RELIABILITY, ACCURACY AND SAFETY OF MEDICAL DEVICES

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In the beginning of 2013 on the site of ResearchGate https://www.researchgate.net/ Phil Petursson raised a question: How do you know that medical devices are reliable, accurate, and safe? Petursson wrote: "I believe that approval ratings that include: 'CE', 'UL', and 'GS' are only electrical safety ratings, and do not evaluate the reliability and validity (accuracy) of a medical device."

Is it true that the CE mark on medical devices (MD) means only electrical safety ratings?
Before any producer of medical device labels his product with the CE mark and introduces them on EU market with medical devices, the device must fulfill the conditions written in Directive 93/42/EEC (MDD), 98/79/EC (IVDD) or 90/385/EEC (AIMDD). In practice this process is called „CE registration".

What does the process of CE registration mean?

The process of CE registration is divided into two parts. First, each producer or EU representant of a manufacturer is obliged to prepare a so called Technical Construction File (TCF). The content of this document consists of:

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The second document it is an “Audit report” which assesses the compliance of Quality management system of the manufacturer with the Council Directive 93/42/EEC or others. After inspection at the facilities of the manufacturer the auditor/s of Notification Body will prepare an “Audit report”. If both TCF and Audit report fulfil the condition of the Directive, the Notification Body (NB) will issue a CE certificate and the producer can mark his product with CE_{xxxx} (CE_{xxxx} - the number xxxx means the registration number of NB).

Now, let’s focus on the TCF document. In the point 10 of the TCF we can find different test reports, conclusions etc. The main parts of it are tests for electrical safety, EMC, test of biocompatibility or toxicology, etc. All these tests are assessing the safety of medical staff and patients when using the device.

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Test Report No: 414102183AL1
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TEST REPORT

ABOUT THE ELECTRICAL SAFETY TEST

of the Electrical impedance computer mammograph MEIK

Test Engineer and Report Author:
Stanislav Malina

Head of Testing Laboratory:
Pavel Vavra

Issue Date: 2013-02-28
Number of pages: 39
Number of Appendices: 3

Distribution List: Institute for testing and certification (Copy No 1)
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TEST REPORT

ABOUT THE ELECTROMAGNETIC COMPATIBILITY TEST

of the Electrical impedance computer mammograph MEIK

Test Engineer and Report Author:
Josef Pistek

Head of Testing Laboratory:
Pavel Vavra

Issue Date: 2013-02-22
Number of pages: 9
Number of Appendices: 0

Distribution List: Institute for testing and certification (Copy No 1)
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Reliability and accuracy of medical device

For the explanation of technical terms “reliability” and “accuracy” of medical device it will be better when we explain these words on a specific medical device – e.g. “electrical impedance computer mammograph MEIK”.

In the TCF document the test for ***reliability*** of the evaluated medical device, in our case for EI mammograph MEIK, is described in point 4. What exactly does software validation for EI mammography MEIK mean? We have extracted the method how to organise the process of software validation from the TCF document of MEIK mammograph.

Process of software validation of EI mammograph MEIK

EI mammograph MEIK is a medical imaging device. The process of software validation is based on the calibration of various phantoms used in connection with imaging (see Figure 1).

For testing of image mode function (see Figure 1), it is necessary to:

Place the stand ST-01 on a horizontal surface.

Fill the tank with NaCl solution (0,02%) up to the control mark.

Place the examined mammograph on the upper part of the stand.

Plug the remote electrode of patient into the mammograph and put the measuring electrodes on the stand in contact with surface, observing the colored mark.

The USB cable of mammograph must be connected to the PC. The green LED placed from the right side on the mammograph body has to shine.

Start the "MEIK. 5.6" software, select the operating mode "Screening".

Press "New". Enter a number (e.g. number 1) in the window "Patient ID".

Fill the windows "Name" and "Date of birth" in the form. Click "Save."

In the upper left corner of the window a "Patient Code" will be shown. Click "Measurement". In the middle of the matrix of electrodes the red laser module should start lighting. Point the mammograph onto a homogenous surface and visually inspect that the laser module is working.

In the form, which appears on the screen, select "Measuring conditions", "Left", "Stand" and than press "Start". Laser module should switch off automatically. 256 small red circles will appear on the screen, representing the matrix of electrodes of the mammograph. The LED diode on the side of mammograph should be flashing in yellow color.

Put the mammograph on the upper part of stand, as is shown in Figure 1. Image of contacts should change from red to green. Press "Start measurement button" on mammograph. The yellow LED should shine continuously and the percentual countdown of the measurement time begins in the window with the image of a matrix of electrodes.

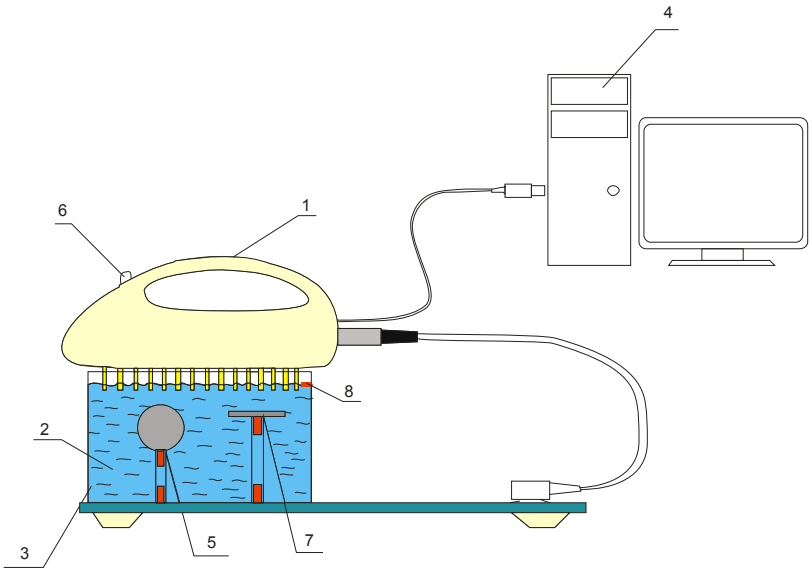


Figure 1. Scheme of phantoms identification used in connection with MEIK mammograph imaging

1 – inspected product, 2 - solution of NaCl (0,02%), 3 - tank with solution, 4 - PC, 5 - ball phantom, 6 - the button "Start", 7 - metal plate phantom, 8 - control mark

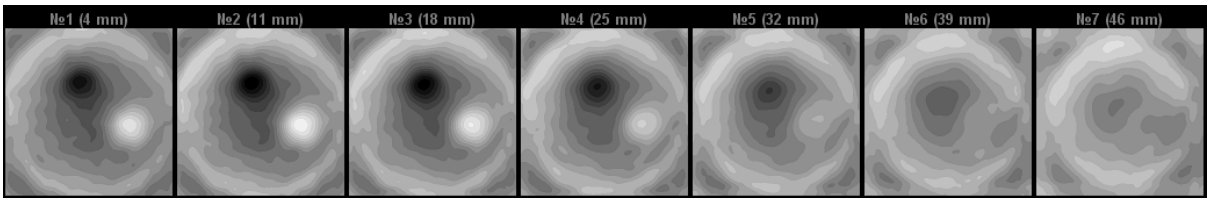


Figure 2 - The reconstructed images of used different phantoms

In our case, the phantoms are distinguishable, machine-readable identification features allow imaging and identifying them automatically, without any intervention by the operator. The "reconstruction of image" with an integral image of the object, is displayed on the screen after the mathematical transformation as seven scan planes. The phantom tests give us the possibility to assess: visualization of objects, definition of size, location, depth and shape of objects, electrical conductivity and resolution capability.

The manufacturer includes the process of software verification in the quality system control and the metod is discribed in TCF document under point 13 - “QMS Procedures“.

More in article: **Electrical Impedance Potential Mammography for Visualization of Objects (Electrochemical Tests)** **http://bioimpedance.bme.ufl.edu/icebi/1889_Alexander.pdf**

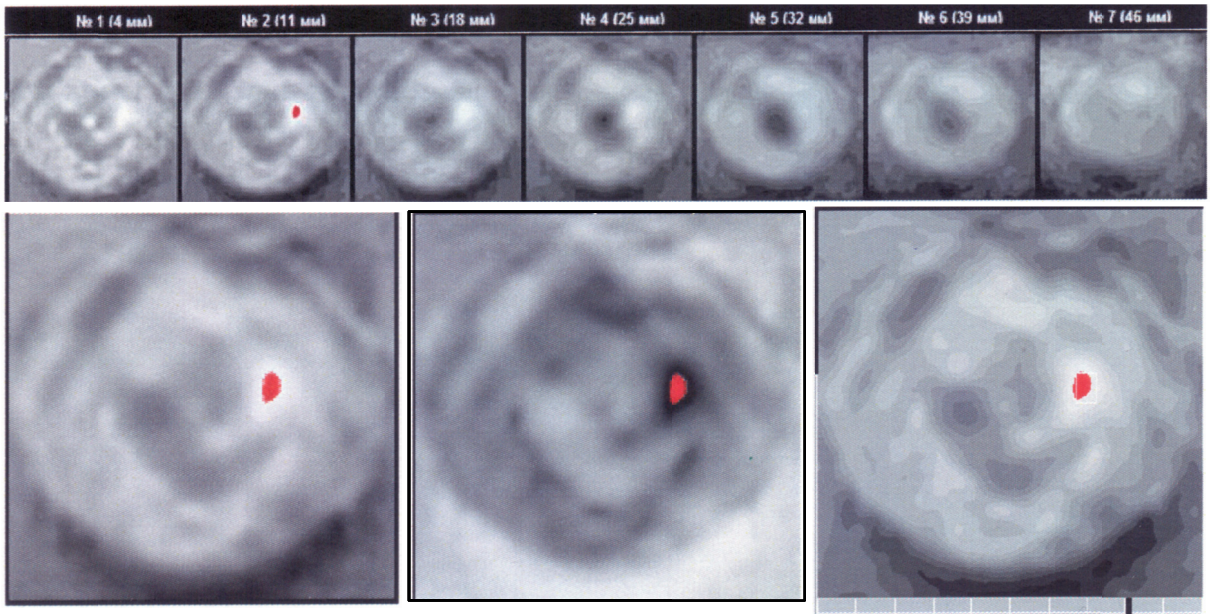
Accuracy of EI mammography MEIK

A useful method for evaluation of accuracy of results of any medical device are so called clinical trials. EI mammograph MEIK has been subjected to many trials where the ability of mammograph to predict the false positive or negative results was evaluated. The documents regarding the clinical trials of electrical impedance mammography MEIK can be found on website http://www.onkocet.eu/en/produkty-detail/250/1/

№	CLINICAL TRIAL	Sensitivity [%]	Specificity [%]	Patient [n]
1	Utilization of EI Tomography in Breast Cancer Diagnosis. Faculty of Medicine, Comenius University, St. Elisabeth Cancer Institute, Bratislava, 2012	87	85	808
2	Report on clinical trial of electrical impedance computer mammograph (MEIK) with software ver. 5.6. Herzen Institute of Oncology, Moscow, 2010	87.39		117
3	EI – new possibilities of examination of the breast gland? Oncological institute of St. Elisabeth, Bratislava, 2010	90.4	86.9	149
4	Report on clinical trials ”Evaluation of the Informativity of the EI mammograph in conjugation with Mammoscintigraphy”. FSI Russian Scientific Center of Radiology and Nuclear Medicine. Moscow, 2008	86.5	92	64
5	A Prospective, Randomized, Blind Study of 3-Dimensional Electrical Impedance Tomography Imaging Modality as an Adjunct to Diagnostic Mammography Radiologic Exam in Detecting and Isolating Breast Cancer to Determine the Necessity of Fine Needle Aspiration, Core Biopsy or Open Biopsy. Technology Commercialization International, Inc., Albuquerque, USA, 2002	92.6	65.4	26
6	REPORT on clinical diagnostic tool for electrical impedance mammography "EM – 003 Korvet"			48

Furthermore, 1 out of 10 pcs from each new series of product is subjected to verification in clinical conditions.

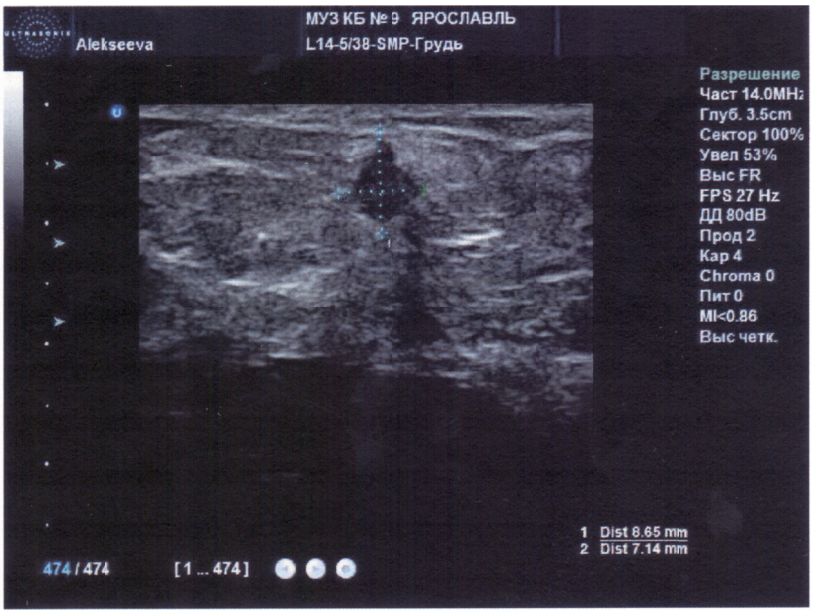
Patient # 74, 52 years. Complain about seal in the breast.



smoothing *inversion*

EIM:

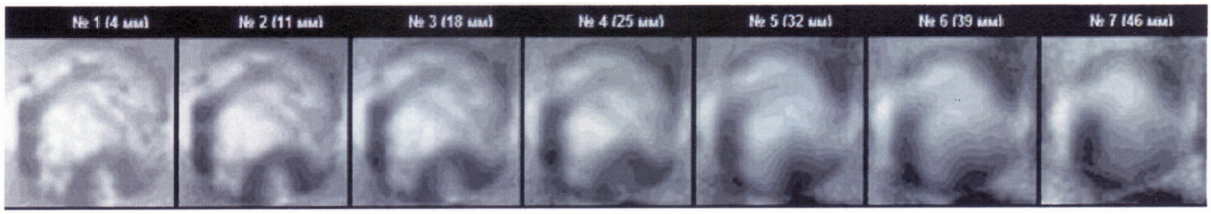
Amorphous type structure of gland (age conductivity > 95 ‰, *ACR* I). The outer segment of the left gland, at 3 hours position near the areola, animpedance area visualized in red on the second scan plane, measuring less than 10 mm. This image is typical for breast cancer.

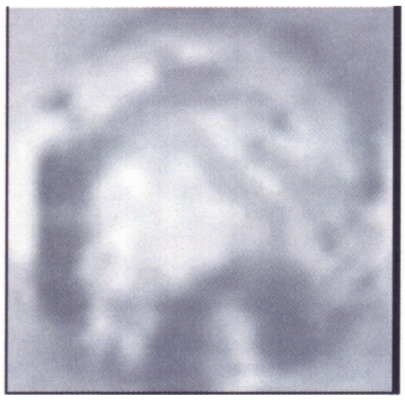


ULTRASOUND:

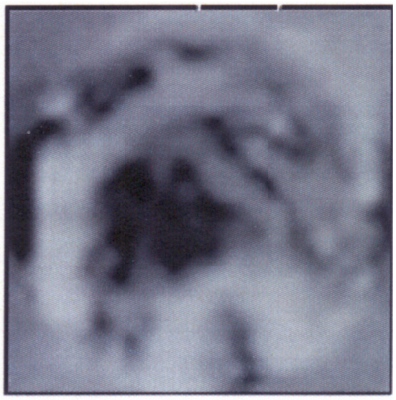
The structure of the parenchyma with fat slices and connective layers. At a distance of 28 mm from the nipple and at a depth of 12 mm irregular shape of the inhomogeneous structure of the 9x9 mm without vascularization. This image is typical for breast cancer.

Mammography ser. # 55. Patient # 169-58, 28 years, standard medical examination.

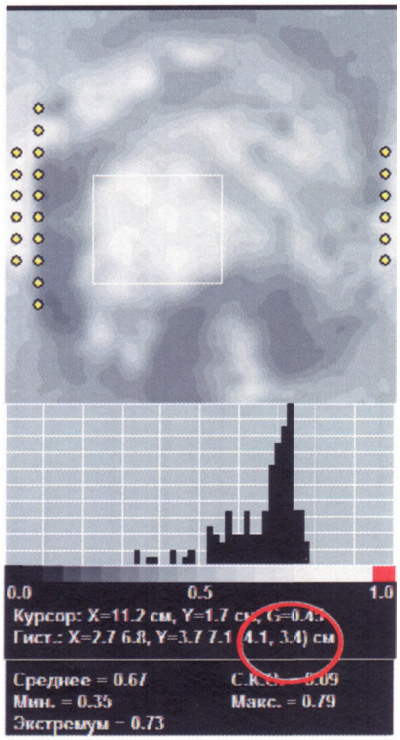




smoothing

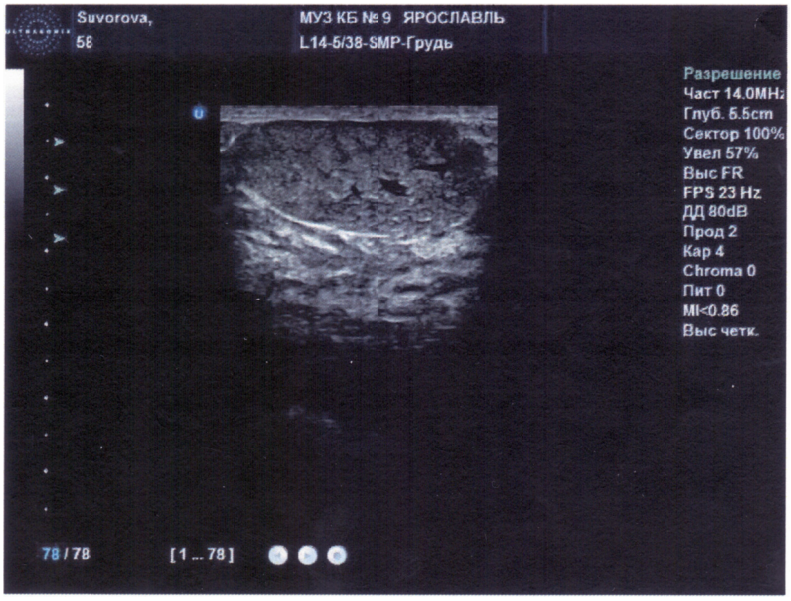


inversion



EIM:

Mixed type of structure of the mammary gland. In upper segment, at 12 o`clock, there is iso-impedance formation with wavy outline and heterogeneous electrical structure (septum) of size 41 x 34 mm. Fibroadenoma (leaf-shaped tumor).



ULTRASOUND:

At 12 o`clock rendered iso-echogenic capsule formation in slotted cavities with vascularization 34 x 15 mm. Fibroadenoma (leaf-shaped tumor).

Ultrasound “Ultrasonix”, Canada ser. no. 37752127 with linear array ultrasound transducer probe 6.6 MHz expandable to 14 MHz was used.

Conclusion.

The aim of this article is to present the types of various tests and examinations which can give answer on question “How do you know that medical devices are reliable, accurate, and safe?“ which occured on ResearchGate website. We know that is very difficult to find some information in medical journals or books regarding the evaluation of medical device concerning the reliability, accuracy, and safety. The leaflets of MD pruducts do not focus detailed attention to reliability, accuracy and safety. So, we decided to release some information from the TCF document, which has been required for registration of EI mammograph MEIK under Directive 93/42/EEC, valid on the theritory of European Union. The producer of MEIK mammograph performed the verification of reliability, accuracy and safety requirements according to his schedule of checking plan.

LITERATURE

1) *IEC 60601-1 third edition 2005-12, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2) *Technical Construction File of Electrical Impedance Computer Mammograph MEIK No. 01/07, revision number 4, issued on September 28th 2012.*

3) *Protocols issued by manufacturer.*

4) *Reports of clinical trials.*

5) *Protocols issued by laboratory of NB 1023.*