

ELECTROIMPEDANCE MAMMOGRAPHY



Ing. Peter Jusko

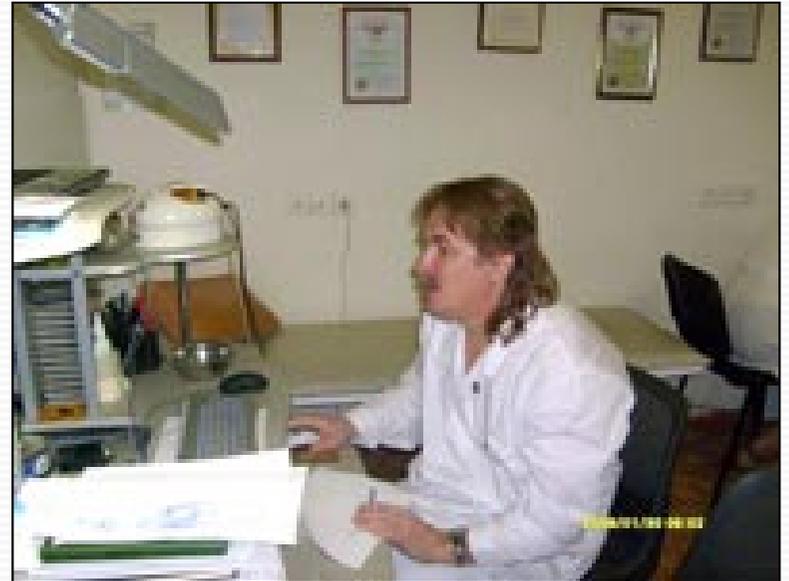
Slovak Republic

ONKO•CET

www.onkocet.eu

History of EIT

- Work on the electro-impedance tomography began in Russia in the 90's of past century.
- A group of scientists of the institute for radio engineering and electronics RAN in 1997 - 1998 could solve the mathematical problem of the visualization of the internal cloths of human body with the electro-impedance tomography.
- The result of this development was the production of the prototype of the instrument for diagnostics of mammary gland, transmitted for conducting the clinical tests into Hospital 9 Yaroslavl to the doctor of the highest category A. Yu. Karpov



History of mammography



EIM 003 "KORVET"



Model 3



Model 5

The first version of diagnostic instrument was called "electro-impedance computer mammogram EIM 003 KORVET"

Patents RF for the invention № 2153285 and № 2127075 and patents of the USA № 6,167,300 and № 6,236,886

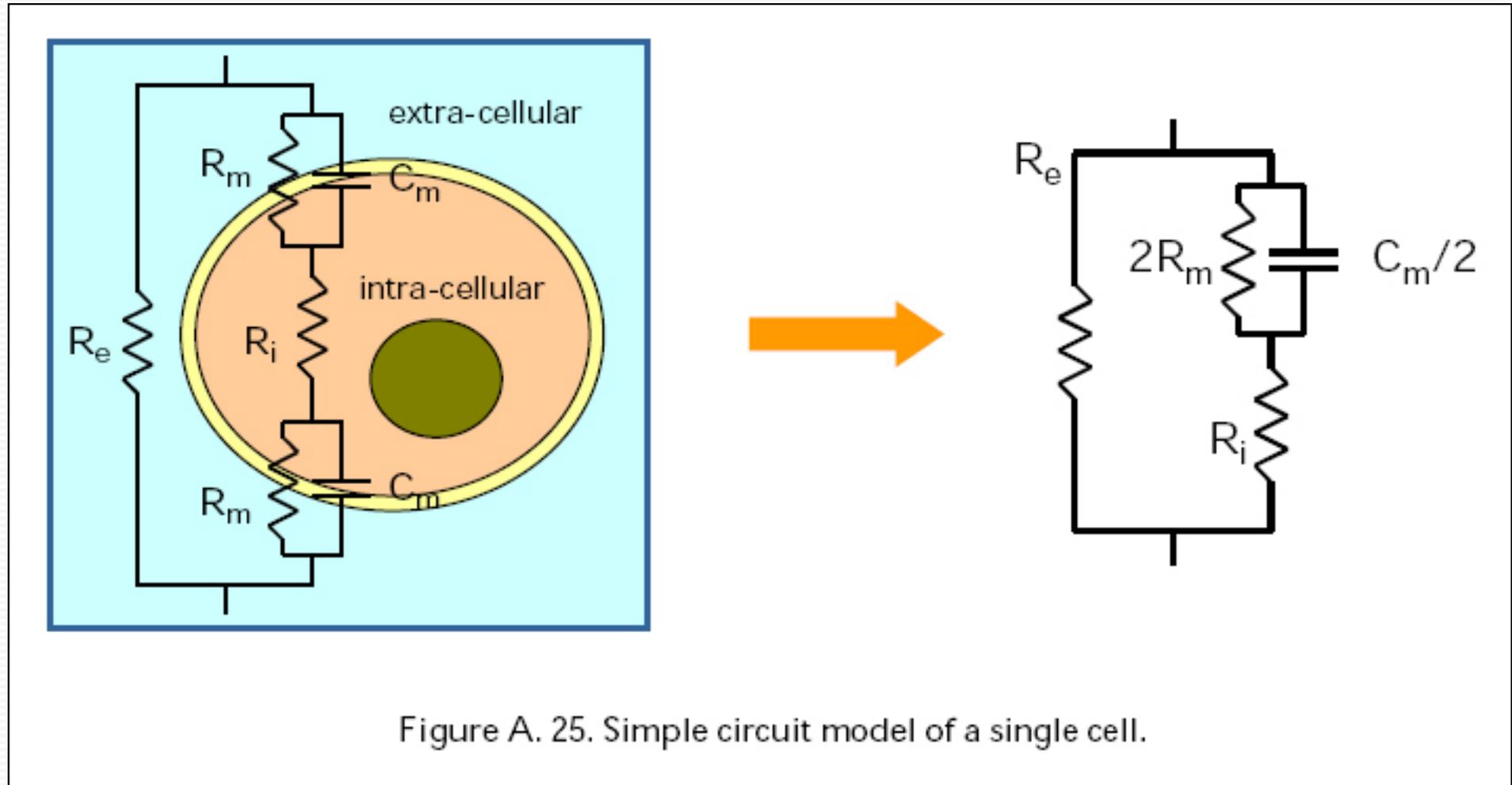
Electro-impedance computer mammogram MEIK®

Electro-impedance computer mammogram MEIK® has high diagnostic capabilities, which can be realized both with screening and early diagnostics of pathologic diseases and with diagnostics and treatment of non-pathologic diseases.



MEIK® makes it possible to conduct studies of adolescents, the women of any age, pregnant and feeding women, gives us opportunity to diagnose cancer of mammary gland, of mastopathy, mastitis, to estimate the function of lactation, to produce control over the state of mammary glands with the treatment of mastopathy.

Simple electrical model of a cell



The ionic concentration of the intracellular medium

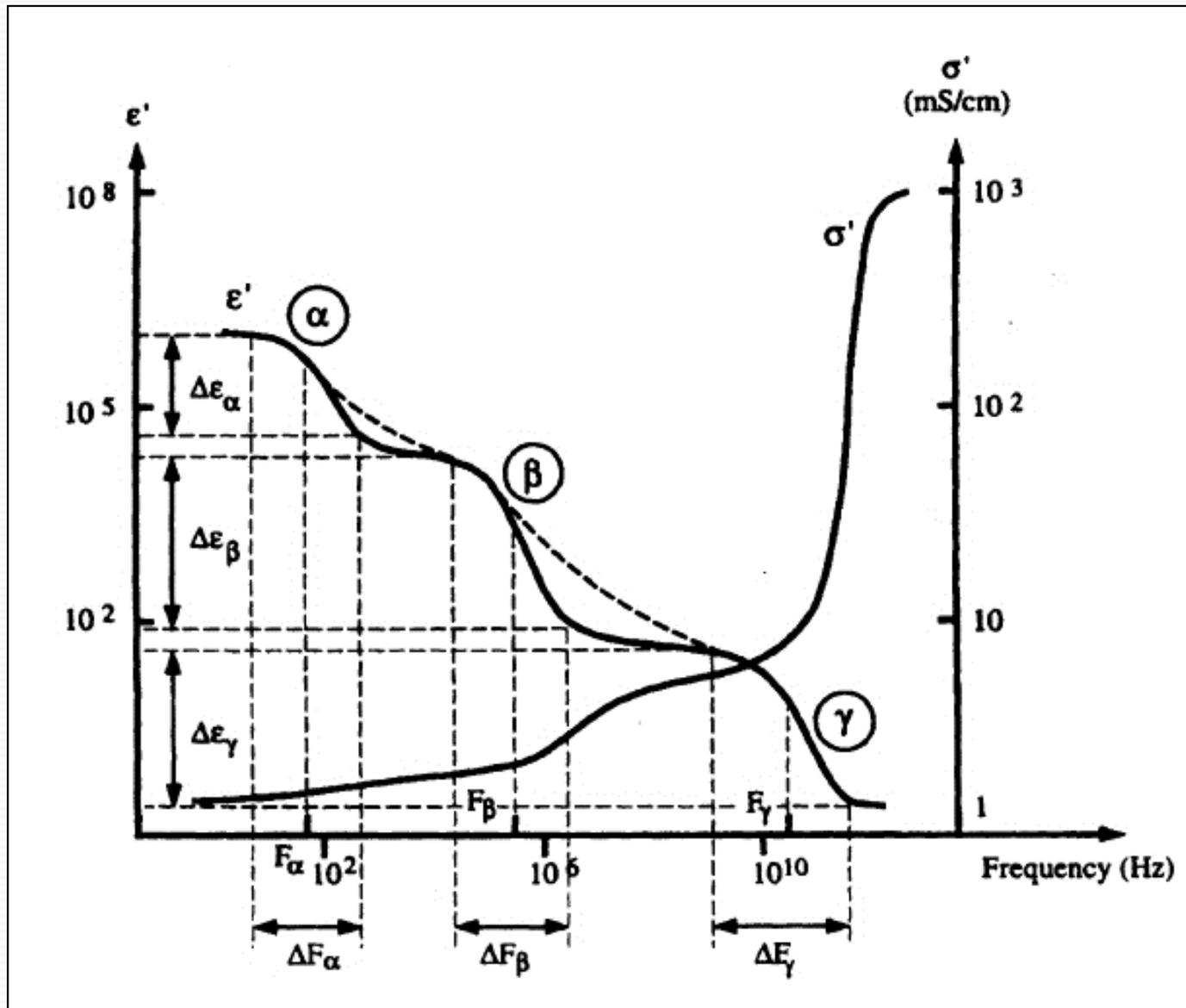


Concentration of electrolytes in body liquids (source: [2]).

| | cations (meq/L) | | | anions (meq/L) | |
|------------------|--------------------|--------------------|--|----------------|---------------|
| | extracellular | intracellular | | extracellular | intracellular |
| Na ⁺ | 142 | 10 | Cl ⁻ | 103 | 4 |
| K ⁺ | 4 | 140 | HCO ₃ ⁻ | 24 | 10 |
| Ca ²⁺ | 5 | 10 ⁻⁴ | protein- | 16 | 36 |
| Mg ²⁺ | 2 | 30 | HPO ₄ ²⁻ + SO ₄ ²⁻ | 10 | 130 |
| H ⁺ | 4×10 ⁻⁵ | 4×10 ⁻⁵ | + organic acids | | |
| Sum | 153 | 180 | Sum | 153 | 180 |

2. Grimnes, S. and Martinsen, Ø. G., *Bioimpedance and bioelectricity basics* London: Academic Press, 2000.

Main dispersions of the conductivity and the permittivity of biological materials

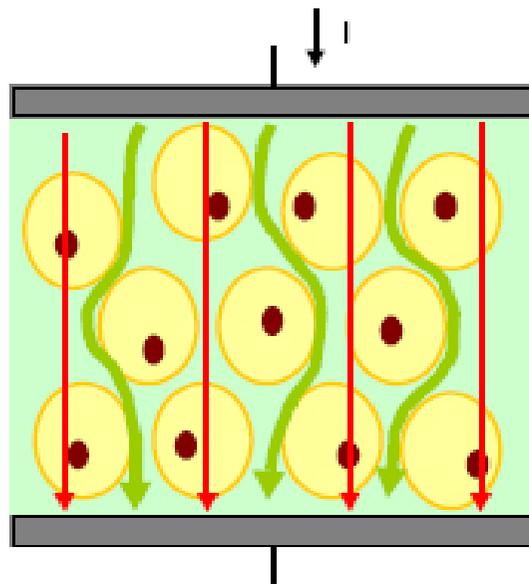


Electrical characterisation of the materials



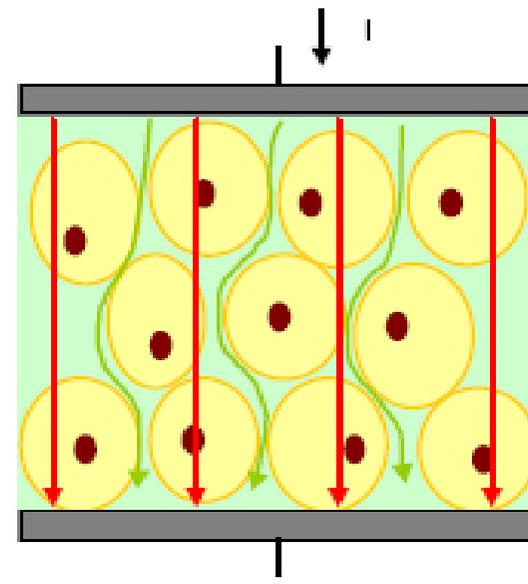
Dielectric properties

| Parameter | Symbols | Units | Equations |
|-----------------------|------------------|-------------|---|
| conductivity | σ, κ | S/cm | $Y = G + jB = K(\sigma + j\omega\epsilon); \quad \sigma = G/K$ |
| permittivity | ϵ | F/cm | $Y = G + jB = K(\sigma + j\omega\epsilon); \quad \epsilon = B/(\omega K)$ |
| relative permittivity | ϵ_r | no units | $\epsilon_r = \epsilon/\epsilon_0$ |
| resistivity | ρ | $\Omega.cm$ | $Z = 1/Y = (R + jX); \quad R=(1/K).\rho; \quad \rho \neq 1/\sigma$ |



low frequency (<1 kHz)

high frequency (>10 kHz)



Advantages of mammograph MEIK®



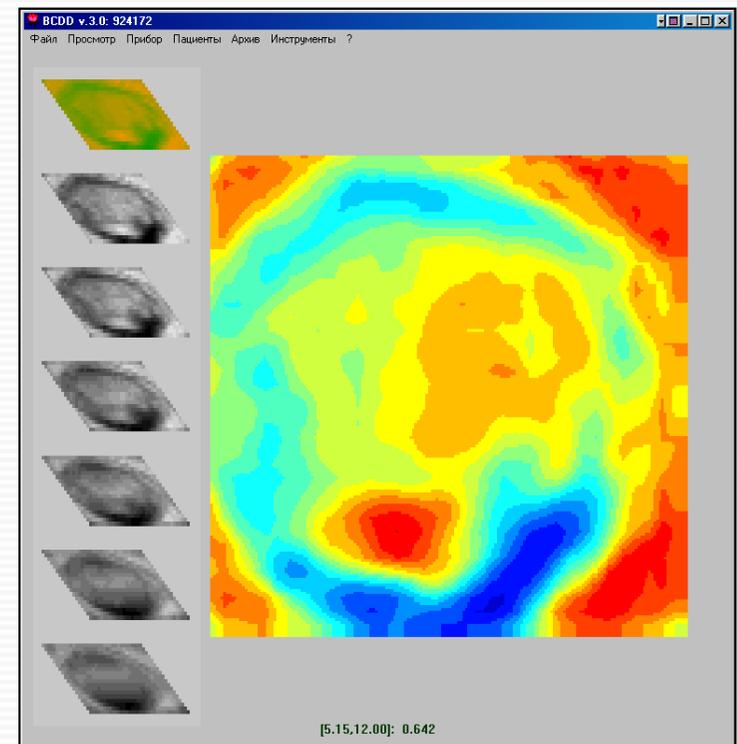
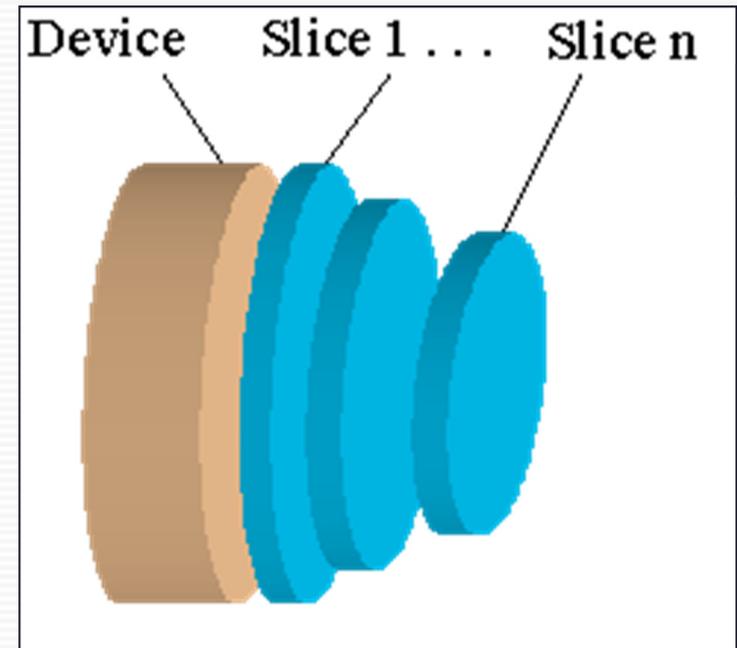
- Examination process is risk-free, safe for the patients and personnel
- Simple usage, no specific operating costs
- Minimal size, transfer-friendly
- Convenient organization of the work site
- Absence of expensive materials provides financial accessibility
- Access to consultations, support and materials of diagnostics in the electronic form
- Possibility to conduct quantitative assessment of the state of mammary gland.

Visualisation

Electro-impedance mammography

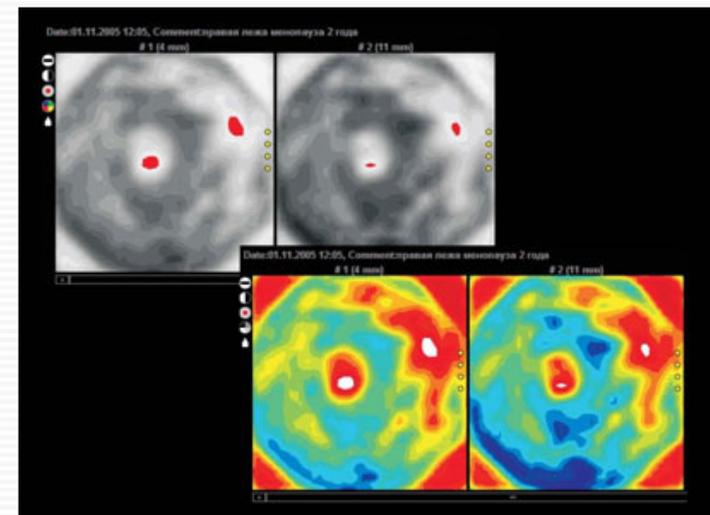
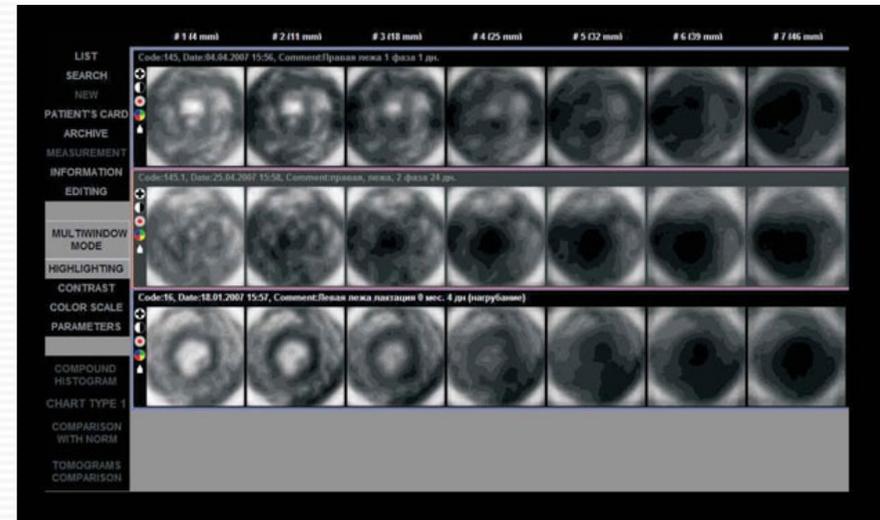
Method, which makes possible:

- to visualise the distribution of electrical conductivity of biological tissues in several cross sections of the mammary gland of patient
- to discover pathology as regions with the anomalous values of electrical conductivity on the images



Visualisation

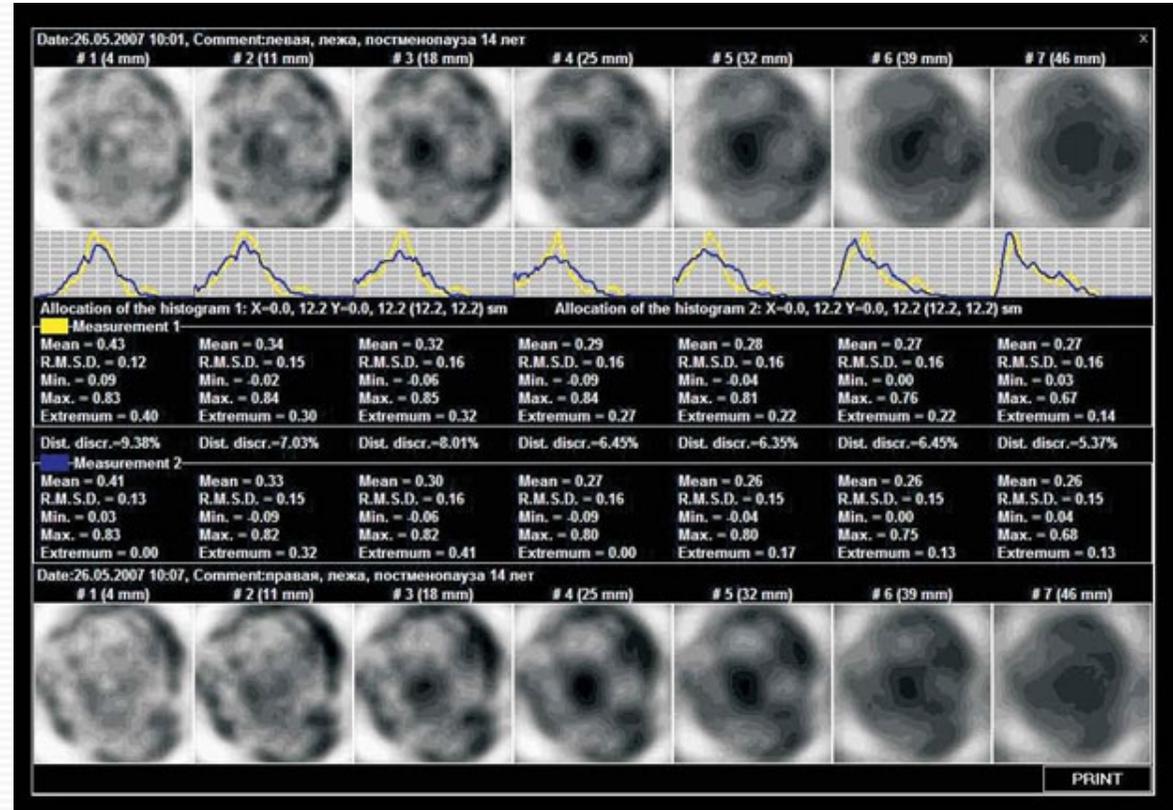
- To work with the image after scanning of mammary gland seven images of mammary gland appear, which correspond to the planes of scanning, parallel to the planes of electrode arrangement, with an increasing depth of 4 to 46 mm
- Several options are available for the additional processing of the obtained images by clicking on the icons located at the left border:
 - the colored scale
 - contrast
 - isolation of the assigned region
 - histogram



Visualisation

Calculations include:

- Determination of the index of average electrical conductivity
- Maximum and minimum electrical conductivity
- Standard deviation
- Mode
- Graphing of the distribution of electrical conductivity is produced simultaneously



- "MEIK" ® provides comparison of obtained data with the "standard" and the calculation of the nonparametric criterion of Kolmogorov - Smirnov - the percentage of the divergence of the distributions of electrical conductivity.
- The comparison of electrical conductivity of left and right gland with the calculation of the percentage of the divergence of the distribution of electrical conductivity is produced as well.

Comparison with other methods of the visualization

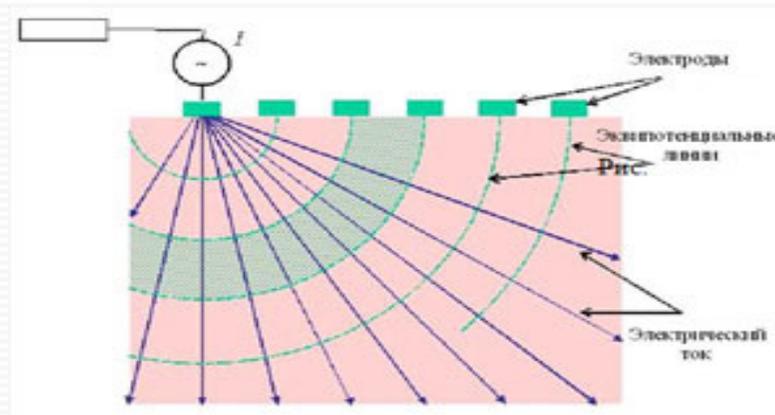
- Use of an electro-impedance method for diagnostics of the diseases of mammary gland requires the development of special equipment and mathematical methods, which differ from those utilized in the known systems of visualization.
- There are several essential differences in the technology, utilized in electro-impedance computer mammography, from other methods of medical visualization, such as X-ray and NMR tomography, ultrasonic techniques.

▪The first difference lies in the fact that the weak alternating electric current (50 kHz, 0.5 mA), is used as the sounding means, and the sensors of instrument record the distribution of the electric potential caused by flow current through the medium which is being investigated.

▪The second essential difference lies in the fact that the energy source and the recording sensors in the electro-impedance method are located in one plane.

On the contrary, in the X-ray tomography emitter and receiver are located in the different planes, connect with the straight equipotential lines intersecting the visualized volume.

Equipotential lines, along which the reverse projection of data is achieved in electro-impedance mammography, are bent and allow the possibility of tomographic visualization with the arrangement of electrodes at the body surface, without covering it from all sides.



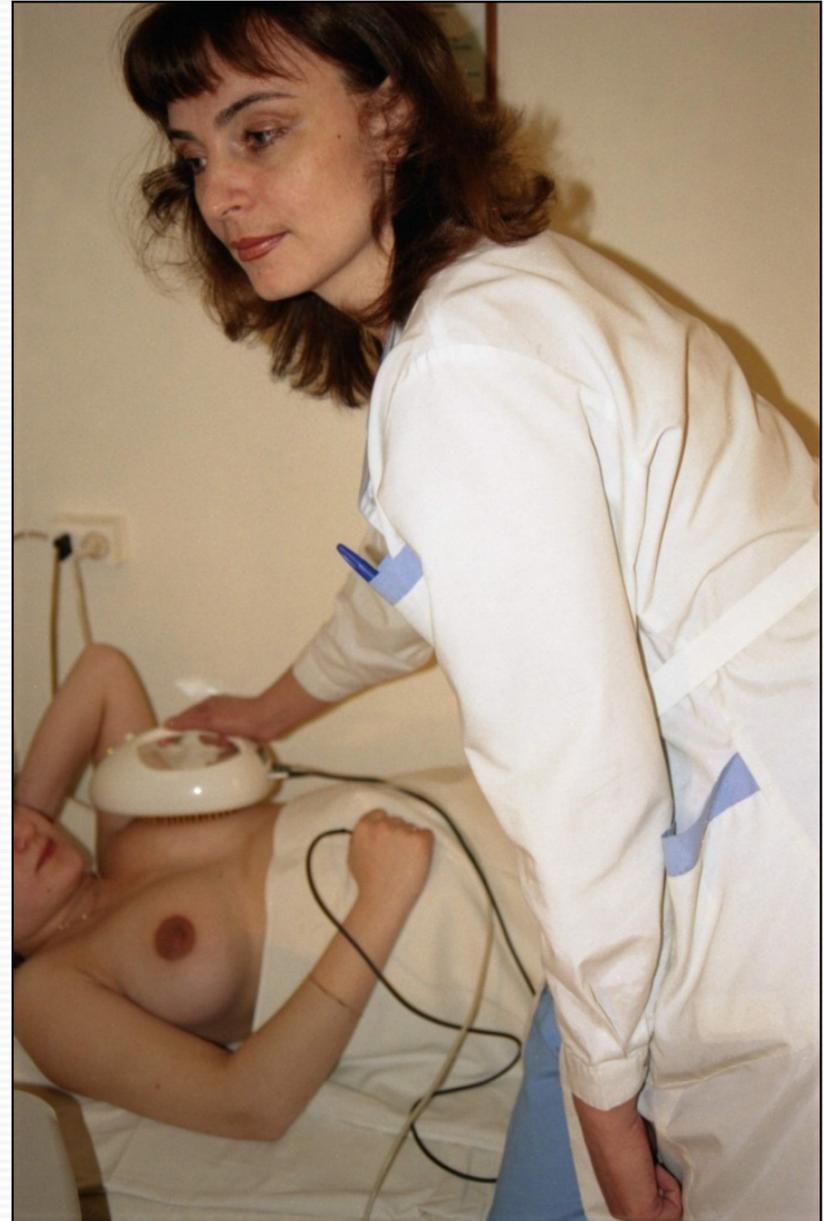
The third vital difference is in the fact that electro-impedance mammography makes it possible to give the quantitative assessment of the state of mammary gland, determining average electrical conductivity and histogram of the distribution of electrical conductivity in the mammary gland.

This gives the possibility to conduct the objective evaluation of the state of mammary gland and comparison with the standard dependent on age.

Fourthly, these are - safety, comfort and the informativeness of the study.

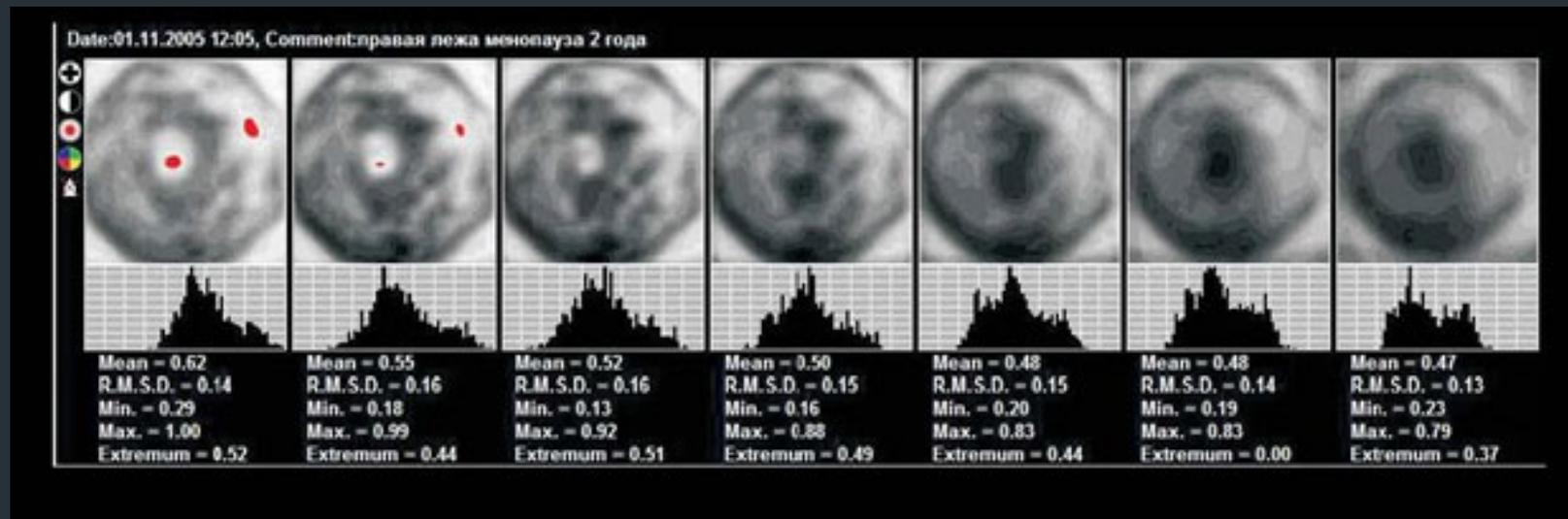
Clinical application

- **Indication for applying electro-impedance mammography is entire spectrum of the diseases of mammary gland, namely:**
 - high-quality and malignant new formations
 - mastopathy
 - mastitis
 - other
- Furthermore, electro-impedance mammography can be used with the dynamic observation of the women, who are included in the mammology file, with the control of the assigned treatment effectiveness.
- Studies in the period of pregnancy bring useful information and it is afterwards ancestral for the control of the formation of lactation function.
This method is not affected by the prescription of oral contraceptives and substitute hormonotherapy in women in the climacteric period.



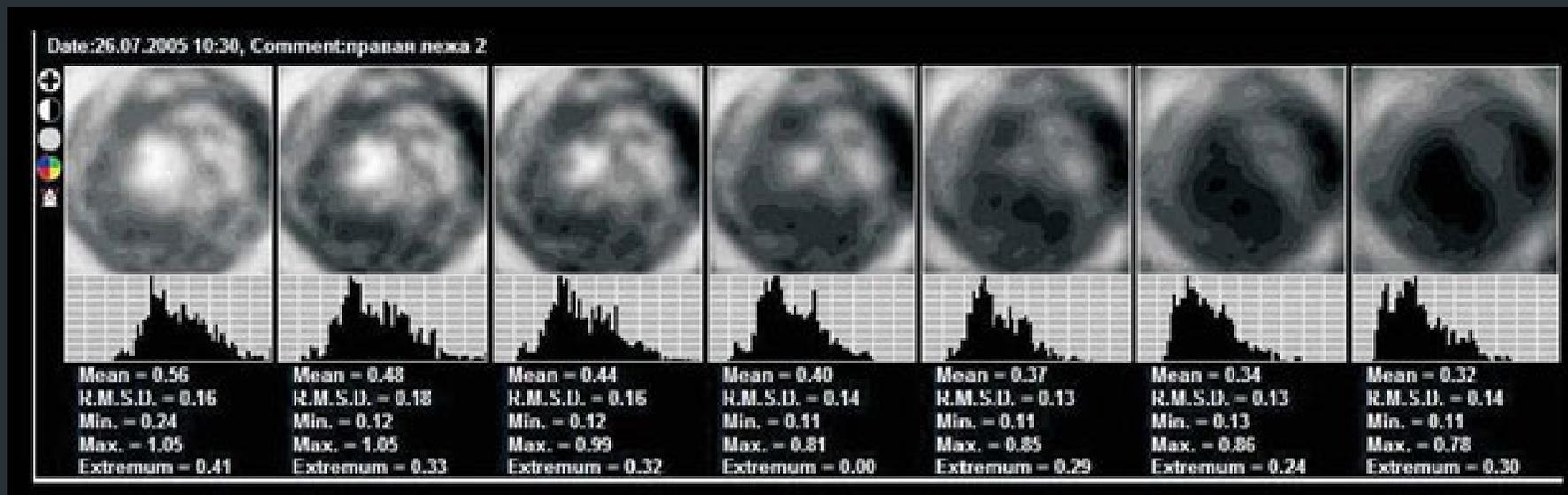
Oncology

In the course of the development of oncological process a change in the electrical properties of both tumor itself and surrounding cloths occurs. These facts can be used for detection and determining the localization of tumors. Principally important for diagnostics is the isolation of the uncomplicated form of disease, which is characterised by high electrical conductivity of tumor cells.

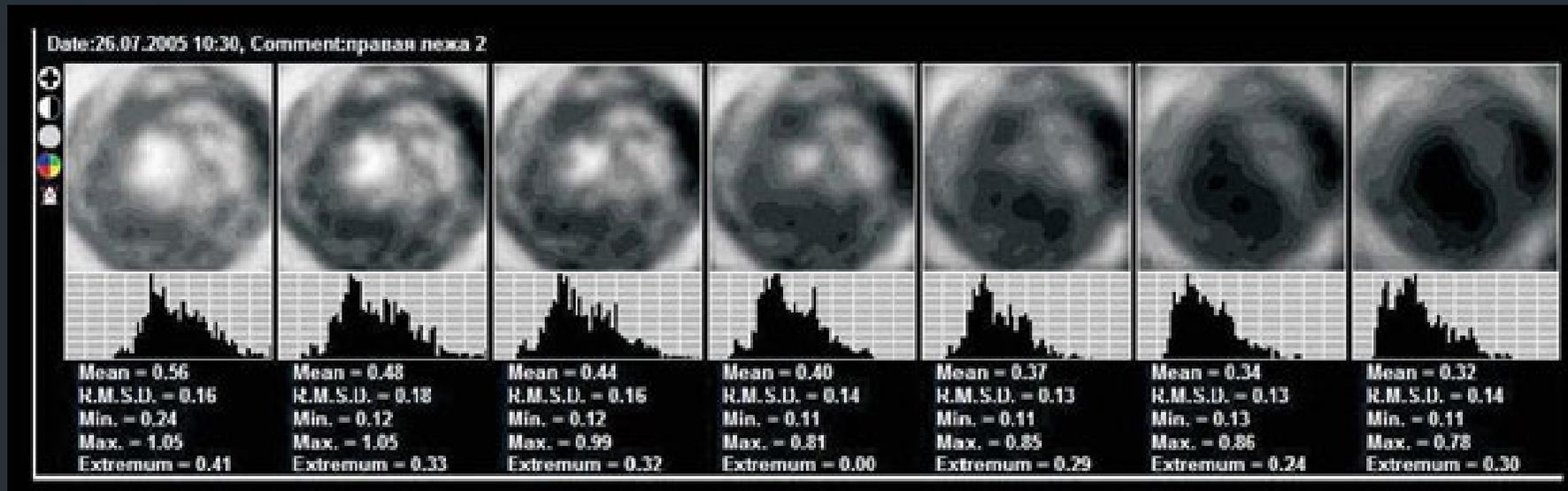


Uncomplicated form of cancer of the mammary gland

- The complicated forms of the disease, characterized by high local or general impedance



Complicated form of cancer of the mammary gland

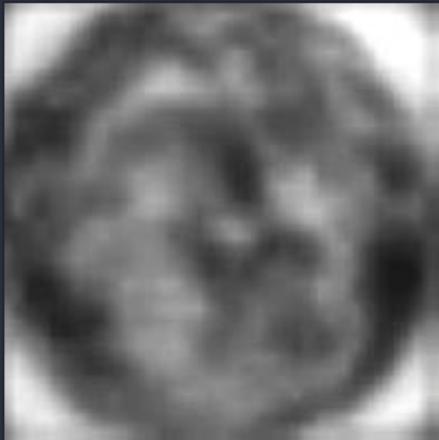


The infiltrative - edematic form of cancer of the mammary gland

Diagnostic possibilities of mammogram

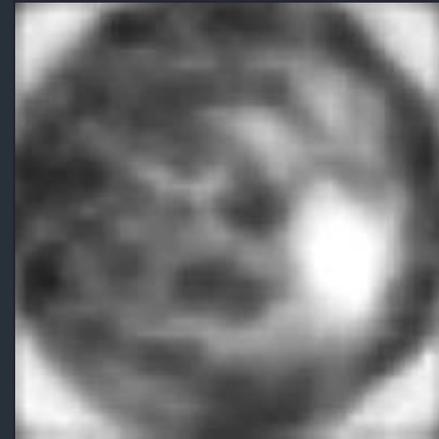
One of the most important diagnostic possibilities of mammogram "MEIK"[®] is diagnostics of precancerous diseases.

Electrical conductivity of malignant tumors is considerably differed from electrical conductivity of healthy tissues already from the earliest stages of tumor process, which also allows to carry out early diagnostics of oncopathology.



EIT the image of mammary gland within the standard.

The cross section shown corresponds to depth of 1.2 cm. Nipple is in the center of the image.



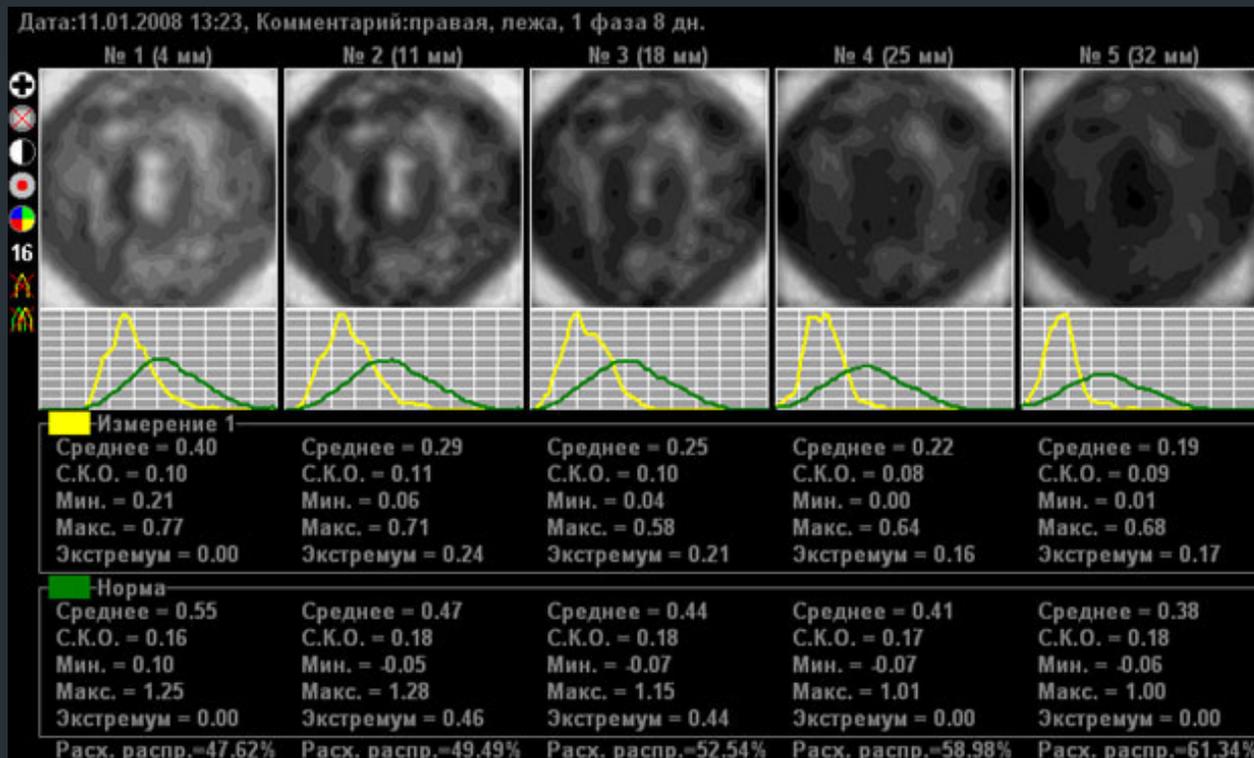
EIT the image of mammary gland with the large carcinoma - bright spot in the right side of the image.

- Section at the depth of 1.2 cm

Mammalogy

Regarding WHO (Geneva, 1984), by mastopathy are understood dysplasia of mammary gland, fibrous- cystic disease, which is characterized by the wide spectrum of proliferating and regressive changes in the tissue of mammary gland with the abnormal relationship of epithelial and connecting components.

Since a quantity and the relationship of the basic woven elements, such as the cells of ductal and alveolar epithelium, collagenic and elastic fibers, cell of adipose tissue, the base material of connective tissue, determine the physical chemistry properties of mammary gland, very attractive and logical is the use of an electro-impedance tomography of mammary gland for diagnostics of mastopathy and control of the carried out treatment.

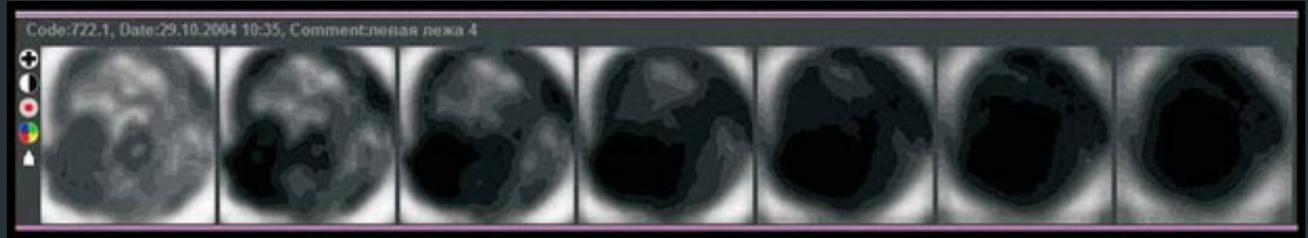


Mastopathy, fibrous form (comparison with the standard).

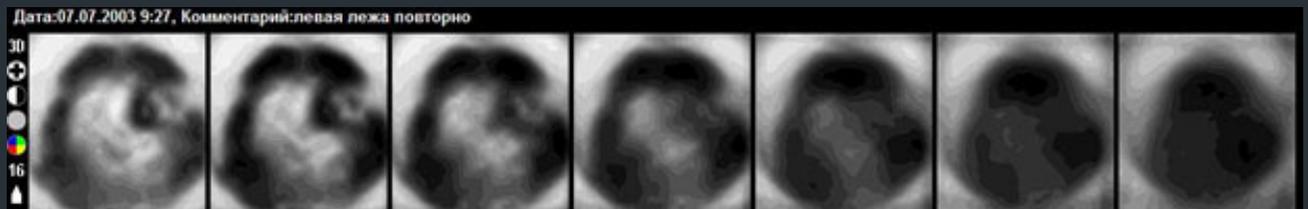
Midwifery

Inflammatory process in the mammary gland is developed in the friable connective tissue and is accompanied by the complex of vascular changes with the exudation of the liquid component parts of the plasma, by the emigration of the cells of the blood and by the proliferation of the cells of stroma.

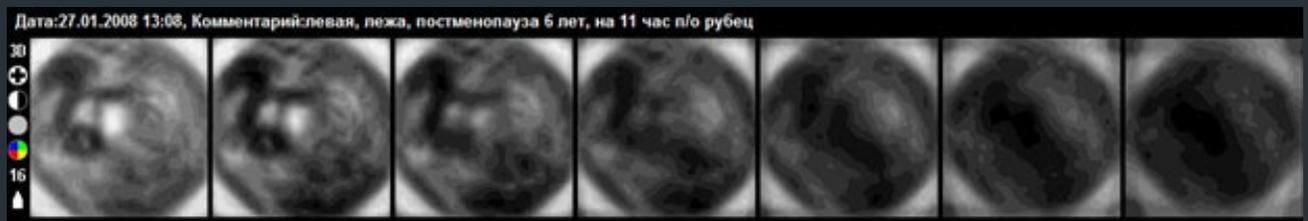
In the process of the development of inflammation, the electrical conductivity of inflammatory center changes.



Mastitis. Stage of the infiltration.



Mastitis. Stage of the abscess formation.



Mastitis. Stage of proliferation (cicatrisation).

MEIK® the 5th version



Gel electrodes to stick on the wrist of the hand, nearest to the mammary gland being investigated, at a distance 1,5 – 2 cm from each other.



To close on them the fastener catches of the cable of patient.

Measurement of impedance

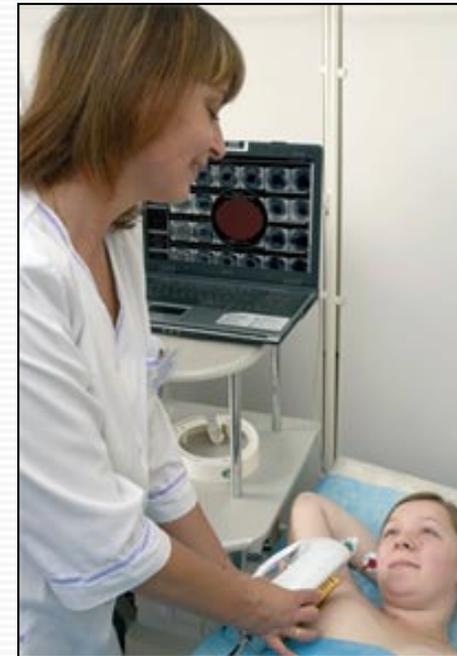
It is necessary to moisten mammary gland evenly by water using the tampon
No presence of drops or dry places is allowed.



Positioning of the microprocessor sensor onto the center of the mammary gland, using a laser view-finder.

Process of examination

- To attain a maximum quantity of good contacts on the dynamic map of contacts.
- After the button "start " is pressed, the process of measurement starts. The duration of the fixation of sensor on the mammary gland is not more than 35 seconds.
- After the computer reconstruction of image, review the quality of mammogrammy. If necessary, repeat the measurements.



Main rules of EI examination

1. patient position - large breasts
- very small breasts

Lying position

Sitting position

2. Receiving the maximum contact of electrodes with the breast

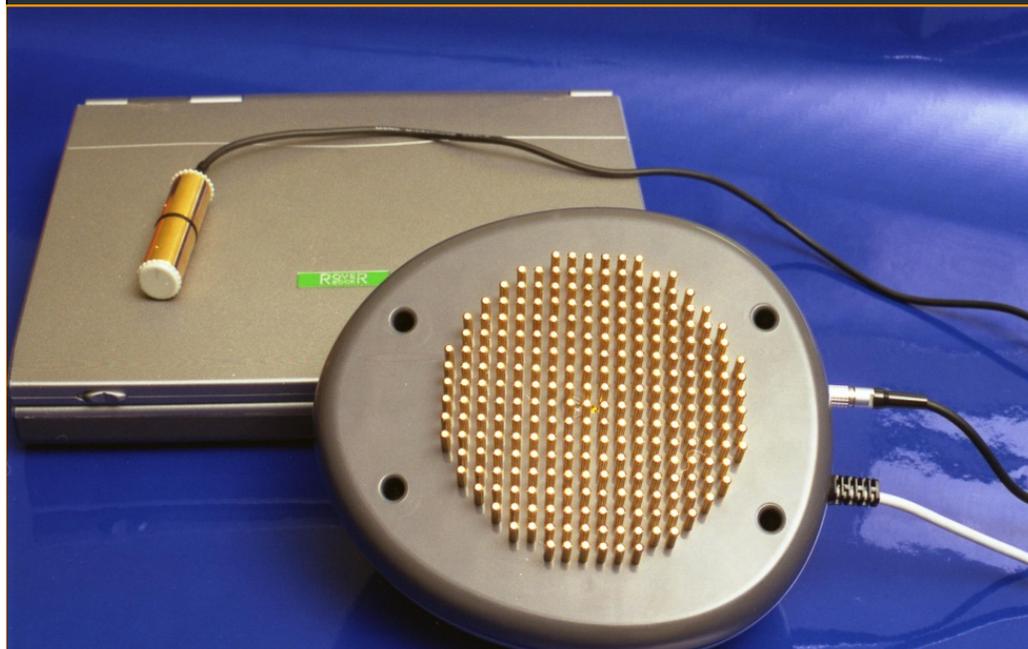
Maximum 256

3. Twice examine the same breast and select the best image

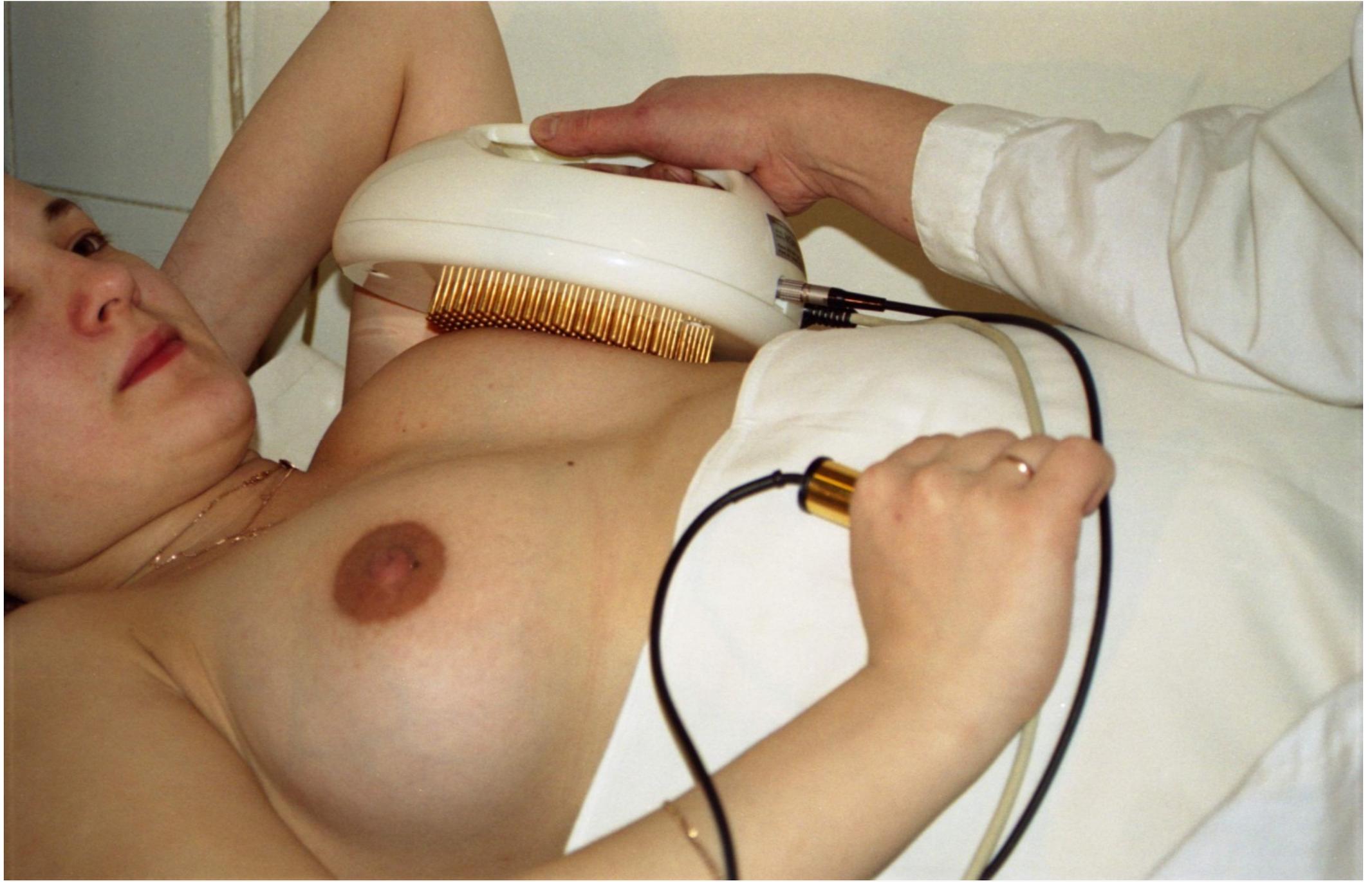
~~210 contacts~~

243 contacts

Diagnostic set











Electric conductivity depending on a patient's position

| Frequency | Position | Phase 1 | Phase 2 | Pregnancy | Lactation | Postmenopause |
|-----------|----------|-----------|-----------|-----------|-----------|---------------|
| 50 kHz | Lying | 0.42±0.09 | 0.39±0.08 | 0.42±0.09 | 0.41±0.09 | 0.64±0.06 |
| | Standing | 0.39±0.08 | 0.43±0.08 | 0.40±0.09 | 0.35±0.09 | 0.64±0.07 |

Electric conductivity depending on the side of scanning

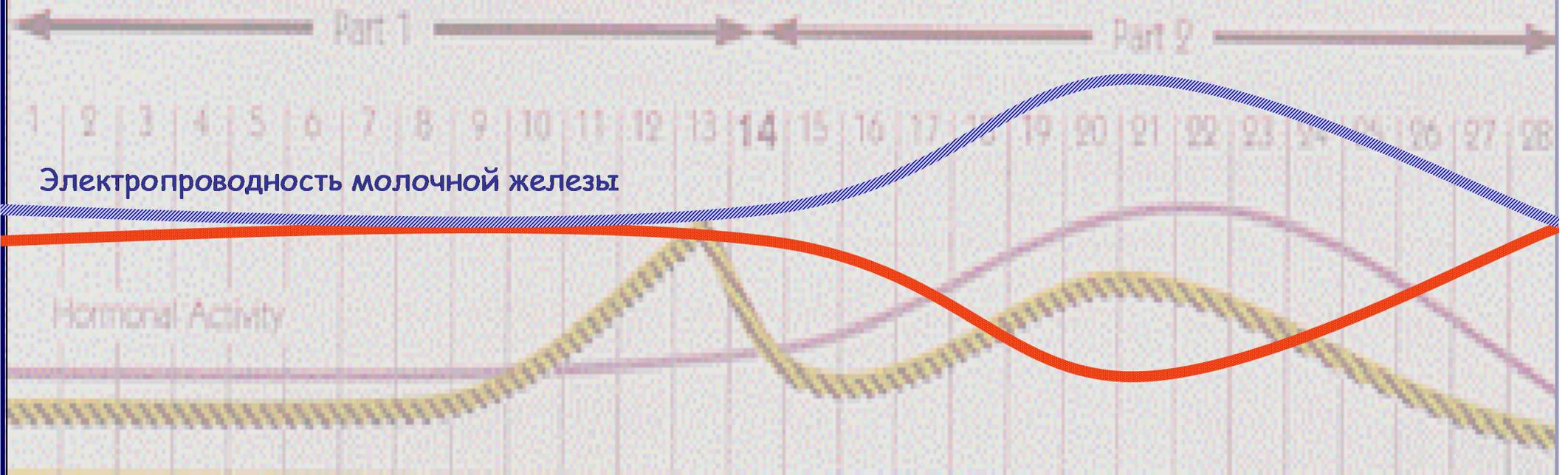
| Frequency | Position | | Phase 1 | Phase 2 | Pregnancy | Lactation | Postmenopause |
|-----------|----------|---|-----------|-----------|-----------|-----------|---------------|
| 50 kHz | Lying | s | 0.41±0.1 | 0.37±0.08 | 0.43±0.09 | 0.44±0.08 | 0.64±0.07 |
| | | d | 0.43±0.08 | 0.4±0.08 | 0.42±0.09 | 0.38±0.1 | 0.64±0.05 |

Electric conductivity distribution at 50 kHz

| Frequency | Electric conductivity distribution | Phase 1 | Phase 2 | Pregnancy | Lactation | Postmenopause |
|-----------|------------------------------------|---------|---------|-----------|-----------|---------------|
| 50 kHz | Unimodal | 37.5% | 31.2% | 35.7% | 37.5% | 5% |
| | Bimodal | 9.4% | 59.4% | 7.1% | 3.6% | 0% |
| | Multimodal | 53.1% | 9.4% | 57.2% | 58.9% | 95% |

Hormonal form of mastopathy

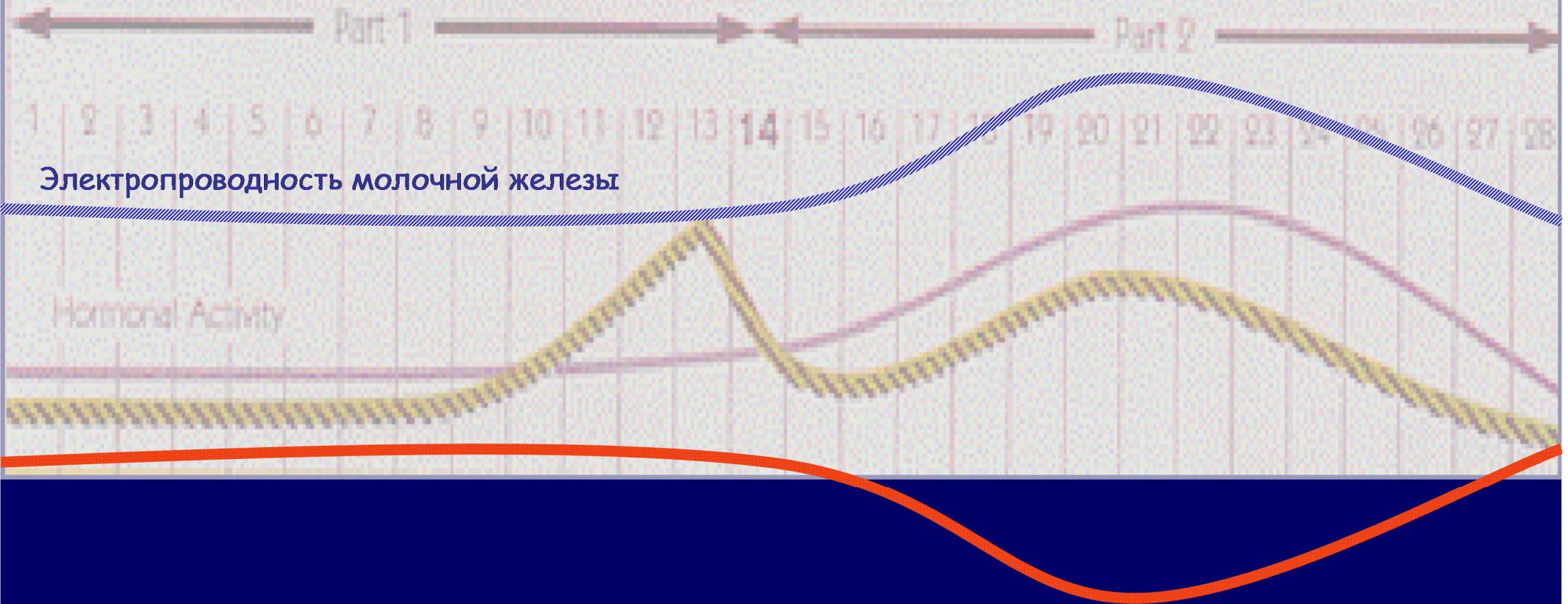
Menstrual Cycle



$Dx > 40\%$

Mixed form of mastopathy

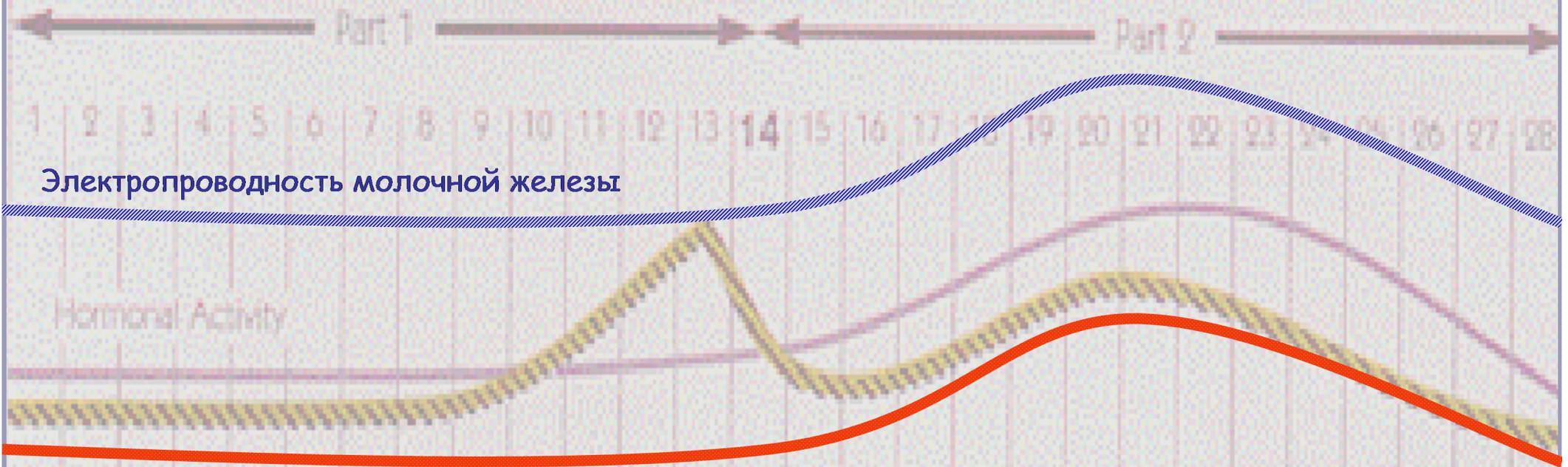
Menstrual Cycle



$D_x > 40\%$

Fibrosis form of mastopathy

Menstrual Cycle



$Dx > 40\%$

Technical Specifications



- Overall dimensions: 180x160x110 mm
- Weight: 2 kg
- The utilized current for the scanning is within the limits of $0,5 \text{ mA} \pm 20\%$ with a frequency of 50 kHz
- Mammogram provides continuous 8 hour work in the operation with the constant load.
- Warranty period - 2 years.
- Mammogram is prepared in the climatic performance UKHL of category 4.2 according to GOST 15150.
- Electrical safety issues - mammogram corresponds to requirements of EU Directive 93/42/EEC, CE 1023 and GOST R50267 according to class to the II type of protection B.

Operating characteristics

- sensitivity - 92%
- specificity - 99%
- the prognostic value of positive result - 73%
- the prognostic value of negative result - 99%



Usage Time Features

- Duration of the procedure: scanning is accomplished in 35 seconds.
- The process of diagnostic inspection, from the moment of the collection of anamnesis to the delivery of conclusion, takes in average up to 15 minutes.
- Inspection with the screening takes 3-5 min.



Requirements for the computer:



- Processor: Intel Pentium IV or above (or compatible)
- Working storage: not less than 512 MB
- Free hard disk space: not less than 500 MB
- USB port
- Video interface: graphic card with the support of the regime of 3D apparatus acceleration, 128 MB or above
- Operating system: Windows XP with SP2
- Display: 15" display