DeepPsy Biomarkers Report Guide

v1.2.1 - 01/08/2025

Contents

1 Label Information

Manufacturer:
DeepPsy AG (https://deeppsy.io/)
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8125 Zollikerberg
Switzerland

Medical Device
DeepPsy Biomarkers

UDI-DI: (01)7649988327926
VERSION: (8012)v1.6.1
PROD DATE: (01)250801
EXP DATE: (01)280801

MED-RAS GmbH
Eichenallee 8H
D-21521 Wohltorf
Germany

Qserve Group UK Ltd.
282 Farnborough Road,
Farnborough, GU14 7NA
United Kingdom

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 DeepPsy AG using the information provided below.

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

In case you require this report guide in printed form, please contact DeepPsy AG using the information above. We will collect your information and send you a printed copy of the report guide.

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 Medical Indication

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

The DeepPsy Report 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	Est. 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
OCD	CBT + SSRI	log HF	51	0.72	0.712
MDD	Ketamine	HRV Power	47	0.42	0.291
GAD	Fluoxetine	Low HF(nu)	77	0.63	0.779
PTSD	iTBS	Total Power	24	1.42	0.914
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

3.2 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 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.

3.3 Patient Group

The patient group includes any patient for whom a physician has requested the respective additional information to support clinical decision-making within the scope of treatments already indicated for the patient.

- The information provided by DeepPsy is not intended to be used in the presence of neurological pathologies (in the EEG) or cardiac pathologies (in the ECG).
- The information provided by DeepPsy is not intended to be used in patients with scalp abnormalities or head injuries.
- The information provided by DeepPsy Biomarkers is not intended to drive diagnosis,

DeepPsy Report 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 Report should not be used with patients in critical conditions nor as a substitute of a standard of care in serious or time-sensitive situations. The risk of software error or failure cannot be completely excluded.

⚠ Special caution has to be taken with Infant and young children since the developing brain of infants may produce EEG patterns that differ from those of adults, requiring specialized interpretation techniques.

⚠ 4 Contraindications

The DeepPsy Report, and every other output:

- Is not intended to be used under the presence of neurological pathologies (in the EEG) or cardiac pathologies (in the ECG).
- Is not intended to replace the expertise and guidance of a physician or psychotherapist.
- Is not intended to be used to make decisions about whether to undergo a psychiatric treatment or not.
- Is not intended to be used as a final, mandatory guideline or recommendation.

- Is not intended to be used for self-diagnosis or self-treatment.
- Is restricted to the approved geographic areas.

⚠ 5 Cautions

- The DeepPsy Report must be used only when requested and interpreted by a physician or psychiatric/medical institutions.
- The DeepPsy Report must be used 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.
- The DeepPsy Report must be used only when the EEG and ECG data from which this report is generated come from certified medical device amplifiers.
- The DeepPsy Report can be used if the requesting doctor has reviewed the EEG and ECG data for neurological or cardiac pathologies or the influence of medications.

6 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.
- Using EEG/ECG data that does not meet the specified quality requirements may lead to unreliable results. Only certified recording machines are supported.

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

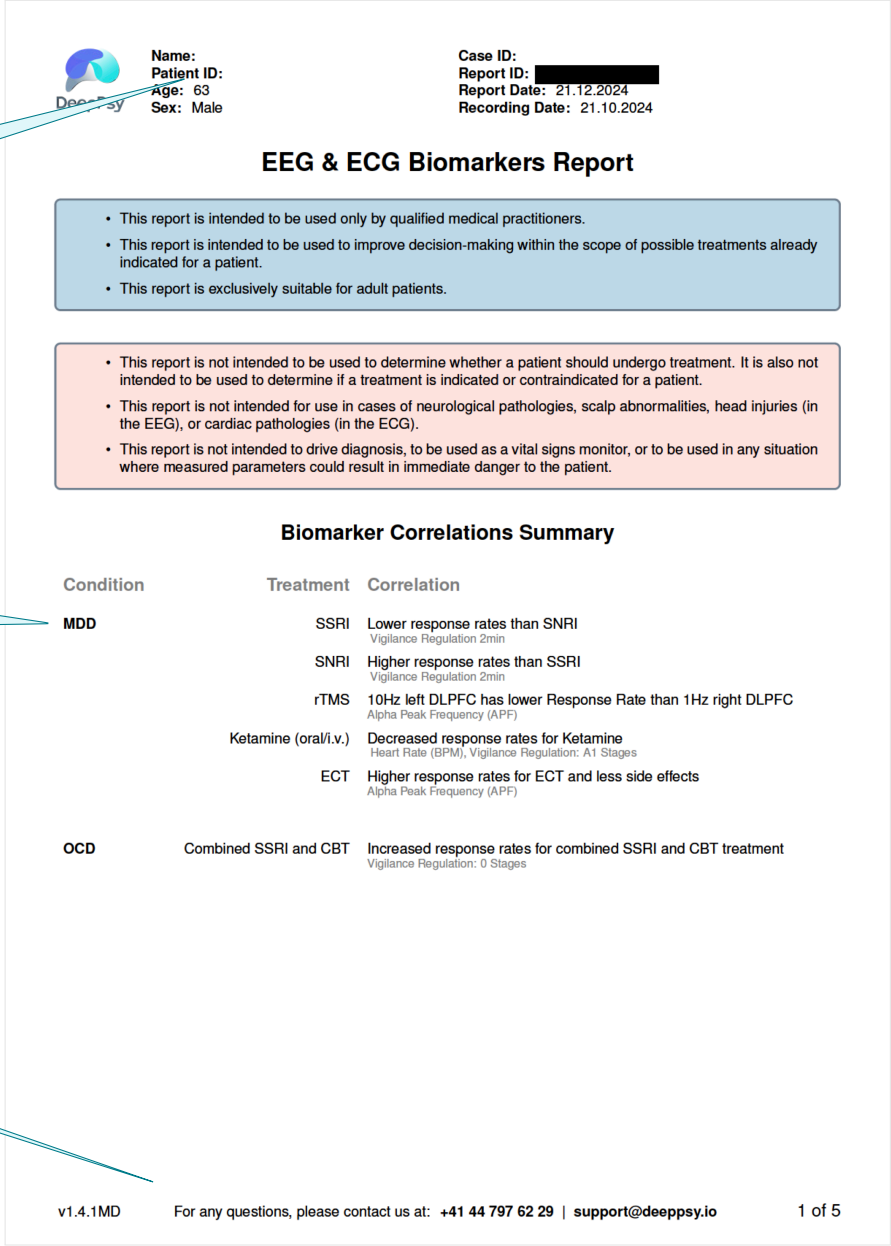
This section breaks down the DeepPsy report page by page, explaining the key components and their significance.

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: [redacted]
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 Vigilance Regulation 2min
	SNRI	Higher response rates than SSRI Vigilance Regulation 2min
	rTMS	10Hz left DLPFC has lower Response Rate than 1Hz right DLPFC Alpha Peak Frequency (APF)
	Ketamine (oral/i.v.)	Decreased response rates for Ketamine Heart Rate (BPM), Vigilance Regulation: A1 Stages
	ECT	Higher response rates for ECT and less side effects Alpha Peak Frequency (APF)
OCD	Combined SSRI and CBT	Increased response rates for combined SSRI and CBT treatment Vigilance Regulation: 0 Stages

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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).

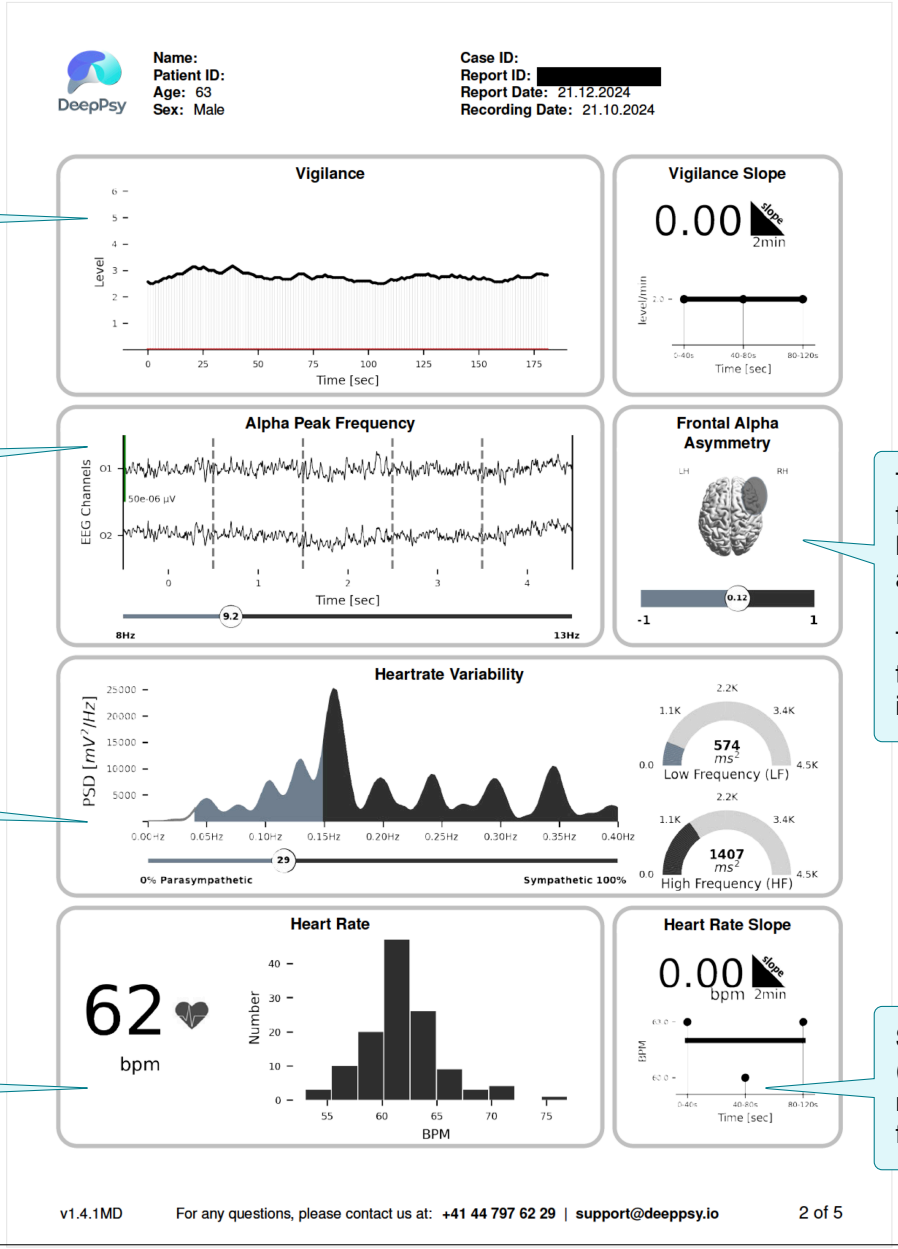
The slope is the value that has predictive clinical implications.

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.

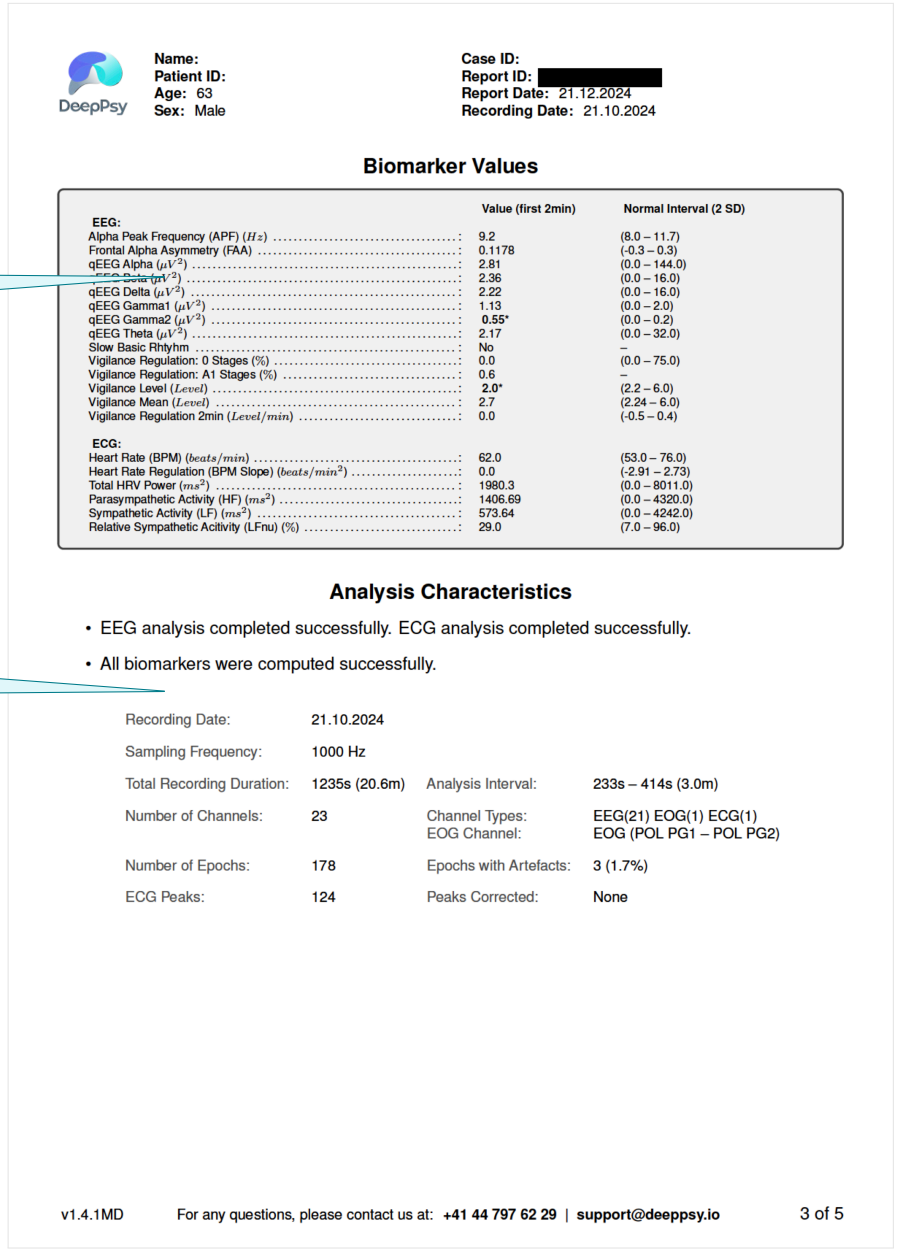
8.3 Page 3: Biomarker Values and Analysis Characteristics

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, theyre shown here. Additionally, if theres any information from the analysis that is important for the interpretation of the results, itll be shown here as well.



DeepPsy

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)	2.36	(0.0 – 16.0)
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 Rhtyhm	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)	Analysis Interval:	233s – 414s (3.0m)
Number of Channels:	23	Channel Types: EOG Channel:	EEG(21) EOG(1) ECG(1) EOG (POL PG1 – POL PG2)
Number of Epochs:	178	Epochs with Artefacts:	3 (1.7%)
ECG Peaks:	124	Peaks Corrected:	None

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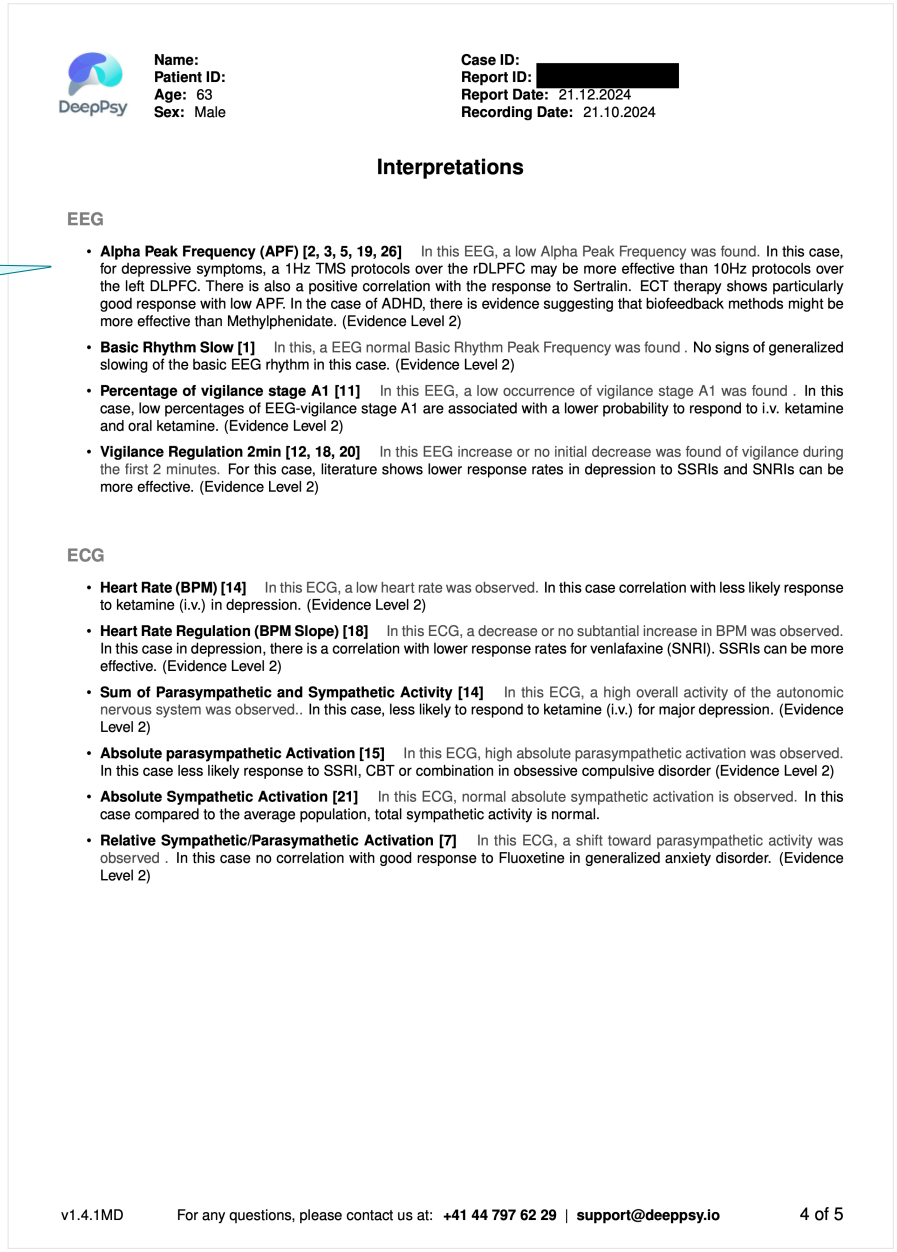
8.4 Page 4: Interpretations

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.



DeepPsy

Name:
Patient ID:
Age: 63
Sex: Male

Case ID:
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 subtantial 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/Parasymathetic 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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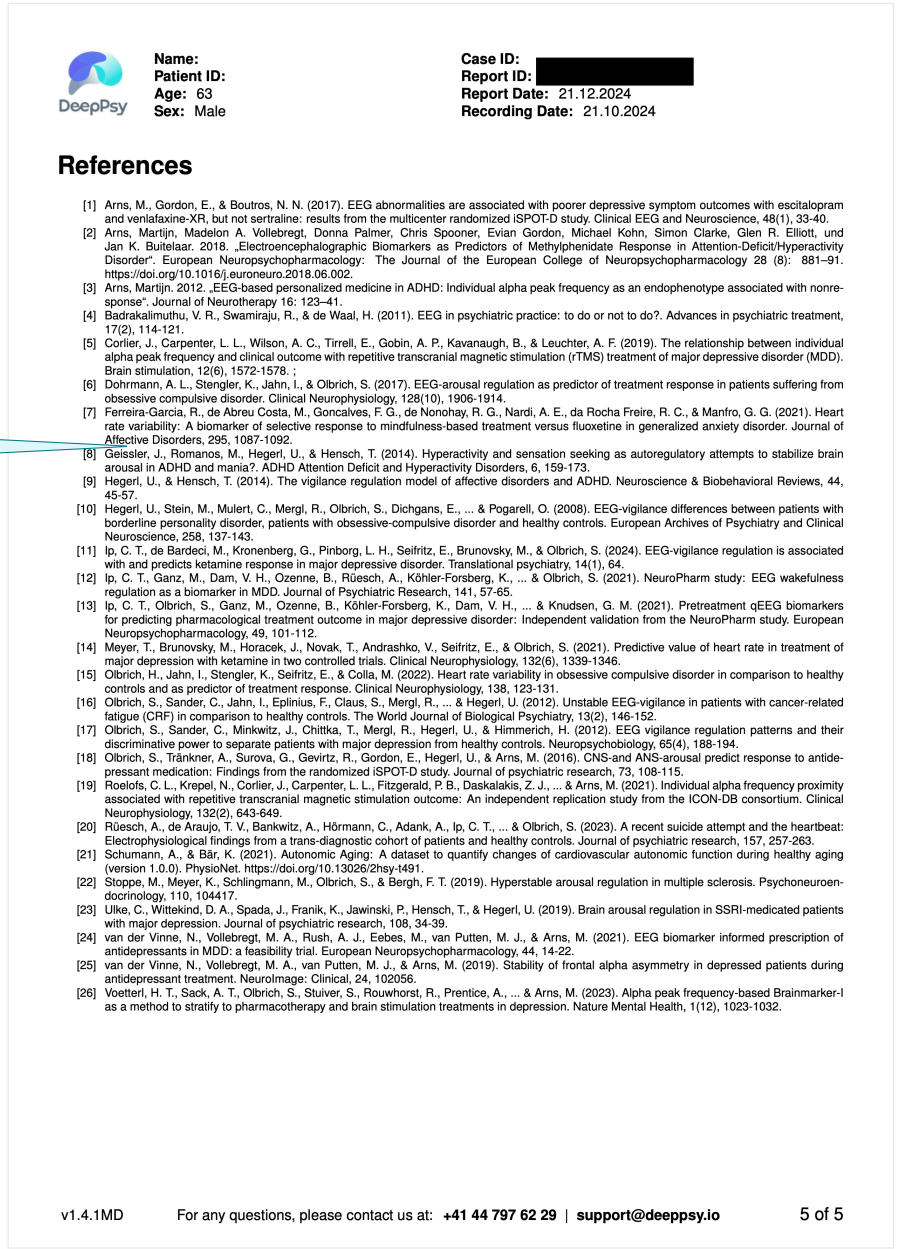
8.5 Page 5: References

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:
Patient ID:
Age: 63
Sex: Male

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

References

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[13] Ip, C. T., Olbrich, S., Ganz, M., Ozenne, B., Köhler-Forsberg, K., Dam, V. H., ... & Knudsen, G. M. (2021). Pretreatment qEEG biomarkers for predicting pharmacological treatment outcome in major depressive disorder: Independent validation from the NeuroPharm study. European Neuropsychopharmacology, 49, 101-112.
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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.