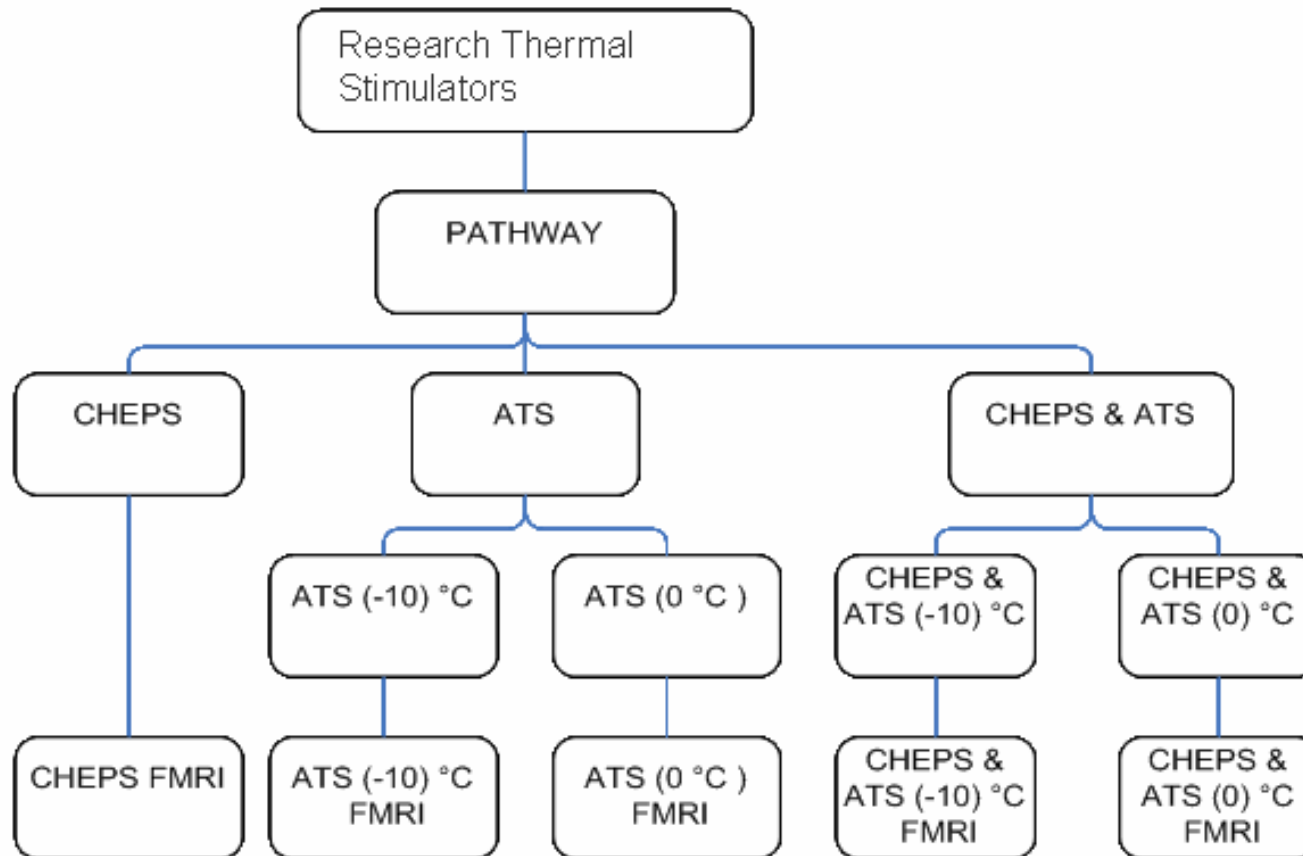


# **PATHWAY: Applications & the Market**

# 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- $\delta$  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- $\delta$  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 test algorithms

# PATHWAY model ATS

## Accessories:

- ✓ Patient response unit
- ✓ 16x16mm thermode
- ✓ Computerized Visual Analog Scale (CoVAS)
- ✓ fMRI thermodes
- ✓ fMRI filter
- ✓ Software development kit (SDK)



# fMRI PATHWAY

- ✓ 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



# 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

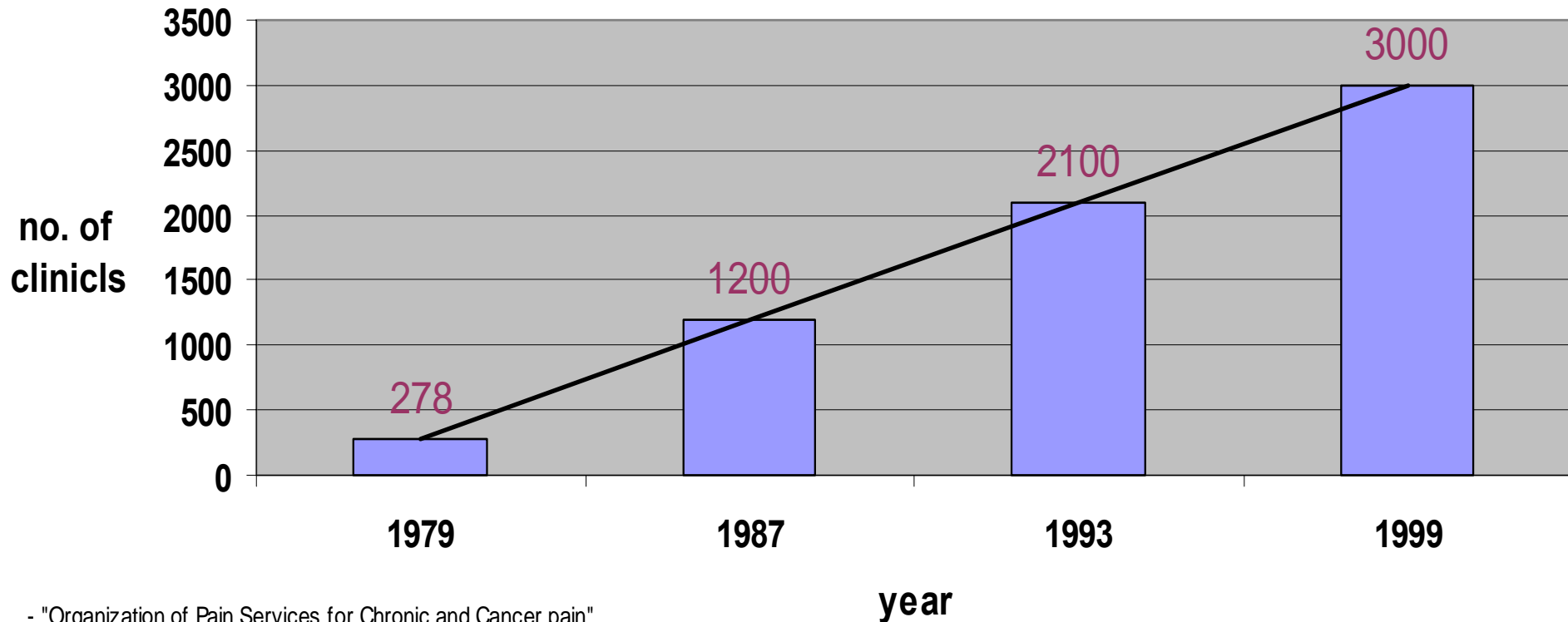
American J. Med, 105(1B):2S-7S, 1998

# 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

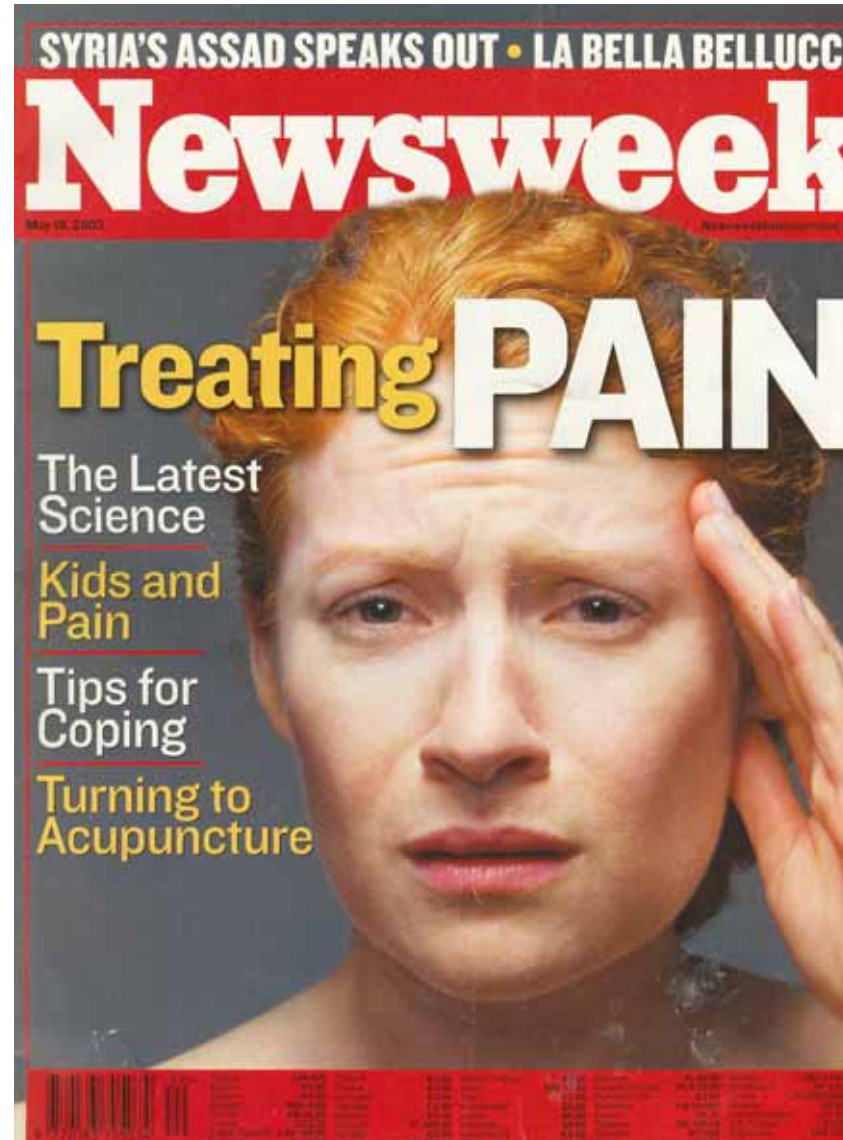


- "Organization of Pain Services for Chronic and Cancer pain"  
Bonica JJ, J Pharm Care Pain Symp Control



# The PAIN Market

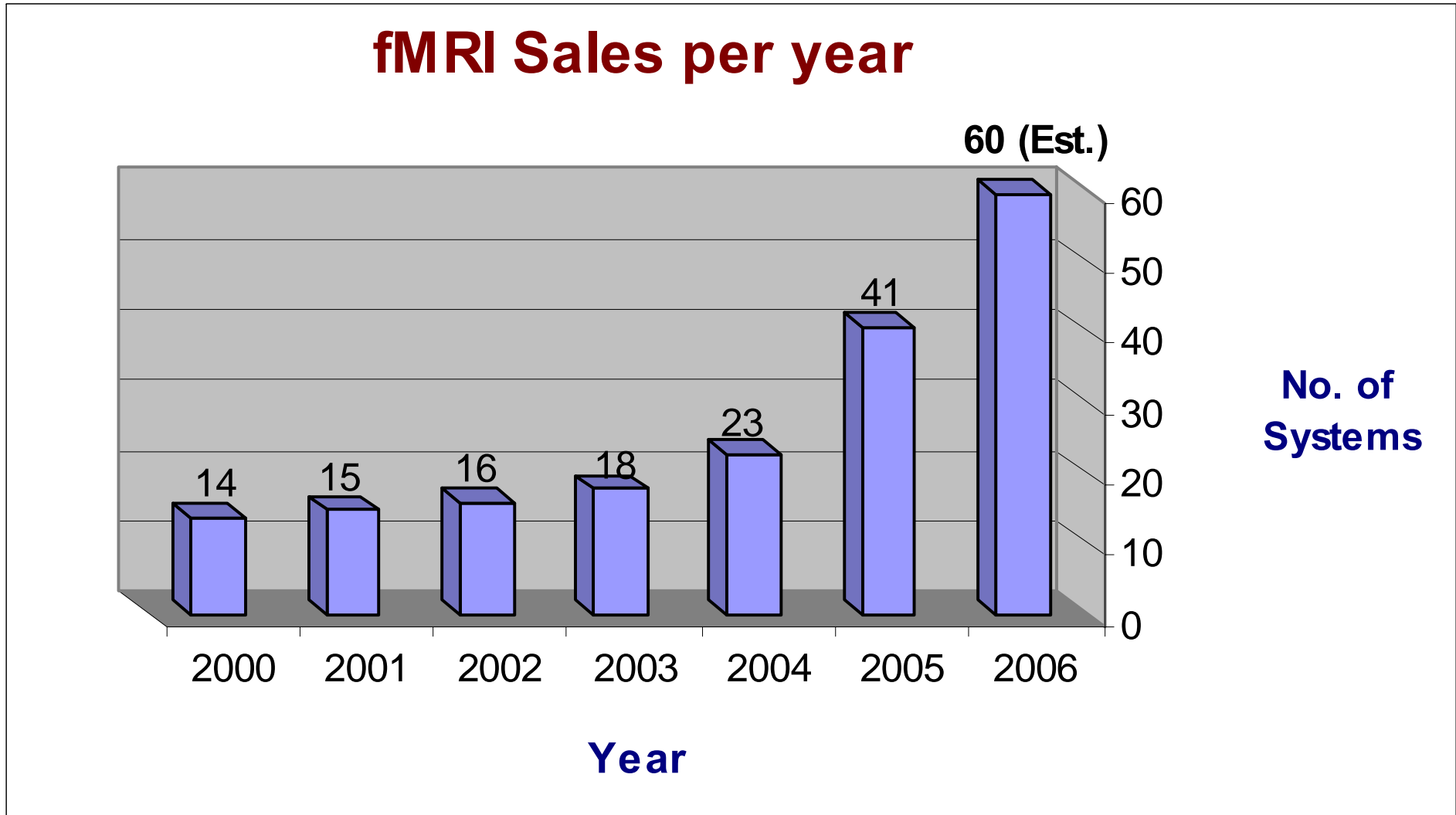
Newsweek Magazine dedicated a special issue (May 2003) to Pain treatment suggesting that pain has become a disease on its own and no longer should be viewed as a symptom of other medical conditions.



# 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

# The fMRI Market



# 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 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



# Thank You