Nhh- Number of healthy patients, who were diagnosed by RTM-01, and said be healthy;
Nt-Total number of patients;

Contents

Chapter I

Clinical Trial Protocols

Approved by
E.G. Pinkhosevitch,
President of Moscow
Association "Mammalogy"
Chief expert on Mammalogy
of Moscow Department of Health,
Honored doctor of Russia
and
L.M. Bourdina,
M.D., Professor of RMAPO,
Chief doctor of №1 Branch of the Moscow Mammalogy Health Center

CLINICAL TRIAL PROTOCOL #2

of the RTM-01 Microwave Radiometer
Developed by RES Ltd, 31 March 1998

The clinical trial of the RTM-01 microwave radiometer, developed by RES Ltd., was carried out over the period from January 21 to March 31, 1998, at the Oncologic Department of Moscow Branch № 1 of the Mammology Health Centre.

Purpose and Methods of Clinical Trial

The purpose of the clinical trial is to estimate the ability to use the RTM-01 microwave radiometer in medical practice.

To carry out the clinical trial the RTM-01-RES microwave radiometer was chosen. It consists of:

- Sensor to measure the temperature of the internal organs with an antenna for detecting natural electromagnetic radiation (RS block)
- Skin temperature sensor
- Processing unit (DP block)

The RTM-01 is a modulated null-radiometer with a slipping circuit for compensating the reflection between the biological object and the antenna.

The Russia patent 2082118 protects the scheme of the device.

The principle of device operation is based on measuring the intensity of natural electromagnetic radiation, from a patient's internal tissues, at microwave frequencies. The intensity of the radiation is proportional to the temperature of tissues according to the laws of physics (Plank's formula).

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

-Thermal abnormality is detected at the depth of ……	3 - 5 cm
-Accuracy of the temperature measurement	± 0,2°C
-Time of measuring one point……	15 sec
-Antenna diameter……	39 mm
-Power consumption from 220 V 50Hz network	15 Watt
-Weight of the basic set	3 kg
-Dimensions :	
DP block.....	260x230x70 mm
RS block.....	200x60x30 mm

Temperature data are displayed as a three-digit number on the panel with discreteness of 0.1°C. The Radiometer may be connected to a PC. Software for inputting and storing data of patients, brief anamnesis, visualization and processing the results of measurements was supplied.

The radiometer may be used in the following modes:

- Autonomous mode (in this case manipulations with device are carried out by a doctor or a nurse, the data received may be input into computer manually);
- Computer based mode (the input of measurement data is made automatically, the visualization and measurement data are processed after the examination of a patient is complete).

Women were tested on 6 to 9 days from the first day of their period of menstruation.

The measurement scheme of the internal breast temperature is shown in Appendix I. Temperature was measured at 9 points on the both breasts, and also the temperature was measured at axillary sites.

The tested patient lies on her back with hands behind her head, in order to normalize the arrangement of the measured points and increase the total accuracy of measurements due to the breasts being naturally flattened in this position.

In order for objectivity to be increased, RTM-diagnosis was carried out independently on breast palpation and mammography. The results were compared after the examination of the patients.

With the help of the radiometer 771 women at the age from 16 to 82 years old were examined. They had breast diseases. These data are represented in the table below.

Table 1.

Breast disease	**Number of Patients**	**%**
Healthy	16	2.1
Fibrocystic Mastopathy	367	47.6
Fibroadenoma	60	7.8
Fibrous-fatty involution	37	4.7
Cyst	56	7.3
Mastitis	33	4.3
Diffuse fibrocystic Mastopathy	81	10.5
Breast cancer	101	13.1
Ductal papilloma	20	2.6
Total	771	100

During the trial the following diagnostic abilities of the radiometer were investigated:

- Differential diagnostics of breast cancer;
- Detection of tumor location.

For differential diagnosis of breast cancer the following basic criteria were used:

- Significant thermal differentials between corresponding points on the right and left breasts;
- An increase in nipple temperature;

- An increase in temperature diversity within one breast.

A malignant tumour may be represented by thermal asymmetry at corresponding points on the left and right breasts and also by a temperature increase in the tumour location, in comparison with the average temperature of the breast.

Software processes and analyses the results of the examination, based upon the mathematical formalization of criteria.

Clinical Trial Results

1. The 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 and the secondary medical staff can operate it. There are no external adjustment elements on the device.

3. Utilization of the device is absolutely harmless for patients and the physicians, therefore the tests can be repeated for the monitoring of treatment.

4. The device was being used for more than 800 hours. Over this period there were no failures.

5. In 86 of 101 studies RTM-results of breast cancer were confirmed by the data of clinical and mammography tests (85 %). 15 cancer patients had no significant thermal abnormality (15%).

157 of 771 patients had all RTM-features of breast cancer (criteria mentioned above), but they were not confirmed by clinical and mammography tests. They are 20.3% of all examined patients.

It is necessary to emphasize that the patients were diagnosed with breast cancer basing only on the data of temperature field measurements. At the same time the use of data received by clinical and mammography examinations in conjunction with radiometry methods will improve the efficiency of the microwave radiometry method.

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

7. The imperfection of RTM-diagnosis is the RTM-features of acute mastitis are similar to RTM-features of inflammatory cancer (the significant thermal differential). However for clinical practice this imperfection is not essential, as physicians may order a conservative treatment if there are any suspicions of acute mastitis and then repeat RTM-diagnosis. This allows comparing results and analyzing dynamics.

In Appendix 2 the thermogram of the healthy woman is shown, in Appendices 3, 4, 5 you can see the thermograms of patients having various types of breast cancer.

Conclusion

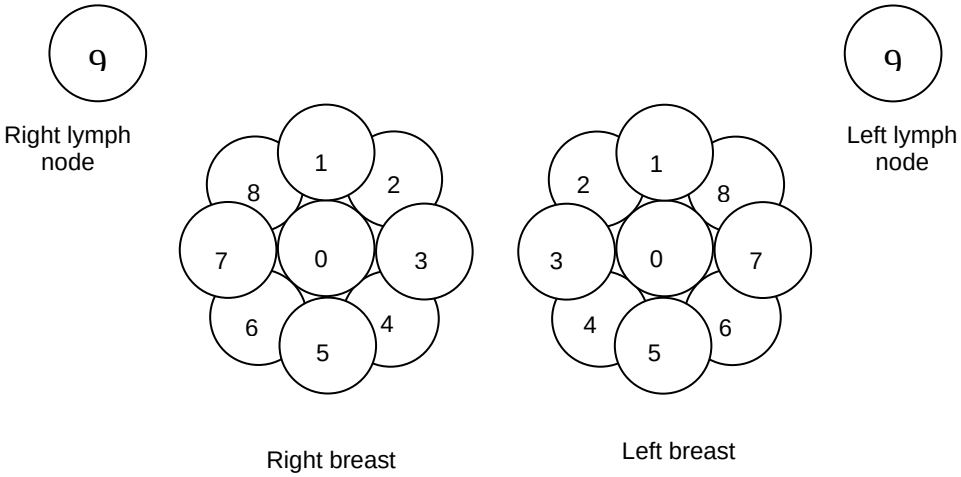
The RTM-01 radiometer is recommended for use in medical practice, for screening at consulting and oncology rooms and at specialized oncology and mammology centers for detection of breast cancer and the monitoring of treatment.

Signed by the Head of Department N.V. Vasina

This is a translation, the original is in Russian.

Appendix 1

MEASUREMENT SCHEME OF INTERNAL BREAST TEMPERATURE



0 – nipple

1 – border of upper quadrants

2 – upper inner quadrant

3 - border of inner quadrants

4 - lower inner quadrant

5 - border of lower quadrants

6 - lower outer quadrant

7 - border of outer quadrants

8 – upper outer quadrant

Approved by the chief doctor of Hospital №40
Honored doctor of Russia Fedorova M.I.

Approved by
The Head of the surgery division of the Moscow Medical Stomatological Institute,
Professor, M.D., Yarema I.V.

CLINICAL TRIAL PROTOCOL of the RTM-01 radiometer (RES LTD)

Basing on Protocol №8 of October 8th, 1995 over the period from October 15 to December 26, 1997 the clinical trial of the RTM-01 radiometer, developed by RES, Ltd., was conducted in the second oncology and surgery division of Municipal Hospital №40.

Purpose and Methods of 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 Russia patent #2082118 protects the device scheme.

The devices operation is based on measuring the intensity of natural electromagnetic radiation from a patient's internal tissues.

Radiation is received by antenna, which is set on the projection of the organ examined. Diagnostics of disease bases on analyzing a thermal abnormality (an 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, may be 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…. 5 cm;
- Accuracy of measuring the averaged internal temperature - $\pm 0{,}2^0$C;
- Time of measuring at a point – 15 seconds;
- Antenna diameter – 39 mm;
- Power consumption from 200V50 Hz network – 20 Watt;
- Weight of the basic set – 3 kg.

Temperature data are displayed as a three-digit number on a panel with discreteness of 0.1 ^{0}C.

The radiometer may be connected to a 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 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. Radiometric results were kept in sealed envelopes and once the trial was complete they were compared with the result of histology.

Trial Results

A total of 46 women aged from 28 to 85 were examined with the radiometer.

3 women without one breast and a woman examined during the period of ovulation were omitted.

35 of 42 patients had verified breast cancer. According to radiometric examination 33 women had breast cancer, it is 94.2%. The tumour location coincided with the location reported by radiometric examination.

According to radiometric examination another two females had breast cancer. Actually the first had acute mastitis and the second had a lieflike fibroadenoma with proliferation of ductal epithelium cells. So the number of false positive results is 4.8 %.

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 being used for more than 50 hours. Over this period there were no failures.
5. 33 of 35 verified breast cancer were confirmed by radiometric examination, i.e. the detective ability of the method exceeded 94 %.
6. 2 of 42 patients had false positive results that are less than 5 %.
7. Imaging when temperature values are linked with measured sites and isotherm lines are drawn through sites having the same temperature help physicals to diagnose.

Conclusion

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

The serial production of the device is recommended.

Mogilevskiy I.L.,
M.D., The head of the second oncology and surgery department

Tkachov V.K.
Deputy of the chief surgeon, M.D., assistant professor of surgery diseases division of the Moscow Medical Stomatological Institute.

This is a translation, the original is in Russian.

Examination protocol # 0001AA00451A

Organ examined: mammary glands
Place of the examination: Municipal Clinical Hospital # 40
Examinating doctor: Tikhomirova **Examination date:** 24.10.1997
Name: P.I.F. **Age:** 73
Medicine card number: **Own doctor:** Mogilevskiy I.L.
Home phone number: **Work phone number:**
Anamnesis: pyelonephritis

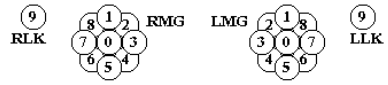
C.: s. **Diam.:** 27 **Cycle:** menopause **D.A.M.:** **D.O.:**
Pregnancies count: **Births count:** **First pregnancy at the age of:**
X-Rays:

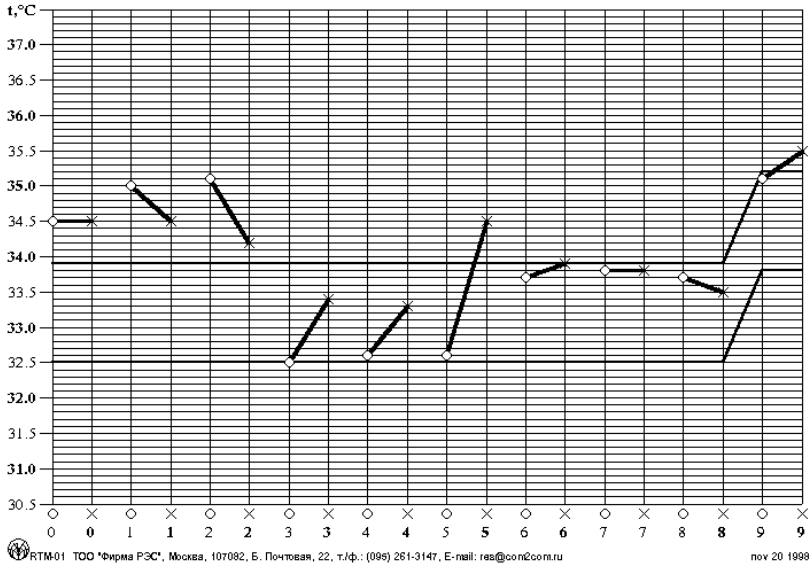
D/P:
Diagnosis: breast cancer
There is a solid, unmovable, tumour without exact boundary on the right breast. The type of cancer is solid cancer T2N0M0.

Radiothermometral examination inference: The thermogram shows the RTM - features of right breast cancer.

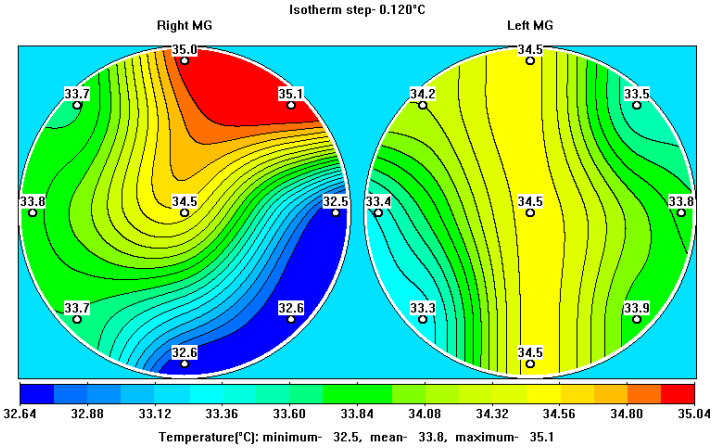
Diagnostic formula: +38.2(+38.2-0.0) +26(969999)
Control view date:
Further treatment recommendation:
Examination scheme:

○ - right MG
× - left MG





RTM-01 ТОО "Фирма РЭС", Москва, 107082, Б. Почтовая, 22, т./ф.: (095) 261-3147, E-mail: res@com2com.ru nov 20 1998



Internal temperature field
Organ examined mammary gland
Name: P.I.F.
Examination date 24.10.1997
Protocol # 0001AA00451A
Medicine card number:
Age: 73

Examination protocol # 0001AA00517A

Organ examined: mammary glands
Place of the examination: Municipal Clinical Hospital # 40
Examinating doctor: Tikhomirova **Examination date:** 10.11.1997
Name: S.T.A. **Age:** 55
Medicine card number: **Own doctor:** Mogilevskiy I.L.
Home phone number: **Work phone number:**
Anamnesis:
operation on uterus

Aggravating heredity

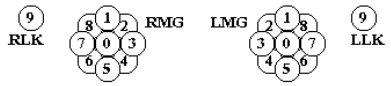
C.: n. **Diam.:** 28 **Cycle:** menopause **D.A.M.:** **D.O.:**
Pregnancies count: **Births count:** **First pregnancy at the age of:**
X-Rays:

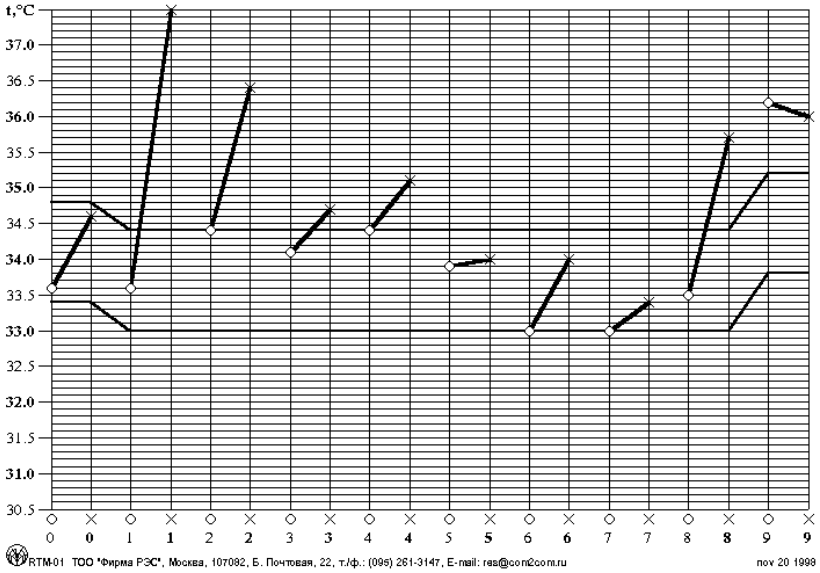
D/P:
Diagnosis: breast cancer
sarcoma without mts. in lymth node

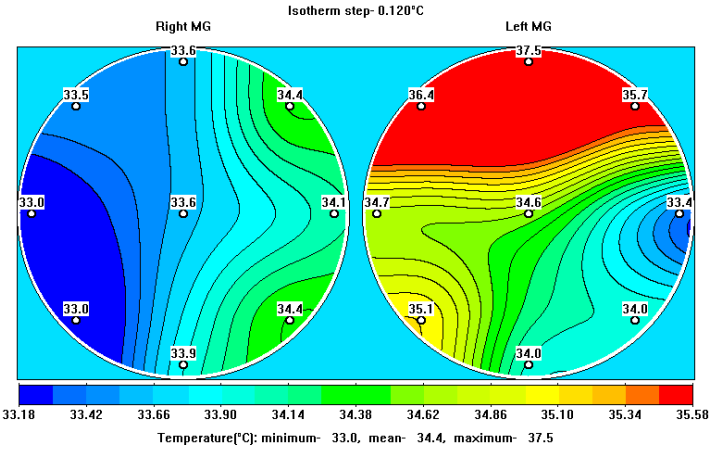
Radiothermometral examination inference: The thermogram shows the RTM - features of left breast cancer.

Diagnostic formula: +60.0(+60.0-0.0) +20(099999)
Control view date:
Further treatment recommendation:
Examination scheme:

○ - right MG
× - left MG







Internal temperature field
Organ examined: mammary gland
Name: S. T.A
Examination date: 10.11.1997
Protocol #: 0001AA00517A
Medicine card number:
Age: 55

Examination protocol # 0001AA00593A

Organ examined: mammary glands
Place of the examination: Municipal Clinical Hospital # 40
Examinating doctor: Tikhomirova **Examination date:** 24.11.1997
Name: S.L.N. **Age:** 54
Medicine card number: **Own doctor:** Mogilevskiy I.L.
Home phone number: _ **Work phone number:**
Anamnesis:
menopause has been for 3 months

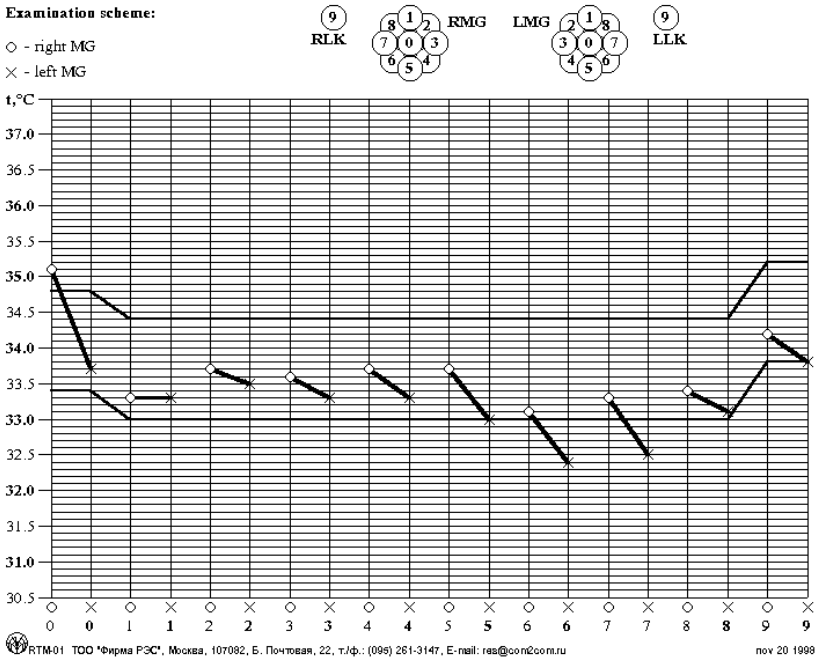
C.: s. **Diam.:** 25 **Cycle:** menopause **D.A.M.:** **D.O.:**
Pregnancies count: **Births count:** **First pregnancy at the age of:**
X-Rays:

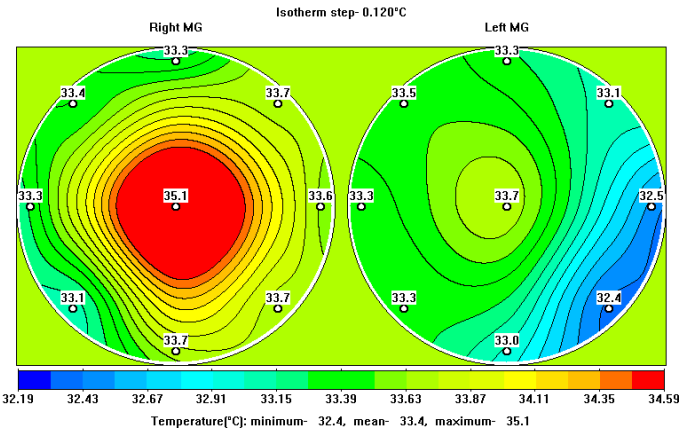
D/P:
Diagnosis: breast cancer
there is a tumor of 2,5 cm without exact boundaries, with radial boundary IIa T2N0M0 in the mesial quadrant. Histology - cancer.

Radiothermometral examination inference: The thermogram shows the RTM - features of right breast cancer.

Diagnostic formula: +20.6(+21.3-0.7) +26(999387)
Control view date:
Further treatment recommendation:
Examination scheme:

○ - right MG
× - left MG





Internal temperature field
Organ examined: mammary gland
Protocol #: 0001AA00593A
Name: S.L.N.
Medicine card number:
Examination date: 24.11.1997
Age: 54

Approved by
M.I.Davidov,
M.D., The Chief of Scientific Research Blokhin Institute of
Clinical Oncology,

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 held in the diagnostic and surgical department.

1. 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 Russian patent #2082118 protects the device scheme.

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

Radiation is received by antenna placed on the projection of the organ examined. Diagnostics of disease is based on analyzing a thermal abnormality (an increase or a 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 a PC, 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 represented in Appendix. The temperature was measured at nine points and at the 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:

$$TP/(TP+FN) \times 100\% = 43/(43+5) \times 100\% = 89{,}6\%$$

The accuracy of the method is:

$$(TF + TN)/(\text{Studies number}) \times 100\% = (43+27)/81 \times 100\% = 86{,}4\%$$

The specificity of the method is:

$$TN/(FP+TN) \times 100\% = 27/(27+6) \times 100\% = 81{,}8\%$$

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

4. Conclusion

The RTM-01 radiometer developed by RES, Ltd. can be recommended for use 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:
Komov D.V.
Head of diagnostic and surgery department
M.D., Professor,

Hailenko V.A.
M.D., Professor

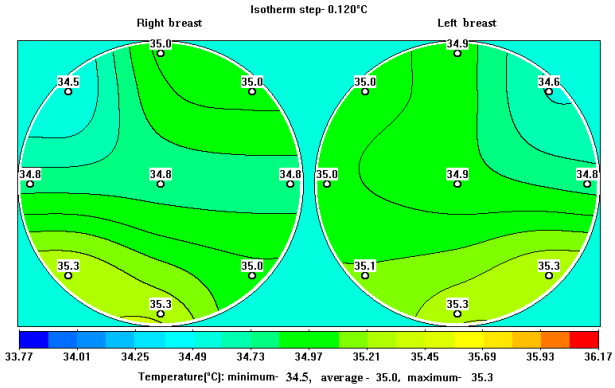
Appendix: Protocols of radiometric examinations (3 protocols).

This is a translation, the original is in Russian.

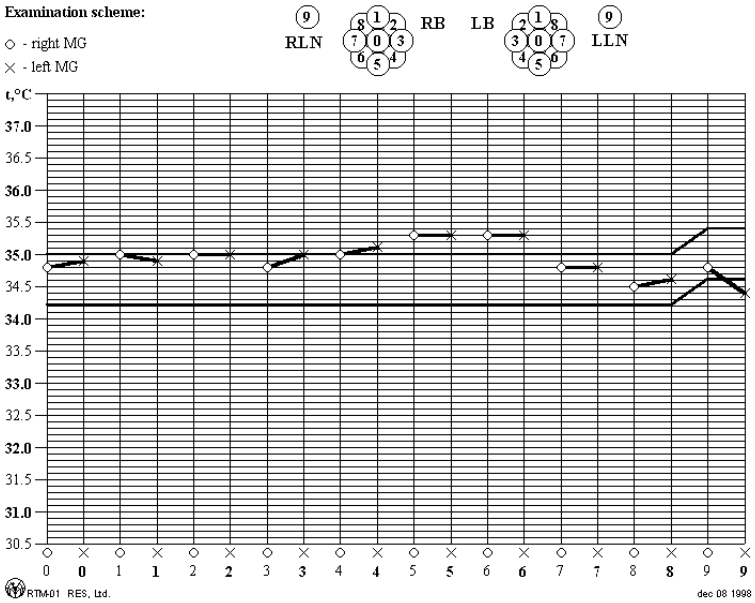
Examination protocol # 001AA00940A

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

INTERNAL TEMPERATURE FIELD



THERMOGRAM



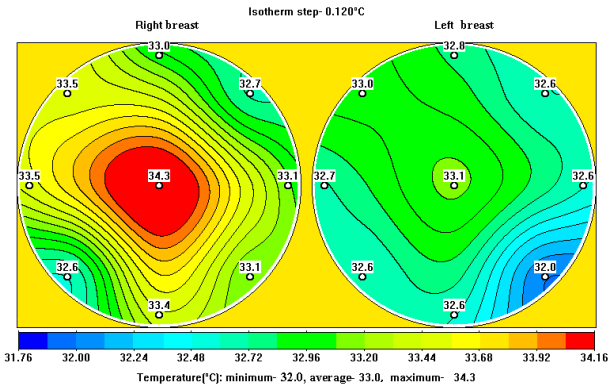
Diagnosis: No RTM-features of breast cancer.

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

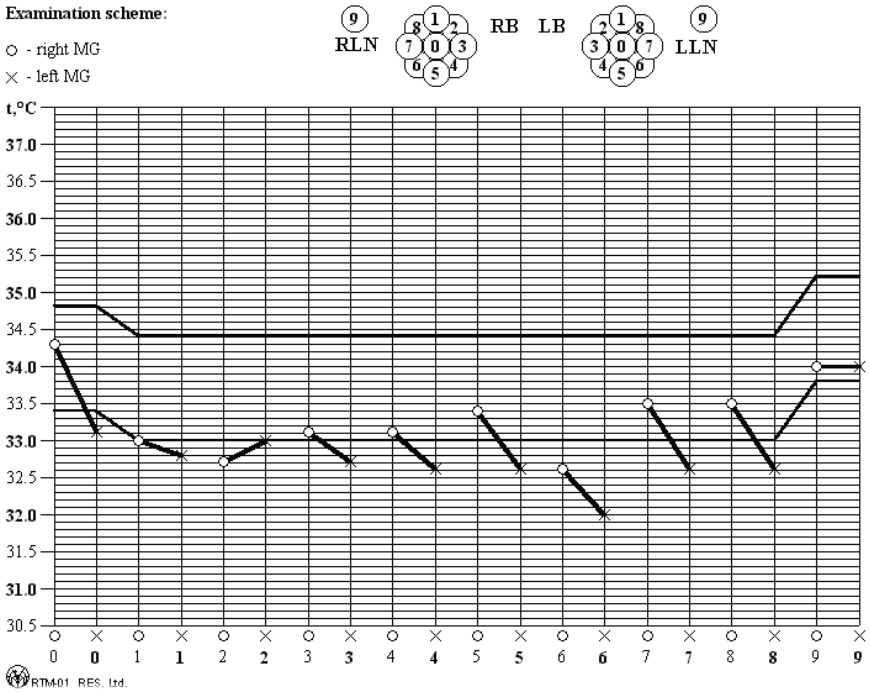
Examination protocol # 001AA00975A

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 case 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.

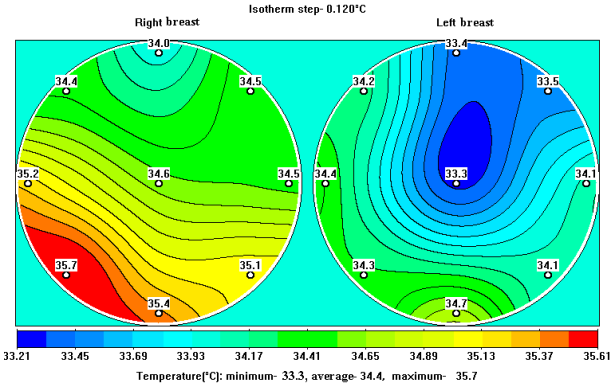
A tumor on the right breast was being observed for two weeks. Cytology 22665-1# - cancer cells. There is a tumor of 3×2cm in the upper outer quadrant of the right breast. The tumor is solid, not very movable, without a fixed boundary.

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

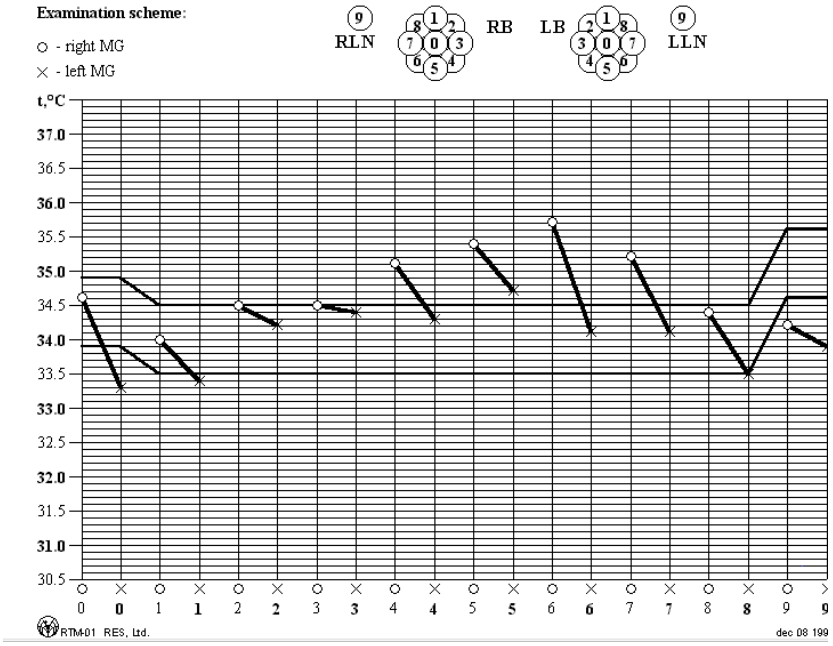
Hystology 4037/98# - there are two tumor of 1 and 1,5cm. The type of cancer is inflomantary cancer, there are metastases in one lymph node.

Examination protocol # 001AA00957A
Name M.M.I. Age: 43 year old History # 98/6609
Place SRI CO Doctor : Ignatenko M.B.

INTERNAL TEMPERATURE FIELD



THERMOGRAM



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 24th March to 17th April, 1998. She was diagnosed with right breast cancer $T_2N_1M_1$ II b stage.

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

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

Approved by
V.M. Kluzev
Head of the Burdenko Major Clinical Hospital
Major-General of medical military service

CLINICAL TRIAL PROTOCOL of RTM-01-RES (Moscow)

Basis: Permission of MMMA # 161/7/2/6245 of 26.11.98

In the Radiological Centre of the Burdenko Major Military Hospital from 17 October to 21 December 2000 the clinical trail of the RTM-01-RES was conducted.

The purpose of the trial was to evaluate the possibility to use the RTM-01-RES diagnostic system to detect breast cancer and select risk patients in the military hospitals. During the trial 51 women were examined.

All patients underwent independent CBE, ultrasound, mammography and RTM-Diagnosis. Final diagnoses were based on the pathologoanatomic investigation. The patients can be divided into the following disease groups:

Table 1

Disease	Number of Patients	Coincidence of Diagnoses	RTM-Diagnosis
Breast cancer	16	13	3 - risk group
Fibroadenoma	6	4	2 - thermogram has features of breast cancer
Proliferative Fibroadenoma	1	1	-
Mastopathy	26	23	3 – risk group
Cyst	2	1	1 – the thermogram has features of breast cancer
Total:	51		

It should be noted that RTM-Diagnosis missed no cancer.

Conclusion: RTM-01-RES is recommended for screening, diagnosis of breast diseases and monitoring the treatment in hospitals and health centres of the Ministry of Defence.

Signed by

K.A.Teterin

Chief radiologist and Head of the Radiological Centre of the Burdenko Major Clinical Hospital

This is a translation copy. The original is in Russian.

Approved by
Y.K. Scripkin,
M.D., Professor, the director of
Central Dermatology and Venereology Research Institute
of Public Health and Medical Industry Ministry
(Russian Federation)
Academician of Russian Academy of Medical Science,

CLINICAL TRIAL PROTOCOL of RTM-01

The RTM-01 is a medical radiometer, designed by RES, Ltd., under the ARIRE.

Over the period from May to August 1996, in the physiotherapy department of Central Dermatology and Venereology Research Institute of Medical Industry and Public Health Ministry (Russian Federation) the diagnostic abilities of the RTM-01 medical radiometer were explored. Patients having chronic uterine adnexitis were examined.

The operation of the device is based on measuring the intensity of natural electromagnetic radiation from the internal organs of the human body, at microwave frequencies. The depth of measurement is 3 to 10 cm. The accuracy of a measuring temperature abnormality is ±0.2 ^{0}C

18 women having chronic adnexitis (aged from 19 to 37) were examined and monitored. Also there were 6 healthy volunteers (aged from 20 to 30).

The radiometric examinations were carried out before and after treatment that included low-intensity laser-therapy and generally indicated drug treatment.

For measuring the temperature of the internal organs, the antenna was put on the abdominal wall over the right and left ovary, over uterine fundus, over right and left edges of uterus, on the left and right Inguinal lymph nodes. To reduce the external noise all measurements were carried out in shielding tent[1].

The trial showed that the patients with chronic adnexitis had an increase in temperature of 1-2 ^{0}C at the tested points in comparison with the temperature at corresponding points of the healthy volunteers. Also the measured temperature of the inflamed and normal adnexa was compared. The average increase in temperature of the inflamed adnexa in comparison with the normal adnexa was 1.2 ^{0}C ($p<0.001$). After treatment the temperature fell, and it approached the temperature of the normal adnexa (the confidence coefficient was 0,02 or less). But there had been still 1.3^{0}C average increase in temperature in comparison with the temperature of the healthy volunteers.

The received data coincided with ultrasound investigation of uterus and oviducts.

Thus, the clinical trial indicated that the RTM-01 radiometer could be used in cases of chronic adnexitis for diagnostic purposes (for example for primary examinations or check-up in observation rooms) as well as for the monitoring of treatment.

Signed by
Balura E.V.
Chief-executor, doctor of medical science,
Volnukhin V.A
Head of physiotherapy department, M.D.
.
August 26, 1996.

This is a translation. The original is in Russian.

[1] At present the new modification of the RTM-01 radiometer is designed and a shielded cabin is not required.

Approved by
Deputy Scientific Work Director of
Cybernetic Medicine Institute, M.D.
Gorayinov S.V.

TESTIMONIAL ON DIAGNOSTIC TRIALS of RTM-01 medical radiometer (RES Ltd)

At the room for treatment and diagnostics of the State Clinical Hospital Cybernetic Medicine Institute #124 the diagnostic abilities of the RTM-01 for examination of the patients with pathology of the urinary-secretory system were explored.

The group of 166 patients was examined. It included 51 men, aged 10 –74.

23 patients were tested repeatedly: 10 women and 13 men.

Patients had the following diagnosis:

- Pyelonephritis chronic, acute, unilateral, and left and right;
- Glomerulonephritis chronic, acute, unilateral left and right, complicated by development of the shrunken kidney for the second time, renal insufficiency;
- Adrenal neoplasm;
- Hydronetyrosis after ureteroplasty.

The patients, who have not specify diagnosis as well as the patients having verified diagnosis were registered. They were 27 men. Some men were examined repeatedly to physician can observe and analyze dynamics when therapy was carry out. In 17 of 23 cases the positive trend was observed as thermal asymmetry reduced.

The group of 27 men having verified diagnosis was examined. They were diagnosed outside of the hospital, at various Moscow clinics. The diagnosis was based on ultrasonography, Rg-logical examinations, blood test (kidney samples), urine test (protein, leucocytes, red corpuscles level, etc).

Diagnosis was confirmed for all 72 men. They included 23 cases of various pyelonephritis types; the fall in temperature at renal pelvis projection sites was 0.1-0.3°C and if there was renal insufficiency the temperature reduced by up to 1-2°C. The temperature in some cortical levels increased (3 cases). 10 volunteers, whose kidneys were not treated, were examined in order to results can be compared.

Clinical trial showed that RTM-01 could be used to diagnose and monitor treatment of chronic disease kidney patients.

20 June 1998

The testimonial was draw up by doctors of Municipal Clinical Hospital #124 for Institute of Cybernetic Medicine.

Signed by Zolkin A.V, M.D. and Polaykova A.V.

This is a translation. The original is in Russian.

Chapter II

Licences • Certificates

THE HEALTH MINISTRY OF THE RUSSIAN FEDERATION

REGISTRATION CERTIFICATE

No *29/05030698/0165-00* Date *14 April 2000*

Expiry Date *04 June 2008*

MEDICAL TECHNIQUE
The RTM-01-RES microwave computer based radiometer for measuring integral internal temperature of soft and bone tissues

NORMATIVE DOCUMENT
ТУ 9441-001-39549185-98 " The RTM-01-RES microwave computer based radiometer for measuring integral internal temperature of soft and bone tissues"

COMPANY-DESIGNER
RES, Ltd., Moscow, ОКПО Code 39549185

COMPANY-MANUFACTURER
RES, Ltd., Moscow, ОКПО Code 39549185

REGISTERED IN THE RUSSIAN FEDERATION
ENTERED IN THE STATE REGISTER ON MEDICAL TECHNIQUES

State registration implies periodical monitoring of production to provide quality, effectivity, safety of medical techniques which are proved to be used in medical practice.

Signed by R.U. Habriev,
Head of the Department on State Monitoring of
Quality, Effectivity, Safety of Drugs and Medical Techniques

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THE GOST R SYSTEM
GOSSTANDARD OF RUSSIA

CERTIFICATE OF CONFORMITY

№ РОСС ru.ИМ02.В12049
Effective Date 20.09.2004 Expiry Date 20.09.2007

№ 6403689

CERTIFICATION AUTHORITY РОСС ru.000I.IIИМ02
ON MEDICAL TECHNIQUE ASRIMT
Kasatkhina, 3, Moscow, Russia, 129301
Tel.: 283-97-92

PRODUCT The RTM-01-RES microwave computer based radiometer for measuring integral internal temperature of soft and bone tissues, Consignment more then 50 units
ТУ 9441-001-39549185-98

OK 005 Code (ОКП): 94 4120

CONFORMS TO REQUIREMENTS OF NORMATIVE DOCUMENTS

ГОСТ Р 50444-92, ГОСТ Р 50267.0-92 (МЭК 601-1-88), ГОСТ Р 50267.0.2-95 (МЭК 601-1-2-93), ГОСТ 23511-79, ГОСТ Р МЭК 601-1-1-96 (МЭК 601-1-1-92)

GN FEA CIS Code: 9025 19 910 0

MANUFACTURER RES, Ltd.
Bolshaya Pochtovaya 22, Moscow, 107082, Russia,
ITN 7701028720

CERTIFICATE ISSUED TO RES, Ltd., Moscow

ACCORDING TO test protocols № 278/21 of 14 September 2004 of Test Center of MD and HEA RSRIMMT, enter № РОСС ru.0001.21ИМ04; №03-08/04 of 24 Augest 2004 of RL CTM and RL EMC № РОСС ru.0001.21МЭ01; Pattern Approval Certificate of Measuring Instruments ru.C.39.003A №7553 of 09 March 2000 of GOSSTANDART of Russia; Registration Certificate of the Health Ministry of the Russian Federation № 29/05020698/0165-00

ADDITIONAL INFORMATION The product is marked by the Mark of Conformity to the State standards of the Russian Federation according to GOST R 50460-92 nearby the trade logotype.

Signed by Head of Authority B.I. Leonov
Signed by Expert T. I. Dubovik
Certificate is effective in the territory of the Russian Federation