

Magnetocardiography

Illya Chaikovsky
Institute of Cybernetics of NAS of Ukraine



KAPITAŁ LUDZKI
NARODOWA STRATEGIA SPÓJNOŚCI

UNIA EUROPEJSKA
EUROPEJSKI
FUNDUSZ SPOŁECZNY



Projekt współfinansowany przez Unię Europejską w ramach Europejskiego Funduszu Społecznego

Magnetocardiography: 10 years intensive experience of clinical work

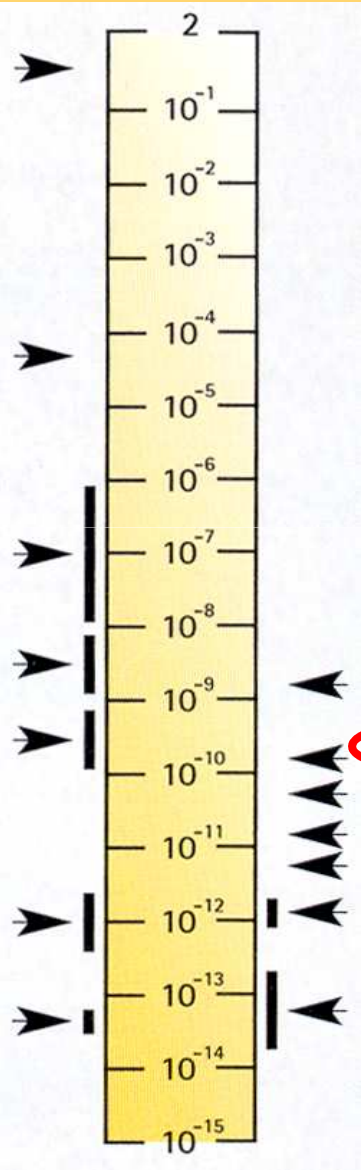


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Magnetocardiography

MR-tomograph



earth field

urban noise

car @ 50 m

screwdriver @ 5 m

transistor, IC chip @ 2 m

transistor die @ 1 m

Environmental fields

Squid working temperature:
4.2 K / -269 °C

lung panicles

human heart

skeletal muscle

fetal heart

human eye

human brain

human brain response

Biomagnetic fields

Types of MCG systems



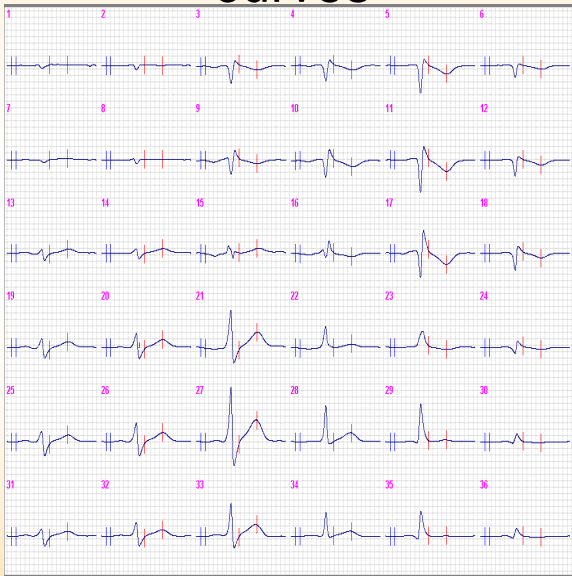
Shielded Room



**MCG 7 in an
Unshielded Room**

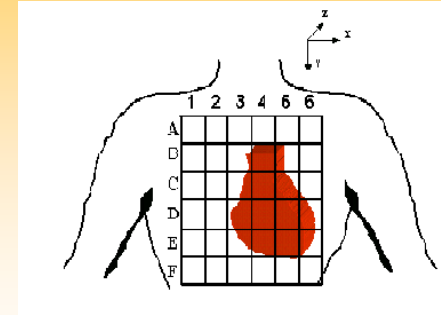
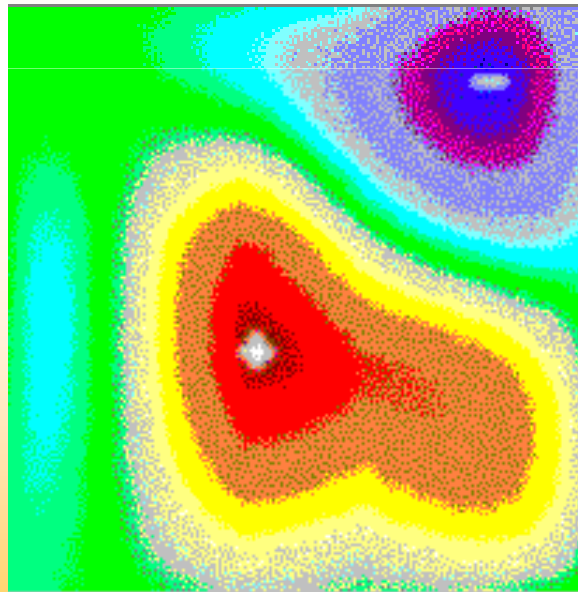
Magnetocardiographic images

From raw MCG-curves



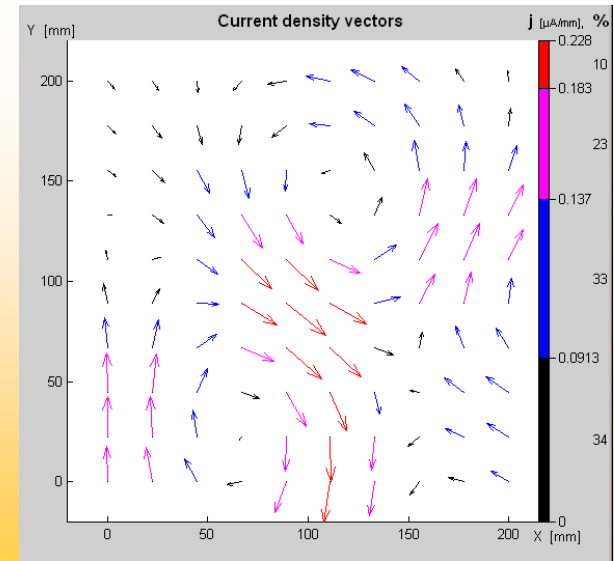
interpolation

to magnetic field map



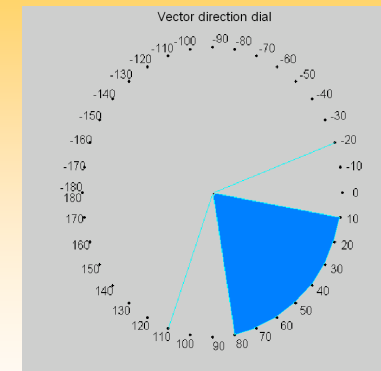
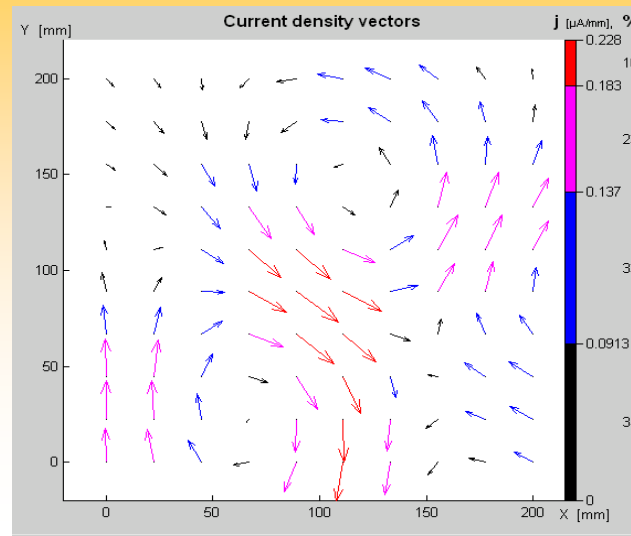
inverse solution

to current distribution map



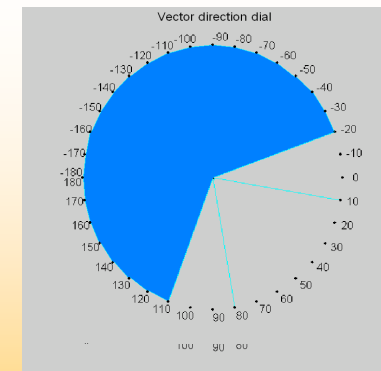
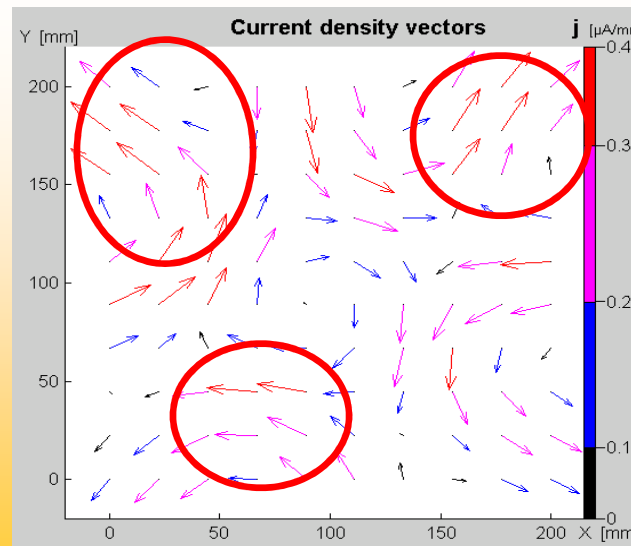
Principles of Analysis of Current Density Vector Maps

- Direction of main current vectors (semiquantitative analysis)



Healthy volunteer

- Presence, number and intensity of additional current



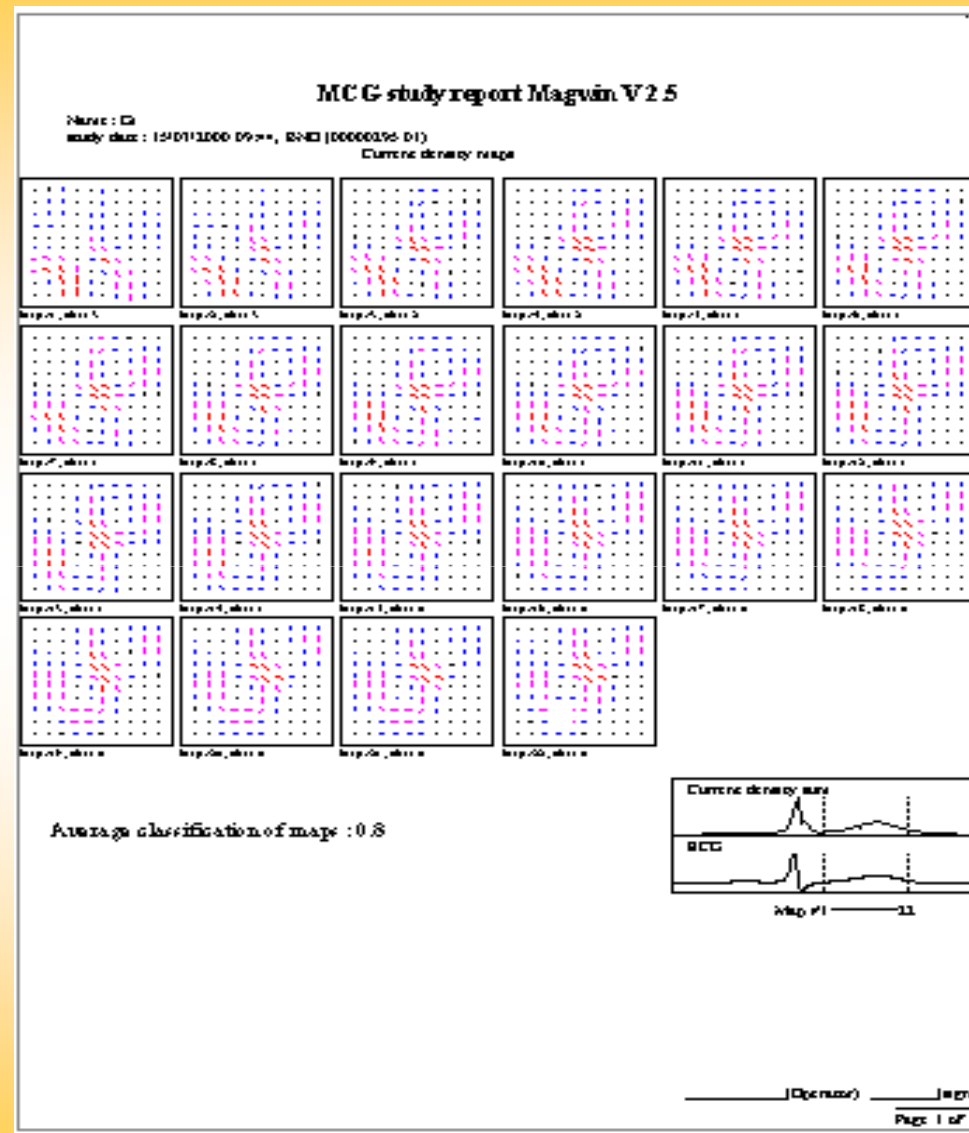
CAD patient with normal resting ECG and uncertain bicycle test

Methods of maps analysis

- a) Visual maps classification;
- b) Computerized classification based on stability of maps within ST-T interval;
- c) Computerized classification based on direction of main vectors and homogeneity of maps;
- d) Computerized classification based topological characteristic of the maps;
- e) Computerized classification based on discriminant analysis;
- f) Computerized analysis based on angle between MCG and ECG.

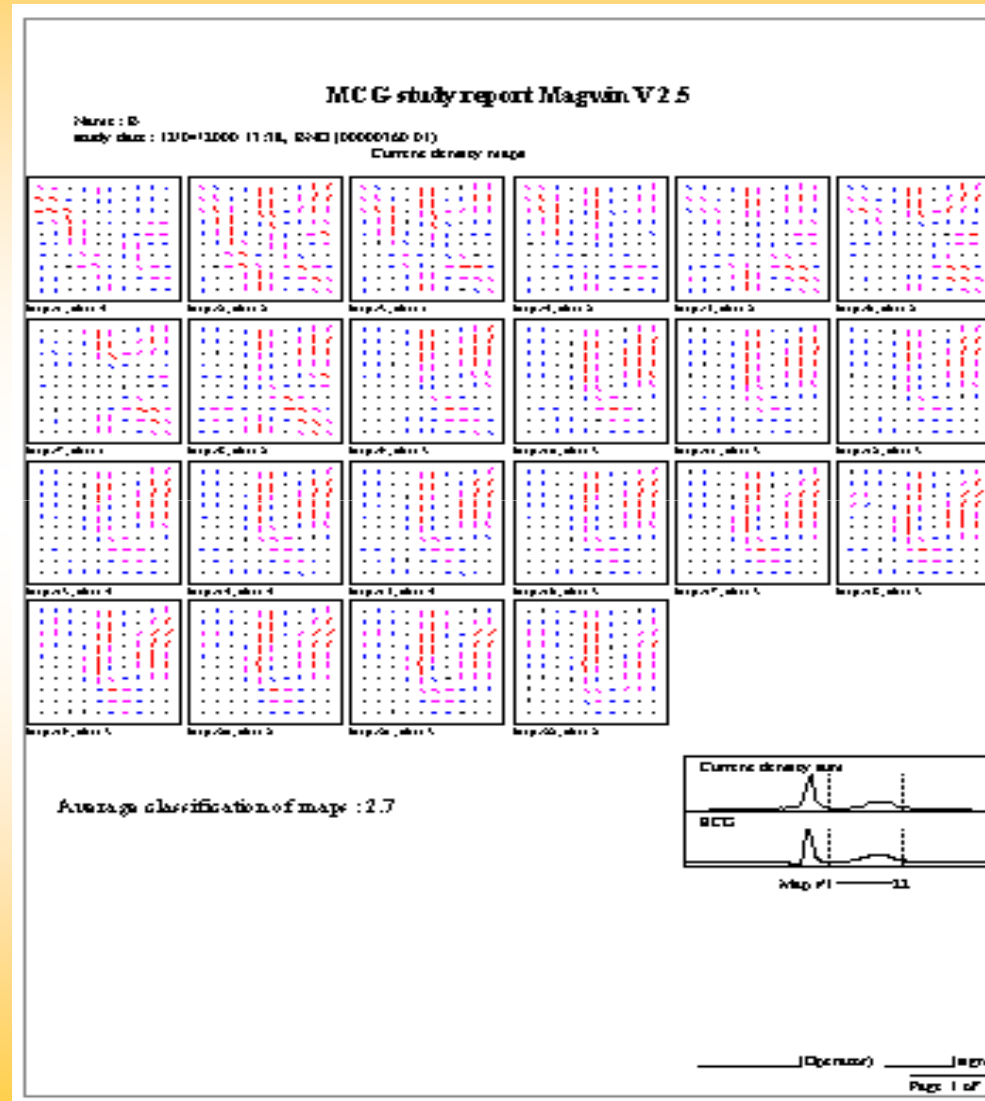
Note : Each person examined was diagnosed!

MCG maps within ST-T interval of healthy volunteer



Note: Diagnosis is always based on a series of images

MCG maps within ST-T interval of CAD Patient with Normal Resting ECG



Note: Diagnosis is always based on a series of images

Розпізнавання типових магнітокардіографічних карт

Файл

Навчання+Екзамен

Навчання

Екзамен

K1 - нормальний стан

K2 - ішемічна хвороба серця

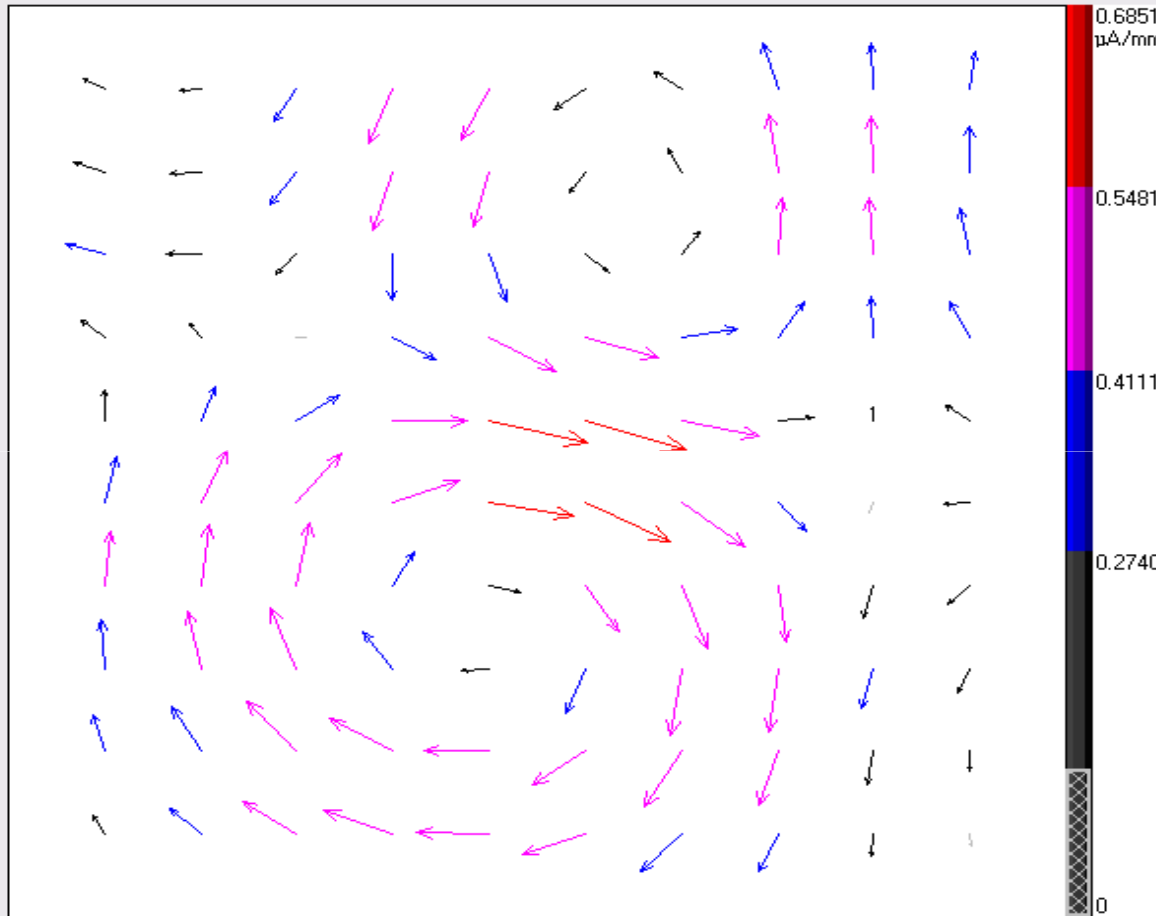
K3 - неішемічна хвороба серця

K4 - шуми серця

Зображення для розпізнавання

Навчання

Екзамен

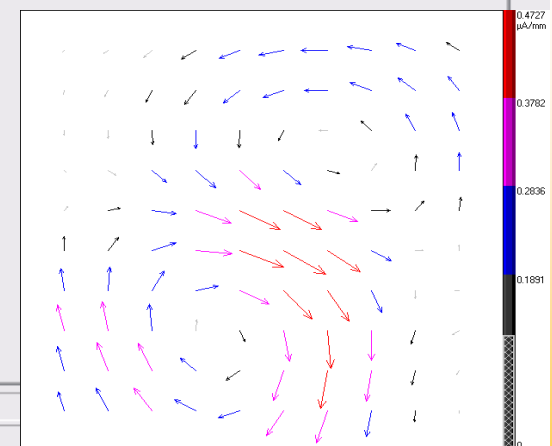


Завантажити

magnetograph

Belong to class X1 (normal state)

OK



Розпізнавання типових магнітокардіографічних карт

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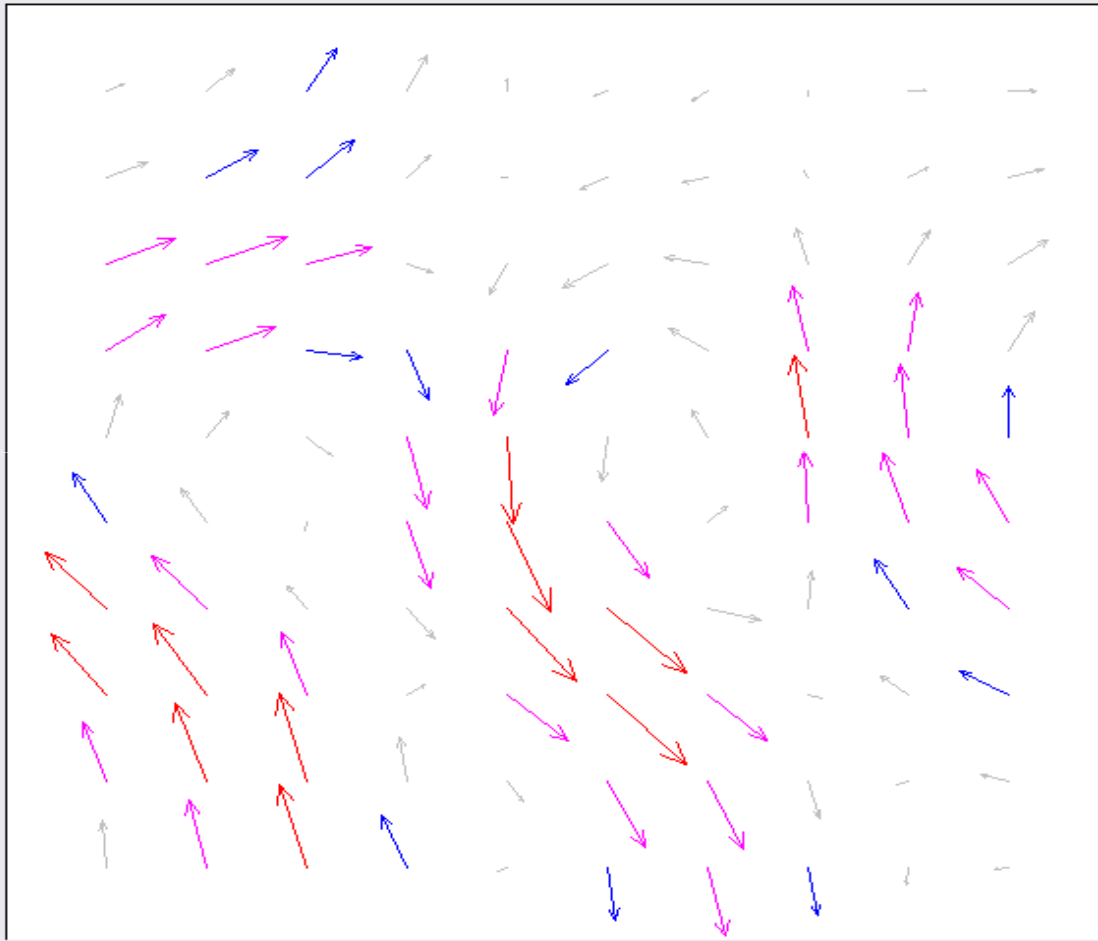
K3 - неішемічна хвороба серця

K4 - шуми серця

Зображення для розпізнавання

Навчання

Екзамен



0.121
μA/m

Завантажити

0.10

magnetograph

Belong to class X2 (ischemic heart disease)

OK

0.071

0.050

0.1764
μA/m

0.1411

0.1058

0.0706

0

Our Vision:

Magnetocardiography

could fill the **gap** between
noninvasive but low-sensitive

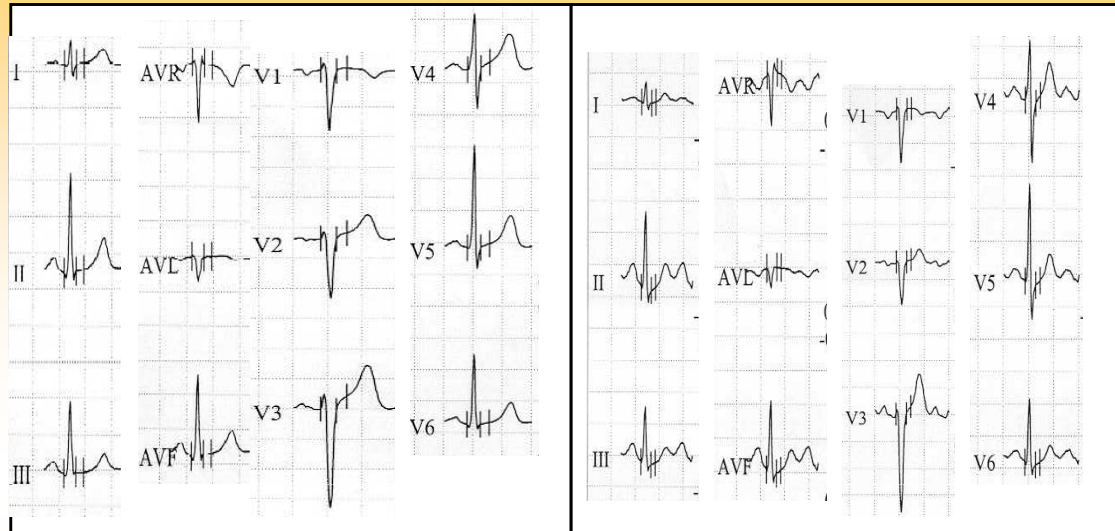
routine techniques

and

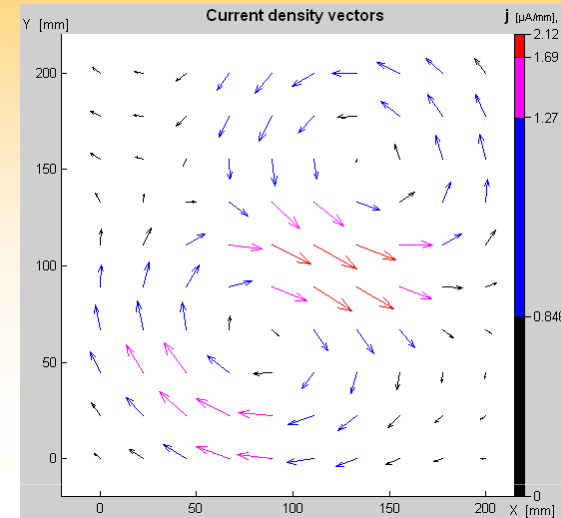
invasive diagnostic methods

Focusing clinical question: Whom should we send home?

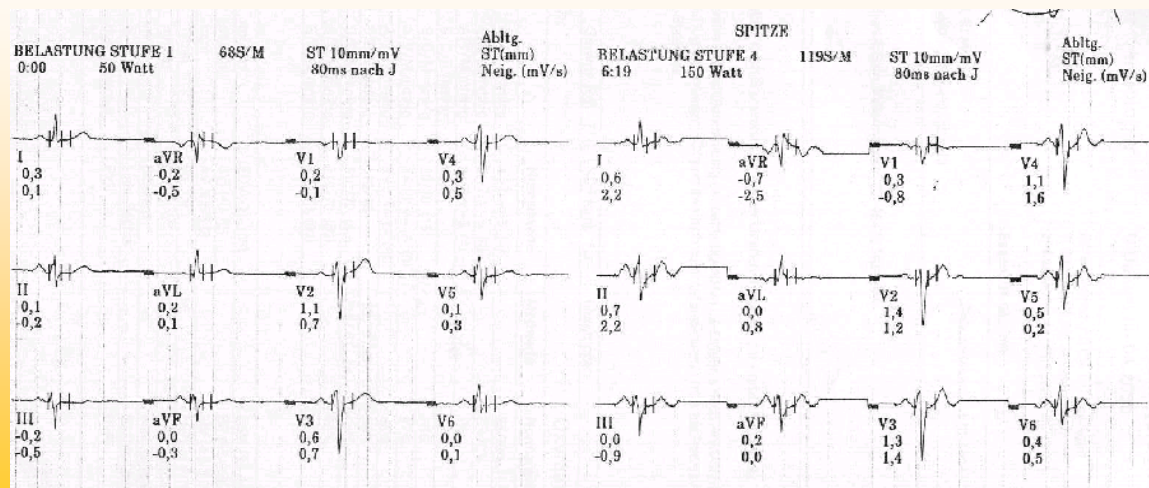
Healthy volunteer



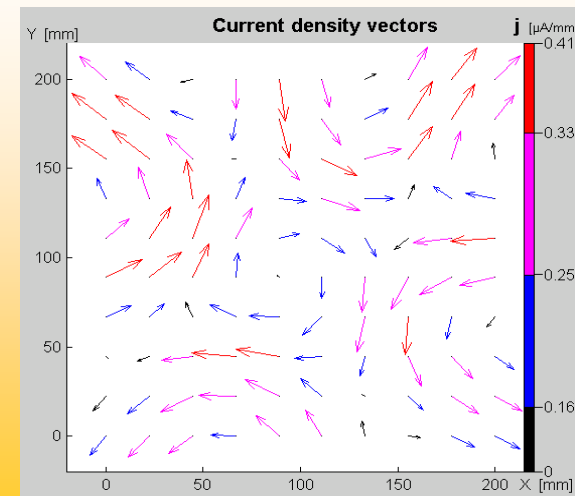
ECG at rest (left) and Stress-ECG (bicycle) test (right)



CDV map in the middle of ST-T interval



CAD patient with 2-vessel disease



Evidence based medicine : levels of evidences

1a.b.c : Randomised controled trials;

2a.b.c : Case-control studies ;

3 : Non-analitical studies (case history) ;

4 : Expert opinion

Aim of the studies :

to check the value of magnetocardiography in unshielded location for the diagnosis of the most dangerous heart diseases, first of all myocardial ischemia, in series of high-ranking western clinics.

Design of studies : prospective single-centers studies.

Gold standards: Coronary angiography , PET.

Surrogate gold standard for control group selection:
no history of heart diseases , normal ECG at rest ,
normal ergometry, normal echocardiography.

CAD-Trial: Katholikal Hospital Phillipusstift (Academic hospital of Essen Universitet)

- **177 patients** with angiographically verified 1-3 vessel CAD
 - **no** previous myocardial infarction
 - **no** pathological ECG at rest
 - **no** ventricular wall motion disturbances
- **117 controls** with no history of CAD
 - **normal** ECG at rest
 - **normal** ergometry
 - **normal** echocardiography

CAD-Trial: Katholikal Hospital Phillipusstift (Academic hospital of Essen University)

Responsible cardiologists: Priv. Doz. B.Hailer, Dr. S. Auth-Eisernitz

Results:

Sensitivity : 74 %

Specificity: 71 %

CAD-Trial: Katholikal Hospital Phillipusstift (Academic hospital of Essen Universitet)

- **60 patients** with angiographically verified 1-3 vessel CAD before, 24 hours and 1 month after PTCA

Responsible cardiologists: Priv. Doz. B.Hailer,
Dr. S. Auth-Eisernitz

Results:

Highly statistically significant improvement of maps classes after PTCA (especially one month after PTCA)

ECG remained unchanged in the course of PTCA

CAD-Trial: Essen University Hospital

- **36 patients** with angiographically verified one vessel CAD (LAD)
 - **no** previous myocardial infarction
 - **no** pathological ECG at rest
 - **no** ventricular wall motion disturbances
- **42 controls** with no history of CAD
 - **normal** ECG at rest
 - **normal** ergometry
 - **normal** echocardiography

CAD-Trial: Essen University Hospital

Responsible cardiologists: Prof R. Erbel, Dr. D.Katz

Results:

Sensitivity : 75 %

Specificity: 74 %

CAD-Trial: German Heart Center (Berlin)

- 102 patients
 - no previous history of heart disease
 - uncertain complaints

Results of coronarangiography :

- 56 patients with stenosis of 1-3 cor. vessels
- 46 patients without stenosis of cor.vessels

CAD-Trial: German Heart Center (Berlin)

Responsible cardiologists: Prof E. Fleck, Dr. J. Lookajczyk

Results:

Sensitivity : 84 %

Specificity: 80 %

CAD-Trial: Heart and Diabetes Center of NRW (Bad-Oeynhausen)

- 59 patients
 - no previous history of heart disease
 - uncertain complaints

Results of coronaroangiography :

- 40 patients with stenosis of 1-3 cor. vessels
- 19 patients without stenosis of cor.vessels

CAD-Trial: Heart and Diabetes Center of NRW (Bad-Oeynhausen)

Responsible cardiologists: Prof D. Horstkotte, Dr. C.Berndt , Dr.J.Kofer

Results:

Sensitivity : 84 %

Specificity: 79 %

CAD-Trial: Heart and Diabetes Center of NRW (Bad-Oeynhausen)

- 26 patients underwent PETat rest and under adenosine induced hyperemia

Results of PET :

- 21 patients with decreased global flow reserve
- 4 patients with normal flow global reserve

CAD-Trial: Heart and Diabetes Center of NRW (Bad-Oeynhausen)

Responsible cardiologists: Prof D. Horstkotte, Dr. C.Berndt , Dr.J.Kofer

Results:

Sensitivity : 95 %

Specificity : 75%

CAD-Trial: Heart and Diabetes Center (Bad-Oeynhausen)

A one year follow up

- 106 patients
 - uncertain complaints

Coronary events during one year :

- 3 non-fatal myocardial infarctions
- 24 revascularizations

CAD-Trial: Heart and Diabetes Center (Bad-Oeynhausen)

Responsible cardiologists: Prof D. Horstkotte, Dr. C.Berndt , J.Kofer

Results:

PPV and NPV of different diagnostic methods to coronary events

Methods	PPV	NPV
MCG, n=106	62%	93 %
Resting ECG, n= 106	20%	77%
Stress ECG, n=59	25 %	80 %
Echo , n=70	30 %	71 %
Stress Echo , n=41	66 %	91 %
PET, n=9	100%	-
Scintigraphy , n=3	100%	-

CAD-Trial: University Medical Center St. Radboud (Nijmegen)

MCG mapping in comparison with 40-leads BSPM

- **27 patients** with angiographically verified CAD
 - **no** previous myocardial infarction
 - **no** pathological ECG at rest
 - **no** ventricular wall motion disturbances
- **23 controls** with no history of CAD
 - **normal** ECG at rest
 - **normal** ergometry
 - **normal** echocardiography

CAD-Trial: Zurich University Hospital

- **23 patients** underwent PET at rest and under adenosine induced hyperemia

Responsible cardiologists: Prof. Lusher , Prof. Kaufmann, Dr. Namdar

Results:

The severity of MCG abnormalities were significantly correlative ($P < 0.02$) with the global flow reserve and highly significantly correlative ($P < 0.01$) with the hyperemic flow. No correlation found with the rest flow.

CAD-Trial: University Medical Center St. Radboud (Nijmegen)

MCG mapping in comparison with 40-leads BSPM

Responsible cardiologists: Prof F.W.Verheugt, Dr. R. Hoekema

Results:

MCG:

Accuracy : 88 %

BSPM:

Accuracy : 76 %

MCG +BSPM:

Accuracy: 90 %

CAD-Trial: China

- About 1000 patients with angiographically verified 1-3 vessel CAD
 - no previous myocardial infarction
 - no pathological ECG at rest
- About 300 controls with no history of CAD
 - normal ECG at rest
 - normal ergometry
 - normal echocardiography

CAD-Trial: China

Responsible cardiologists:

Prof. Runlin Gao (Fuwai Hospital , Chinese Academy of Medical Sciences , Beijing);

Prof. Li Yingmei (Rui Jin Hospital , Shanghai Second Medical University , Shanghai)

Results:

Sensitivity : about 80 %

Specificity: about 75 %

CAD-Trial: Yonsei University College of Medicine (Seul, South Korea)

- 33 patients with angiographically verified 1-3 vessel CAD

CAD-Trial: Yonsei University College of Medicin (Seul, South Korea)

Responsible cardiologists:

Prof. Namsik Chung , Dr. Young-Sup Byun

Results:

Sensitivity : 93 %

Specificity: 67 %

CAD-Trial: Animal Studies(Erasmus University Rotterdam)

Acute ischemia

Animal:

11 Pentobarbital anesthetized 25 kg pigs under artificial respiration

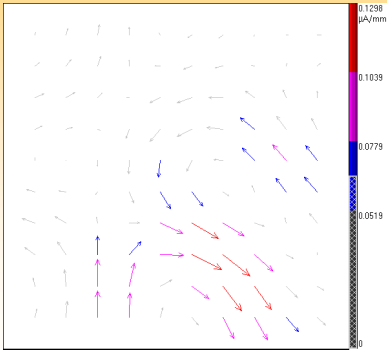


Measurements:

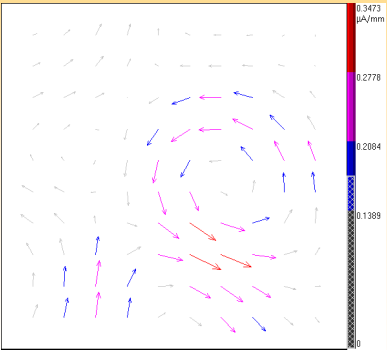
ECG and MCG,
arterial blood gases, arterial blood pressure, regional wall
function using sonomicrometry

CAD-Trial: Animal Studies (Erasmus University Rotterdam)

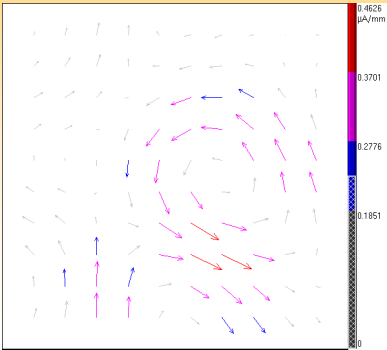
Initial state



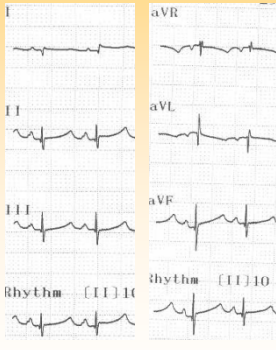
Beginning of ST-T interval



Middle of ST-T interval

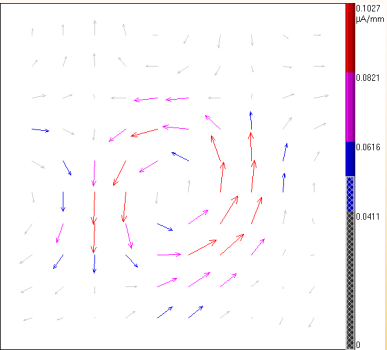


End of ST-T interval

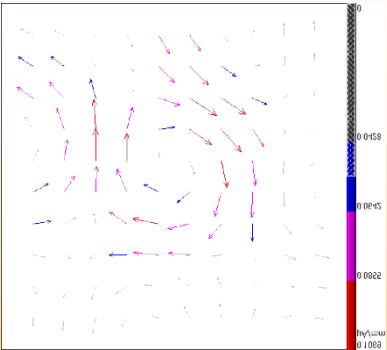


6-lead ECG

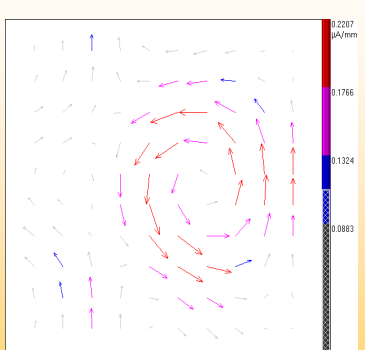
90 min. after partial LAD occlusion (appr.60%)



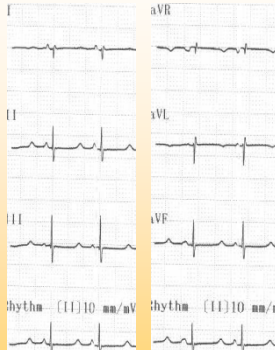
Beginning of ST-T interval



Middle of ST-T interval



End of ST-T interval



6-lead ECG

CAD-Trial: Conclusions

More than 1800 verified patients and healthy volunteers examined, including „difficult-to-diagnose“ patients

Overall sensitivity around 80%

Overall specificity around 75 %

Positive results in 14 Ukraine, Western European and Asian university clinics achieved

Positive results of animal study achieved

Публикации

Опубликовано более 100 научных работ в том числе в ведущих международных журналах, таких как Circulation, European Heart Journal, Clinical Cardiology, PACE и др.

Наши результаты повторены в нескольких ведущих клиниках в том числе знаменитых американских госпиталях Цедар Синаи, Джон Хопкинс и Мейо. Имеются многочисленные ссылки на наши работы в оригинальных статьях, обзорах, международных руководствах по биомагнетизму.

Ongoing 1-st class studies

ClinicalTrials.gov archive

A service of the U.S. National Institutes of Health

Linking patients to medical research

Developed by the National Library of Medicine

[← Archive home](#)

[← History of this study](#)

[↑ Current version of this study](#)

View of NCT00572949 on 2007_12_12

ClinicalTrials Identifier: NCT00572949

Updated: 2007_12_12

Descriptive Information

Brief title Magnetocardiography (MCG) in the Diagnosis of Chest Pain Syndrome

Official title Magnetocardiography (MCG) in the Diagnosis of Chest Pain Syndrome

Brief summary

The purpose of this research study is to evaluate a better way of diagnosing heart artery disease, heart attack and damage to the heart muscle early on. Currently, it often takes several hours after admission before lab tests will show that there has been any damage to the heart muscle. Although the standard electrocardiogram is quick and non-painful it may miss many cases of significant coronary heart disease. We are proposing that a new entirely non-contact tool, the Magnetocardiograph (MCG), with high accuracy is able to predict the presence of significant coronary heart disease early on before other studies become positive. We hope by this that we can develop an algorithm for better triage and management of patients with chest pain.

This research study is designed to test the effectiveness of the investigational use of the Magnetocardiograph (MCG) that has been approved by the U.S Food and Drug Administration (FDA). While the MCG used in the study is FDA-approved as a tool for the non-contact measurement and display of the magnetic fields of the heart generated by the electrical currents, it is not yet approved for the specific diagnosis of heart artery disease (ischemia).

Ongoing 1-st class studies

Cedars-Sinai Medical Center Non-invasive Cardiac Laboratory will be the first center in the US evaluating the CardioMag Imaging MCG in a clinical environment for the detection of ischemia in an acute coronary syndrome patient population. Patients will be enrolled in a similar protocol at Johns Hopkins Medical Center, Baltimore, Mayo clinic, Rochester, and at Klinikum Hoyerswerda, Germany. The early detection of ischemia (before Troponins become positive) with high negative and positive predictive values may prove cost effective and decrease risk by improving prompt treatment and triage to higher or lower grade monitoring at time of hospitalization.

Study type	Observational
Condition	Chest Pain
Reference	Citation: 1) Cohen D, Edelsack EA, Zimmerman JE. Magnetocardiograms taken inside a shielded room with a superconducting point-contact magnetometer. Appl. Phys. Lett. 1970, 16, 278-280. MEDLINE:
Reference	Citation: 2) Nakaya Y, Sumi M, Saito K, Fujino K, Murakami M, Mori H. Analysis of current source of the heart using isomagnetic and vector arrow maps. Jpn. Heart J. 1984, 25, 701-711. MEDLINE:
Reference	Citation: 3) Stroink G, MacAuley C, Montague TJ, Horacek BM. Normal and abnormal components in magnetocardiographic maps of a subject with myocardial infarction. Med. Biol. Eng. Comp. 1985, 23, 61-62. MEDLINE:
Reference	Citation: 4) Brazdeikis A, Taylor AA, Mahmarian JJ, Xue Y, Chu CW. Comparison of magnetocardiograms acquired in unshielded clinical environment at rest, during and after exercise and in conjunction with myocardial perfusion imaging. Biomag 2002, 530-532. MEDLINE:
Reference	Citation: 5) Chaikovsky I, Primin M, Nedayvoda I, Vassilyev V, Sosnitsky V, Steinberg F. Computerized classification of patients with coronary artery disease but normal or unspecifically changed ECG and healthy volunteers. Biomag 2002, 534-536. MEDLINE:

MCG in CAD diagnosis: certifications status

Full certification and State prize
in the field of science and technique - Ukraine

Full certification – China

Partial certification - Germany

MCG in CAD diagnosis: reimbursement status

Health care system consulting organisation in Germany defined cost of MCG examination which is similar to scintigraphy :

293 euro

Private insurances pay in special request in Germany

What we need?

Program-maximum –

to initiate European multicentral study
through European institutions

Realistic program –

to find scientific and/or commercial partner in Poland

Thank you for your attention !



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FUNDUSZ SPOŁECZNY



Projekt współfinansowany przez Unię Europejską w ramach Europejskiego Funduszu Społecznego