

# Psychometric Test Batteries for Clinical Trials

## **BeriSoft Cooperation**

Frankfurt, Germany

[www.erts.de](http://www.erts.de)

**2/22/2003**

**E. Merck, Germany**

**Merz+Co., Germany**

**Novartis, Switzerland**

**Boehringer Ingelheim, Germany**

**Rhône-Poulenc Rorer, France**

**Sanofi-Synthelabo, France**

**Tropon, Germany**

**Abbott, Germany / USA**

**Aventis, Germany**

**ASTER, France**

**Parexel, Germany**

**Quintiles, Germany**

**FARMOVS, South Africa**

**L.A.B., Germany**

**VanTx, Switzerland**

## **Software license limited to study schedule**

- **PC-based run-time system approved by more than thousand installations**

## **Psychometric tests tailored to individual objectives**

- **Psychometric test battery tailored to drug profile, study focus, and protocol**
- **Sensitive and reliable test applications**

## **Training and implementation**

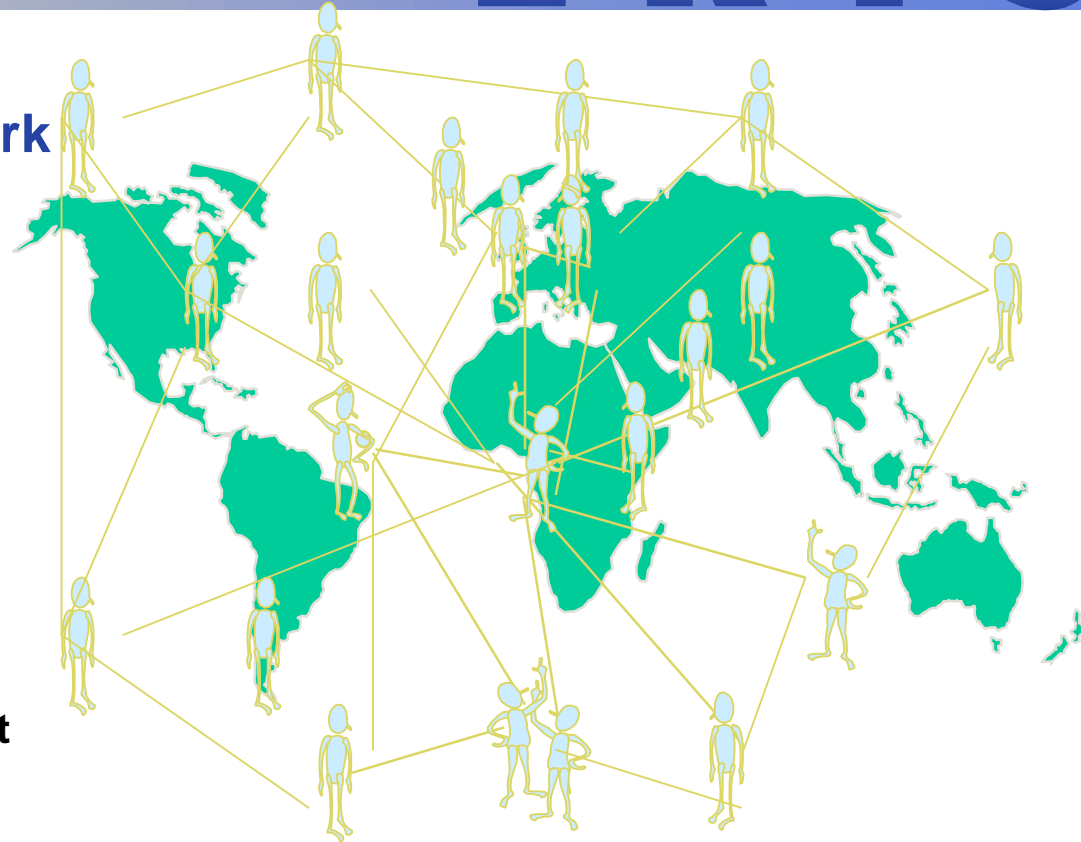
- **Easy-to-use session launcher for automated test executions**
- **On-site installation and training**

## **Data management and interpretation**

- **Data clearing**
- **Data analysis and reporting**
- **Expert review**

## Access to academic network

- Academic advisors from
  - Cognitive Research
  - Neuropsychology
  - Functional Brain Mapping
- Continuous transfer from general to applied research
- Co-development of new test applications



- *Our international installed base includes leading cognitive research labs*



## PC-based run-time system approved by more than thousand installations

- Real-mode operating system for millisecond real-time experiment control
- VGA graphics with dual-buffer image flipping
- External response keys connected via EXKEY at standard parallel port
- Soundblaster™ ISA support
- EEG/MRI compatible

• *Turn any PC or Laptop into a psychometric test station*

- **EXKEY (External Keyboard Logic)**
  - TTL-based interface for registration of external response keys
  - Millisecond accuracy
- **Response pads with accurate switches**
  - Super flat case for ergonomic position
  - Short switching travel
  - Low operating force

## Control of external TTL-based stimulation devices

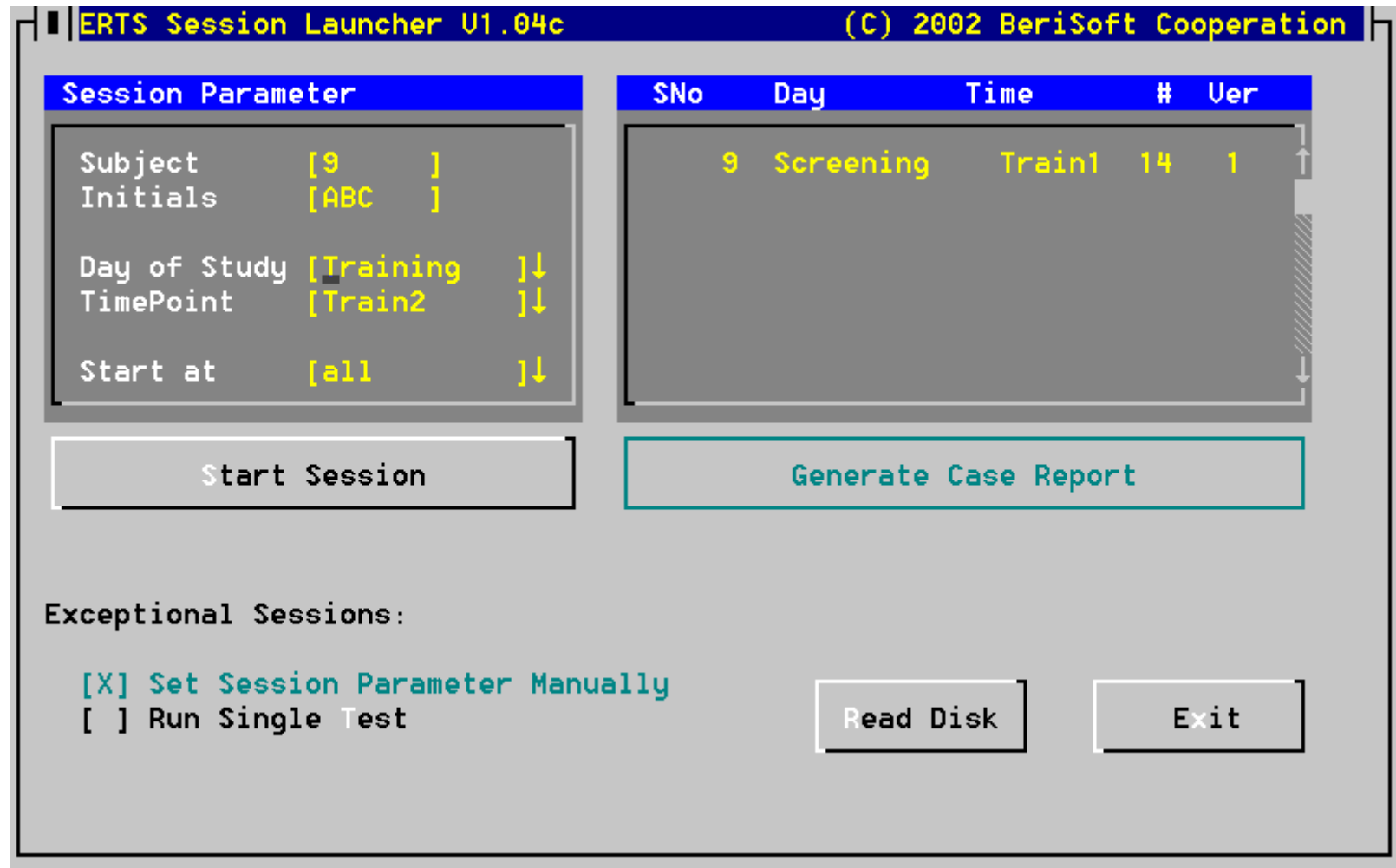
- Shutter
- Mixer
- Pain stimulation

## Integration of external TTL-devices

- Bio-signals
- MRI-signals
- Eye tracking
- Voicekey

## EEG, PET, MRI compatible

- Synchronization markers for stimulus- or response-locked averaging



The session launcher provides a simple way of coding and starting sessions

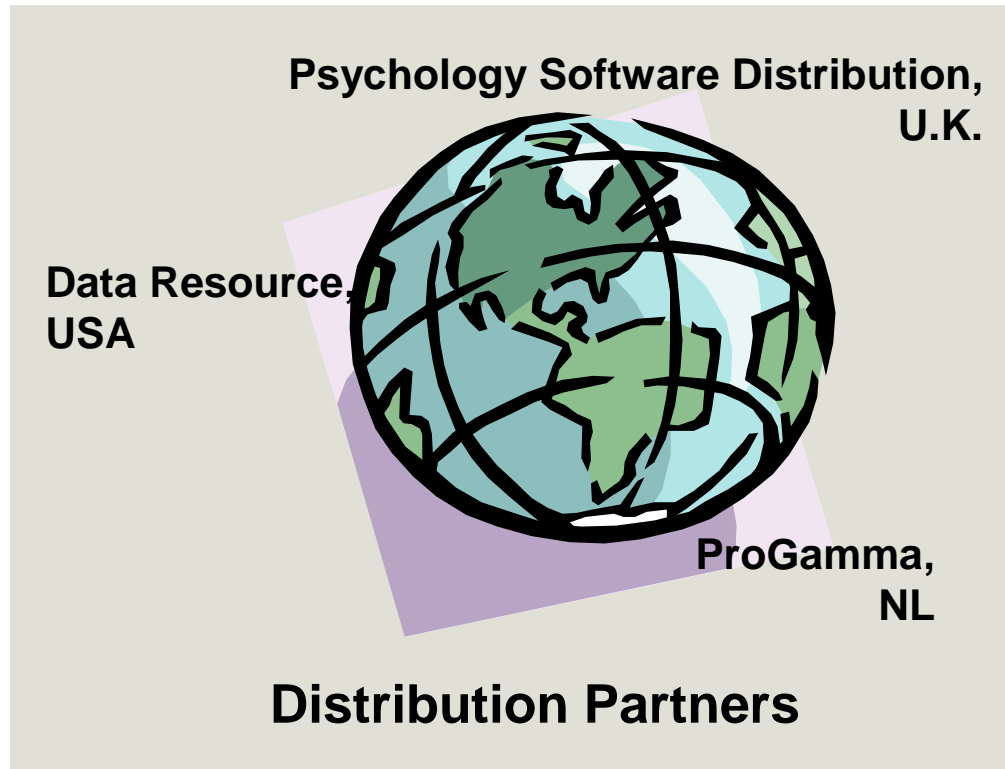
## Our run-time kernel has been successfully used for

- **Testing effects of micro-gravity in several MIR-missions**
- **Screening airline pilots**
- **Innovative cognitive research in world-leading labs like**
  - Max-Planck, Karolinska
- **Functional brain mapping studies (EEG, MEG, MRI)**
- **Testing psychometric effects in clinical trials**
- **Applied industrial research**
  - Daimler Chrysler, SAP, Unilever, DLR

Recommended by CIPS (Collegium Internationale Psychiatriae Sclalarum) as an innovative and validated test system

Rated excellent (4 stars from 4) in Psychology Software News November 94, York, UK

„Fastest commercial response device tested to date“ ELTS – validation report , 2002



Germany	213
Australia	2
Belgium	4
Canada	1
China	7
France	9
Greece	1
United Kingdom	44
Ireland	1
Italia	1
Japan	2
Luxembourg	1
New Zealand	2
Netherlands	16
Norway	4
Austria	4
Portugal	1
Scotland	1
Sweden	8
Swiss	9
South Africa	1
Spain	9
Taiwan	2
Hungarian	1
USA	27

**More than 1000 user world-wide**

## Raw data

- Complete trial-wise logging of tests

## Case reports

- ASCII report generator for
  - print-outs and
  - direct quality control

## Data clearing

- Aggregation of raw data into test-specific key figures
- Merging of sessions
- Conversion into export format

CSF generated on 25/06/2001, 23:39 Page 1-1

Study: ????????????????	Subject: 9999 ( JB)
Place: PLACE1	Day : 1
Time : 25.06.10 / 23:18	Hour : 1

TAPP started at 23:18, N=392 [tapps]

Tapping	NVal	Mean	Stdv
Tapps	392	151.1	34.2

DSST started at 23:20, N=81 [corr responses]

Response	N	Mean	Stdv
Correct	81	1293.5	425.6
False	4	2028.1	1004.7
Miss	0	0.0	0.0

SRT started at 23:23, Mean=291.3 [correct Rt in ms]

Response	N	Mean	Stdv	N%
Correct	39	291.3	190.0	97.5
Miss	1	0.0	0.0	2.5

FIXMEM started at 23:27, MD1=374.5 MD4=468.7 [corr Rt in ms]

Response	1		4		Σ	
	N	Median	N	Median	N	Median
Correct	47	374.5	44	468.7	91	409.3
Wrong	1	352.9	4	462.2	5	408.7
Miss	0	0.0	0	0.0	0	0.0

WLREC (#13) started at 23:32, N=24 (% 60) [correct words]

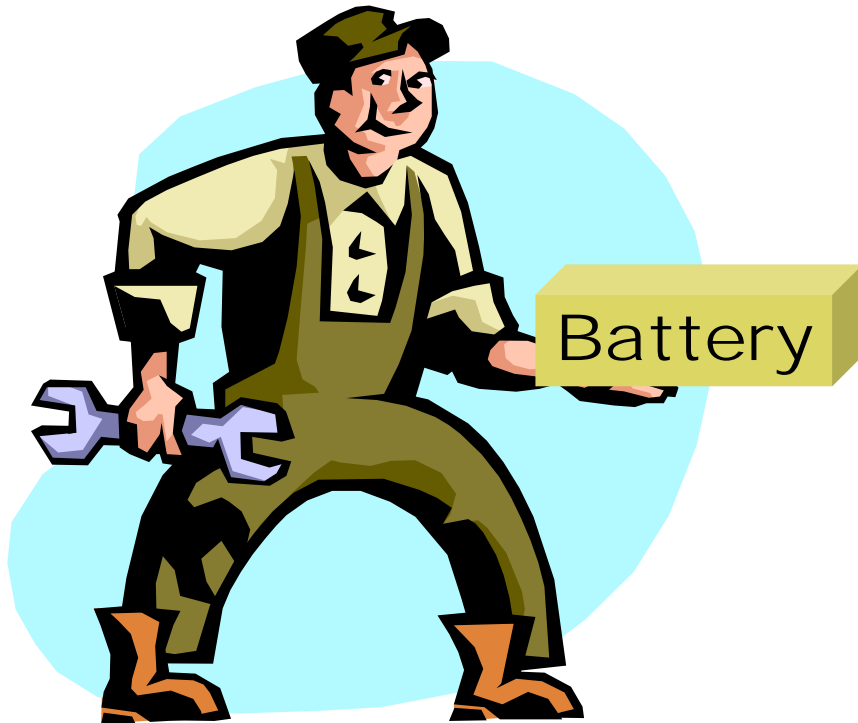
Categ	Hit	FA	Miss	Reject	Σ
NVal	11	7	9	13	40
Medi	762.8	803.4	776.9	708.1	777.2



*beyond paper & pencil testing*

## Take advantage of new technology

- Adaptive testing for estimating performance thresholds
- Drop-out mode
- Tachistoscopic displays for visual scanning tasks and backward masking
- Trial and stimulus randomizations for repeated testing
- Analog tracking tasks
- EEG-Synchronization
- Millisecond resolution
- Electronic data logging



## Select from

- a large set of state-of-the-art test application

## and customize depending on

- Objective of study
- Predicted effects
- Available test time
- Target population

## to meet your objective

- Select tests that measure cognitive concepts of interest
- Increasing test durations for selected concepts
- Design vertical (focused) or horizontal (wide)

• *Adjusted to the focus of your clinical investigation*

## Processing speed

- Simple reaction time
- Choice Reaction Time
- Executive operations

## Adaptive performance thresholds

- Visual masking
- Inhibition threshold
- Memory span

## Number of correct responses

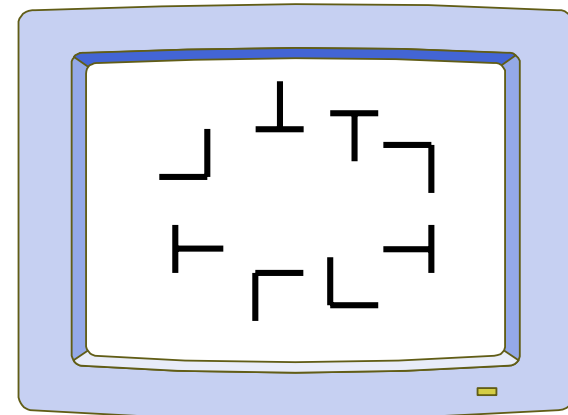
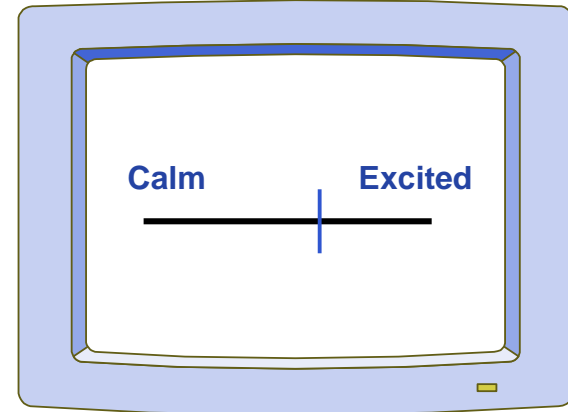
- Continuous performance
- Word list

## Signal detection

- Visual Search
- Vigilance test

## Scales

- VAS, Multiple Choice, Check List



## Phonological Loop

- Memory Search
- Digit Span

## Working Memory

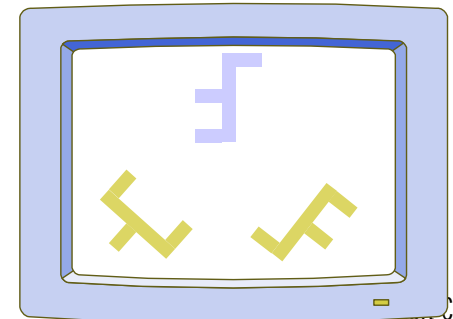
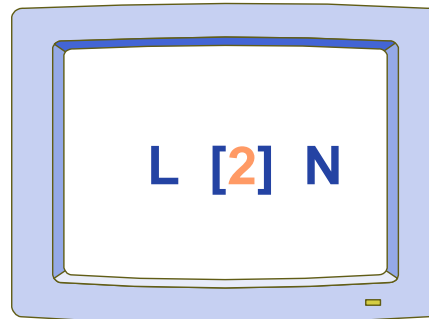
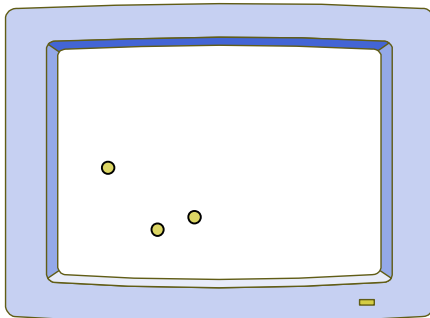
- Delayed Matching to Sample
- 2-Back task
- Dot memory task
- Sequence Reproduction
- Implicit Sequence Learning

## Long Term Memory

- Word List

## Executive working memory

- Learning
  - Implicit sequence learning
  - Card sorting
- Active retrieval from long term memory
  - Alphabetic arithmetic task
- Symbolic operations
  - Mathematical Processing
  - Grammatical Reasoning
- Spatial operations
  - Mental Rotation



## Selective

- Visual Search
- Flanker tasks
- Stroop
- Backward Masking
- Endo- exogenous visual orientation

## Attentional Shift

- Task Switching
- Cross-Modality Effect
- Between global/local
- Negative Priming

## Divided

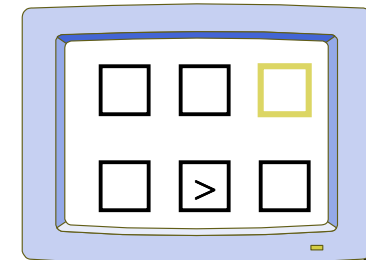
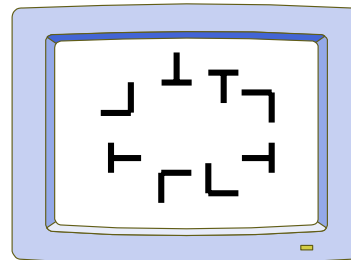
- VS for multiple targets
- Dual tasks

## Sustained (vigilance)

- Clock Test
- Continuous Attention Task
- Continuous Digit Test
- Simple Reaction

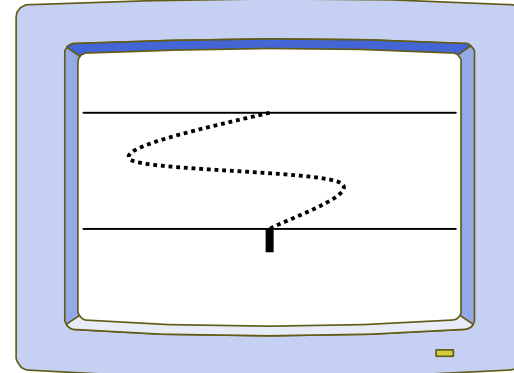
## Continuous Performance

- Digit Symbol Substitution
- “Find d”- Test
- Serial Addition Task



## Motoric coordination

- Pursuit Tracking
- Compensatory Tracking
- Unstable Tracking

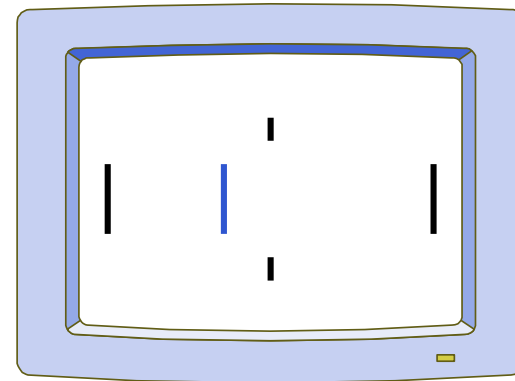


## Motoric timing

- Interval Timing
- Tapping

## Response selection

- Simple vs. choice reaction
- Choice Reaction
- S&R compatibility



## Inhibition

- Stop & Go tasks

## Plan

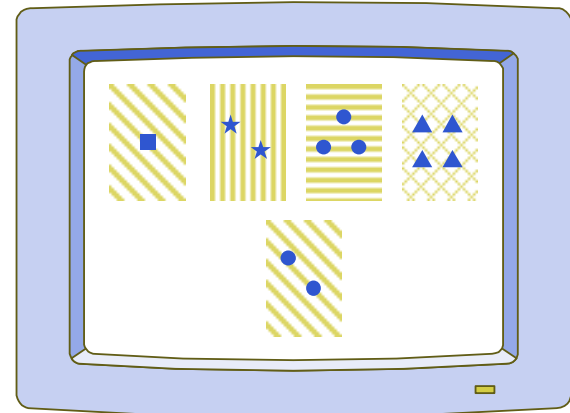
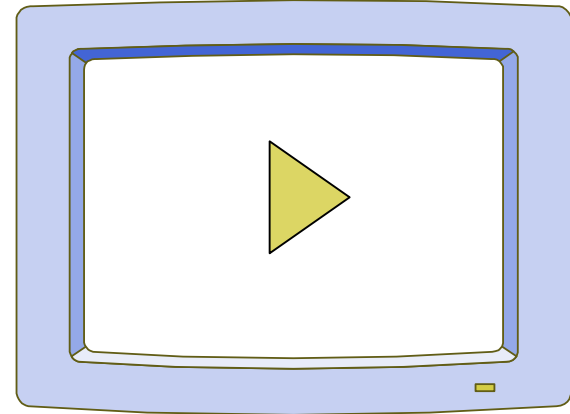
- Generation of random sequence
- Rhythm reproduction

## Pace

- Digit search

## Learning

- Card sorting



## Concepts we target ...

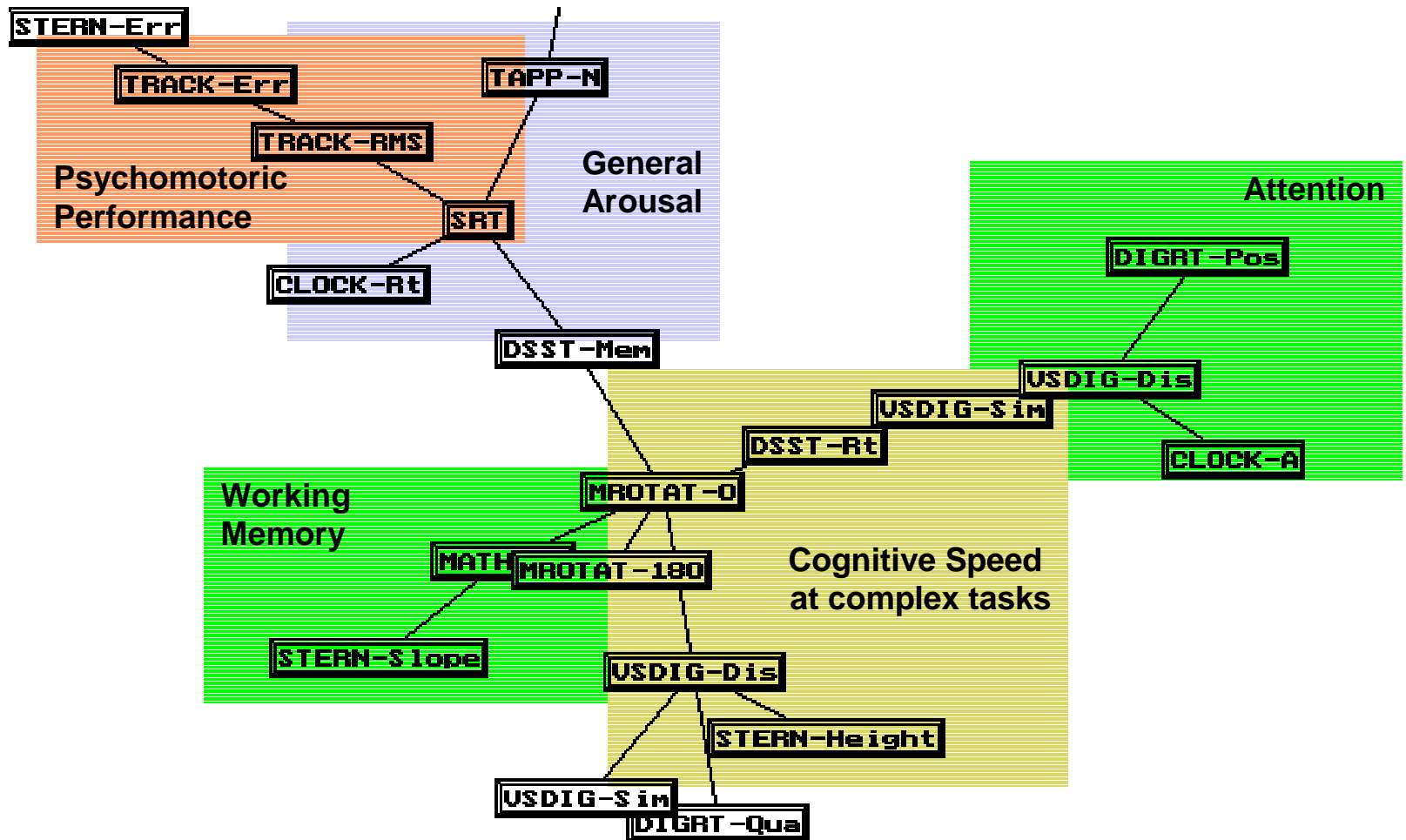
- **Sensory and perceptual processes**
- **Motor processes**
- **Attention (selective and sustained)**
- **Memory (working, spatial, symbolic, long term)**
- **Executive functions (learn, plan, inhibit)**

## ... factors we find

- **Cognitive speed at complex tasks**
- **Psychomotoric performance**
- **Sensoric processes**
- **Speed at simple tasks**
- **Vigilance and general arousal**
- **Working memory**

# We measure more than just speed

# ERTS



## Validation of the software package

- Plant, R.R. (2002). Experimental Timing Standards Lab Validation Report ETSL/ ERTS3.33/RP/ 20020729: „Experimental Run-Time System (ERTS) version 3.33 by Berisoft Cooperation“. LTSN Psychology, University of York, YO10 5DD, UK
- Beringer, J. (1992). Timing accuracy of mouse response registration on the IBM microcomputer family. Behavior Research Methods, Instruments, & Computers, 24 (3), 486-490.
- Beringer, J. (1993). Entwurf einer Anwendersprache zur Steuerung psychologischer Reaktionszeitexperimente. European University Studies, Series XLI, Informatic, Peter Lang: Frankfurt, Paris, New York.
- Beringer, J. (1990). Validierung von ERTS. In Empfehlenswerte apparative Methoden zur Arzneimittelentwicklung innovative Verfahren, Collegium Internationale Psychiatriae Salarum (CIPS), internal report.

## General description

- Beringer, J. (1992). Computerunterstützte kognitive Testverfahren. In J. Oldigs-Kerber und J.P. Leonard (Hrsg.), Psychopharmakologie, Experimentelle und klinische Aspekte, 134-149, Gustav Fischer Verlag: Jena, Stuttgart.
- Beringer, J. (1994). CiP94 Abstracts: ERTS-IPL: Tachistoscopic color image displays and accurate response registration on IBM PCs. Psychology Software News, 5(2), 37-38, CTI Centre for Psychology, University of York.

## Independent third party reviews

- Dutta, A. (1995). Experimental RunTime System: Software for Developing and Running Reaction Time Experiments on IBM-compatible PCs. Behavior Research Methods, Instruments, & Computers, 27 (4), 516-519.
- Iwanek, R. (1994). Review of the Experimental RunTime System. Psychology Software News, 5(2), 65-67, CTI Centre for Psychology, University of York.

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