



DeepPsy

**DeepPsy Biomarkers
Report Guide**

v1.2.4 - 20/05/2026

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1 Label Information

**Manufacturer:**

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Switzerland



Medical Device
DeepPsy Biomarkers



UDI-DI: (01)7649988327940
VERSION: (8012)v1.8.2
PROD DATE: (01)260520
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Certification Pending
(logo only for display)



The **Instructions for Use (IFU)** of the medical device can be found at <https://manuals.deeppsy.io/>.

2 Contact & Incidents

In case of serious incident or near-incident caused by DeepPSY Biomarkers software, please immediately report to the Quality Assurance Officer. Alternatively, contact the DeepPsy AG using the information provided below.

Email support@deeppsy.io
Phone Number +41 44 797 62 29

If you require a printed copy of these Instructions for Use, please contact DeepPsy AG using the contact details above. A printed copy will be provided free of charge by post within 7 calendar days of receiving your request.

For further information and support material, please visit the DeepPsy website at <https://manuals.deeppsy.io/>.

3 Introduction

The DeepPsy Biomarkers Report is generated from an analysis of patient EEG and ECG data. It provides a concise summary of the analysis performed, detailing the biomarkers identified from the physiological signals. The report includes charts that offer a comprehensive view of the mainly predictive markers for optimization of treatment and the patient's condition, alongside interpretations of the data, which are based on current scientific literature. This guide will provide a description of the different sections in the report and how they can be interpreted and used.

3.1 Intended Purpose

DeepPsy Biomarkers is a standalone software that assists in displaying, analyzing, and providing information through the examination of electrophysiological signals derived from human electroencephalogram (EEG) and electrocardiogram (ECG) data. The software is exclusively intended for use within DeepPsy AG and by specialists accredited by DeepPsy AG. It is designed to analyze resting-state EEG and ECG recordings to compute physiological biomarkers.

A subset of the EEG and ECG biomarkers has been associated in the literature with psychiatric treatment outcomes and can assist in distinguishing subgroups of patients who may respond more favorably to specific treatments.

The information provided by the software is intended to be used only by physicians and is intended to influence treatment decisions only between treatments that are already indicated for the patient and that have a positive risk-benefit ratio. It is not intended to influence any diagnostic process or to establish or exclude any diagnosis. The treating psychiatrist remains fully responsible for diagnosis, indication, and final treatment choice.

3.2 Medical Indication

This can include conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

The medical device is intended to provide additional information for medical professionals when treating with psychiatric disorders. It is designed to improve decision-making within the scope of treatments already indicated for the patient.

The DeepPsy Biomarkers software has been evaluated in clinical studies using EEG and ECG biomarkers in MDD population. Performance varies with biomarker and treatment type; detailed study data are available in the Clinical Evaluation Report.

This medical device is not intended to determine the indication or contraindication of a specific treatment. The responsibility for determining whether a treatment is appropriate or inappropriate for a patient rests solely with the medical professional.

Indication	Intervention	Biomarker	Sample Size	Effect Size	Estimated Power
MDD	Sertraline	APF	225	0.28	0.552
MDD	10Hz rTMS	APF	90	0.66	0.872
MDD	10Hz rTMS	APF	68	0.63	0.726
MDD	10Hz rTMS	APF	59	0.52	0.501
MDD	1Hz rTMS	APF	564	0.28	0.913
MDD	ECT	APF	564	1.07	1.000
MDD	Sertraline	APF	564	0.33	0.975
MDD	10Hz rTMS	APF	564	0.20	0.659
MDD	Escitalopram, Sertraline	Vigilance Slope	263	0.24	0.492
MDD	Escitalopram, Sertraline	Vigilance Slope	263	0.19	0.336
MDD	Citalopram, etc.	Vigilance Level	78	0.59	0.730
MDD	Escitalopram, Duloxetine	Vigilance Slope	79	0.47	0.541
MDD	Ketamine	Stage A	48	1.39	0.997
MDD	Ketamine	Stage A Prediction	48	0.79	0.764
MDD	CBT, SSRI	Stage 0	51	0.90	0.883
MDD	Escitalopram, Sertraline	FAA	203	0.30	0.566
MDD	Escitalopram, Sertraline	FAA	258	0.55	0.993
MDD	Escitalopram	FAA	56	0.68	0.705
MDD	SSRI, SNRI, Tricyclic	BPM	34	0.22	0.095
MDD	SSRI, SNRI, NDRI, TCA	BPM	28	0.63	0.362
MDD	Ketamine	BPM	47	0.60	0.521
MDD	Ketamine	HRV Power	47	0.42	0.291
MDD	Tricyclic	Log LF@week4	33	0.65	0.440
MDD	Tricyclic	Log HF@week4	33	0.48	0.267
MDD	Tricyclic	Log LF/HF@week4	33	0.08	0.056
MDD	Venlafaxine	BPM slope	184	0.26	0.419

Table 1: Clinical Study Data: Biomarker Performance Across Different Interventions and Indications

MDD: Major Depressive Disorder; GAD: Generalized Anxiety Disorder; OCD: Obsessive Compulsive Disorder.

3.3 Performance Characteristics

3.3.1 Preprocessing Steps

Preprocessing Step	Performance Specification
ECG Preprocessing	
ECG Auto-Flip	Detects and corrects inverted ECG signals based on statistical polarity checks (Automatic, inspected by specialist)
Automatic Peak Detection	Detects R peaks in ECG traces (Automatic)
Automatic Peak Filtering	Filters out physiologically implausible peaks by applying minimum inter-peak interval threshold (Automatic)
Automatic Peak Correction	Identifies and corrects ectopic beats, interpolates missing peaks, removes physiologically implausible intervals (Automatic, optional)
Manual Peak Selection	Enables visual inspection and manual selection of missing ECG peaks (Manual)
EEG Preprocessing	
Bandpass Filter	EEG: Signal power preserved within 0.1–70 Hz band, attenuated (>20 dB reduction) for frequencies <0.05 Hz and >75 Hz; EOG: Signal power preserved within 0.05–70 Hz band, attenuated (>20 dB reduction) for frequencies <0.01 Hz and >75 Hz; ECG: Signal power preserved within 0.01–30 Hz band, attenuated (>20 dB reduction) for frequencies <0.005 Hz and >35 Hz (Automatic)
Notch Filter	Power at 50 Hz reduced by ≥ 20 dB compared to unfiltered signal; neighboring frequency content (± 5 Hz) preserved (Automatic spectrum analysis)
Interpolation for Broken Channels	Interpolated signal computed as weighted spatial average using spherical spline interpolation (per Perrin et al., 1989) (Automatic)
Re-referencing	EEG signals re-referenced to average of all channels (Automatic)
Epoching	Output data shape transforms from 2D matrix (nChannel \times pnts) to 3D matrix (nChannel \times pntsPerSegment \times nSegment) (Automatic)
Bad Segment Selection	Bad epochs visually identified by trained analyst and marked in metadata (Manual)
Independent Component Analysis	ICA applied to decompose EEG into independent components; artifact-related components identified and removed by trained analyst (Manual)

3.3.2 Biomarkers

Biomarker	Performance Specification
ECG Biomarkers	
Beat Per Minute (BPM)	Produces output range of 35–200 BPM; Achieves tolerance of ± 1 BPM vs. Kubios; Ensures $\geq 90\%$ of samples meet criterion
ECG Frequency Measures	Produces output LF, HF, LF/HF ≥ 0 ; Achieves adaptive tolerance of Max($10 \mu V^2$, 5%) vs. Kubios; Ensures $\geq 90\%$ of samples meet criterion
BPM Slope	Ensures slope reflects correct direction (pos/neg/zero); Computes via linear regression on valid BPM values
EEG Biomarkers	
Alpha Peak Frequency (APF)	Produces output range of 8–13 Hz; Uses channel from predefined list; Achieves tolerance of < 0.25 Hz vs. MATLAB; Ensures $\geq 90\%$ of samples meet criterion
Frontal Alpha Asymmetry (FAA)	Produces output range of -1 to 1; Achieves tolerance of < 0.1 a.u. vs. MATLAB; Ensures $\geq 90\%$ of samples meet criterion
EEG Vigilance	Produces median vigilance of 0–6; Ensures percentages of stages per block sum to 1; Achieves declining slope in $\geq 85\%$ of cases; Ensures Stage A > B BPM is statistically significant
QEEG Powers	Produces power ≥ 0 in all frequency bands; Achieves tolerance of Max($10 \mu V^2$, 10%) vs. MATLAB; Ensures $\geq 90\%$ of samples meet criterion

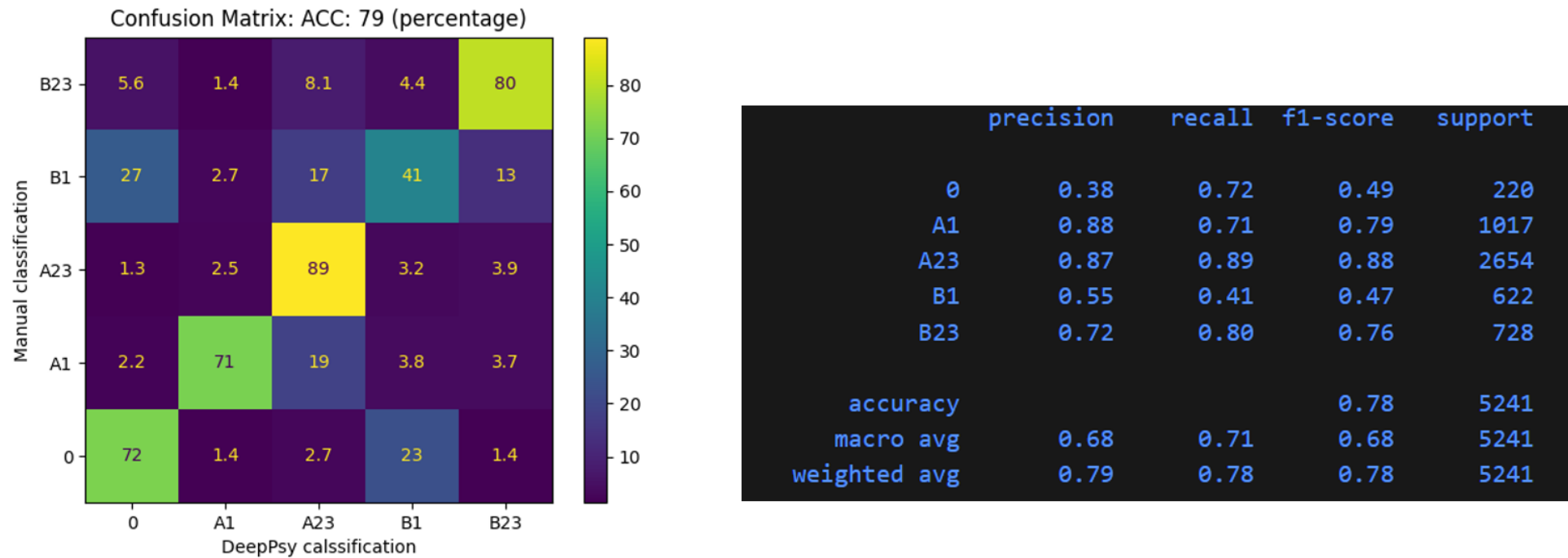


Figure 1: Performance of the VIGAZ algorithm for the calculation of EEG-Vigilance Regulation.

3.4 Intended User

The intended users of this software are qualified specialists trained in electrophysiology and accredited by DeepPsy AG. The software is intended to be used in-house only.

The intended users of the information provided by the software (DeepPsy Report) are qualified medical practitioners, who need to exercise their professional judgment when using this information. The information are delivered in the form of a "DeepPSY Biomarkers Report" outlined below.

3.5 Patient Group

This can include age group, weight range, health, or condition.

The patient group includes any patient for whom a physician requests the respective additional information to support clinical decision-making within the scope of treatments already indicated for that patient, provided that:

Patient condition:

- Patients with a diagnosis of depression or suspected depression.

Age group:

- The information provided by the DeepPsy Biomarkers Software is intended to be used only in Patients aged 18 and older.

Prerequisites:

- The treating physician has determined that a psychiatric treatment is needed for the patient.
- The treating physician has determined that the applicable treatment is indicated for the patient.

3.6 Intended Clinical Benefit

This medical device is designed to offer insights into a patient's electrophysiological parameters. It also incorporates the latest findings from state-of-the-art literature in the field of precision psychiatry, which is intended to aid in the interpretation of these electrophysiological data.

The DeepPsy Biomarkers has the intended clinical benefit of improving patient quality of life by supporting the decision process for psychiatric disorders and their comorbidities by providing supporting information from patients electrophysiology.



4 Contraindications

The DeepPSY Biomarkers software, DeepPSY Biomarkers's Report, and every other output:

- Is not intended to replace the expertise and guidance of a physician or psychotherapist.
- Is not intended to be used as a final, mandatory guideline or recommendation.
- The information provided by DeepPsy Biomarkers is not intended to drive diagnosis.
- Is not intended to decide whether a treatment is indicated.
- Is not intended to be used to make decisions about whether to undergo a psychiatric treatment or not.

- The DeepPSY Biomarkers report may only be used if the requesting physician has confirmed the absence of neurological or cardiac pathologies and the absence of clinically relevant medication effects on the EEG and ECG data.
- Not for self-diagnosis, self-treatment, or for making independent treatment decisions.
- Not for use in life-support or acute emergency settings.
- DeepPsy Biomarkers is not intended to be used as vital signs monitor not in any situation where measured parameters could result in immediate danger to the patient. DeepPsy Biomarkers should not be used with patients in critical conditions nor as a substitute of a standard of care in serious or time-sensitive situations.



5 Cautions

- Must be used only when requested and interpreted by a physician or psychiatric/medical institutions.
- Clinical decisions must always be made by a qualified medical professional only as an additional source of information alongside other clinical and paraclinical sources of information, and the relevance of the report is weighed in the context of the entire clinical picture.
- Use in elderly patients (>75) requires careful clinical interpretation.

6 Limitations

6.1 Clinical Limitations

- The performance is unclear under the presence of neurological pathologies (in the EEG) or cardiac pathologies (in the ECG).
- Certain medication might influence the EEG and ECG patterns.
- The performance is unclear in patients with scalp abnormalities or head injuries.
- Performance may differ in elderly patients (>75) as EEG/ECG patterns can vary from those of typical adults.
- Use is restricted to approved geographic areas as per local regulatory authorization.
- Frontal alpha asymmetry (FAA) is used only for female patients, as the supporting predictive evidence is limited to that subgroup; it is not applied as claim-supporting treatment-selection information outside the female population.
- Using EEG/ECG data that does not meet the specified quality requirements may lead to unreliable results.

6.2 EEG and ECG data limitations:

- **Data length:** 3 minutes
- **Recording condition:** Resting state with eyes closed
- **Channel positioning:** Recommended: 10-20, Possible: 10-10, 10-05. We need at least: One electrode per lobe, one electrode on each side.
- **Channel number:** 19
- **Sampling frequency:** 250 Hz
- **ECG channel:** at least bipolar recording at one of the following: wrist, or neck, or breast
- Maximum length of recording is 3600 seconds. Longer recordings will be truncated.
- Maximum sampling frequency is 1000 Hz. Higher sampling frequencies will be downsampled to 1000 Hz.

7 Evidence Level

Each "Interpretation" in the interpretations section (page 4 of the report) has a label with the "evidence level". This is a statement about the strength of the evidence in this finding.

To rank the evidence level, we are using the "The Oxford 2011 Levels of Evidence" from the Oxford Centre for Evidence-Based Medicine. The system categorizes evidence from Level 1 (high-quality evidence) to Level 5 (lowest evidence level). In the case of our predictive biomarkers, we follow:

Level 1	Level 2	Level 3	Level 4	Level 5
Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a

8 Overview of the Report Sections


This section breaks down the DeepPsy report page by page, explaining the key components and their significance.

8.1 Page 1: Biomarker Correlations Summary

Header
The header and footer contain basic identifying information that appears on every page of the report. This includes patient details, report IDs, and dates.

Biomarker Correlations Summary
This table provides a summary of the correlations indicated by scientific literature, given the electrophysiological profile derived from the analysis. The correlations are presented summarized here for your convenience, they can be derived from the "interpretations" texts below.

Footer
The footer displays the version of the software used to generate the report. Contact information for questions, feedback or complaints, and the page number alongside the total number of pages.



Name:
Patient ID:
Age: 63
Sex: Male

Case ID:
Report ID: ██████████
Report Date: 21.12.2024
Recording Date: 21.10.2024

EEG & ECG Biomarkers Report

- This report is intended to be used only by qualified medical practitioners.
- This report is intended to be used to improve decision-making within the scope of possible treatments already indicated for a patient.
- This report is exclusively suitable for adult patients.

- This report is not intended to be used to determine whether a patient should undergo treatment. It is also not intended to be used to determine if a treatment is indicated or contraindicated for a patient.
- This report is not intended for use in cases of neurological pathologies, scalp abnormalities, head injuries (in the EEG), or cardiac pathologies (in the ECG).
- This report is not intended to drive diagnosis, to be used as a vital signs monitor, or to be used in any situation where measured parameters could result in immediate danger to the patient.

Biomarker Correlations Summary

Condition	Treatment	Correlation
MDD	SSRI	Lower response rates than SNRI <small>Vigilance Regulation 2min</small>
	SNRI	Higher response rates than SSRI <small>Vigilance Regulation 2min</small>
	rTMS	10Hz left DLPFC has lower Response Rate than 1Hz right DLPFC <small>Alpha Peak Frequency (APF)</small>
	Ketamine (oral/i.v.)	Decreased response rates for Ketamine <small>Heart Rate (BPM), Vigilance Regulation: A1 Stages</small>
	ECT	Higher response rates for ECT and less side effects <small>Alpha Peak Frequency (APF)</small>

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8.2 Page 2: Biomarker Plots and Visualizations

The Vigilance section (EEG) has a plot with the level of vigilance of the patient throughout the whole recording (left panel) and the slope of the vigilance level over the first two minutes (right panel).

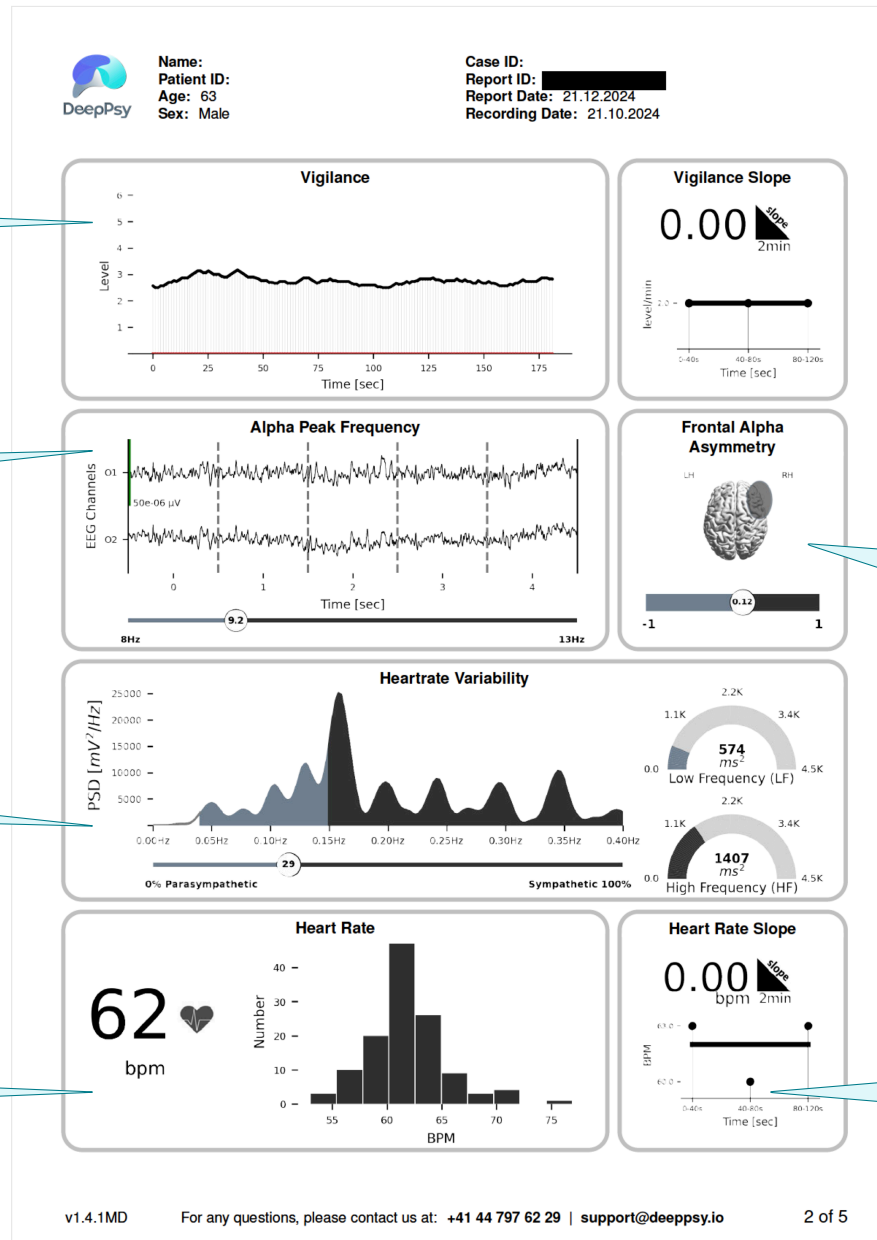
The slope is the value that has predictive clinical implications.

The plot shows an example of segments with the Alpha Peak Frequency (APF) for the patient (EEG). From the APF as the basic rhythm of the brain, several predictive aspects can be concluded.

This plot shows the distribution of Heart Rate Variability, derived from the ECG. High values of Low Frequency (LF) power reflect the adaptive capabilities of the autonomic nervous system. Low LF values are usually associated with the potential for good relaxation.

High values of High Frequency (HF) power are associated with a relaxed state, where low HF power values can be associated with stress or anxiety.

Histogram of beat per minute (BPM) for the ECG. This marker has predictive value for treatment options.



The hemisphere with greater frontal alpha power was highlighted for the frontal alpha asymmetry.

This marker has predictive clinical implications specific in female patients.

Slope of the beat per minute (BPM) for the ECG. This marker has predictive value for treatment options.


8.3 Page 3: Biomarker Values and Analysis Characteristics

Biomarker Values Table
 The individual values or each of the biomarkers can be found here.

For eligible biomarkers, the normal range in the healthy population is presented. Values outside the boundary of two standard deviations are presented in bold type.

Analysis Characteristics Section
 This section gives general information about the EEG or ECG itself (date, length etc) and the analysis performed by the DeepPsy specialist.

If there were any problems during the analysis, they're shown here. Additionally, if there's any information from the analysis that is important for the interpretation of the results, it'll be shown here as well.



Name:
Patient ID:
Age: 63
Sex: Male

Case ID:
Report ID: [REDACTED]
Report Date: 21.12.2024
Recording Date: 21.10.2024

Biomarker Values

	Value (first 2min)	Normal Interval (2 SD)
EEG:		
Alpha Peak Frequency (APF) (Hz)	9.2	(8.0 – 11.7)
Frontal Alpha Asymmetry (FAA)	0.1178	(-0.3 – 0.3)
qEEG Alpha (μV^2)	2.81	(0.0 – 144.0)
qEEG Beta (μV^2)	2.98	(0.0 – 18.0)
qEEG Delta (μV^2)	2.22	(0.0 – 16.0)
qEEG Gamma1 (μV^2)	1.13	(0.0 – 2.0)
qEEG Gamma2 (μV^2)	0.55*	(0.0 – 0.2)
qEEG Theta (μV^2)	2.17	(0.0 – 32.0)
Slow Basic Rhythm	No	–
Vigilance Regulation: 0 Stages (%)	0.0	(0.0 – 75.0)
Vigilance Regulation: A1 Stages (%)	0.6	–
Vigilance Level (Level)	2.0*	(2.2 – 6.0)
Vigilance Mean (Level)	2.7	(2.24 – 6.0)
Vigilance Regulation 2min (Level/min)	0.0	(-0.5 – 0.4)
ECG:		
Heart Rate (BPM) (beats/min)	62.0	(53.0 – 76.0)
Heart Rate Regulation (BPM Slope) (beats/min ²)	0.0	(-2.91 – 2.73)
Total HRV Power (ms ²)	1980.3	(0.0 – 8011.0)
Parasympathetic Activity (HF) (ms ²)	1406.69	(0.0 – 4320.0)
Sympathetic Activity (LF) (ms ²)	573.64	(0.0 – 4242.0)
Relative Sympathetic Activity (LFnu) (%)	29.0	(7.0 – 96.0)

Analysis Characteristics

- EEG analysis completed successfully. ECG analysis completed successfully.
- All biomarkers were computed successfully.

Recording Date: 21.10.2024

Sampling Frequency: 1000 Hz

Total Recording Duration: 1235s (20.6m)

Number of Channels: 23

Number of Epochs: 178

ECG Peaks: 124

Analysis Interval: 233s – 414s (3.0m)

Channel Types: EEG(21) EOG(1) ECG(1)
EOG Channel: EOG (POL PG1 – POL PG2)

Epochs with Artefacts: 3 (1.7%)

Peaks Corrected: None

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8.4 Page 4: Interpretations

EEG and ECG Interpretations

Report interpretations concisely summarize the associations found in the scientific literature between EEG and ECG biomarkers and treatment effectiveness.

All references to the corresponding studies are given alongside with a rating of the clinical evidence (level 1 -highest level of evidence- to level 4 -lowest level of evidence). You may find the referenced papers in the last page of the report.

Note: Since there exist several different markers for specific treatments (e.g. for SSRIs), the results sometimes can be contradictory between biomarkers. The results need to be put into the clinical context by a physician and to be discussed with the patient.



Name: [REDACTED]
Patient ID: [REDACTED]
Age: 63
Sex: Male

Case ID: [REDACTED]
Report ID: [REDACTED]
Report Date: 21.12.2024
Recording Date: 21.10.2024

Interpretations

EEG

- **Alpha Peak Frequency (APF) [2, 3, 5, 19, 26]** In this EEG, a low Alpha Peak Frequency was found. In this case, for depressive symptoms, a 1Hz TMS protocols over the rDLPFC may be more effective than 10Hz protocols over the left DLPFC. There is also a positive correlation with the response to Sertralin. ECT therapy shows particularly good response with low APF. In the case of ADHD, there is evidence suggesting that biofeedback methods might be more effective than Methylphenidate. (Evidence Level 2)
- **Basic Rhythm Slow [1]** In this, a EEG normal Basic Rhythm Peak Frequency was found . No signs of generalized slowing of the basic EEG rhythm in this case. (Evidence Level 2)
- **Percentage of vigilance stage A1 [11]** In this EEG, a low occurrence of vigilance stage A1 was found . In this case, low percentages of EEG-vigilance stage A1 are associated with a lower probability to respond to i.v. ketamine and oral ketamine. (Evidence Level 2)
- **Vigilance Regulation 2min [12, 18, 20]** In this EEG increase or no initial decrease was found of vigilance during the first 2 minutes. For this case, literature shows lower response rates in depression to SSRIs and SNRIs can be more effective. (Evidence Level 2)

ECG


- **Heart Rate (BPM) [14]** In this ECG, a low heart rate was observed. In this case correlation with less likely response to ketamine (i.v.) in depression. (Evidence Level 2)
- **Heart Rate Regulation (BPM Slope) [18]** In this ECG, a decrease or no substantial increase in BPM was observed. In this case in depression, there is a correlation with lower response rates for venlafaxine (SNRI). SSRIs can be more effective. (Evidence Level 2)
- **Sum of Parasympathetic and Sympathetic Activity [14]** In this ECG, a high overall activity of the autonomic nervous system was observed.. In this case, less likely to respond to ketamine (i.v.) for major depression. (Evidence Level 2)
- **Absolute parasympathetic Activation [15]** In this ECG, high absolute parasympathetic activation was observed. In this case less likely response to SSRI, CBT or combination in obsessive compulsive disorder (Evidence Level 2)
- **Absolute Sympathetic Activation [21]** In this ECG, normal absolute sympathetic activation is observed. In this case compared to the average population, total sympathetic activity is normal.
- **Relative Sympathetic/Parasympathetic Activation [7]** In this ECG, a shift toward parasympathetic activity was observed . In this case no correlation with good response to Fluoxetine in generalized anxiety disorder. (Evidence Level 2)

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8.5 Page 5: References

Literature References
 Literature references of all cited papers in the interpretation section.

Each title in the "Interpretations" section may be accompanied by one or more reference numbers. These are the papers on which the interpretation is based for each case.



Name: [REDACTED]
Patient ID: [REDACTED]
Age: 63
Sex: Male

Case ID: [REDACTED]
Report ID: [REDACTED]
Report Date: 21.12.2024
Recording Date: 21.10.2024

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9 Frequently Asked Questions (FAQs)

Why are some of the recommendations contradictory? It's possible that some biomarkers give contradictory information. This is the nature of assessing different sources of information from complex physiological signals. It is important to weigh the merits of the different interpretations against each other and, most importantly, against the patient's complete clinical history and presentation. The report is a tool to aid, not replace, clinical judgment.