Multifrequency Electrical Impedance Mammograph

MEM 20-11

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Now we are the sole distributor of MEM product manufactured by Impedance Medical Technologies, located in Russia.

ИМТ

Impedance Medical Technologies, Russia founded in 1993 Creating common technological solutions for developing and producing high-tech equipment for conducting diagnostic and scientifica analysis by PCR.

PCR-laboratories starting from the laboratory plan, supplies of equipment and reagents to promotion of a wide range of research. Producing awide range of reagents for clinical becteriology, virology and gene diagnostics. Producing a wide range of reagents for detecting DNA of agricultural plant infections and diagnostics of genetically modified organisms.

Contents

Electric Impedance Multifrequent Mammographer (MEM)

Electrical impedance mammography is a modern highly informative and safe method of mammary glands examination that has been proven effective in action.

MEM multifrequent electrical impedance mammographer is intended for diagnostics of abnormal changes of breast tissue. Electrical impedance diagnostic method is based on significant correlation of electrical conductivity (ability to conduct electricity) of biological tissues with their physiological state. It is known that electrical conductivity of many newgrowths, in particular malignant breast tumors, is substantially different from this of surrounding healthy tissues. That very phenomenon determines high sensitivity of mammographer.

This device allows getting a pattern of biological tissues electrical conductivity distribution in cross sections of the breast at different frequencies using electrical impedance tomography method (EIT). Electrical conductivity distribution of each cross section is visible on the monitor screen of the personal computer. The main advantage of electrical impedance diagnostic methods is absolute safety, high information capacity of testing, compactability and low cost of equipment and testing procedure simplicity. The mammographer is intended for use in specialized hospital departments and clinics.

MEM effectively complements conventional diagnostic methods as it is based on other physical principles. Simple operation and high accuracy of this mammographer makes breast diagnosis more accessible to physicians and their patients.

Purpose of Mammographer

Diagnosis of abnormal and non-pathological changes in breast tissues by measuring their electric conductivity and by layer-by-layer reconstruction and visualization of electric conductivity distribution throughout the test organ as tomographic cross sections.

Benefits of Electrical Impedance Mammography Method (EIM)

- Testing safety (non-invasiveness, absence of radiation exposure) that remove restrictions on patients' age and number of procedures
- High accuracy and information capacity
- Layer-by-layer 3D imaging of breast conductivity distribution on the computer screen
- Unbiased quantitative criteria for assessing changes in breast
- Easy-to-understand diagnosing scheme
- Early detection of breast pathology; detection of tumorous and precancerous changes
- Simple diagnostic procedure, no discomfort for patients
- May be performed during pregnancy and lactation, and in any day of the menstrual cycle.

Device Advantages

- Easy operation
- Compactability and portability
- Measurement of electrical conductivity at two frequencies of 10 kHz and 50 kHz increases information capacity of testing results
- Relatively low cost includes training of one operator
- Does not require specially equipped office and expensive consumable products.

Application Scope

- Cancer screening - MEM can be applied for mass screening and selection of women at risk
- Differential diagnosis of diffuse and focal diseases of mammary gland
- Monitoring:
- reliable monitoring of the mammary glands in women taking hormonal contraceptives and HRT
- case monitoring of identified pathologies
- drug therapy effectiveness evaluation

Brief history: towards a multi-frequency electrical impedance mammographer

1978
Transthoracic impedance image of the chest has been obtained for the first time (R.P. Henderson, J.G. Webster)

1982
Electrical impedance tomographic image has been obtained for the first time (B.H. Brown, D.C. Barber) Sheffield, United Kingdom

1987
Scheme for rapid reconstruction of impedance images or "back view method" has been developed (Brown B.H., Barber D.C., Seagar AD., Eyuboglu B.M.) Sheffield, United Kingdom

1995
First operational three-dimensional electrical impedance tomographer prototype has been developed by RAS Radioengineering and Electronics Institutenamed after V. A. Kotelnikov (Cherepenin, A., Korzeniowski AV.) Moscow, Russia

1998
First model of electrical impedance mammographer EIM-003 "Corvette" has been developed (Cherepenin VA, Korzeniowski A. V.) Moscow, Russia 2003

2003
Development and serial production startup of single-frequency electrical impedance computer mammographer MEIK (V. A. Cherepenin, A.V. Korzhenevsky) Moscow, Russia 2007
Development and serial production of multi-frequency electrical impedance mammographer MEM (V. A. Cherepenin, A.V. Korzhenevsky, "IMT" LLC, Yaroslavl)

Electrical impedance tomography is an advanced technology that has been developing since the 1980s by several dozen research groups worldwide. Most groups are located in Western Europe, primarily in the UK, Spain, Germany, France, and the United States. Significant progress in medical applications development was made by the following groups:

- B. H. Brown group (UK) – works in the field of neonatology and oncology;
- D. S. Holder group (UK) – works in the field of neurophysiology;
- I. Frerichs group (Germany) – works in the field of pulmonology;
- PJ. Riu group (Spain) – works in the field of physiology of the lungs;
- A. Hartov, J. Newell, and D. Isaacson group (USA) – works in Oncology.

RAS Radioengineering and Electronics Institute named after V. A. Kotelnikov, Moscow is a world leader in development of electrical impedance mammography method. Research in electrical impedance tomography has been conducted there since the mid 1990s under supervision of RAS associate member, Professor V.A. Cherepenin.

National standard
Electrical impedance mammography method is included in the national standard for medical care for patients with malignant tumors of mammary gland, section 1.1. "Diagnostics", method code A05.20.001 (approved by Order of the Ministry of Health and Social Development of the Russian Federation No. 744 of December 1, 2005)

EIM method has been included in the National Mammology Manual edited by V. P. Kharchenko, N. I.Rozhkova since 2009.

Chapter 2. Diagnostic Method for Breast Diseases.
2.1. Methods for selection of women at risk.

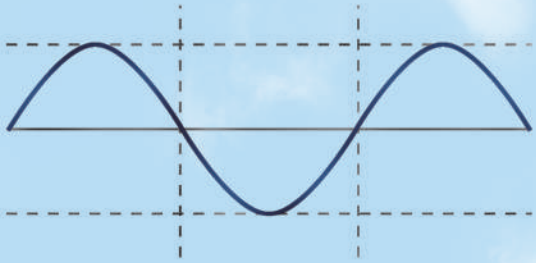
Chapter 8. Mammary Glands Examination System. Diagnostic Schemes.

Electric Impedance Mammography Method (EIM)

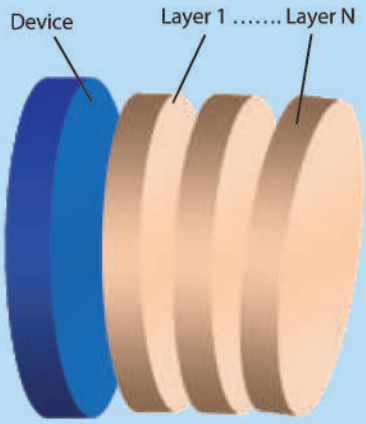
Electrical Impedance Diagnostic Method is based on biological tissues ability to conduct electrical current. An important characteristic of the current is that is searches for the least effort path. Studies have shown that this path is going through body fluids that are electrolyte - spinal fluid, lymph and blood so they have the highest electrical conductivity that means the least resistance or impedance. Fat and bone tissues and dry skin have very low electrical conductivity. The impedance of tissues and organs depends on their physiological state so information about relative change of electrical conductivity is used for assessment of biological tissues functional condition, the presence of inflammatory processes or detecting abnormal changes in permeability of cell membranes and walls of blood vessels or effect of various factors impact on organism, for evaluation of blood filling of organs and tissues vessels.

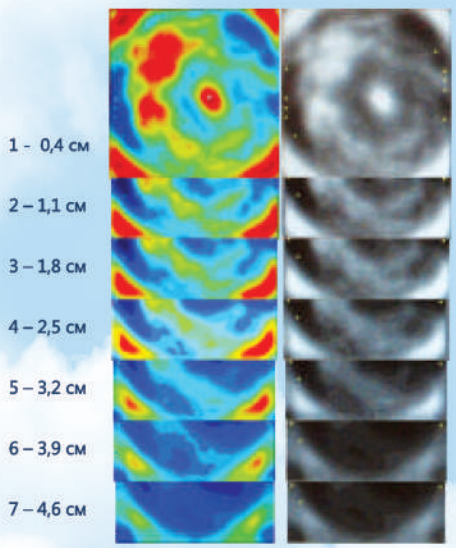
Electrical impedance tomography (EIT) allows detecting pathology as areas with abnormal electrical conductivity values. The EIT principle of body scanning with a further conversion of electrical signals into tomographic images by computer processing of the obtained data and application of back view mathematical methods is similar to that of computer tomography (CT) despite the differences in applied radiation. In CT X-rays are used while in EIT – weak alternating current. Both methods are based on the biological tissue thickness influence on the electric field or the radiation penetrating the object.

Electrical impedance mammography (EIM) is an innovative, high-tech and safe method of breast examination allowing obtaining three-dimensional images of their conductivity by ac sounding and subsequent computer processing and reconstruction of the impedance distribution by means of solving of so-called inverse problem for the electric field equation in heterogeneous medium. A set of electric measurements made by multielectrode sensory device placed on the surface of the breast is used for calculations.

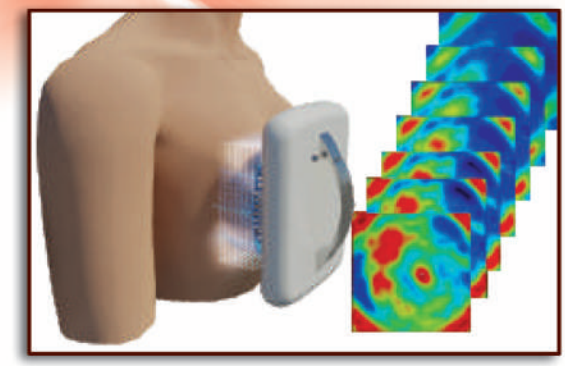


Electrical impedance of biological tissues is used to determine their viability in various diagnostic methods. Rheography method has become widespread: a method of examination of blood supply to organs based on changes of tissue electrical resistance due to changing blood filling. Electrical impedance spectroscopy is being actively developed – this method determines dependence of tissue impedance on applied current frequency to assess body composition and volume of extracellular and intracellular fluid.

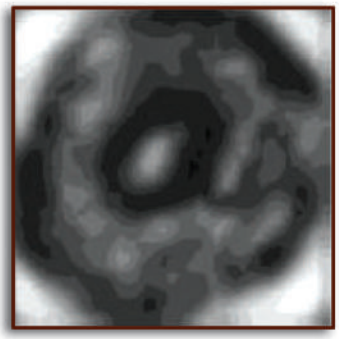




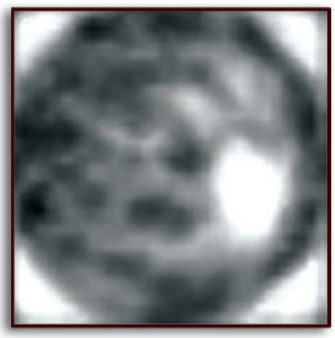
Electric Impedance Mammography Method (EIM)



EIT image of the breast, reconstructed by results of clinical measurements:



EIT image of the mammary gland in normal condition. Cross-section to a depth of 1.1. cm; the nipple is in the center of the image.



EIT image of the breast with large carcinoma - a bright spot on the right side of the image. Cross-section at a depth of 1.1 cm

EIM Technology

MEM multifrequent electrical impedance mammographer is used for EIM. The device consists of an instrument unit with an integrated microprocessor control system that hosts 256-electrode matrix. Instrument unit is connected to discharge unit consisting of input and output electrodes. During the test this unit is placed on the patient's arm. In the scanning process the device alternatively injects weak alternating electric current into the patient's body and scans corresponding electric potentials distributions on its surface by other electrodes. The data obtained are then used for electrical impedance tomogram reconstruction by mathematical algorithm on a personal computer connected to the mammographer.
The intuitive interface of software simplifies specialist's work. The software was developed with direct participation of doctors and based on their feedback. Numerics data and images storage allows full observance of patient's dynamics.

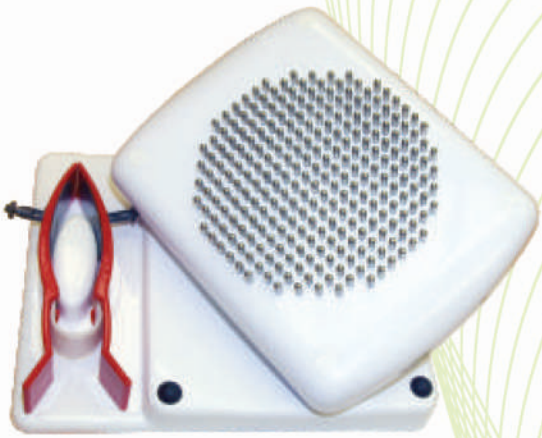
AC of sufficiently high frequency is used for diagnostics. The working frequency for electrical conductivity visualization may vary in the range from 10 kHz to 50 kHz. Instrument unit electrode voltage does not exceed 12V. Current of measurement does not exceed 1 mA. This current amplitude is acceptable being below any health standards; it does not cause changes of biological tissues and therefore is widely used for diagnostic purposes. Applied measurements scheme makes imaging results practically insensitive to the condition of skin surface.

Electrical conductivity of healthy and abnormal breast tissues, including malignant tumors, are significantly different at the earliest stages of the disease. This is why:
- EIM allows diagnosing of various pathological changes in the breast before they become visible by other test methods;
- EIM allows visualize and objectively assess the state of mammary glands, as at the moment and at runtime;
- EIM has no contraindications and does not cause discomfort and due to its safety may be used for women of all ages, including pregnant and lactating ones.
- EIM in many cases may replace x-ray examination, being safe and affordable alternative or additional method.

Application of Electric Impedance Mammographer (MEM)

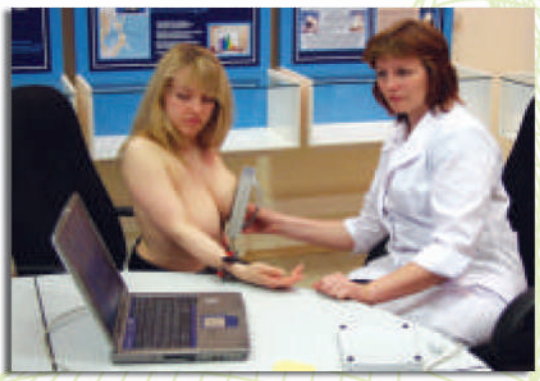
MEM Principle of Operation

• The device performs a series of measurements of breast tissue electrical conductivity through non-invasive weak current sounding and reconstructs its three-dimensional distribution pattern on the computer screen.
• The software records individual characteristics of each patient, medical history (physical, gynecological, obstetric), age, phase and day of menstrual cycle, hormonal drugs dose and adjusts the average rate of electrical conductivity for each cross-section.
• The result of scanning and data processing:
-seven layer-by-layer images of the breast, corresponding to seven scan planes located parallelly to the chest at a depth from 0.4 to 4.6 cm, every other 0.7 cm;
- design electrical conductivity values at each level: normal, average, maximum and minimum conductivity, mean square deviation, extreme point and dispersion; electrical conductivity values in selected region of pathology;
- chart and histogram of conductivity frequency distribution.



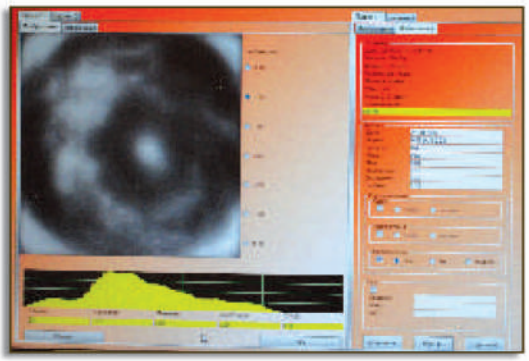
• Two modes of image visualization:
- filtration mode in the gray scale step
- color scanning mode
The conductivity is measured at two frequencies, 50 kHz and 10 kHz increasing diagnostic capability of device.
• Two-window view is convenient for comparison of data (current and past examinations, left and right breast, examined breast and average norm, etc.).
• The total examination time, including measurement and evaluation of received data is 10-15 minutes, which is an obvious benefit, especially in the context of mass screening.

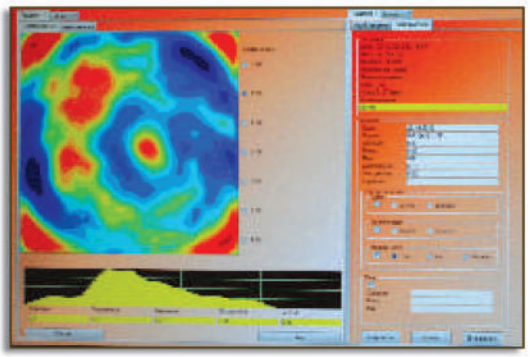
Advantages of Electric Impedance Mammographer Application



- It allows distinguishing mastalgia as a symptom of premenstrual tension from painful symptoms of dishormonal breast diseases.
- It allows accurate identification of different types of mastopathy.
- Accurate diagnostic criteria of mastalgia of various nosetiology identified by electrical impedance examination allows determining the tactics for management of patients with breast pain syndrome, which is significant in the practice of obstetrician gynecologist.
According to oncologists some abnormal changes in the breast may not manifest clinically and not constitute a life threat. The method of multifrequent electrical impedance mammography allows not exposing patients to excessive treatment assigning the required monitoring for numeric electrical conductivity of identified pathology instead

Application of Electric Impedance Mammographer (MEM)

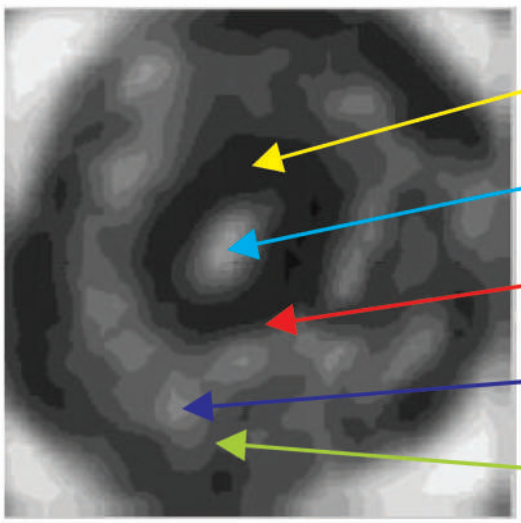




Images in main window of the software application allow performing the following evaluation:

- Acutance and contrast of images
- Symmetry of images at all scanning levels
- Presence or absence of contour extrusions indicating edema or large breast tumor or retractions indicating scar deformity
- Presence or absence of hyperimpedance contour around the image
- Electrical impedance anatomy of mammary glands at different scanning levels
- Correlation of received electrical impedance images with breast age structure (juvenile, reproductive, premenopausal, postmenopausal). A mismatch indicates the presence of a pathological process in the breast or subinvolution tissue changes.
- Correlation of received electrical impedance images with woman's life physiological period (the first phase of the menstrual cycle, the second phase of the menstrual cycle, pregnancy, lactation, menopause).
- Presence or absence of hypoimpedance "areoles" and their localization.

Electrical impedance anatomy of the mammary gland

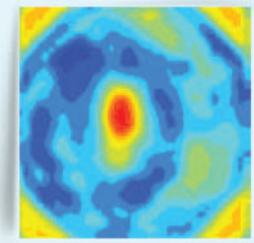


50 кГц, 2-й уровень сканирования

Application of Electric Impedance Mammographer (MEM)

Electrical impedance image in normal condition

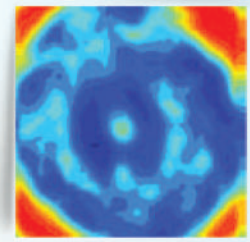
• A clear internal structures architectonics and anatomical landmarks visualization.
• Mosaic structure of parenchyma and connective tissue images with smooth transitions of grayscale shading.
• Correlation of electrical impedance image with mammary glands age structure.
• No deformation of image contour.
• No focal lesions.
• No difference between images taken from different views and sides of scanning.
• Symmetry of conductivity frequency distribution graph.



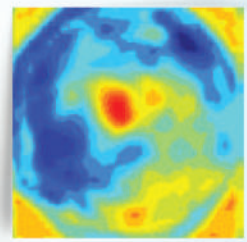
36 years old. Normal condition

Electrical impedance image in mastopathy

• A clear, undeformed breast contours, absence of internal structures displacements
• Damage of the images architectonics due to breast tissue reproportioning resulting in mismatch of electrical impedance image type (juvenile, reproductive, premenopausal, postmenopausal) to actual age.
• Increase of hyperimpedence areas (1) at mastopathy images due adipose tissue fibrotic changes, fibrosis of ducts walls and Cooper's ligaments.
• Increase of hyperimpedence areas (1) at mastopathy images due adipose tissue fibrotic changes, fibrosis of ducts walls and Cooper's ligaments.
• Increase of average conductivity (2) areas of adenosis images due to hyperplasia of the glandular tissue.
• Appearance on mammograms hypoimpendance inclusions with clear contours matching breast cysts or expressed pocket ectasis of ducts.



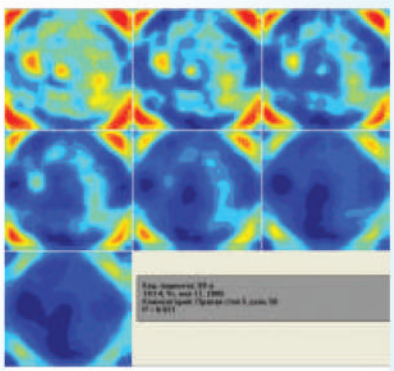
37 years old. Mastopathy (1)



53 years old. Mastopathy (2)

Mammary glands cysts

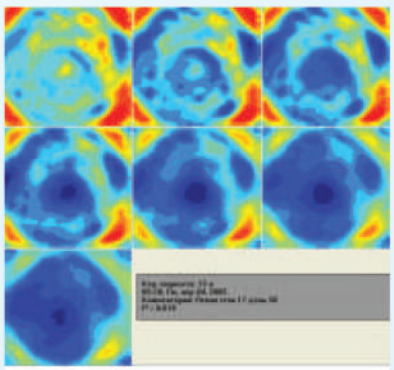
• In gray scale step cysts appear as circular hypoimpendance formations with clear contours with conductivity of 0.6- 0.94 standard units starting from the second scanning level. At scanning depth increase the conductivity is reduced to 0,35 - 0,4 standard units.
• In color scale mode localization of cysts is highlighted in orange-red color.
• In image filtering mode cysts localization areas are not shown as the conductivity does not exceed 0,95 standard units.



39 years old. A cyst of the right breast at 10 o'clock position on 1, 2 and 3 levels of scanning

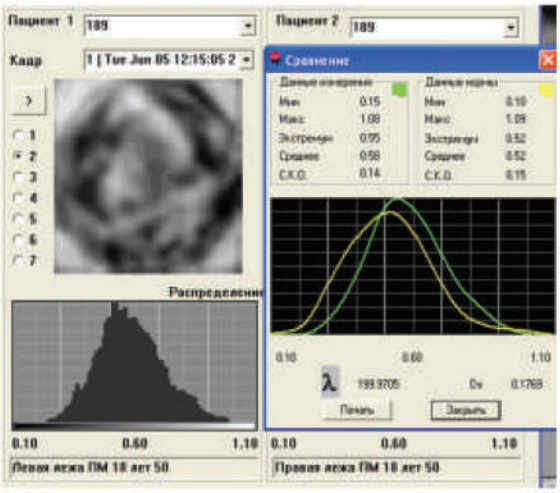
Fibroadenoma

• In gray scale step electrical impedance tomograms fibroadenoma appear as circular hypoimpendance formations with slightly fuzzy edges with a conductivity of 0.5 to 0.65 standard units starting from the second scanning level. At scanning depth increase the conductivity is reduced to 0,35 - 0,4 standard units.
• In color scale tomogram mode localization of fibroadenomas is highlighted with a yellow-orange color.



33 years old. Fibroadenoma of left breast on 1, 2 and 3 levels of scanning

Application of Electric Impedance Mammographer (MEM)

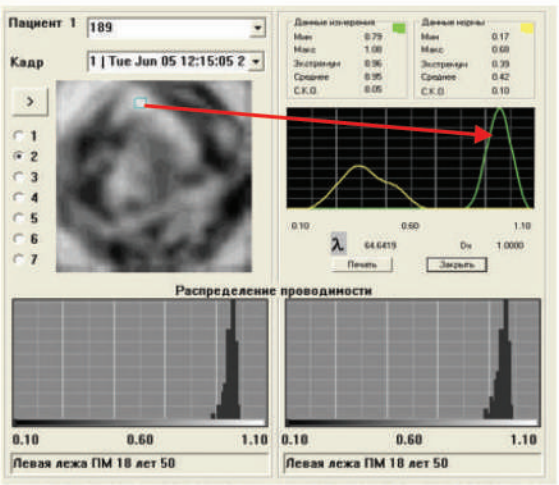


The average conductivity of the left breast is 0.58 standard units according to the age norm

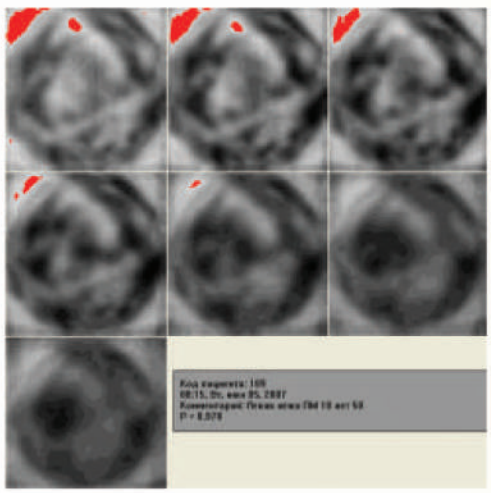
Cancer diagnostic criteria

- Contours deformation with internal structures displacement.
- Hypoimpendance area with a conductivity of 0.95 standard units extending to several scan planes.
- A dramatic shift of electrical conductivity frequency distribution graph in focus matching the tumor location at the right (above the norm).
- The difference in electrical conductivity between the affected and healthy breast.

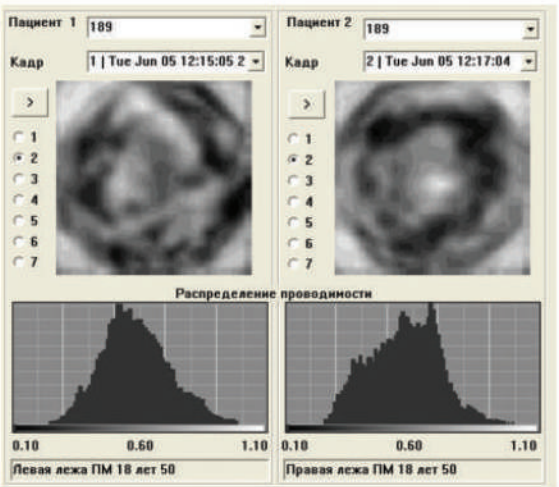
EIM, 73 years old. Cancer of left breast at 12 o'clock position, right breast (norm). 2 scan level. 50 kHz.



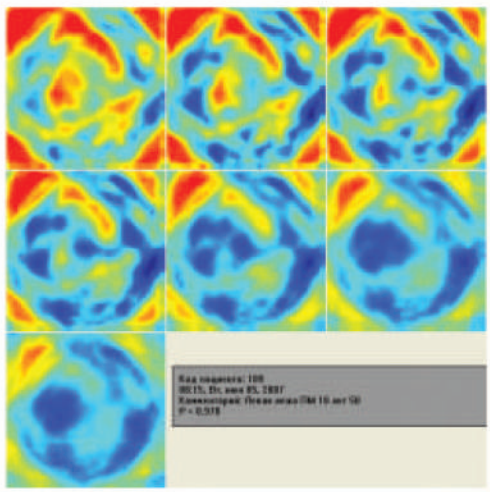
Conductivity in the zone of localization of malignant tumor is 0.96 standard units. The graph of conductivity frequency distribution is sharply declined to the right



When using an additional contrasting high conductivity areas are colored in red.

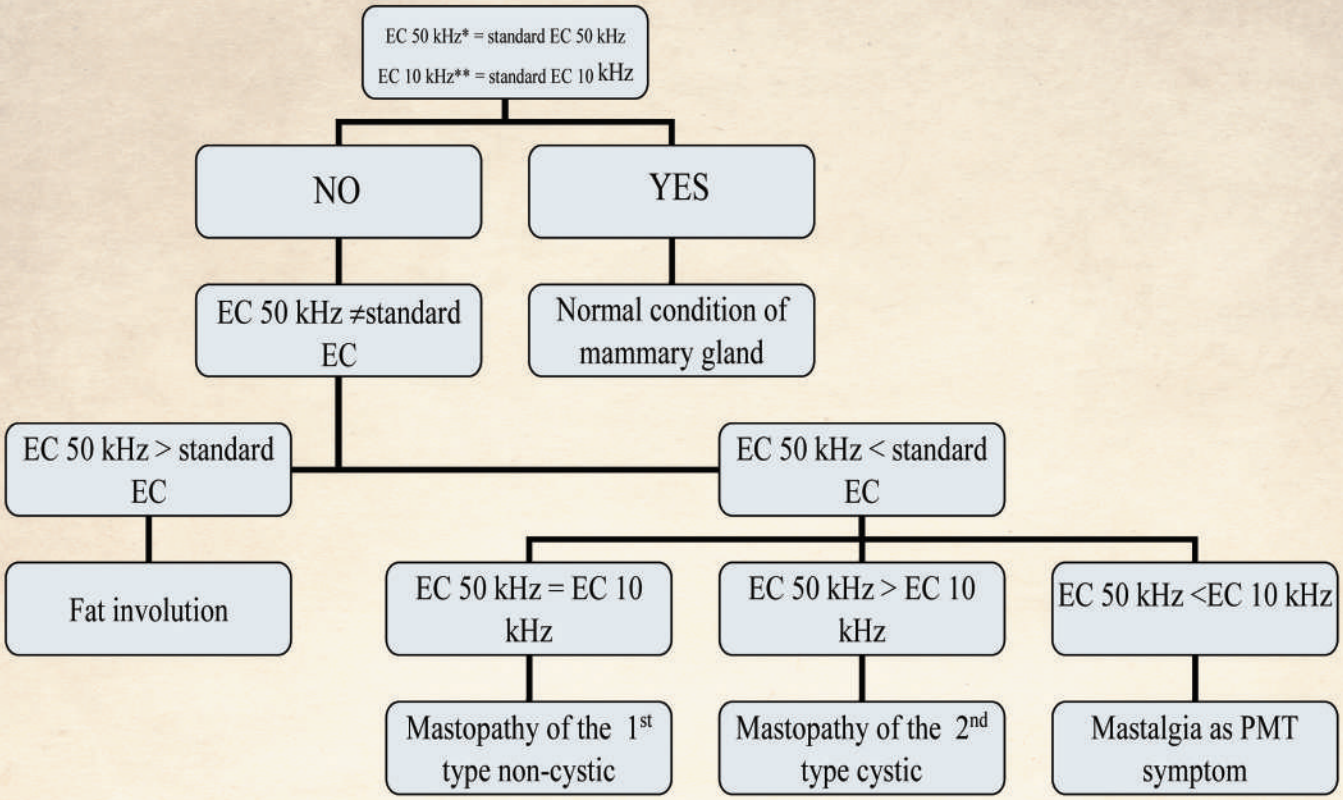


Change of architectonics and internal structures displacement of the left breast compared to right breast. Hypoimpendance area at 12 o'clock position in the left breast with blurred, fuzzy contours matching the localization of cancer.



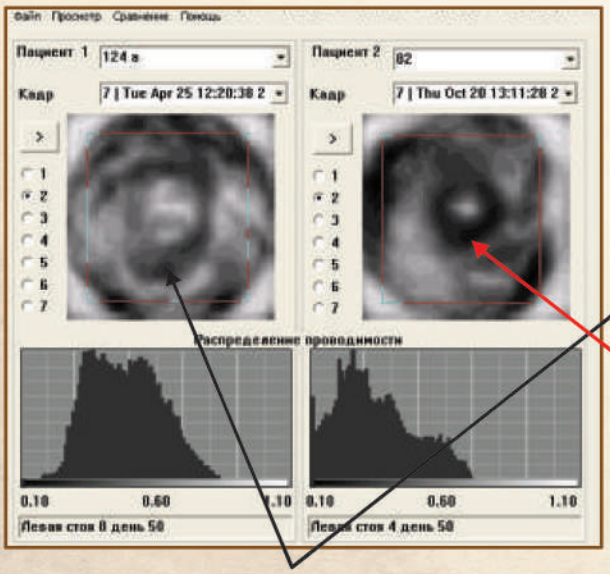
In color scale mode zones with a conductivity of 0.95 standard units are also highlighted in bright red color

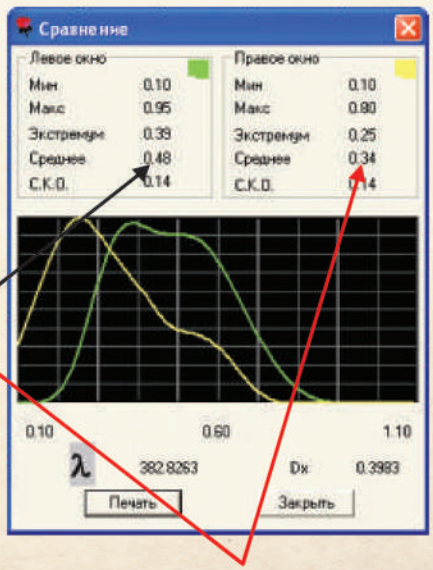
Scheme of Electrical Impedance Differential Diagnosis of Breast Cancer



**EC50 kHz – average electric conductivity at frequency of 50 kHz*
***EC10 kHz – average electric conductivity at frequency of 10 kHz*

The shift of electrical conductivity chart frequency distribution to the left (yellow) compared to the norm (green)





Electrical impedance mammograms are within norm in a patient of 41 years old (left image) and in a patient of 42 years old with mastopathy (right image)

The average conductivity is 0f48 standard units (normal condition)

The average conductivity is 0f34 standard units (mastopathy)

EIM Diagnostic Values

Electrical impedance mammography method is very effective for diagnosis of nonmalignant and malignant breast tumors supported by sensitivity values evidence received in the course of clinical studies (proportion of patients in whom disease symptom or symptom frequency are determined) and specificity (frequency of symptoms absence in healthy people).

Diagnostic Index	Breast cysts	Cystic mastopathy	Breast fibroadenomas	Breast cancer
Sensitivity	91%	98%	64%	92%
Specificity	99%	97%	91%	98%
Positive predictive value	93%	95%	70%	92%
Negative predictive value	99%	99%	88%	98%

For comparison:
- the sensitivity of the method x-ray mammography 71%-87%, specificity is 38%;
- the sensitivity of ultrasound method 98%, specificity is 59%.

"Method of electrical impedance mammography shows high sensitivity in the diagnosis of nonmalignant breast diseases, and most importantly, allows to confidently selecting a group of patients with increased risk of development of malignant process. The aforesaid makes it sensible to use electrical impedance tomography for dynamic monitoring of patients with diffuse and node-positive forms of mastopathy. It is possible to use electrical impedance tomography as a screening method in examination rooms and oncological offices of clinics and maternity welfare centers. Furthermore, it appear feasible the use this method for primary visiting patients to clarify indications for invasive diagnostic procedures. The most effective area of its application is the definition of hormonal causes of mastopathy, control of its conservative treatment and individual selection of hormonal contraception."
"Electrical impedance classification of mastopathy unlike x-ray takes into account causes of functional disorders leading to structural changes in the body. Knowledge of disease development mechanisms is decisive for the choice of tactics of further examination of women and appropriate treatment of the disease."
N. I. Rozhkova, main breast physician of the Russian Federation

"Based on a complex breast examination data the effectiveness of electrical impedance computer mammography (EICMG) was 87.39% allowing recommending the method to use in outpatient-and-polyclinic institutions, maternity welfare centers, maternity hospitals due to radiation exposure absence. EICMG is possible to use as screening method of mammary glands pathological changes at primary visiting of women and drug treatment monitoring. In cases of changes detected by electrical impedance computer mammographers compulsory additional examination is required: physician examination, ultrasound and mammography.
This method ensures safety, comfort, speed and information capacity of examination. Federal State Institution "Moscow Scientific Research Oncological Institute named after P. A. Herzen of Russian Mmedical Technologies", Moscow, 2010

"Electrical impedance mammography device helps to reliably determine the presence of pathological process in the breast. Electrical impedance mammographer can be used for dynamic monitoring of patients at risk.
The device can be used to monitor the effectiveness of adjuvant chemotherapy use."
Moscow Scientific Research Institute "Russian Scientific Center of Radiology and Medical Technologies", Moscow, 2009

Mammographer MEM Specifications

Specifications

Name Quantity	pcs
1. Multifrequenct electrical impedance mammographer MEM (instrument unit)	1
2. Full-duplex limb lead electrode	1
3. Support	1
4. Software (CD) with USB key	1
5. Personal computer*	1
6. User's Manual	1
7. Passport	1

** Supplied by request*

Standard Equipment

Dimensional specifications of instrument unit	210 x 160 x 100 mm
Mammographer weight (without PC)	no more than 2 kg
The device is powered by the permanent current with a 5V nominal voltage	via standard USB port of the PC
The current is consumed by mammographer through USB port	no more than 0.4 A
Mammographer makes alarm "bad contact" at transfer electrode-skin resistance	20 kiloohm and more

Suggested equipment list for electrical impedance diagnostics room

Name of equipment and arnamentarium	Minumum requirement
Multifrequenct electrical impedance mammographer MEM	1 pc.
Personal computer with a color printer	1 pc.
Furniture (table, chairs, bed)	as required
Climate control system (fan, air conditioner, if necessary, depending on climate zone)	1 pc.
Chair, medical screen, clothes rack in place for undressing	as required
Alcohol, cotton wool or gauze fabric, sanitizer	as required
Fire extinguisher	1 pc.

Safety Requirements and Prestarting Procedures

• The computer attached to the mammographer must be located outside of the patient's environment, i.e. at a distance of not less than 1.5 m from him.

• When powered from the electric mains the computer must be grounded: plugged in by Europlug in a special mains socket with a PG contact.

• Parts of device in contact with the patient's body must be disinfected with 3% peroxide solution with addition of 0.5% "Lotus" type washing agent.

Manufacturer Warranty for MEM Device
12 months from the sales date.

Training

The training is hosted by the **Yaroslavl State Medical University.** The training is conducted by the leading experts in subject matters of medicine and medical bioimpedance technology. Study duration is 144 hours.

Doctors of any specialization dealing with mammary gland problems (breast physicians, oncologists, obstetrician - gynecologists, ultrasonic medical investigation specialists, etc. may attend this training.

Training course includes:

1. Anatomy and physiology of the mammary gland in different periods of a woman's life
2. Methods of examination of mammary glands: advantages and disadvantages
3. Breast ultrasound
4. X-ray mammography. Invasive methods of diagnosis (needle biopsy)
5. Bioimpedance basics. Electrical impedance computer tomography: software
6. Mammary glands examination by electrical impedance mammography method
7. Normal electrical impedance anatomy of mammary glands
8. Electrical impedance mammography in women of reproductive age
9. Electrical impedance mammography in women during pregnancy and lactation
10. Electrical impedance mammography in women of perimenopausal period
11. Electrical impedance pattern of nonmalignant breast diseases
12. Mass lesions with suspected malignancy. The stages of diagnostics and tactics of management
13. Electrical impedance mammography in women taking hormonal contraceptives and HRT drugs
14. Electrical impedance images of mammary glands at multiple frequency measurements

Formal Certificate of professional advancement is issued at completion of the training course.

Approval Documentation

- Registration Certificate of Federal Supervisory Agency for Health Care and Social Development (amendment to RU No. FSR 2008/02744 of May 22, 2008)
- GOST R Certification System Certificate No. ROSS RU.MM04.H08296 of May 29, 2012
- Sanitary-epidemiological conclusion No.77.99.37.944.D.011926.11.08 of November 01, 2008
- European certificate No. 08 0031 C/NB of January 21, 2008

Developers and Patents

The method is protected by the Russian Federation patents for the invention No. 2153285 and No. 2127075, by the U.S. patent No. 6.167.300 and No. 6.236.886, European patent EP1180967.

The developers of the method and its titleholders are Alexander Vladimirovich Korzhenevsky (Institute of Radio Technologies and Electronics of the Russian Academy of Science team leader of electromagnetic tomography, PhD in Physico-Mathematical Sciences, lead researcher)
Vladimir Alexeevich Cherepenin, (Deputy Director of Institute of Radio Technologies and Electronics of the Russian Academy of Science, RAS associate member, PhD in Physico-Mathematical Sciences, Professor)
Medical part of the software:
Olga Valentinovna Trokhanova (Associate Professor of Obstetrics and Gynecology, Yaroslavl State Medical Academy, PhD in Medicine, Professor, MD of higher category)

The invention that is fundamental for device is awarded by:
Gold medal of the "Eureka 99"inventions exhibition in Brussels
Gold medal of "MEDSIB - 2004" exhibition
Silver medal of "Archimedes - 2000" exhibition
Silver medal of"Archimedes-2006" exhibition
Silver medal of "Archimedes" - 2007" exhibition
Diploma of “Biotech World - 2006" exhibition

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