PATHWAY & TSA-II: Applications and the Market
PATHWAY
Pain & Sensory Evaluation System
A computerized thermal stimulator designed for advanced Neurological & Pain research
PATHWAY

Hardware capabilities:

✓ Accurate temperature control loop (200 Hz)
✓ Self test and built-in test (BIT)
✓ In & Out event synchronization
✓ Computerized Visual Analog Scale (COVAS)
✓ Manual trigger
✓ Response Unit
✓ Emergency safety shut down
✓ Upgradeable configuration
PATHWAY

Software Capabilities:

- 32 Bit .Net Microsoft based technology
- Top level design for safe and friendly usage
- License protected
- Authorization levels
- Patient, program and test results management
- Database management
- Demo and online modes
PATHWAY Advantages

- Large thermodes, enabling activation of greater number of nociceptors, thus evoking a stronger brain response
- Stimulation protocol - Stimulation duration can be determined for selectively activating the A-δ and C fibers (responsible for pain sensation)
- Superior safety mechanisms
- Quick set-up and test initiation
- Easy hardware & software upgrading
- A mobile system
- Temperature measurement on the thermode’s active area
PATHWAY model CHEPS

Unique Features:

- Heating rate of up to 70°C/sec.
- 32°C to 55°C in 250 ms
- Cooling rate of down to 40°C/sec.
- For Cold sensation EP - cooling rate of down to 15°C/Sec. from adaptation to 25°C
- 27 mm diameter Thermode - stronger cerebral response
PATHWAY model CHEPS

Applications:

- **Objective** measurement of pain perception
- Pain Evoked Potentials: Selective A-δ and C fibers stimulation
- Heat Pain & Warm Sensation
- Cold Sensation Evoked Potentials
- Temporal Summation (Windup)
- Sensory function investigation
- Flexible test algorithms
PATHWAY model CHEPS

Accessories:

✓ BrainPath 8 or 16 channel EEG system
✓ Computerized Visual Analog Scale (CoVAS)
✓ Software development kit (SDK)
✓ fMRI Thermode
✓ fMRI Filter
PATHWAY model ATS

Unique features:

✓ Thermal stimulation of up to 54°C
✓ Extreme cold pain stimulation of down to -10°C
✓ Thermodes of several sizes (mm): 30x30, 16x16

Thermode 30x30mm  Thermode 16x16mm
PATHWAY model ATS

Applications:

- Rapid and reliable measurement of Thermal Sensation & Pain thresholds
- Cold Pain studies
- Variety of test protocols
- Flexible text algorithms
PATHWAY model ATS

Accessories:

✓ Patient response unit
✓ 16x16mm thermode
✓ Computerized Visual Analog Scale (CoVAS)
✓ fMRI thermodes
✓ fMRI filter
✓ Software development kit (SDK)
Both CHEPS and ATS models can be configured for use in magnetic environment

When using fMRI PATHWAY (ATS / CHEPS) researchers can administer noxious and innocuous stimuli and obtain the brain’s response

In PATHWAY model CHEPS: Stimuli can be synchronized with an fMRI compatible EEG system for multi-modality study of selective nerve fibers activation and cortical response
fMRI PATHWAY

Accessories:

- 10m long CHEPS Thermode
- 10m long ATS Thermode
- fMRI filter
- fMRI CoVAS
- 10m long panic button
- 10m long Patient Response Unit
Thermal & Vibratory Quantitative Testing (QST) for evaluating nerve impairment in small and large sensory fibers
Unique features:

- Wide stimulation range: 0°C to 50°C
- Built-in Normative data with automatic conclusions
- Comprehensive report generator
- Thermodes of several sizes (mm): 30x30, 16x16, 5x5
TSA-II

Applications:

✓ Investigation of small & large fiber neuropathies
✓ Identification of early progression of neurological deficit
✓ Assists in treatment selection and follow-up
✓ Early detection of diabetic neuropathy of small nerve fibers
✓ Rapid and reliable measurement of thermal sensation thresholds and pain thresholds
✓ Efficient tool for detecting CRPS
Accessories:

- VSA (Vibratory Sensory Analyzer)
- Hand held vibrator
- Computerized Visual Analog Scale (CoVAS)
- Various thermod sizes (30x30 / 16x16 / 5x5 mm)
- Digital Calibration Kit
Market Segmentation

- Clinics
- Pain
- Neurology
- Diabetes

- Pain research
- fMRI

- Pharmaceutical Companies
- Clinical Trials
The PAIN Market

Statistics of pain in the USA

- 75 million experiencing serious pain
- 50 million are diagnosed with chronic pain
- 25 million suffer acute pain due to injury or surgery
- 45% of all Americans seek care for constant pain at some point in their lives

Attitudes Towards Clinicians:

- 25% Think that doctors don’t know to control their pain
- 20% feel that doctor don’t consider pain as problem
- 15% report never being asked about their pain

The PAIN Market

• In the past, Pain Clinics were a part of either the Anesthesiology or the Neurology departments.

• Today, Pain is considered an independent discipline, and as such the number of Pain Clinics is rapidly growing.

• Patients suffering from Chronic / Acute Pain are more aware of these Pain clinics, and turn to them seeking for solutions.

• Misdiagnosis and under-treatment of Pain conditions continue to prove harmful, reinforcing the need for better Pain management.

• Billions of dollars are invested annually in finding solutions to Pain conditions and their validation.
The PAIN Market

Increasing Number of Pain clinics in the U.S

- "Organization of Pain Services for Chronic and Cancer pain"
  Bonica JJ, J Pharm Care Pain Symp Control
The PAIN Market

Newsweek Magazine dedicated a special issue (May 2003) to Pain treatment suggesting that pain has become a disease on its own and no longer should be viewed as a symptom of other medical conditions.
The fMRI Market

• The PATHWAY is used as a thermal stimulator for advanced pain research in fMRI

• fMRI is a rapidly growing market. With each year, more and more systems are sold for use in fMRI application.

• fMRI has become a fundamental tool in the western world, and the same trend is seen in the Far East, where fMRI studies achieve meaningful results.

• Worldwide researchers in the functional MRI (fMRI) field are using Medoc’s fMRI compatible devices for investigating the nervous system and cortical functioning

• fMRI can be used as a means of validation for Pain conditions treatments

• The increasing number of scientific fMRI related articles in which the methodology includes Medoc’s devices - reinforce the company’s important role in pain management

• Medoc sold about 150 systems worldwide for fMRI use only
fMRI Users

Selected fMRI users list:

- NIH (National Institute of Health)
- Massachusetts General Hospital
- University of Toronto
- University of Munich
- National Yang-Ming University, Taipei
The Diabetic Neuropathy Market

A few statistics from the U.S.A.

• 20.8 million, 7% of the population, have diabetes
• 14.6 million are diagnosed while 6.2 million are not
• 41 million are pre-diabetic
• In 2005, 1.5 million new cases of diabetes were diagnosed in people aged 20 years or older
• Age 20 - 60: 9.6% of all people in this age group have diabetes (20.6 million)
• Age 60 or older: 20.9% of all people in this age group have diabetes (10.3 million)
The Diabetic Neuropathy Market

• The number of patients suffering from diabetes is growing every year. While in the past diabetes was considered a western world illness, today it had spread to the Far East and Asia too.

• Excessive research is made in the field of Diabetic Neuropathy in order to find new methods for early diagnostics and treatment.

• Research proves that thermal & vibratory stimuli could detect nerve impairment in early stages of Diabetic Neuropathy, sometimes 3 years before conventional methods such as EMG.

• This early detection is possible thanks to the evaluation of the small (A-δ and C) & Large (A-β) sensory fibers, which are the first ones to be damaged in case of DN.
The Diabetic Neuropathy Market

• Pharmaceutical companies (Eli Lilly, Takeda, Dainippon, etc.) invest Billions of dollars, seeking for a compound / drug for diabetic neuropathy (which doesn’t exist today)

• Medoc products, which are considered the Gold –Standard in QST, are used as a Primary or Secondary Efficacy Parameters in Clinical Trials, since our products are validated for such trials

• The key opinion leaders in the field of diabetic Neuropathy are using Medoc’s systems (Vinik, Bril, Tesfaye, Valensi, Ziegler, Kempler, Arezzo, Malik, Etc.)
The Pharmaceutical Trials Market

• Medoc products are used by world-known pharmaceutical companies conducting clinical trials – such as Pfizer, GlaxoSmithKline, Merck, etc.

• Prospective compounds for Neurological, diabetes, analgesic and Pain conditions can be validated by examining the nervous functionality using Medoc’s systems

• This validation is enabled due to the abilities to:
  - Find thermal thresholds of sensations and pain
  - Selectively activate small and large sensory nerve fibers which are responsible for mediating pain inputs
  - Form neurological phenomena as Temporal Summation for detection of nervous abnormalities
  - Objective response to Pain by recording Brain Waves using EEG
The Pharmaceutical Trials Market

Clinical Trials benefits

- New “surrogate marker” for evaluation of new compounds efficacy
- Providing effectiveness data starting in Phase-I of Clinical Trials
- Helping in decision making between multiple compounds, especially in Clinical Trials Phase-IV
- Reducing statistical sample size
- Reducing time to market
- Saves money and other resources
Selected Pharmaceutical Companies

Medoc’s systems have also been selected for use in pre-clinical and multi-center pharmaceutical trials of companies such as:

✓ Pfizer

✓ GlaxoSmithKline

✓ Merck

✓ AstraZeneca

✓ Sigma Tau

✓ Dainippon

✓ Unilever