



PROTOCOL
RECORDING OF STANDARDIZED ALL-NIGHT SLEEP RECORDS
(VERSION 2.0, July 1998)

SUBJECTS AND PATIENTS

For patients, the inclusion criteria are based on the ICD-10. They must have been free of psychopharmacotherapeutic drugs for at least 5 times the half-life of the medication. Patients with on-going non-psychopharmacotherapeutic medication (which may have psychotropic effects) must have been in a steady state for at least 2 months prior to the investigation (i.e. no changes in medication and/or dosage within these 2 months and for the duration of the investigation). All medications must be well- documented.

The exclusion criteria for patients and subjects are

- subjects with a history of drug abuse or habituation, including alcohol
- subjects requiring psychoactive medication and/or other drugs that might interfere with the study assessments (e.g. beta blockers).
- subjects who are unable or unwilling to comply with the protocol.
- subjects who work at night.

Additional exclusion criteria for normal healthy subjects are

- subjects with any significant medical disorder interfering with the aim of the study
- subjects with a MMSE* score < 25
- subjects with a PSQI* global score > 5
- subjects with a usual bedtime (see: PSQI-Item 1) before 22.00 or after 00.00
- subjects with a SAS* raw score \geq 33
- subjects with a SDS* raw score \geq 35

* For details see: APPENDIX

If in the course of the initial screening some clearly pathological values are observed, this finding will be regarded as an exclusion criterion. Single laboratory values outside the normal range are generally not regarded as an exclusion criterion provided that:

- a) they are not accompanied by clinical symptoms
- b) the context of related laboratory values does not indicate a pathological process
- c) the investigator regards these laboratory values as clinically irrelevant and documents that in written form on the Case Report Form.

Subjects will be informed that during the days of the study they must not consume more than their habitual rate of coffee, alcohol and cigarettes. If the subjects predicts that he will exceed any of these (e.g. planned party), or if he predicts unusual night-time behaviour (e.g. dance ball), this will be another exclusion criterion.

If subjects fulfil the inclusion criteria and do not demonstrate any of the exclusion criteria, they will be accepted for the examination.

ENTRANCE EXAMINATION

The entrance examination will be carried out not more than 4 weeks before starting data acquisition. Subjects will be informed about the aim of the study. For all patients: If they agree to participate in the study by written consent, the doctor who transferred them will be informed.

- **Physical examination**

- **Classification according to ICD-10**

For patients this includes:

Generalised Anxiety Disorder (F51.0, F41.1)

Mood Disorder (F51.0, F3)

Apnoea (G47.3)

Periodic Leg Movements (G25.8)

Parkinson's Disease (G20)

- **Documentation of the anamnesis, psychopathological and somatic findings and medication (AMDP 1-5*)**

- **Mini-Mental State Examination (MMSE*)**

- **Self-rated scales**

- Clinical evaluation of sleep quality (Pittsburgh Sleep Quality Index, PSQI, *Buysse et al.*)

- Quality of Life questionnaire (*Mezzich and Cohen*)*

- Generalised Self-Efficacy Scale (*Schwarzer*)*

- Self-rated Anxiety Scale (SAS*, *Zung*)

- Self-rated Depression Scale (SDS*, *Zung*)

- Personal Inventory (NEO-PI, NEO-FFI* *Costa & McCrae*)

* For details see: APPENDIX

BLOOD TEST

Routine laboratory tests: haemoglobin, haematocrit, erythrocyte count, leukocyte count, platelet count, ALT, AST, gamma-GT, bilirubin, alkaline phosphatase, creatinine, free T3.

WRIST ACTIGRAPHY

Actigraphy starts on day 1 at 12:00 and lasts until day 15, 12:00 (see time schedule). Actigraphy is obligatory in controls and strongly recommended in patients (30 s time resolution, threshold mode, non-dominant hand, documentation of times when actigraphs was taken off for brief periods).

SLEEP-LOG

The self-rating questionnaire for sleep and awakening quality (SSA^{*}, *Saletu 1987*) is completed every morning (after breakfast, approximately one hour after awakening) one week before to one week after the first polysomnographic night (see time schedule).

* For details see: APPENDIX

EVENING PSYCHOMETRIC TESTS

The psychometric tests in the evening start 2 hours before the individual bedtime (item 1 of PSQI) and take approximately 1 hour.

- ASES^{*}: 100 mm visual analogue scales for mood, drive, affectivity and drowsiness
- Bf-S^{*} (or Bf-S' randomised): Befindlichkeitsskala (*von Zerssen*) well-being scale
- Day Questionnaire (DQ^{*})
- AD-Test^{*}: Alphabetic cross-out test for attention, concentration
- Fine Motor Activity Test^{*}: psychomotor activity
- Digit Span Test^{*}: numerical memory
- Reaction Time Test^{*}
- Vigilance Test^{*} (simultaneous EEG recording is recommended)

^{*} For details see: APPENDIX

NIGHT PROTOCOL

- Electrode impedance check (evening, morning)
- Calibration
- Event log (e.g. toilet, sensor readjustment)
- Heart rate (evening, morning)
- Systolic and diastolic blood pressure (evening, morning)
- Start time and end of polysomnographic recording

POLYGRAPHIC RECORDINGS

All-night polygraphic recordings start at the usual bedtime (item 1 of the PSQI). Subjects have to stay in bed until the time they usually get up (item 3 of the PSQI). The subjects will not be awakened before 8 hours after "lights out".

For calibration, 60 s of a sine wave signal must be recorded (10Hz, 100 μ V recommended). In exceptional cases, when recording of a sine wave signal is impossible, calibration can be done using a square wave signal.

Recording channels (obligatory)

- 1: Fp1- M2
- 2: C3 - M2
- 3: O1 - M2
- 4: Fp2- M1
- 5: C4 - M1
- 6: O2 - M1
- 7: M2 - M1
- 8: Pos 8¹ - M1
- 9: Pos 18 - M1
- 10: EMG mental or submental
- 11: EMG (linked electrodes left and right anterior tibialis)
OR: 11: EMG (left anterior tibialis)
32: EMG (right anterior tibialis)
- 12: ECG (chest)
- 13: Airflow
- 14: Chest wall movements
- 15: Abdominal movements
- 16: Oxygen saturation

¹ Haekkinen V, Hirvonen K, Hasan J, Kataja M, Vaerri A, Loula P and Eskola H. The effect of small differences in electrode position on EOG signals: application to vigilance studies. *Electroenceph. Clin. Neurophysiol.*, 1991, 79:36-44

Optional (recommended / high priority)

- 17: Fz - M1
- 18: Cz - M1
- 19: Pz - M1
- 20: F3 - M2
- 21: P3 - M2
- 22: T3 - M2
- 23: F4 - M1
- 24: P4 - M1
- 25: T4 - M1

Optional (recommended / lower priority)

- Additional EEG leads
- Body temperature
- Snoring microphone

Filter settings and sampling rates

For EEG and EOG the time constant should be as long as possible (minimum 1 s). For EMG and ECG time constants between 0.01 and 0.1 s should be used (Since our sampling rates are far below 1000 Hz, the determination of the Q-, R- and S-waves of the ECG signal seems inadequate. For pulsatile measures, a short time constant will ensure that the baseline remains relatively constant.).

The anti-aliasing filters must be chosen appropriately, depending on the steepness of the filters and the sampling rate. The sampling rate for EEG, EOG, EMG and ECG should be as high as possible (minimum 100 Hz). For respiratory signals a sampling rate of 16 Hz and for the oxygen saturation signal a sampling rate of 1 Hz is sufficient.

MORNING PSYCHOMETRIC TESTS

The psychometric tests in the morning are carried out after washing, getting dressed and breakfast (with habitual coffee and cigarettes, no alcohol) between 1 and 2 hours after getting up.

- Self-rating Questionnaire for Sleep and Awakening Quality (SSA)
- ASES: 100 mm visual analogue scales for mood, drive, affectivity and drowsiness
- Bf-S' or Bf-S: Befindlichkeitsskala (*von Zerssen*) well-being scale
- AD-Test: Alphabetic cross-out test for attention, concentration
- Fine Motor Activity Test: psychomotor activity
- Digit Span Test: numerical memory
- Reaction Time Test
- Vigilance Test (simultaneous EEG recording is recommended)

Recommended (wherever possible):

Vigilance Test longer than 25 min

Multiple sleep latency test (MSLT) at day 8 (after the second polysomnographic night):

Four recording sequences (20 min recording time for each sequence starting at 10.00, 12.00, 14.00, and 16.00) with the same montage as night PSG recordings.

URINARY DRUG SCREENING

The screening should include: barbiturates, benzodiazepines, cannabinoids, amphetamines, cocaine and opiates. The urinary sample is to be taken in the morning of day eight (after the first polygraphic night).

TIME SCHEDULE

Diagnostic and other procedures	Entrance Visit	Day 1	Day 7	Day 8	Day 15
Entrance examination	X				
Blood test	X ^o				
Study start		X			
Wrist Actigraphy		X	-----		X
SSA		X	-----		X
Psychometric tests (evening)			X	X	
Polygraphic recording			X	X	
Psychometric tests (morning)			X	X	
Urinary drug Screening (morning, after the 1 st PSG night)				X	
Study end					X

^o Within the last month

DATA STORAGE

Data format

European Data Format (EDF)¹

polysomnographic data
visual sleep scoring files

ASCII

Actigraphy raw data files
Clinical test files (as created by MS-ACCESS test forms)
Vigilance and reaction time test files

All recordings from one subject are stored on one CD-ROM.

Directory structure for recordings on CD-ROM

\--**XYnnn**

polysom [*clean EDF-files*]

XYnnn01.rec/ XYnnn02.rec

data [*as created by a special-purpose MS ACCESS program*]

XYnnn.am1/ XYnnn.am2/ XYnnn.am3/ XYnnn.am4/ XYnnn.am5

XYnnn.aty / XYnnn.cli / XYnnn.drm / XYnnn.npr / XYnnn.psq / XYnnn.ssa

XYnnn.01.psy/ XYnnn.02.psy/ XYnnn.03.psy/ XYnnn.04.psy

actigr [*as created by actigraphy software*]

XYnnn01.awd/ XYnnn02.awd

rtest [*as created by the test software and a special shell script*]

XYnnn01.ra/ XYnnn01.ras/ XYnnn01.rb/ XYnnn01.rbs/ XYnnn02.ra/

XYnnn02.ras/ XYnnn02.rb/ XYnnn02.rbs

vtest

XYnnn01.va/ XYnnn01.vas/ XYnnn01.vb/ XYnnn01.vbs/ XYnnn02.va/

XYnnn02.vas/ XYnnn02.vb/ XYnnn02.vbs

¹Kemp B, Vaerri A, Rosa AC, Nielsen KD and Gade J. A simple format for exchange of digitized polygraphic recordings. *Electroenceph. Clin. Neurophysiol.* 1992;82:391-93

APPENDIX

Psychometric and psychological tests and questionnaires

Alphabetical Cancellation Test (AD-Test)

Author: Gruenberger J (1977)

Speed test (paper pencil test) for quantification of attention, concentration and attention variability.

Literature:

Gruenberger, J. *Psychodiagnostik des Alkoholkranken. Ein methodischer Beitrag zur Bestimmung der Organizitaet in der Psychiatrie*. Wien Maudrich; 1977

Gruenberger J, Linzmayer L, Dietzl M, Saletu B. The effect of biologically-active light on the noo- and thymopsyche and on psychophysiological variables in healthy volunteers. *Int J Psychophysiol* 1993;15:27-37

ASES 100 (Visual Analogue Scale)

Self assessment scale, consisting of four 100 mm visual analogue scales for drive, mood, affectivity and drowsiness

AMDP System[#]

Authors: Association For Methodology And Documentation In Psychiatry

The AMDP system consists of five observer scales*

AMDP 1: Demographic Data (21 items)

AMDP 2: Life Events (2 item groups)

AMDP 3: Psychiatry History (14 items)

AMDP 4: Psychopathological Symptoms (100 items)**

AMDP 5: Somatic Signs (40 items)**

Literature:

**The AMDP-System. Manual for the Assessment and Documentation of Psychopathology*

Eds.: Guy W and Ban THA. Springer, 1982

***International Scales for Psychiatry*. Eds.: Collegium Internationale Psychiatriae Sclarum (CIPS). 4th Edition, Hogrefe, Goettingen 1996

[#] These tests are published in: *International Scales for Psychiatry*. (Eds): Collegium Internationale Psychiatriae Sclarum (CIPS). 4th Edition, Hogrefe, Goettingen 1996. Tests are translated in: English, French, Spain and German

BF-S/BF-S' Well-Being Scale[#]

Author: vonZerssen D (1970)

Self assessment scale consisting of 28 items (two (parallel) forms)

Literature:

Von Zerssen D, Koeller DM and Rey ER. Die Befindlichkeitsskala (B-S): Ein einfaches Instrument zur Objektivierung von Befindlichkeitsstoerungen, insbesondere im Rahmen von Laengsschnittuntersuchungen. *Arzneimittelforschung (Drug Research)*, 1970;20: 915-18
Von Zerssen D: *Die Befindlichkeits-Skala. Parallelfornen Bf-S und Bf-S'*. Weinheim, Beltz; 1976

Day Questionnaire (DQ)

Author: This questionnaire was exclusively designed for S.I.E.S.T.A.

Self rating scale consisting of nine items asking for daytime events and daily activities prior to sleep lab nights

Digit Span A (Digit Span B, parallel form)

Numerical memory test consisting of two parts (1st part: seven rows of three to nine digits must be memorised forward; 2nd part; seven rows of two to eight digits must be memorised backward)

Fine Motor Activity Test (FM-Test)

Author: Gruenberger J (1977)

Paper pencil test (speed test) for evaluation of changes in psychomotor activity and drive (left and right hand).

Literature:

Gruenberger J. *Psychodiagnostik des Alkoholkranken. Ein methodischer Beitrag zur Bestimmung der Organizitaet in der Psychiatrie*. Wien Maudrich; 1977

Gruenberger J, Linzmayer L, Dietzl M, Saletu B. The effect of biologically-active light on the noo- and thymopsyche and on psychophysiological variables in healthy volunteers. *Int J Psychophysiol* 1993;15:27-37

[#] These tests are published in: International Scales for Psychiatry. (Eds): Collegium Internationale Psychiatriae Scalarum (CIPS). 4th Edition, Hogrefe, Goettingen 1996. Tests are translated in: English, French, Spain and German

Generalised Self-Efficacy Scale

Author: Schwarzer R (1994)

Ten item self assessment scale based on the concept of generalised self efficacy (Schwarzer, 1994: "Generalised self-efficacy is a stable personality characteristic that reflects an individual's belief that he or she can cope with difficult demands.").

Literature:

Schwarzer R. Optimistische Kompetenzerwartung: Zur Erfassung einer personellen Bewaeltigungsressource. *Diagnostica* 1994;40:105-123

Schwarzer, R. *Measurement of perceived self-efficacy. A documentation of psychometric scales for cross-cultural research.* Berlin: FU, Inst. for Psychology 1993

Mini Mental State Examination (MMSE)

Author: Folstein FM (1975)

Observer inventory consisting of 30 items for testing cognitive functions especially in the elderly (orientation, concentration, memory, etc.).

Literature

Folstein MF, Folstein SE and McHugh PR. Mini Mental State: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-198

NEO-PI, NEO FFI (Personality Inventory)

Authors: Costa P, McCrae R (1978, 1985, 1991)

Personality inventory available in three versions : NEO-FFI (NEO-Five Factor Inventory: 60 items), NEO-PI (Neo Personality Inventory: 181 and 240 item version)

Literature:

Costa PT and McCrae RR. The NEO Personality Inventory. Manual Form S and Form R . Odessa, Florida 1985: Psychological Assessment Resources

Tests are available by: PAR (Psychological Assessment Resources), Inc. Odessa, Florida
Testzentrale des Berufsverbandes Deutscher Psychologen, D-37079 Goettingen

Pittsburgh Sleep Quality Index (PSQI)

Authors: Buysse DJ, ReynoldsIII CHF, Monks TH, Berman S and Kupfer DJ (1988)

Self-rated questionnaire consisting of ten items which assesses sleep quality and disturbances over a one month time interval

Literature:

Buysse DJ, ReynoldsIII CHF, Monks TH, Berman S and Kupfer DJ. The Pittsburgh Sleep Quality Index: A new instrument for Psychiatric Practice and Research. *Psychiatry Research* 1988;28:193-213

Quality of Life Questionnaire (Quality of Life Index)

Authors: Mezzich JE, Cohen NL (1996)

The quality of life index (self rating scale) is composed of ten items covering corresponding dimensions of the concept of quality of life such as physical well-being, psychological well-being, self care, independent functioning, etc.

Literature:

Mezzich JE, Cohen NL and Rupiérrez MA. A quality of life index. Brief description and validation. Abstract: *Congress of the International Federation for Psychiatric Epidemiology* Santiago de Compostella, Spain 1996

Self Rating Anxiety Scale (SAS) #

Author: Zung WWK (1971)

Self rating scale for the assessment of anxiety (20 items)

Literature:

Zung WWK. A rating instrument for anxiety disorders. *Psychosomatics* 1971;12;371-379

Self Rating Depression Scale (SDS)#

Author: Zung WWK (1965)

Self rating scale for the assessment of depressive symptoms (20 items)

Literature:

Zung WWK. A self-rating depression scale. *Arch Gen Psychiatr* 1971;12;371-379

These tests are published in: *International Scales for Psychiatry*. (Eds): Collegium Internationale Psychiatricae Scalarum (CIPS). 4th Edition, Hogrefe, Goettingen 1996. Tests are translated in: English, French, Spain and German

Self Assessment Scale for the Evaluation of Sleep and Awakening Quality (SSA)

Authors: Saletu B, Wessely P, Gruenberger J and Schultes M (1987)

Self rating scale consisting of four parts:

1st part: sleep quality (seven items)

2nd part: awakening quality in the morning (8 items)

3rd part: somatic complains (five items)

4th part: subjective estimates of total sleep periods, sleep latency, etc.

Literature:

Saletu B, Wessely P, Gruenberger J and Schultes M. Erste klinische Erfahrungen mit einem neuen schlafanstoßenden Benzodiazepin, Clomazepam, mittels eines Selbstbeurteilungsbogens fuer Schlaf- und Aufwachqualitaet (SSA). *Neuropsychiatrie* 1987;1:169-76

Computer Assisted Tests

Reaction Time Test

The test unit allows measurements of multiple choice reactions (yellow light plus acoustic stimuli presented simultaneously). Test duration approximately 5 minutes.

Vigilance Test

Computer based version of the Quatember Maly clocktest (originally published by Macworth 1957).

Description: A bright dot moves very slowly along a circular path. Sometimes the dot jumps two positions at once. The subject must respond to these events as quick as possible (by pressing the space bar on the keyboard). The duration of the test can be varied. The recommendations are: minimum 25 minutes but longer test runs will lead to better results (40 to 50 minutes).

All test results and score have to be encoded electronically by means of test templates (MS ACCESS V2.0) and by double data entry.