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Honored doctor of Russia  
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Approved by The Head of the  
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Medical Stomatological Institute,  
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## **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 the Municipal hospital №40.*

### **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.

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, 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....5cm;
- Accuracy of measuring the averaged internal temperature -  $\pm 0,20\text{C}$ ;
- Time of measuring at point - 15s;
- Antenna diameter - 39mm;
- Power consumption from 200V50Hz network – 20Watt;
- Weight of the basic set - 3kg.

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

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 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.

## **2. The results of the trial**

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 proliferaty of ductal epithelium cells. So the number of false positive results is 4,8 %.

## **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 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 is 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 physcials to diagnose.

#### **4. Conclusion**

The RTM-01 radiometer developed by RES, Ltd. is 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 the monitoring of treatment.

The serial production of the device is recommended.

The head of the second oncology and surgery department, doctor of medical science, Mogilevskiy I.L.

Deputy of the chief surgeon, doctor of medical science, assistant professor of surgery diseases division of the Moscow Medical Stomatological Institute, Tkachov V.K.

*This is a translation, the original is in Russian.*

## Examination protocol # 0001AA00451A

Organ examined: mammary glands

Place of the examination: Municipal Clinical Hospital # 40

Examining 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)

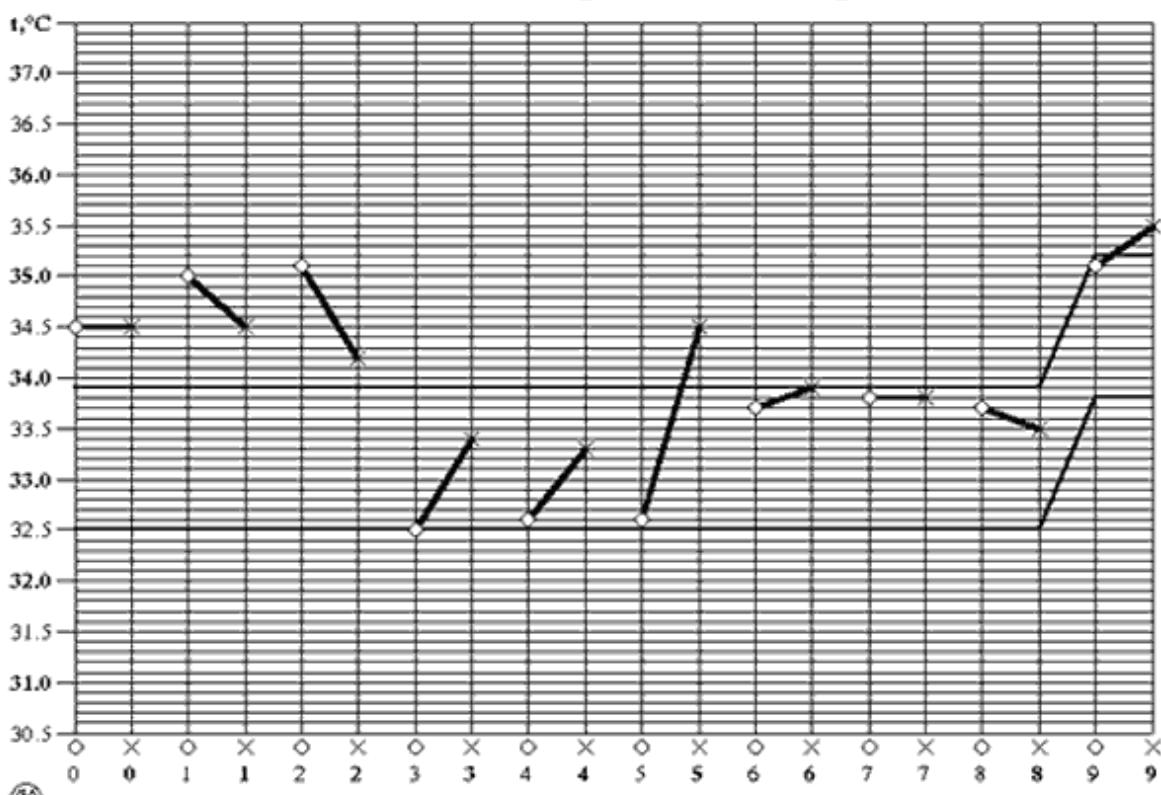
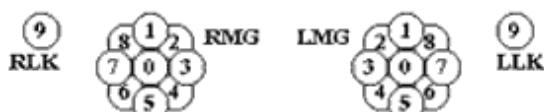
Control view date:

Further treatment recommendation:

Examination scheme:

○ - right MG

× - left MG



Organ examined mammary gland

**Internal temperature field**

Protocol # 0001ÀÀ00451À

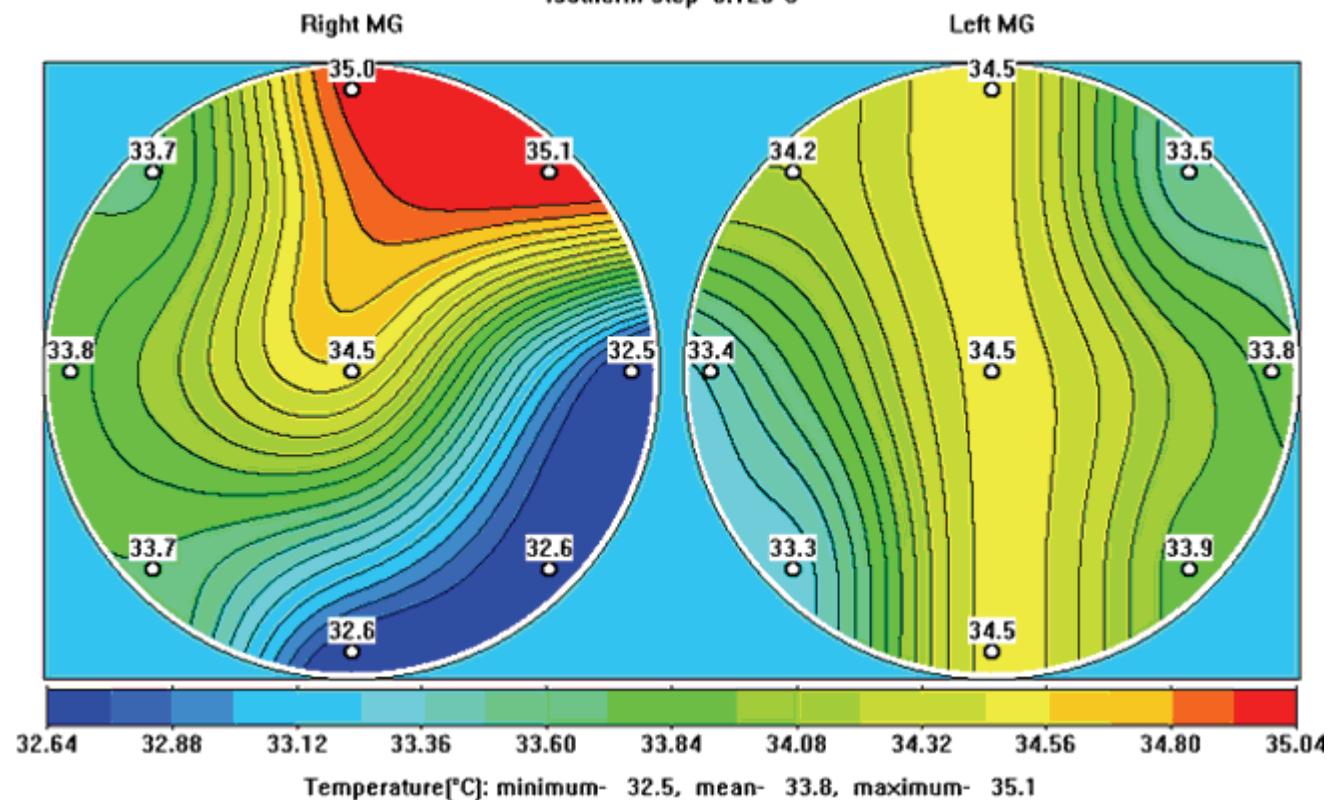
Name: P.I.F.

Medicine card number:

Examination date 24.10.1997

Age: 73

Isotherm step- 0.120°C



## **Examination protocol # 0001AA00517A**

**Organ examined:** mammary glands

**Place of the examination:** Municipal Clinical Hospital # 40

**Examining 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 lymph node

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

**Diagnostic formula:** +60.0(+60.0-0.0) +20(099999)

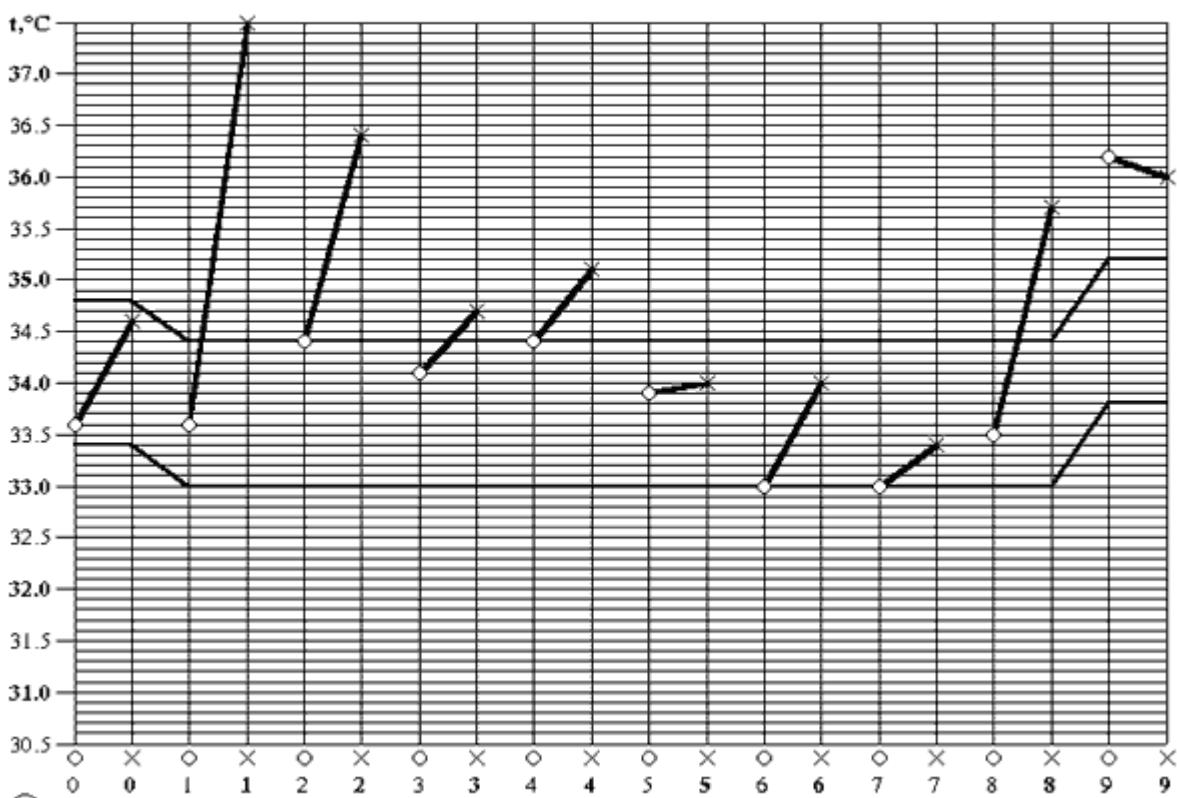
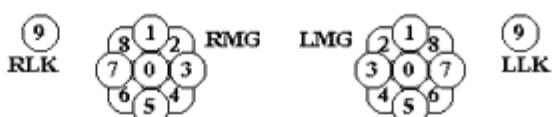
**Control view date:**

**Further treatment recommendation:**

**Examination scheme:**

○ - right MG

× - left MG

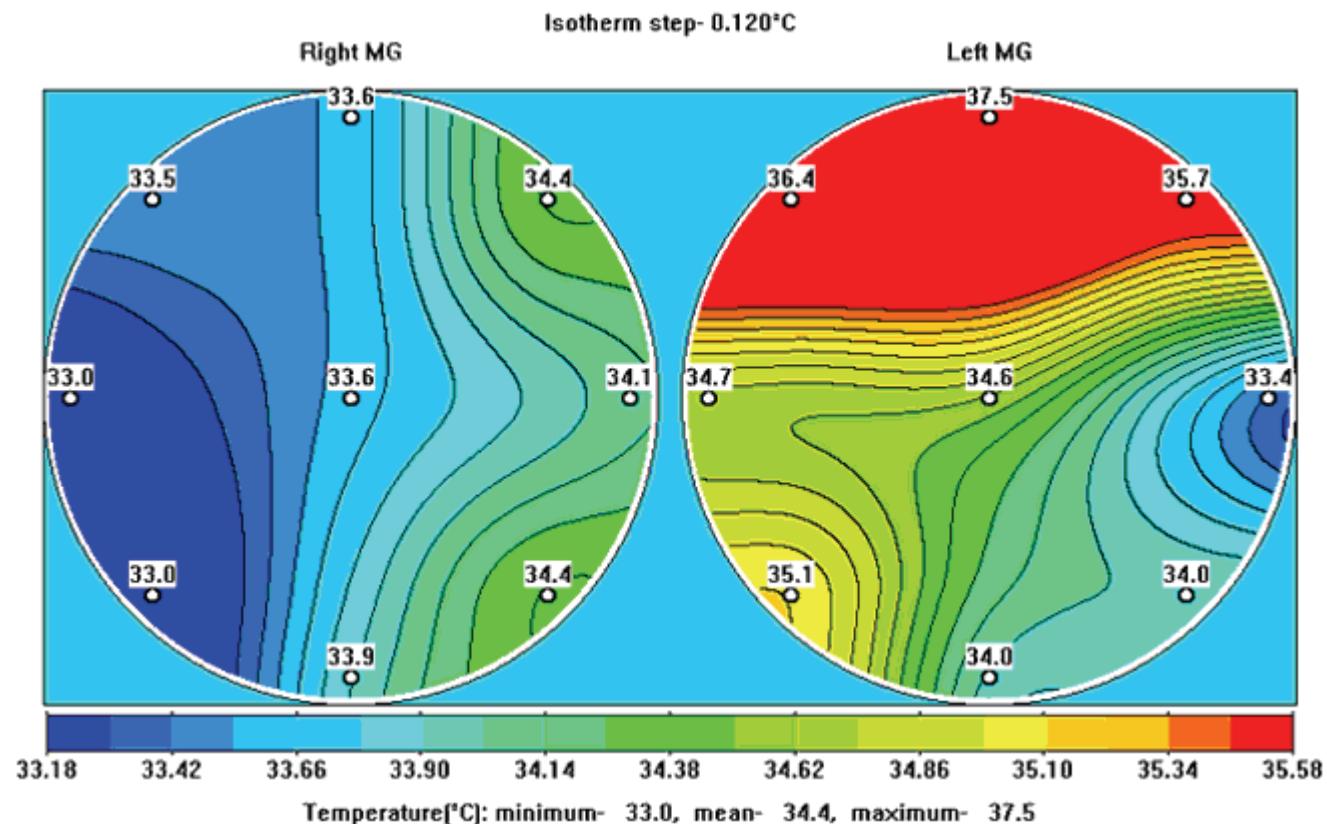


Organ examined: mammary gland  
Name: S. T.A  
Examination date: 10.11.1997

## Internal temperature field

Protocol #: 0001ÀÀ00517À

Medicine card number:

Age: 55

## **Examination protocol # 0001AA00593A**

**Organ examined:** mammary glands

**Place of the examination:** Municipal Clinical Hospital # 40

**Examining doctor:** Tikhomirova

**Examination date:** 24.11.1997

**Name:** S.L.N.

**Age:** 54

**Medicine card number:**

**Own doctor:** Mogilevskiy I.I.

**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)

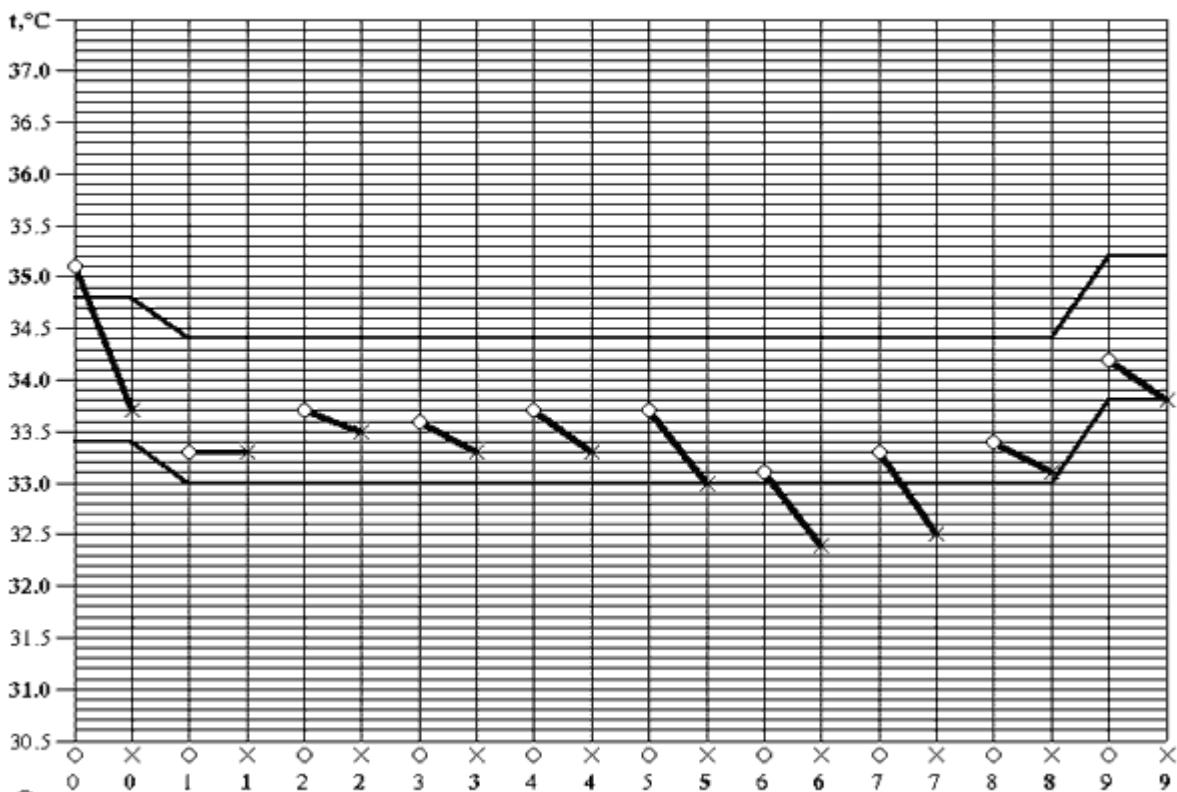
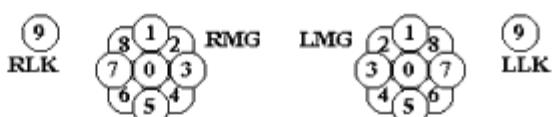
**Control view date:**

**Further treatment recommendation:**

**Examination scheme:**

○ - right MG

× - left MG



Internal temperature field

Organ examined : mammary gland

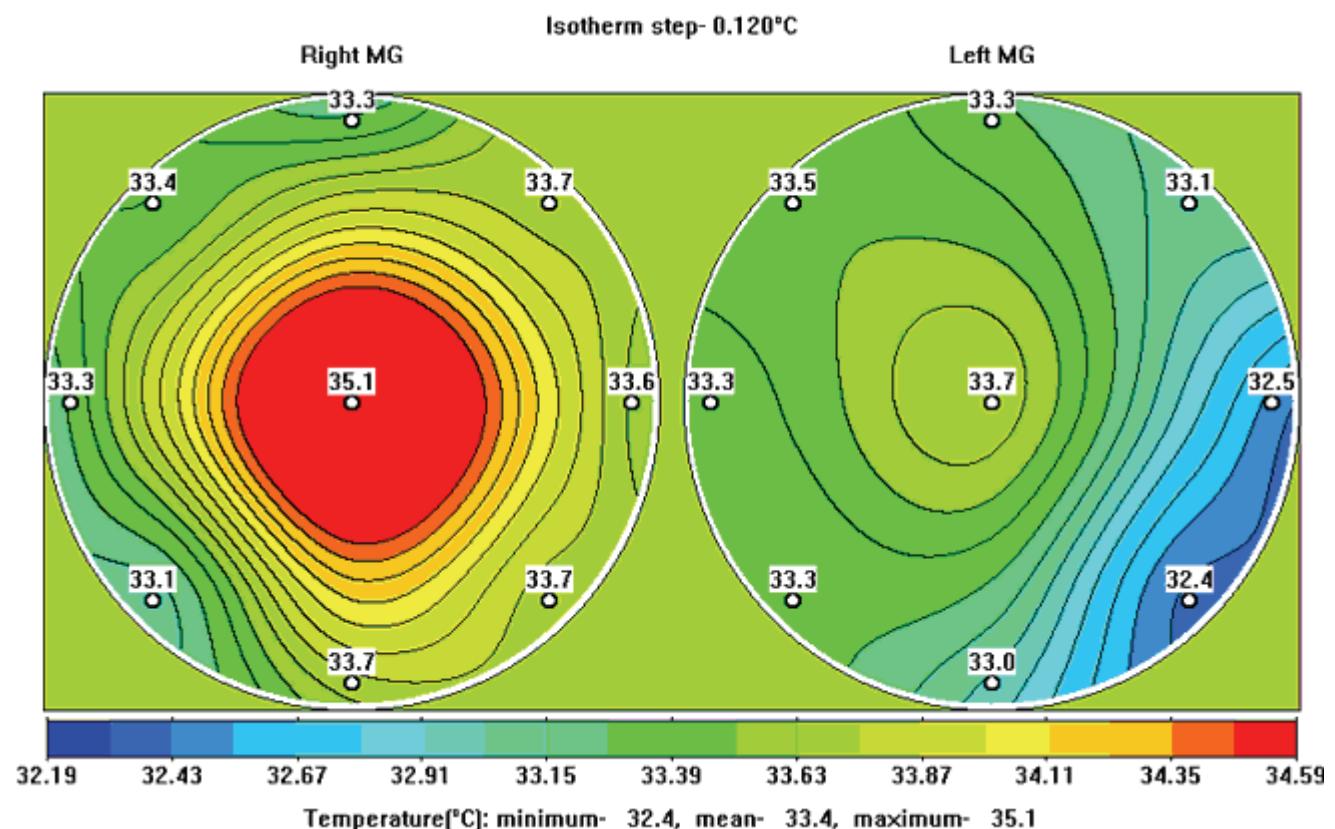
Protocol #: 0001ÀÀ00593À

Name: S.L.N.

Medicine card number:

Examination date: 24.11.1997

Age: 54



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