

## "MEM" MULTIFREQUENCY ELECTRIC IMPEDANCE MAMMOGRAPHY SYSTEM

User Manual Device Certificate

6.1



Fig. 1. « E » device models and accessories: MEM-2011 at the top, MEM-2008 in the middle, accessories at the bottom.

### « E » elements:

1 ó electrode array;

2 ó connector for limb lead electrode cable;

- 3 ó dual limb lead electrode;
- 4 ó connector for the USB cable;
- 5 ó stand;
- 6 ó power indicator;
- 7 ó activity indicator;
- 8 ó sensors for measurement start;
- 9 ó manufacturer seals;
- 10 ó target LED.

« E » accessories»:

5 ó stand;

11 ó USB (AM-BM) cable to connect MEM to the computer;

12 óUSB cable plug (AM) to connect to the computer;

13 óUSB cable plug (BM) to connect to the device;

14 ó cable for dual limb lead electrode connection;

15 ólead cable plug (14) to connect to the device;

16 ó plugs for lead cable (*14*) connection to the dual limb lead electrode;

17 ó screw clips on dual electrode for lead cable fixation.

### CONTENTS

INTRODUCTION	4
TECHNICAL DESCRIPTION	5
<b>O</b> PERATING <b>P</b> RINCIPLE AND <b>D</b> EVICE <b>C</b> ONSTRUCTION	5
PACKAGE CONTENTS:	6
TECHNICAL CHARACTERISTICS	6
SAFETY REQUIREMENTS	7
EXAMINATION PROCEDURE	8
Software Installation and Initial Device Connection	8
Setting-up Procedure	9
Main Window of the Program	9
WINDOW «PATIENTS»	
PATIENT'S FILE COMPLETION IN WINDOW «PATIENT'S FILE»	
PATIENT PREPARATION FOR EXAMINATION	14
MEASUREMENTS	15
MEASURED DATA ANALYSIS AND PROCESSING	21
Setting up Measured Data Presentation	21
Preliminary Measured Data Analysis in Main Window	24
3D SLICE DISPLAY	25
Measured Data Analysis and Processing Capabilities in Two Window Mode	26
ANALYSIS AND COMPOSING OF EXAMINATION PROTOCOL	
ADDITIONAL SOFTWARE CAPABILITIES	
IMAGE PRINTING IN PROGRAM	
GIVING RESULTS IN ELECTRONIC FORM	40
IMAGE TRANSFER TO EXTERNAL DOCUMENTS	
Export and Import Single Measurements from Database	41
SETTING OF DATABASE	43
Export image to DICOM format	
OUR INTERNATIONAL DISTRIBUTORS	45
CONTACTS & SERVICE	46
DEVICE CERTIFICATE	47
PACKAGE CONTENTS:	47

The present description is given for « E » Software version 6.1 and devices, produced since 2014

### Introduction

Multifrequency Electric impedance Mammograph « E » is a specialized system to carry out electrical impedance computed tomography. MEM application allows to detect breast tissue pathology as well as the pathologies of other human body near-surface regions by measuring the relative change in conductivity (ability to carry out an electric current) of biological tissues in cross sections of the organs under examination at different frequencies and to visualize the conductivity distribution pattern on the screen of the personal computer (PC). The main advantages of the electrical impedance diagnostic approach are the following: absolute examination safety; high informational content due to considerable biological tissue conductivity correlation with tissue physiological status; compact size of the equipment and ease of examination procedure.

The present mammograph is designed for application in specialized hospital departments and Health system clinics.

The present Manual is a reference tool, and is not a substitute for a qualification program training course "Electric Impedance Mammography", followed by a Diploma (one specialist training is included in the cost of the device).

### **Technical Description**

### **Operating Principle and Device Construction**

Each human body organ has personal electric characteristics which are defined by the tissue conductivity, forming it, by the properties of intra- and extracellular fluids, by the quality and state of blood vessels. For example, it is well-known that certain tumors particularly breast malignant tumors, have their specific electric conductivity significantly different from the conductivity rate of the surrounding healthy tissue. The electric impedance mammograph carries out visualization of spatial distribution of biological tissue conductivity in several cross sections of a patient body and allows to detect such type tumors on the obtained images as areas with an abnormal level of conductivity. The electric impedance mammography approach significantly expands opportunities of doctors of many specialties in instrumental diagnostics of breast diseases and gives them unique opportunities to provide objective estimation of the breast state as it is an essential element of integrated reproductive system.

The proposed program of multifrequency electric impedance examination significantly expands diagnostic opportunities of the previous single-frequency examination technology since it allows to formulate clear diagnostic criteria of various diffuse and focal breast pathology, to differentiate mastalgia of various etiology that is important for an adequate choice of management tactics suitable for women with breast diseases. Confirmation of visual changes on tomograms by the quantitative adjectives of the conductivity excludes subjective estimation when diagnosing. Due to its safety the electric impedance mammography approach can be used for Screening Examination and Monitoring of young women.

Appearance of modern multifrequency electric impedance mammograph  $\ll E \gg$  is shown with parts descriptions (See Fig. 1, cover page).

The device consists of a measuring unit, with a built-in microprocessor control system, where the matrix with 256 electrodes (1 in Fig. 1) is placed. The dual limb lead electrode (3 in Fig. 1), which is placed on the patient¢ hand during the examination, is connected to the measuring unit via the connector (2 in Fig. 1) by means of the cable (14 in Fig. 1). During the process of scanning the device by means of each matrix electrode one-by-one injects weak alternating electric current into a patient¢ body and takes the corresponding electric potential distributions on its surface using the other electrodes.

Then the obtained data are applied to an electric impedance tomogram reconstruction on the basis of mathematical algorithm, presented at PC, to which the device is connected through the connector (4 in Fig. 1) by means of USB cable (11 in Fig. 1).

The algorithm allows to reconstruct 3D conductivity distributions (in the form of tomography cross sections at different depths) and get detailed images. This measurement

circuit makes visualization results practically insensitive to the skin surface state. The  $\langle E \rangle$  system affords an opportunity to carry out measurements at different frequencies which allows to make more exact and detailed diagnosis, than the diagnosis based on the analysis of electric properties of tissue at only one frequency, since tissue state is connected not only with its electric properties, but also with dependence of these properties at frequency.

Descriptions	Quantity, pieces.
1. Multifrequency Electric impedance Mammograph	1
(measuring unit)	1
2. Device stand	1
3. Dual limb lead electrode	1
4. Cable for lead electrode connection;	1
5. USB cable to connect to a computer	1
6. õMEMö software and documentations (Medical Atlas,	1
User Manual) on CD	1
7. Medical sponge to moisten the skin of a patient	20
8. Antistatic bag with moisture adsorbent	1
9. Manufacturer package (box)	1
10. Notebook/personal computer <sup>*</sup>	1
Documentation	
11. User Manual and Device Certificate	1
*- may not include in base configura	tion

Package contents:

### Technical characteristics

Visualization of the spatial distribution of the electrical properties of tissue for the human organ under examination is presented on the screen of a PC monitor in the form of seven cross sections parallel to the plane of the electrodes, with the step 7 mm. Operating frequency, at which conductivity visualization is set, is adjusted in the range with a minimum frequency less than or equal to 10 Hz and a maximum frequency equal to or more than 50 Hz. Voltage at measuring unit electrodes is not more than 12 V. The measurement current is less than 1 . The mammograph provides an indication a «poor contact» in case of the transition resistance «electrode 6 skin» is equal to 20 k hm and more. Time of one measurement circle is no more than 25 sec. Overall size of the mammograph measuring unit is less than or equal to  $210 \times 160 \times 100$  mm. Mammograph mass (without a PC) is less than 2 g. The device power supply is performed via a standard USB port of a PC by direct current with nominal voltage equal to 5 V. The current consuming by mammograph from USB port is no more than 0,4 .

### Safety Requirements

Before you start, please read the User Manual.

To work with the device it is necessary to have an appropriate qualification, confirmed by a state-recognized Diploma, given as a results of a successful training on course «Electric Impedance Mammography».

Before examination of the patient with implanted cardio stimulator check to make sure that this cardio stimulator are able to work stable during applying of current with characteristic bandwidth 10-50 kHz, amplitude up to 1 mA to the patient.

The computer, used together with the mammograph, should be placed at the distance not less than 1,5 from a patient.

The computer should be earthed and/or galvanically isolated from the electrical network and connected to a power supply with a plug connector of European standard and a special socket-outlet with an earth contact protection.

Cleanse the mammograph components, contacting a patient¢s body, with «Veltosept» or a similar agent in accordance with MU-287-113 (Russia).

Wipe dry the device after cleansing and operating. If necessary, dry it with soft warm air.

Device isnot waterproof, so never dip it entirely or separate components into any liquid. Only short-time cleansing of the working surface with a damp cloth is allowed.

Avoid ingress of moisture into the plugs and cable connectors, compression terminals of dual lead electrode, the device connectors ((it can lead to corrosion and galvanic effects, which prevent correct measurements).

# Observe antistatic safety precautions during the transportation, operating and storage of the device <u>(damage of the measuring units by static electricity is treated as a mechanical damage)</u>:

ó In order to equalize the potentials, first touch the patient's skin with your hand (exposed skin), and only then connect the lead electrode and apply the measurement matrix of the device to the patient;

ó avoid using one-time synthetic sheets on the examination couch with synthetic covering (put down a cotton cloth, pre-treated by an antistatic agent, between the examination couch and a one-time sheet);

ó it is undesirable to apply the device in the premises with utility-type linoleum, plastic, synthetic or lanolin floor covering;

ó be especially careful with static electricity problems during cold and dry seasons;

ó if necessary to treat a working place with an antistatic agent, use other antistatic safety measures too;

ó carry out the device transportation and storage in the antistatic bag only, which is included in the original package, with active absorbent. Dongt try to repair the device on your own, in particular, to restore damaged device cables (*it can cause measuring circuit disorder, galvanic effects and lead to incorrect <u>examination results</u>).* 

### **Examination Procedure**

### Software Installation and Initial Device Connection

Before the initial device connection to the computer it is necessary to make sure that E software has already been installed on the computer (there is the shortcut õMEMö on the Desktop), otherwise install the software using the CD, included in the package contents. For this purpose follow the Program Setup Manual.

Place the device on the support (5 in Fig. 1). Insert the plug (15 in Fig. 1) of the cable for the connection of the dual lead electrode, executed in the form of a pin (3 in Fig. 1) into the device connector (2 in Fig. 1), insert two other plugs (16 in Fig. 1) into the clamping screws (17 in Fig. 1) of the dual lead electrode (3 in Fig. 1). Tight firmly the clamping screws (17 in Fig. 1), make sure it is securely connected. Connect the cable for connection to the computer (2 in Fig. 1) to the USB device connector (4 in Fig. 1) by the end USB cable plug BM (13 in Fig. 1), and by the opposite end the plug AM (12 in Fig. 1) ó to the free USB port of the computer. In Fig. 2 a photograph of a connected device, which is ready to work, is presented.



Fig. 2. Device prepared for operation

During the initial device connection to a computer it may need some time (tens of seconds) for Windows System to identify the device and install the drivers for work. It will happen automatically and information will be displayed in the Operating system status window (bottom-right corner, usually). After completing the driver installation procedure power indicator (6 in Fig. 1) will turn green, indicating the device availability.

### Setting-up Procedure

If necessary, restore the commutation of the device, the computer and the dual lead electrode (See section «Software Installation and Initial Device Connection»). In Fig. . a photograph of a connected device ready for

operation is presented.

Check the availability of the green power indicator light at the mammograph top panel (6 in Fig. 1) indicating that the device connection to the computer is correct.

### Main Window of the Program

Start the « E » Program on your PC. At the Program main window a column of buttons is placed, which activates key windows of the Program (Fig. 3):



Fig. 3. Main window of E Program

- button «Patients»: opens the window «Patients» to work with patientøs files (See section «Window «Patients»»);
- button «Patientøs file», which is available under a selected patient: activates the window «Patientøs file» (See section «Completing a Patientøs File at Window «Patientøs file»);
- button «Measurement», **available under a selected patient**: opens the window of examination procedure start (See section «Conduct of Measurements»);
- button «View»: activates the window «View» for image correction (See section «Setting-up Measured Data Presentation»);

- button «Protocol», active under availability of examination protocols of the selected patient: opens the window «Protocol» with the records of a patient's examination results (See section «Analysis and Formation of Examination Protocol»);
- button «Archive»: opens the window «Archive», is used to configurate the Program database (See section «Export and Import of Single Measurements from the Database»);
- button «About»: opens the window with information about the Program (See section «Software Version Validation»);
- button «Exit»: allows to close the « E » Program.

### Window «Patients»

The window «Patients» (Fig. 4) opens from the main window of the Program (See Fig. 3) pressing the button «Patients». The given window functionality are available if there are patients in the database. It allows:

- **look through a patient's data:** move the cursor to the name of a patient and in the right side of the window the following information will be displayed: code of the patient, the date of birth, registration date, the number of measurements saved in the database;
- **delete a patient** *is* **file and the measurements from the database:** use the cursor to select the name of the needed patient from the list and click the button «Delete»;
- load the measurements and patient records selected from the list: use the button «Select»;



Fig. 4. Window of the E Program «Patients»: list of patients

• move up and down the list of patients by the surname initial letter: pressing letters on the keyboard will be accompanied by moving up and down the list (Fig. 5);



Fig. 5. Window of the E Program «Patients»: patient selection

- **create record of a new patient:** by activating the button «New» opens a multipage window with a patient file (Fig. 6);
- close the window õPatientsö and return to the main window of the **Program:** press the button «Cancel».

If it is necessary to examine a large number of the patients, for example in case of clinical examination to get to measurements directly is enough to enter a patientøs name, code, date of birth and then click « » to pass on directly to the measurements. It is possible to enter the rest of the data later any time by selecting the required patient and using the button «Patientøs file» in the main window (See Fig. 3).

As for a code of a patient it is convenient to use his/her insurance certificate number.

### Patient's File Completion in Window «PatientB file»

Create a new patient's record from the window «Patients» or activate a patient record and open his/her file using the button «Patient file» in the main window of the Program.

Fill in all the given columns, concerning complaints, gynecological and somatic anamnesis, by earlier made examinations and diagnosis. For this purpose activate one-by-one the appropriate tabs of the window «Patientøs file»:

- ✓ «Complaints» (Fig. 7);
- ✓ «Anamnesis» (Fig. 8);

- ✓ «Examinations» (Fig. 9);
- ✓ «Diagnosis and treatment» (Fig. 10);

General Complaints Anam	nesis Examinations Diagnosis and treatment
Full name	
Code	14
Date of birth (DD.MM.YYYY)	17.04.1984
Registration date (DD.MM.YYYY)	27.02.2013
	OK Cancel

Fig. 6. Window «Patientøs file»: tab «General»

<ul> <li>no</li> <li>serous</li> <li>puruloid</li> <li>blood-tinged</li> <li>Colostrum</li> </ul>	General Pain no befor not re	Complaints Anamnesis I e menstruation lated with menstrual cycle discharge	Examinations Diagnosis and treatment
	<ul> <li>no</li> <li>serou</li> <li>purulo</li> <li>blooc</li> <li>Colos</li> </ul>	s bid I-tinged strum	

Fig. 7. Window «Patientøs file»: tab «Complaints»

General Complaints Anamnesis Examinations Diagnosis and treatment	
Menstrual function Somatic Gynecological Obstetrical Lactation	
• I phases of menstrual cycle	
disturbance of menstrual cycle	
postmenopause (years)	
pregnancy	
taking hormonal contraceptive or hormone-substitutive preparations	
Name	
duration of taking medicine (years)	
	-3
OK	

Fig. 8. Window «Patientøs file»: tab «Anamnesis»

General Complaints Ar	amnesis Examinations Diagnosis and treatment	
norm	Comment	
🔲 focal lumps		
diffuse changes		
Ultrasound		-
norm	Comment	=
📃 focal lumps		
diffuse changes		
X-ray mammography		
norm	Comment	
📄 focal lumps		1.136
diffuse changes		
Biopsy		
📃 norm	Cyst Cancer	
	Channel and a second	

Fig. 9. Window «Patientøs file»: tab «Examinations»

General	Complaints	Anamnesis	Examinations	Diagnosis and trea	Itment
Diagn	osis				
Treat	nent				1
			_		
		ОК			Cancel

Fig. 10. Window «Patientøs file»: tab «Diagnosis and treatment»

After entering all the data save the information clicking on « ». To exit without saving it, click on «Cancel».

### Patient Preparation for Examination

- It is recommended to start a patient examination in a supine position, then in a standing (or sitting) position.
- Moisten the breasts with water evenly, using the sponge, supplied in the delivery set, so that there are no drops (Fig. .).
- In case of any fatty cream remaining on the breast, it is required to remove it before the examination.

(fat does not conduct electricity and does not allow to get information about the patient).

- Do not use any gels, particularly, the ones for US and ECG, to moisten the patients skin (usually gels have a significant electrical conductivity, their application bridges the electrodes, making it impossible to obtain information about the patient).
- Moisten the wrist surface with water where the «pin» with dual lead electrode (3 in Fig. 1) is applied.



Fig. 11. Breast moistening before examination

### Measurements

Make sure the device is connected to your computer and is ready to function. The LED power of the device (6 in Fig. 1) should be green.

It is recommended to test the device is in operation with the computer and the installed software before you start the measuring procedure. To do this, click in the main program window the button "Measurement" and activate the button "Test" in the opened window (Fig. 12).



Fig. 12. Window of measurement preparation

The window with the message informing that the device is in order and ready for operation appears (Fig. 13). Click on « » to close the window and return to the window of measurement preparation.



Fig. 13. Window of device testing

Before you start it is essential to enter the information about the planned measurement in the opened window (See Fig. 12). Bars «Optional» are desirable but not required to be filled. When you select the panel «Iron» pay attention: the **left** and **right** ones are relative to the patient. After that, start the measurement by clicking «Start».

The measurement procedure starts with selecting the device optimal position, accompanied by the amber light activity blinking (7 in Fig. 1) on the top panel and the target LED continuous light (10 in Fig. 1, set in the centre of the device electrode matrix (1 in Fig. 1). Then a window with an image of the device working surface as a dynamic two-color contact map (Fig. 14) will appear on the screen, where green-colored electrodes present a good contact with the patient, and black-colored ones a bad contact or its absence.



Fig. 14. Window with contact map: optimal position choice



Fig. 15. Selection of the optimal position with the help of the target LED

Hold the mammograph to the breast so that the upper/lower, right/left sides of the breast image, produced on the computer screen, reflects the upper/lower, right/left sides of the mammary gland image correspondingly, and the nipple area coincides with the centre of the mammography working surface. To this effect, watch the spot of the target LED (Fig. 15).

It is recommended to put the auxilary electrode on the wrist which is opposite to the mammary gland under examination (Fig. 16). During the measurement process the hand with the recording electrode shouldnøt touch any bare parts of the patientøs body; otherwise the measurement results may be incorrect.



Fig. 16. Examinations in supine and sitting (standing) positions

It is necessary to start measurements with a minimum of bad contacts (not more than 30), and avoid poor contact in the centre of the image. Correction of the device position allows to reduce the number of bad contacts, that provides a more accurate measurement and more qualitative evaluation of the conductivity level.

Pressing of the button «Start» in the window of the dynamic map of contacts (See Fig. 14) or touching of the sensor on the device (8 in Fig. 1) will cause start of measuring proved by sound notification. Duration of the measurement is around 20 seconds. While it the

yellow indicator on the device top panel is continuous lighting (7 in Fig. 1) and the percentage of the operation completion in the top part of the map of contacts is running (Fig. 17). When the data acquisition is finished sound will be produced. If you would like to avoid sound notification of start, finished data acquisition, turn of sound in settings of your Windows system.



Fig. 17. Window with the map of contacts and a progress indicator at data collection

## During this time it is not allowed to change the position of the device in relation to the body of the patient.

If while measuring more than 128 poor contacts are detected, the measurement procedure will be interrupted and the message window (Fig. 18) will inform about it. In this case the measurement should be repeated.

Measu	urement conditions
Freque	leasurement indicator
Pos	
•	
- In a	
	Too many bad contacts
0	
0	ОК 3)
0	Contacts map
0	Start Cancel ;)
Start	Test

Fig. 18. Message window «Too many bad contacts»

### After completing the scanning procedure, wipe the device surface with electrodes with a dry napkin or cloth. Non-compliance with the requirement may lead to incorrect device functioning during further measurements.

After the measuring is finished reconstruction procedure will start automaticaly. It takes around 10 seconds and accompanied by the informational message (Fig. 19). After the reconstruction procedure window of preliminary view appears on the screen (Fig. 20) with 7 electrical impedance mammary gland images, corresponding to 7 scan planes. The first scan 18

plane corresponds to the depth of 0,4 cm from the skin surface, then every 0,7 cm deep down there are 6 more planes (cross-sections are not ideal, there is an interval on the object depth and they can intercross).



Fig. 19. Measurement completion: reconstruction procedure



Fig. 20. Window of preliminary view of scan results

The images demonstrate spatial distribution of electrical conductivity of breast/mammary gland tissue at different depths. Higher conductivity corresponds to light tones (lower specific impedance).

Give all the necessary information in the string «Comment», for example, side, examination position, menstrual cycle phase and working frequency under scanning and other characteristics. Click «Save» to save the images. By clicking «Cancel» you delete the taken measurement.

After activating the button «Save» you return to the main window of the « E » Program. The examination section displays all the existing in the database measurements with the information regarding to the examination date, the position, the scanning side, working frequency and menstrual cycle phase of the selected patient (Fig.21). The carried out measurement will be added above the previous one. Please take notice that while looking through all the measurements in the main window, it is possible to correct or add comments to them (Fig. 22).

We recommend to take full set of 8 measurements during an examination of a patient: left/right, supine/standing (sitting) positions, 10/50 Hz. Extent of examinations can be cut by half, up to 4 measurements in a supine position. However, if you suspect presence of focal symptoms (cystis, fibroadenoma, carcinoma), it is strongly recommended to carry out an additional examination in a standing position.

Izabella V	/in Mars				
Patients Patient's file Measurement View Patienel	Date: 27.02.2013 01:39:37 Frequency: 10 kHz Age: 24.868 Position: standing Gland: left Labor: no Phase 1, 10 (days) Comment: Left, Stand 10kHz Unprocessed	0.40 cm	1.10 cm	1.80 cm	2.50 cm
		[11.85;6.88] 1.00	[11.85;1.22] 0.93	[0.31;0.23] 0.74	
Archive	*			m	
About					
Exit					

Fig. 21. Main window: measurements, available in database for selected patient

## **Measured Data Analysis and Processing**

### Setting up Measured Data Presentation

After completion of the examination of mammary glands begin the visual analysis of the images. Click the button "View" in the main window for setting the image presentation parameters.

lmage ○ color ● b	lack/white	dations of color 16	- View
Contrast by default manually lower limit	Area	Additionally centre grid Contacts	[11.90;10.92] 0.90
upper limit	upper limit		min max

Fig. 22. Window «View»: setting of image parameters

Select in the opened window (See Fig. 22) the necessary for the image analysis items in the appropriate fields. In the right part of the window there is an image constructed with the selected settings. It is updated by clicking the button «Update» on the panel «View».

✓ Panel «Image» has the option «color» or «black/white». If the option «color» is chosen, it is possible to evaluate electric impedance pictures in color scale gradation (Fig. 23). The choice of «black/white» will allow to evaluate electric impedance images in grey scale gradation (Fig. 24).

√

1 Com			
110			
	9	1	
		u de la compañía de	
Charles and	-		
[0.00;0.30] 0	66		
[0.00;0.30] 0 Refr	66 esh		
[0.00;0.30] 0 Refr	66 esh		

Fig. 23. Example of an image in the color scale in the window «View»



Fig. 24. Example of an image in black/white color in the window «View»

- ✓ Panel «Color gradation» defines the number of gradations: 16, 32 or 64.
- ✓ Panel «Contrast» sets the scale: «on default» «manual». If the regime «on default» is selected maximum and minimum conductivity values take maximum and minimum values at the color scale. In the regime «manual» the values are given in accordance with minimum and maximum conductivity presented at the color scale (all outside values will be colored in minimum and maximum scale gradation colors).
- ✓ Panel «Area» allows to start automatic scanning of the areas (foci) with the given conductivity range and highlight them in pink (Fig. 25). For this purpose select item «display» and set lower and upper limits (it is recommended to use limits 0,95 1,3).



Fig. 25. Example of an image with automatic scanning of foci in the window «View»

✓ Panel «Optional» a display of additional information in the pictures.

• If you select the option «centre», the centre of the image is marked with a cross (Fig. 26).



Fig. 26. Image example with pointed centre in window «View»

• Option «grid» gives the opportunity to divide the electric impedance images in segments (Fig. 27) corresponding to hour sectors on a clock dial and complementing the division on external and internal segments helps to describe pathology foci location.



Fig. 27. Example of an image with division into segments in the window «View»

- Activation of the option «contacts» provides visualization of bad contacts on the electric impedance images in the form of yellow spots (Fig. 29).
- •



Fig. 28. Example of the image with visualization of bad contacts in the window «View»

- ✓ In panel «View» (See Fig. 22) using the button «Update» it is possible to look at the active measurement of the first cut image with selected options of the presentation.
- ✓ The button « → is used to exit and to save the selected settings of the presentation, the button «Cancel» 6 to exit and save the previous settings.

### Preliminary Measured Data Analysis in Main Window

### Images in the main window of the Program allow to evaluate:

- quality and contrast of the pictures;
- symmetry of the images at all scanning levels;
- presence or absence of convex contours (which may indicate a large tumor or swelling of the breast) or indrawing (which may indicate a scar deformity);
- presence or absence of hypoimpedance contour around the image;
- the impedance of breast anatomy at different levels of scanning;
- correspondence of the obtained under examination electric impedance images to the age type of the mammary gland structure (juvenile, reproductive, predmenopauzalny, postmenopausal). Mismatch indicates the presence of a pathological process in the breast or subinvolyutivnyh changes in tissues;
- correspondence of the electric impedance image to a physiological period of a woman's life (first phase of menstrual cycle, second phase of menstrual cycle, pregnancy, lactation, postmenopausa);
- presence or absence of foci hypoimpedance areas and their location;
- presence or absence hypoimpedance «areola» around the focus.

## Image examples with descriptions are presented in the Medical Atlas, included in the $\ll E \gg$ Software.

For more simple detecting of hypoimpedance areas use the color contrast regime, in which the suspicious areas (high conductivity) are coloured in bright orange and red on the yellow-blue background and image filtration regime, which allows to mark areas with high conductivity in pink (for this purpose select «View» in the main window of the Program, then in the panel «Area» activate the option «display» and define upper and lower levels in the appropriate fields (See section «Setting-up Measured Data Presentation» and Fig. 22).

Interested section can be viewed in 3D imaging. To do this, place your mouse over the image of interest, open the context menu by clicking the right mouse button, select in the shortcut menu the item «Show 3D» (Fig. 29). A three-dimensional display of the selected slice will appear (Fig. 30). The use of the other functions of the shortcut menu are described in the sections «Print» and «Export of measurements».

Patients	Date: 13.06.2012 12:49:14	0.40 cm 1.10 cm
D	Frequency: 10 kHz Age: 36.551	Export
Patient's file	Position: supine	Create DICOM file
Measurement	Labor: yes	Select all
	Phase 1, 8 (days)	Select all frames of this measurement
View	Comment: ПЛ 10 8	Unselect all frames of this measurement
	Processed	Unselect all
Protocol		Print selected
		[1.3 Show 3D
Archive	*	
	Date: 12.05 2012 12:49:14	0.40 cm 1.10 cm

Fig. 29. Shortcut menu in the main window

### 3D Slice Display

The window of 3D image opens from the main window or from a dual view regime by activating the item «Show 3D». The relief (height) of the surface corresponds to the conductivity (the higher surface is the higher conductivity).

The window has the following functions:

- rotate the image: holding the left mouse button, move the cursor;
- zoom in/out the image: move the mouse cursor, simultaneously holding down the right button (up, left ó to reduce; right, down ó to increase);
- **shift the image:** holding the button «Ctrl» move the image pressing the left or right mouse button;

- **resize the 3D window:** move the mouse cursor to the corner of the window to change the cursor shape to a double arrow. Taking the frame with the left mouse button, set the desired window size;
- **close the 3D window:** click on the red cross (X) in the upper right corner, press the button «Esc» or «Alt+F4».

### It is recommended to close the 3D window before going on to the other regimes.



Fig. 30. Window with 3D slice image

### Measured Data Analysis and Processing Capabilities in Two Window Mode

A two window mode is the main tool for the data processing, comparison of the results and composing of the protocol (Fig. 31and etc.).



Fig. 31. Two Window Mode

ode 123456789-12	
leasurements	Information
3.06.2012 12:41:09 3.06.2012 12:45:40 3.06.2012 12:47:47	Frequency: 10 kHz
3.06.2012 12:49:14	Position: supine
3.06.2012 12:49:14	Gland: right
	Age: 36.551
	Labor: yes
	Phase 1, 8 (days)
	ПЛ 10 8
	ок

Fig. 32. Additional window of dual view regime for measuring setting-up

The present regime is activated by selecting one of scanning cross-section in the main window (click it with the left mouse button). It is possible to switch every window from two

ones separately between the cut image regime and the data analysis one, using tabs «Image», «Information» in the top part. Tabs «Measurement 1» and «Measurement 2» allow to switch between two selected measurements.

The buttons «Measurement 1» and «Measurement 2» allow to use an additional window (Fig. 32) to select necessary measurements for the analysis. If it is necessary to compare the images of different patients, use the button «Change» of the additional window (See Fig.32) and choose the patientøs record in the window similar to the window «Patients» (See. Fig. 4), but with a limited functional.

Two window mode allows to carry out the following actions:

- omparison of different on depth slices of the same measurement. Make sure that in the line «Measurement 1» and «Measurement 2» one and the same measurement is displayed. Activate tab «Image» in both windows. To look at the cross-section images of different levels use depth pointers, placed on the right from the images;
- comparison of the right and left mammary gland images. Using the buttons «Measurement 1» and «Measurement 2» select necessary measurements (See Fig. 32) to display in one window a left mammary gland image, in the other window a right one;
- comparison of the images at different menstrual cycle phases or if there are previous examination data in the database in different age periods. Using buttons «Measurement 1» and «Measurement 2», set from the database necessary for the analysis measurements;
- 4. **setting-up the image contrast, the color scale and identification markers.** For this purpose close the dual view regime, activate the panel «View» (See Fig. 22) in the main window of the Program. After selecting necessary setting-up items press « » and enter the two window mode again. It will use use the chosen settings of the image identical to the main window of the Program (See section «Setting-up Measured Data Presentation»);
- 5. **automatic selection of a hypoimpedance image area.** Similar to the previous item set up the window «Area» in the panel «View» (See Fig. 22), defining the conductivity thresholds to point the areas of the image in pink (See Fig. 25). The recommended values are 0.95 and 1.3;
- conductivity investigation in 3D regime. Activate the shortcut menu (Fig. 33), by moving the cursor to the tab «Measurement 1» and pressing the right mouse button. Select the item «3D» and the window 3D will appear (See Fig. 30 and section «3D slice image»);



Fig. 33. Shortcut menu of tab «Measurement»

7. evaluation of conductivity distribution on the part of the image and on the whole one. At the bottom part of the window the conductivity distribution histogram is placed, where abscissa axis (X) presents conductivity values in relative terms, and on axis of the ordinates (Y) the number of points are placed with conductivity value corresponding to the value on the abscissa axis. The histogram is constructed on the selected part of the image (crimson frame at Fig. 34). By default (in the absence of the selection) the entire image of this slice of the breast is analyzed, with the exception of the area of angles and bad contacts, which will always be automatically excluded from analysis by the program. The part of the image for analysis is defined by the mouse: click a mouse button in the corner of the selected area (left or right button) and then set the second angle by moving the mouse and click again. When you select, you do not have to hold down the mouse button. Under the histogram statistic data are presented of the selected part of the image: «maximum» (maximum conductivity value), «minimum» (minimum conductivity value), «extreme value» (conductivity value on the X axis, at which maximum is achieved on the Y axis), «RMSD» (root mean square deviation of conductivity);



Fig. 34. Two window mode: definition of the area and focus of analysis

- 8. **conductivity value analysis.** Select the measurement for analysis, opening it in the tab «Measurement 1» or «Measurement 2». Select the corresponding tab in both windows. In the left part of the window activate the tab «Measurement», and in the right part activate the tab «Information». If analysis area limitation is needed, define it as it was described above in item 7. Then press the button «General» (at the left bottom of the window) to carry out the analysis. Results will be displayed in the right section of the window in the tab «Information» of the panel «Analysis» (Fig. 35);
- 9. focus conductivity analysis. Open tabs as mentioned in item 8. Select the image area with suspected focal symptoms as pointed in item 7. Analyze the received conductivity distribution histogram on the selected area. Press the button «Focus» (at the bottom of the form) to analyze the area and transfer the results to the tab «Information» of the panel «Focus» (See Fig. 35 and Fig. 36). If the result of the image area analysis disproved the suspicions and it is necessary to cancel entering of these data, delete the tick under the title of the panel «Focus» (See Fig. 36), otherwise, the information regarding the focus will be saved automatically in the examination protocol during its formation;

Measurement 2	Exit	
Measurement 1 Nazarova Elena Victorovna; CODE: 123456789-12; Measurement:13.06	2012 12:49:14 (ПЛ 10 8)	
Measurement 2 Nazarova Elena Victorovna; CODE: 123456789-12; Measurement: 13.06.	2012 12:49:14 (ПЛ 10 8)	
Measurement 1 Measurement 2		Measurement 1 Measurement 2
Image Information		Image Information
	Depth (cm)	Conditions Date: 13.06.2012.12.49:14 Frequency: 10.kHz Age: 36.551 Position: supine Gland: right
	1.10	Labor, yes Phase 1, 8 (days) Commert: (111 10 8
	1.80	Analysis           Date:         16.02.2013           Nom:         0.44 (+/) 0.09           Mean:         0.30
	© 2.50	Max.:         0.80           Min.:         0.04           Dispersion:         0.12           Extremum:         0.21
Alaca	○ 3.20	Depth: 1.10 Depthylion Suft: V left 0 right
	3.90	Asymmetry I left O right
[11.95.2 97] 0.38	◎ 4.60	Modality Uni  BI  Multi
Mean Maximum Minimum Extrem 0.42 0.88 0.22 0.32	m SD 0.12	Focus Mean: Mean: Mex.: Min.:
General	Focus	Save Nom To protocol

Fig. 35. Image area analysis in two window mode

			🔘 Uni	Bi	🔿 Multi
Extremum	SD	Focus Mean: Max.: Min.:	0.6 0.8 0.4	64 06 14	
0.57	0.11	L			
	Focus	Sav	re	Nom	To protocol

Fig. 36. Focus analysis in two window mode

10.measurement data processing and information preservation in the database. To save the process measurement data in the current tab «Information» press the button «Save». In this case the content of the tab will be saved in the database and a pop-up message will appear (Fig. ! .). This measurement will be displayed in the main window of the Program with status «processed» (See Fig. 29). During the reopening of the measurement in two window mode the content of the tab «Information» will be restored;



Fig. 37. Message about saving analysis data in the database

11.enter the data in a composing protocol. After completing the correction and filling up the fields of the tab «Information», press the button «To protocol» to transfer the data into the current protocol. A message informing that the data are added in the current protocol (Fig. ! .) will appear. Note that in the current protocol up to 8 measurements can be placed automatically in accordance with their parameters: left/right, standing/supine position, 10/50 Hz;



Fig. 38. Message informing that the data are added successfully in the current protocol

12.compare the conductivity values with normal range for different groups. Click the button «Norm...» to open the window with reference standards of conductivity values for different groups (Fig. 39) for the second scanning level (depth 1.1 cm). Tab titles of the window correspond to the groups for which normal range values (norms) are presented. Displayed norms are the result of the data selection from the general statistics by taking into account the **age group of the patient**, working scanning frequency and other anamnesis data (that can influence not only on the content, but also on the presence/absence of norms in the window for the considered patient).

abor(s)	Lactation /	Abortions	COC	HRTh (Estradiol+Levonorgestrel) HRTh (Climodien)	
Nun	nber			Phase 1 of MC or postmenopause	Phase 2 of MC
	0			0,40±0,08	0,40±0,05
	1-2			0,47±0,06	0,46±0,07
	3 and m	ore		0,46±0,05	0,46±0,05

Fig. 39. Window with normal range values for the second level (depth 1.1 cm) for different groups

### Analysis and Composing of Examination Protocol

After obtaining the set of measurements and making their preliminary estimate in the main window of the Program, go on to their careful sequential analysis in two window mode. For this purpose open two window mode for the first measurement from the examination series. Select one-by-one the second, third, fourth, fifth scanning level for analysis, define the area of the mammary gland in the picture and press the button «General» (for details see item 8). As a result on the right in the panel «Analysis» conductivity normal range values of the considered scanning level on depth and calculated conductivity values for the defined area will appear. Use the second scanning level values as the most informative for the analysis and including in the Protocol.

After the analysis of the graph of the frequency distribution of conductivity fill the tab "Information" in the panel "Distribution" (Fig. 40).

mage Information	n	
Conditions Date: 13.06.201 Frequency: 10 k Age: 36.551 Position: supine Gland: right Labor: yes Phase 1, 8 (days Comment: ПЛ 10 8	2 12:49:14 Hz	
Analysis		
Date: Nom: Mean: Max.: Min.: Dispersion: Extremum: Depth: Distribution State Asymmetry I O Modality	16.02.2013 0.44 (+/-) 0.09 0.30 0.80 0.04 0.12 0.21 0.40 left ● nght left ● nght	
Focus Mean: Max.: Min.:	0.64 0.86 0.44	

Fig. 40. Tab «Information» in two window mode

After filling up of the all necessary fields, activate the buttons «Save» and «To protocol». The window with the message «Processed data have been saved» (See Fig. ! .) will indicate that the data is saved and the window with the message «Current protocol was updated» (See Fig. ! .) will confirm that the protocol is updated. All the received information

is automatically recorded in the protocol of the patient examination.

If there is any focal symptoms, select hypoimpedance image areas, using the button «Focus» (for details see item 9), analyze the obtained results: the histogram and the values in the tab «Focus» (See Fig. 36). For analysis convenience and correction on patient individualities use the window «Norm», with the tabs, where statistical norms for various groups of patients (See Fig. 39) are presented. Nevertheless, take into account that the value s presented in the tabs of the window «Norm» are given for the second scanning level and deeper hypoimpedance foci usually have lower conductivity values.

For a complete examination take the analysis of all the obtained images the same way. Use the button «Measurement 1» in the left top part of the window open the measurement selection dialogue (See Fig. 32).

After the analysis select in the main window the button «Protocol» and in the opened window press the button «Current» (Fig. 41).

Select
Current
Cancel
Total: -

Fig. 41. Window «Protocol»

Fill out all the required fields by activating one-by-one the tabs «Common» (Fig. 42), «Visual estimate» (Fig. 43), «Conductivity (10 Hz)» (Fig. 44), «Conductivity (50 Hz)» (Fig. 45), «Focal symptoms» (Fig. 46), «Results» (Fig. 47).

All the results of image analysis in two window mode are entered into the current protocol automatically after activation of the button «To protocol» with the regard to the measurement parameters (left/right, 10/50 Hz, standing/supine position ô up to 8 measurements in one protocol) in appropriate tabs.

Common Vis	ual estimation	Conductivity (10 kHz)	Conductivity (50 kHz)	Focal symptomat	tology Results		
Full name	Anna Ivanova	a Lubimova					
Code	144						
Age	36.551						
Menstrual	function	Phase 2	2 🔘 Phase 2 🔘	postmenopause	pregnancy	C lactation	
Lactation							
Pri	nt (	Save				Exit	

Fig. 42. Window «Protocol»: tab «Common»

Common Visual estimation Conductivit	y (10 kHz) Conductivi	ty (50 kHz) Focal symptomatology	Results	
	Left mammary gland		Right mammary gland	
Electrical impedance anatomy	not changed	Changed	ont changed	Changed
Cleamess of contour	) clear	deformed	🔿 clear	
Displacement of internal structures	no	🔘 yes	no	🔘 yes

### Fig. 43. Window «Protocol»: tab «Visual estimation»

.eft mammary	gland				Right mamma	ry gland			
Supine Mean	Minimum	Maximum	SD	Norm	Supine Mean	Minimum	Maximum	SD	Norm
0.00	0.00	0.00	0.00		0.30	0.04	0.80	0.12	0.44 (+/-) 0.
Modality	💿 Uni	🔘 Bi	0	Multi	Modality	🔘 Uni	Bi	C	Multi
Symmetry	<ul> <li>symmetry</li> </ul>	netrical	🔘 asymme	trical	Symmetry	🔘 sym	metrical	asymm	etrical
Shift	💿 no	🔿 right	۲	left	Shift	🔘 no	ight	C	left
Standing					Standing				
Mean	Minimum	Maximum	SD	Norm	Mean	Minimum	Maximum	SD	Norm
0.00	0.00	0.00	0.00		0.00	0.00	0.00	0.00	
Modality	Uni	🔿 Bi	O	Multi	Modality	Uni	🔘 Bi	C	Multi
Symmetry	symr	netrical	🔘 asymme	trical	Symmetry	sym	metrical	🔘 asymm	etrical
Shift	🔘 no	🔘 right	O	left	Shift	🔘 no	🔘 right	۲	left
Conductivity di	fference		Corre	spondence					
Right/left, supi	ne 0.00	%	to	nhase of menst			() n	ot correspon	d
Right/left, stan	ding 0.00	%	10	pridae of monat			0.		
Right, standing	/supine 0.00	%				-	~ .		
and standing (	0.00	%	to	age norm		<ul> <li>correspond</li> </ul>	🔘 hi	gher 🔘	lower

Fig. 44. Window «Protocol»: tab «Conductivity (10 Hz)»

mmon Visual e	stimation Co	onductivity (10 k	(Hz) Conductiv	rity (50 kHz)	Focal symptomatol	ogy Res	ults		
Left mammary gla	and				Right mammar	y gland			
-Supine Mean	Minimum	Maximum	SD	Norm	Supine Mean	Minimur	n Maximum	SD	Norm
0.00	0.00	0.00	0.00		0.00	0.00	0.00	0.00	
Modality	<ul> <li>Uni</li> </ul>	🔘 Bi	🔘 Mu	lti	Modality	۲	Uni 🔿 Bi	C	Multi
Symmetry	symmetry	netrical	🔘 asymmetrica	al	Symmetry	۲	symmetrical	🔘 asymm	netrical
Shift	💿 no	🔘 right	<ul> <li>left</li> </ul>		Shift	0	no 📀 right	t @	left
Standing Mean	Minimum	Maximum	SD	Norm	Standing Mean	Minimur	n Maximum	SD	Norm
0.00	0.00	0.00	0.00		0.00	0.00	0.00	0.00	
Modality	<ul> <li>Uni</li> </ul>	O Bi	🔘 Mu	lti	Modality	۲	Uni 🔿 Bi	C	) Multi
Symmetry	<ul> <li>symmetry</li> </ul>	ietrical	asymmetrica	al	Symmetry	۲	symmetrical	🔘 asymm	netrical
Shift	🔘 no	🔘 right	Ieft		Shift	O	no 🔘 right	t @	) left
Conductivity diffe	erence		Correspon	ndence					
Right/left, supine	0.00	%	to pha	ase of menstr	ual cycle	Correst	oond 💿 r	not correspon	d
Right/left, standi	ng 0.00	%							
Right, standing/s	supine 0.00	%				-			
Left standing (au	0.00	%	to ag	e nom		<ul> <li>correst</li> </ul>	oond 🔘 h	nigher 🥘	lower

### Fig. 45. Window «Protocol»: tab «Conductivity (50 Hz)»



Fig. 46. Window «Protocol»: tab «Focal symptomatology»

Common	Visual estimation	Conductivity (10 kHz)	Conductivity (50 kHz)	Focal symptomatology	/ Results	
Deeu						
Electr	n reconductivity of ma	ammory glads is higher th	an norm (typical for fat in	avolution) in left mammo	ory glad on 13 o'clock area of increased conductivity	
That i	s definitive for cyst	s.				
Reco	mmendations					
Ultra-	Sonic reasearch is	strongly recommended w	vith further mammalogy o	onsultation.		

Fig. 47. Window «Protocol»: tab «Results»

After filling all the necessary protocol sections go to the tab «Common» (See Fig. 42) and print the protocol (press the button «Print»). To save the protocol in the database press the button «Save». A message that the protocol is saved will appear (Fig. !



Fig. 48. Message regarding protocol saving

To close the protocol, press «Exit». Saved protocols appear in the list and are available to be viewed or printed. When resaved, the edited protocol is saved separately, as a new one with the right date (Fig. 49).



Fig. 49. Window «Protocol» for two versions of one protocol, displayed as two different documents with different date and time

The time interval it takes for the examination of one patient (application of the electrodes, conduct of measurements, image reconstruction, visual estimate of the images, conductivity measurements and their analysis) is equal to 15625 min.

## **Additional Software Capabilities**

### Image Printing in Program

MEM software allows print through standard Windows print dialogue:

-examination protocol;

-chosen image set;

-chose single slice with details.

**Print examination protocol.** Open fulfilled protocol. For it use button õProtocolö in main window of the program (See Fig. 21), further chose urgent protocol from the list (See Fig. 49). Start print by pressing of button õPrintö, which located on tab õCommonö (See Fig. 42) of window õProtocolö.

**Print chosen image set.** It can be produced from main window of the program (See Fig. 21) in case of having measurements displayed on it. Tick images which desire to print (to facilitate use context menu, activated by right mouse button click on images, for select/select whole image set for measure), and chose item õprintö in context menu list.

**Print single slice with details.** First open necessary image in two window mode (See Fig. 31). Use double left mouse button click on image to choose image from main window background (See Fig. 21). To print the current image from two window mode press the right mouse button in the tab «Measurement 1» (or «Measurement 2»). Select «Print» in the opened menu (See Fig. 33).

### Giving results in electronic form

There are several way how to pass results in electronic form:

-print in pdf format;

-print in xps format;

-transfer through external documents;

-export single measure from data base;

-send complete data base;

-share result in DICOM format.

**Print in pdf format.** For it requires having pdf printer installed in system (software that emulate printing and creating files instead of paper n printing). For instance, take free software pdfcreator (<u>http://pdfcreator.ru/</u>). After choosing item õPrintö (See previous subsections) standard Windows print dialogues will appear. Choose installed pdf printer among them to print data in file ( . . . 50).

**Print in xps format.** XPS format is included in Windows (XP version and further). After choosing item õPrintö (See previous subsections) standard Windows print dialogues will appear. Choose õMicrosoft XPS Document Writerö as a printer among them to print data in file ( . . . 50).

**Transfer through external documents.** Transferring in external document describe below (See subsection õImage Transfer to External Documentö). Thus, any information displayed in the program can be captured through Window exchange buffer and saved in external document and can be send in electronic form so.

<u>И</u> мя:	\\TOMOS\HP Universa	al Printing PCL 5 ( 👻 Сво <u>й</u> ства		
Состояние: Тип:	\\TOMOS\HP Universal Printing PCL 5 (v5.5 \\TOMOS\HPUniver.Color Fax			
Место:	Microsoft XPS Documer	nt Writer		
Комментарий:	PDFCreator	📃 Пеуать в фа		
Диапазон печа	ти	Копии		
) <u>B</u> ce		Число копий: 1		
🖱 Страницы	с: до:	<u>Р</u> азобрать по копиям		
) В <u>ы</u> деленный	фрагмент	112233		

. 50. Example of Window print dialogue

**Export single measure from data base.** The export method is described below in subsection õExport and Import Single Measurements from Databaseö. This is the most informative data transfer for other doctor, but to open it require having MEM software.

**Send complete data base**. Produce archivation of folder contains data base (by default folder My Documents of current user, for whom MEM software have been installed) and send this created archive file. To look data base MEM software is need. Detail information concerning database presented in subsection õSettings of databaseö.

**Share result in DICOM format.** Context menu (See Fig. 29 and subsection õExport image to DICOM formatö) of images displayed on background of main (See Fig. 21), allows convert slice set of one to international medical format. DICOM file contains patient and measure information besides of image set. To look such file need any DICOM viewer program. We recommend (checked the proper work with) use Radi Ant DICOM Viewer version 1.9.14 (http://www.radiantviewer.com/).

### Image Transfer to External Documents

To save images in external documents (for example, MS Word) with the possibility of their further printing by a printer device use the standard Windows function of the window content copying to the Windows clipboard. Open the required image in the window of the Program MEM and press the button «Print Screen» at computer keyboard (usually it is placed in the upper right part of the keyboard, can be titled as «Prt Sc»). This command copies active window content to the Windows communication buffer. Further use button combination «WIN» + «D» (button «WIN» usually located on the left bottom part of the keyboard Windows logo ó flag cut on 4 parts inside circle) to minimize all windows and chose needed one. Open the document, in which it is necessary to insert the image, and choose paste from the clipboard (combination of the buttons «Ctrl» + «v»). Now it is possible to crop, format, save the image with the document and print, send in electronic form. Also external document can be print in pdf, xps formats too.

#### Export and Import Single Measurements from Database

Export and import allow physicians to exchange measurement results, in particular, to discuss the examination results or to consult with specialists on the received image interpretation.

Export is carried out with a specially composed file «\*.mem». To export the image, one should select a patient in the main window of the Program, press the right mouse button at the image required and in the opened shortcut menu choose «Export...».

Import of file data is carried out from the window «Archive» (See Fig. 51), activated from the main window by pressing of the button «Archive» (See Fig. 3). Data addition is performed in the current archive. By pressing the button «Import...» standard dialogue on file name selection for reading is opened. Selecting a file and pressing « », it is possible to see

one of two information messages, in which the results of the import are presented: in the first case it is informed that a new patient is added to the current archive (Fig. 52), in the second case that new measurement data are added to the data of already existing patient (Fig. 53).

Current archive:	C:\Users\TT\Docur	ments\MEM database\	
Create	Change	Import	Cancel

Fig. 51. Window «Archive»

mport	
New patient v Artemenko Lu	vas added: udmila Ivanovna
	OK

Fig. 52. Message informing that new patient is added as a result of the measurement import

mport	
New data we Artemenko L	re added: .udmila Ivanovna
	ОК

Fig. 53. Message informing that new measurement is added to existent patient

### Setting of database

After installation by default is located inside of folder My Documents of current user (for whom MEM software have been) named as folder MEM database. In õArchiveö (See Fig. 51) window there are buttons implemented to create new database and change actual. To create new database use button õCreateö and set location and name of new folder. Button õChangeö will help to switch active database through the pointing of desire database folder location. After allocation working database will switch on chosen one.

Convenient to split database to accelerate working and search, by some criteria, somewhat: year of measures providing, location or organization of patients.

### CAUTION

### operation with database settings can cause data lose

### Export image to DICOM format

DICOM (*Digital Imaging and Communications in Medicine*) ó international medical standard for writing, storing, transferring and visualization of medical images and documents of patient examination results. The standard define format of data storing and location in file and demand obligatory to store with graphic images (set of image can be stored in a) common information about patient and measure. Images and the information from any DICOM file can be opened by any medical system or program with DICOM standard support. To export a measure to DICOM use item õCreate DICOM file (ö in context menu of measure displayed in background on main window (See Fig. 21).

## **DEVICE CERTIFICATE**

Multifrequency Electric impedance Mammograph "MEM" is made in accordance with the requirements of the manufacturer project specifications TU 9442-002-71188036-2008 and GOST R 50 444. The device is manufactured in climatic design UHL as per GOST category 4.2 15150. In terms of safety mammograph satisfy the requirements of IEC 601-1-1, as regards electrosafety device made in class II, type B. As regards resistance to mechanical stress the device is included in Group 2 by GOST R 50 444. The device contains electrical components and circuits, which are the sources of radio interference, the emission level of which must satisfy the requirements on electromagnetic compatibility of noise emission GOST R 50267.0.2. The device in accordance with its operating principle is sensitive to industrial interference and must survive under the influence of electromagnetic interference, not exceeding the standards required by GOST R 50267.0.2 for electromagnetic compatibility IEC 601-1-1. Class of potential risk of the device is IIa GOST R 51609-2000.

Descriptions	Quantity, pcs.			
1. Multifrequency Electric impedance Mammograph	1			
(measuring unit)				
2. Device stand	1			
3. Dual limb lead electrode	1			
4. Cable for lead electrode connection;	1			
5. USB cable to connect to a computer	1			
6. õMEMö software and documentations (M edical Atlas,	1			
User Manual) on CD				
7. Medical sponge to moisten the skin of a patient	20			
8. Antistatic bag with moisture adsorbent	1			
9. Manufacturer package (box)	1			
10. Notebook/personal computer <sup>*</sup>	1			
Documentations				
11. User Manual and Device Certificate	1			

#### Package contents:

\*- may not include in base configuration

#### WARRANTY CARD

Device serial number:

Produced:

201\_\_\_

Date of sale:

Name and stamp of seller:

Sellerøs signature: \_\_\_\_\_ Customerøs signature: \_\_\_\_\_

Guarantee period is 24 months from the date of sale under normal use. Guarantee does not apply to devices with mechanical damage (including damage by static electricity, cable break), and signs not authorized intervention (as well as integrity losing of manufacturer seals).

## **Gynecological Electrical Impedance Tomograph õGITö**

Proposed diagnosis tool is based on Electric Impedance Tomography (EIT) approach, which allows without invasive intervention to obtain electric conductivity values of the portio vaginalis cervicis at the depth up  $1\div1.5$  cm. Device can be successfully applied for early diagnosis of the vesical cervix cancer and the precursors (dysplasia). The main area of the application is the following: screening procedure, regular examination by the specialists - gynecologists.

The device is under clinical trials. The first medicine results are available at our WEB cite: <u>http://medimpedance.com/products.html</u>

