宏智生醫科技股份有限公司
HippoScreen Neurotech Corp

憂可視腦波壓力評估系統

Stress EEG Assessment System

Product Brochure

It's all about your brain.

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Introduction

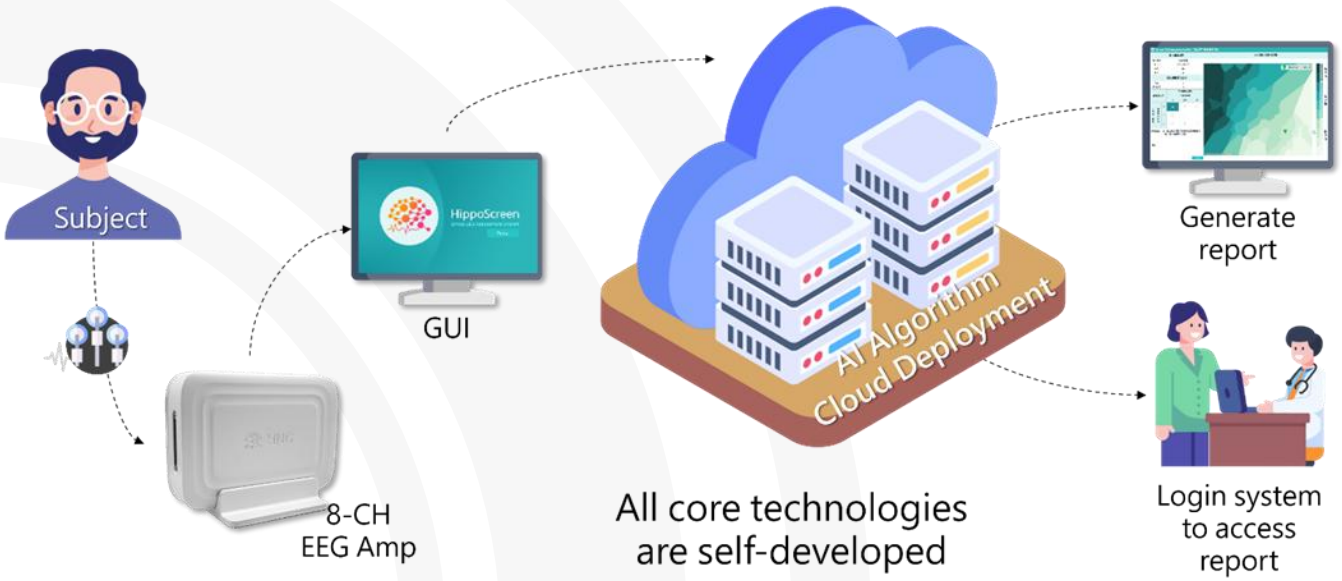
Depression affects 300 million people worldwide and is a leading cause of disability and disease burden. Though effective treatments exist, diagnosis is often delayed or missed. Research indicates that about 70% of patients report only physical symptoms like chest tightness, palpitations, or unexplained pain, and 10% even deny psychological issues entirely. This leads to multiple specialist referrals, causing delays and increased healthcare costs before depression is correctly diagnosed and treated. Low awareness and stigma remain major barriers to timely diagnosis and treatment.

Depression is currently diagnosed through subjective methods like self-reports and clinical interviews. Objective, physiological assessments could help identify cases lacking insight, enable better referrals, and reduce stigma by framing depression as a medical condition rather than personal failure.

The Product

The Stress EEG Assessment (SEA) system developed by HippoScreen Neurotech includes an EEG amplifier for data collection and signal processing, a GUI for test process control, and an AI algorithm for data analysis. It records 90-second brainwave signals to analyze with proprietary AI algorithm, and generates an objective stress index score and intuitive data distribution maps in the assessment report. The SEA system can screen individuals—even those lacking insight—and delivers objective, physiology-based risk scores, making it a powerful AI tool for mental health screening and clinical support.

System Architecture



The EEG amplifier (EAmp) suppresses noise and amplifies the subject's brainwave signal, performs analog-to-digital conversion, and then transmits it to the computer. The GUI provides user-friendly operation for the detection process, while data analysis is done through AI algorithms deployed on the cloud. The assessment report generated is also stored in the cloud database. The administrator can log in to the report website to access the results.

Detection Process

1 Wear EEG Cap

2 Fill in basic info
& PHQ-9 questionnaire (optional)

3 Apply gel into electrodes

4 Gaze at the cross on the screen
for 90 seconds

The detection process is simple and takes only 15–20 minutes, including setup and report generation.

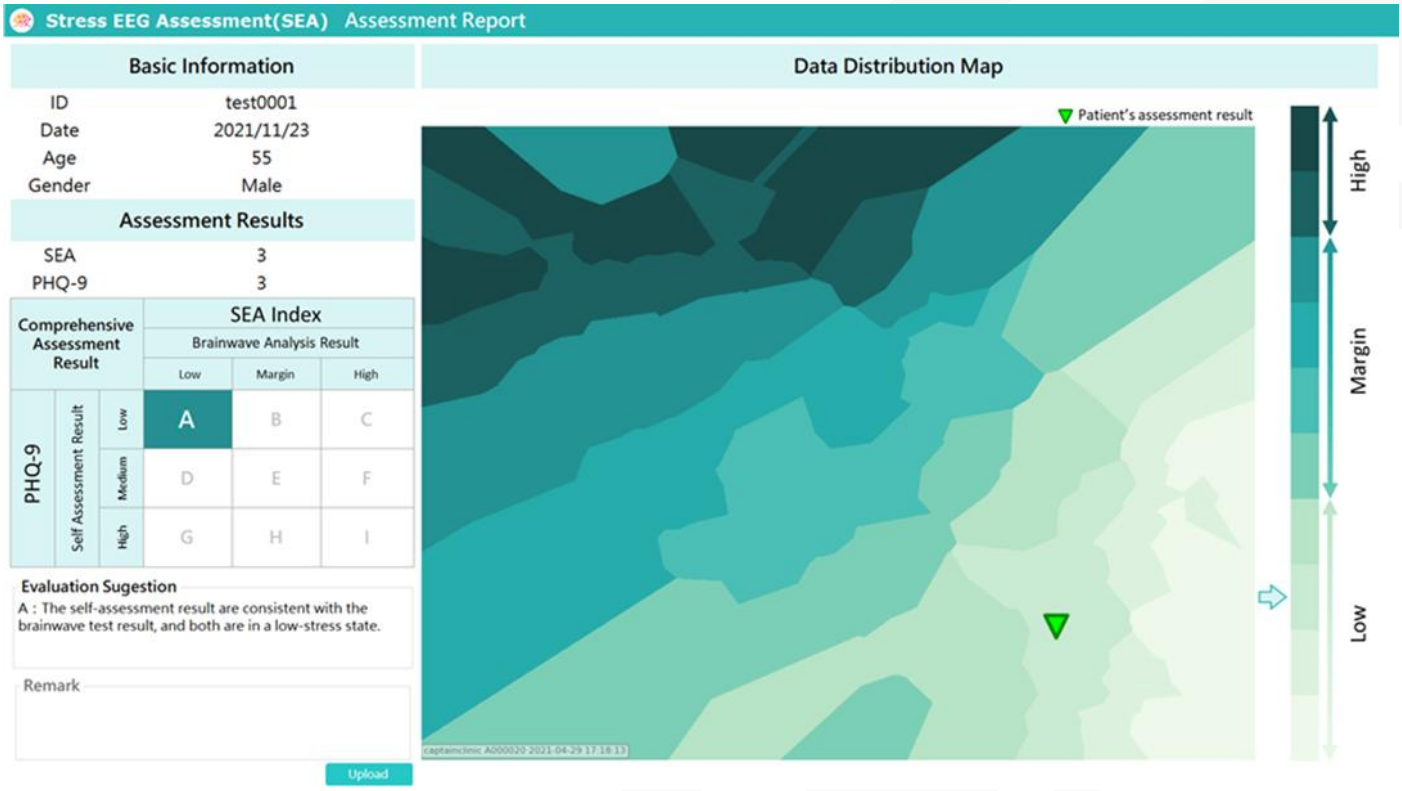
First, the operator fits the EEG cap and guides the subject to complete basic info and the optional PHQ-9 self-assessment. Conductive gel is applied to reduce the impedance and ensure the EEG signal quality. Once set up, the subject simply relaxes and looks at a display for 90 seconds while EEG data is recorded. The system then analyzes the data and generates an assessment report.

Actual Scene

Because EEG is sensitive to interference, it's best conducted in a quiet, separate room.

During the 90-second recording, sudden loud noises or flickering lights should be avoided, as they may affect the results. While the system includes noise-reduction features and indicates whether the data quality is sufficient for analysis, minimizing external interference during the recording is recommended.

Assessment Results



The data distribution map on the right side is generated using brainwave data from an IRB-approved study with three Taiwanese medical centers, combined with the subject's EEG data for features extraction and analysis.

Color intensity corresponds to the SEA index (1–10), indicating depression risk. The green dot represents the test subject—darker areas around it suggest higher stress levels.

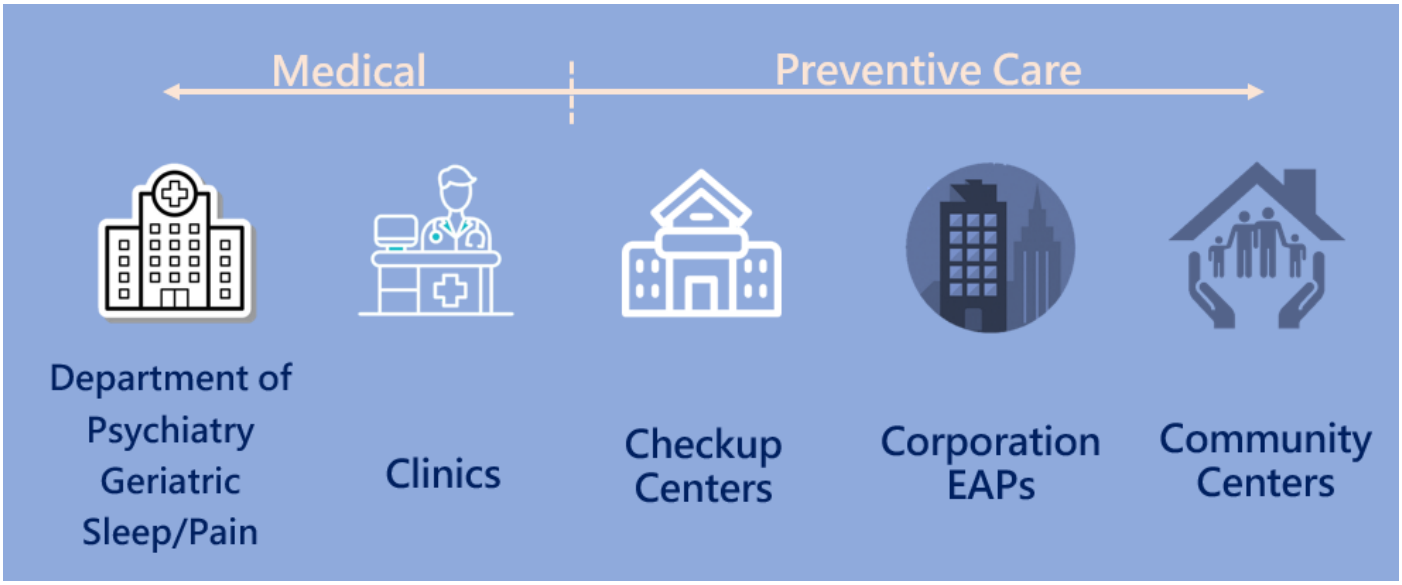
As for the nine-grid table on the left, it is a two-dimensional comprehensive evaluation of self-assessed result (the PHQ-9 score) versus the physiological result (the SEA index from the brainwave

analysis). Through this evaluation, it can help professionals to understand the mental state of the subjects more comprehensively and accurately.

These results are included in a 16-page report booklet that includes background knowledge on depression and EEG, an individualized SEA score and recommendation, and visualized brainwave raw data.

USAGE

The SEA system has both medical and non-medical applications.



Regulatory Approval

The EEG amplifier is cleared by both USA FDA and Taiwan FDA. The SEA software is approved software as medical device (SaMD) by Taiwan FDA.

衛生福利部醫療器材許可證

衛部醫器製字第 007081 號

案卷文件號碼：DHA05500708106

中文名稱：“宏智”腦波描記器

英文名稱：“HNC” 8-CH Electroencephalography Amplifier

類　　別：第K類：神經學科用裝置

規　　格：EAmp-0001
以下空白

廠商名稱：宏智生醫科技股份有限公司

製造廠名稱：宏智生醫科技股份有限公司
委託仁寶電腦工業股份有限公司平鎮廠製造

製造廠地址：桃園市平鎮區南勢里南東路8號1、2樓及8之1號1、2、3、4、5樓

效　　能：詳如中文仿單核定本

處　　方：空白

前項醫療器材經本部審核與藥事法之規定相符應發給許可證以資證明

衛生福利部部長

陳時中

發證日期 110 年 03 月 06 日

有效日期 115 年 03 月 06 日

MF 013714

衛生福利部醫療器材許可證

衛部醫器製字第 008104 號

中文品名：“宏智生醫”量可視腦波壓力評估系統

英文品名：“HippoScreen” Stress EEG Assessment System

類　　別：第K類：神經科學

醫器材商名稱：宏智生醫科技股份有限公司

規格或型號：SEA-0001
以下空白

製造業者名稱：宏智生醫科技股份有限公司

製造業者地址：台北市內湖區瑞光路 578 號 2 樓

效能、用途或適應症：輔助診斷疑似有無罹症的軟體醫材(SaMD)，透過演算法分析取出腦波描記器所量測腦波數據中的時域與頻域特徵，並產生量化指標(SEA Index)，提供給專業醫事人員作為診斷參考，此系統僅供專業醫事人員在臨床工作流輔助診斷疑似有無罹症的參考，不能取代專業醫事人員之判斷。

前項醫療器材經本部審核與醫療器材管理法之規定相符應發給許可證以資證明

衛生福利部部長

薛瑞元

發證日期 112 年 10 月 13 日

有效日期 117 年 10 月 13 日

MF 017365

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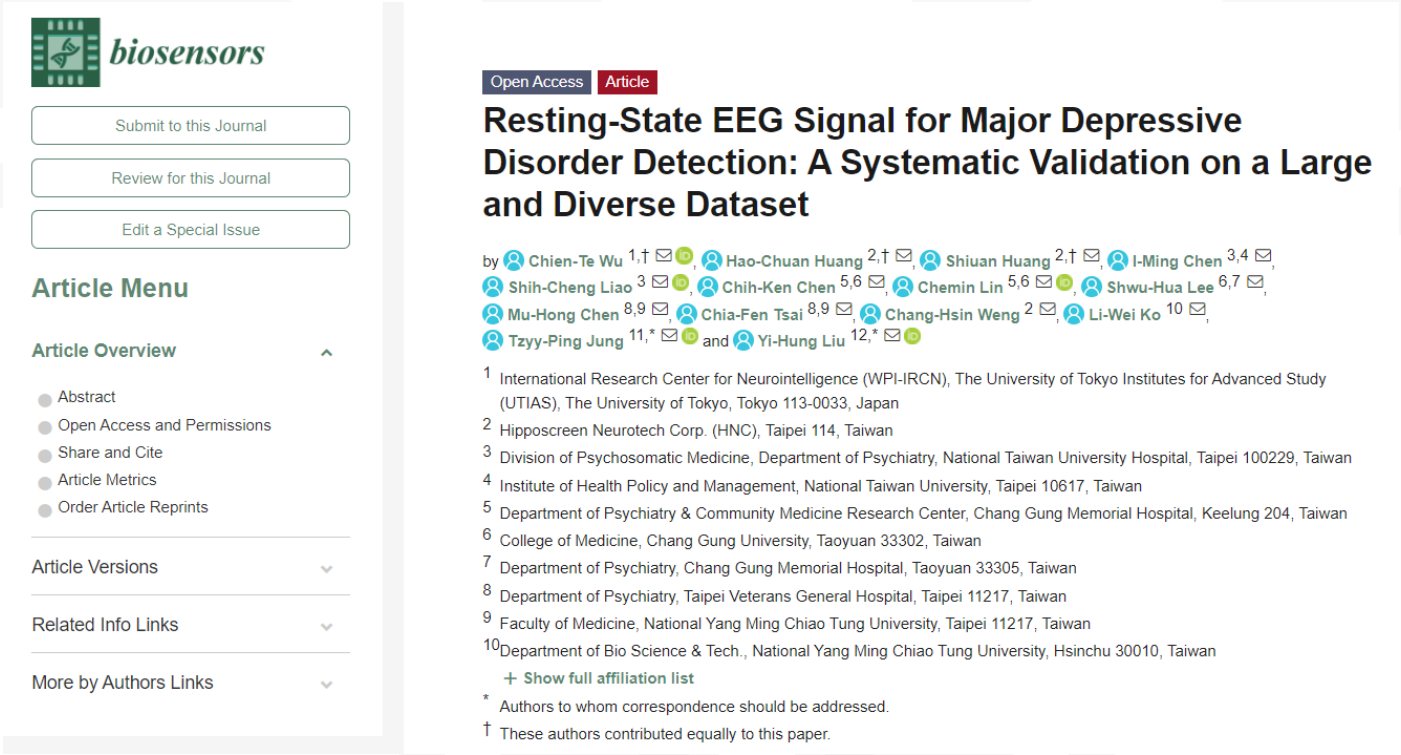
Device Classification Name	Amplifier, Physiological Signal
510(K) Number	K201747
Device Name	8-CH Electroencephalography Amplifier
Applicant	HippoScreen Neurotech Corp. 2F., No. 578, Ruiguang Rd., Neihu District Taipei City, TW 11492
Applicant Contact	William Lan
Correspondent	HippoScreen Neurotech Corp. 2F., No. 578, Ruiguang Rd., Neihu District Taipei City, TW 11492
Correspondent Contact	William Lan
Regulation Number	882.1835
Classification Product Code	GWL
Subsequent Product Code	OMC
Date Received	06/26/2020
Decision Date	12/27/2020
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Published Paper



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Open Access Article

Resting-State EEG Signal for Major Depressive Disorder Detection: A Systematic Validation on a Large and Diverse Dataset

by Chien-Te Wu [1,†], Hao-Chuan Huang [2,†], Shiuan Huang [2,†], I-Ming Chen [3,4], Shih-Cheng Liao [3], Chih-Ken Chen [5,6], Chemin Lin [5,6], Shwu-Hua Lee [6,7], Mu-Hong Chen [8,9], Chia-Fen Tsai [8,9], Chang-Hsin Weng [2], Li-Wei Ko [10], Tzyy-Ping Jung [11,*] and Yi-Hung Liu [12,*]

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9 Faculty of Medicine, National Yang Ming Chiao Tung University, Taipei 11217, Taiwan
10 Department of Bio Science & Tech., National Yang Ming Chiao Tung University, Hsinchu 30010, Taiwan

+ Show full affiliation list

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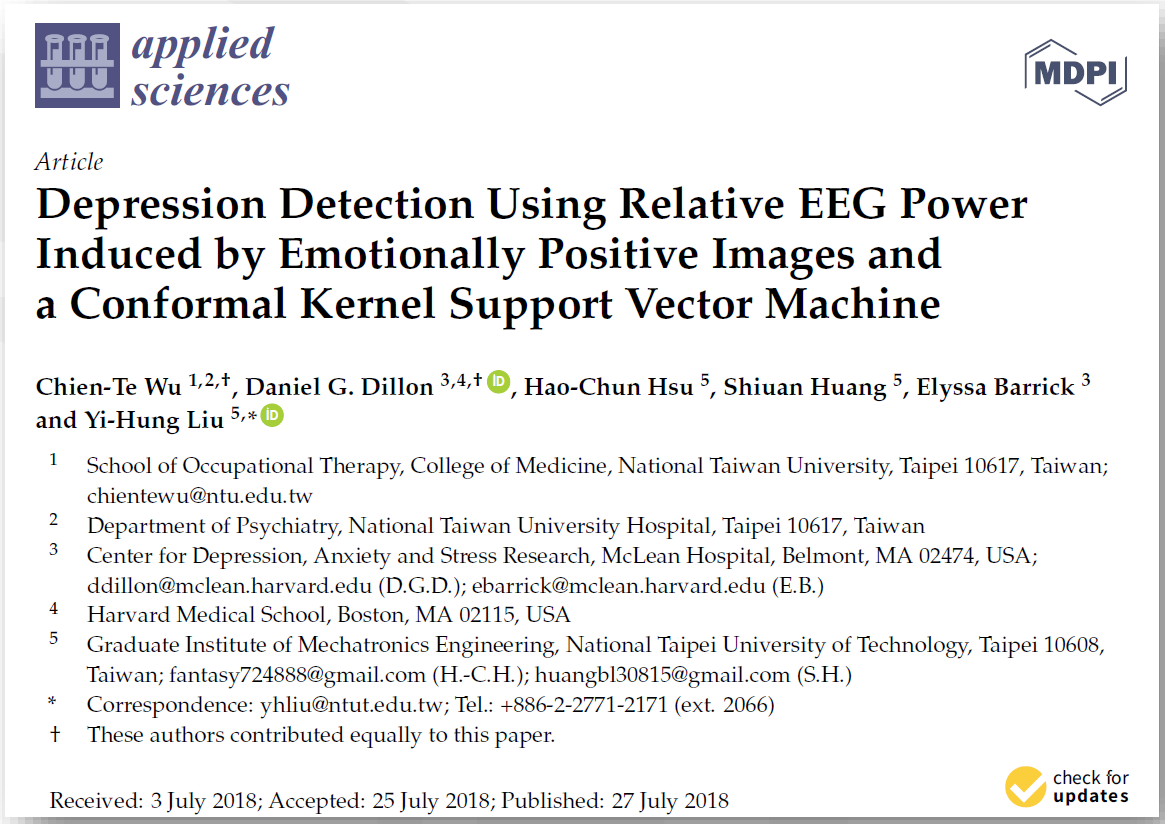
† These authors contributed equally to this paper.

Collaboration with 3 medical centers (4 sites) in Taiwan to collect the biggest multi-site EEG depression dataset in the world. The optimal feature subset and classifier achieve a high five-fold cross-validation accuracy of 91.07% on the training set (140 MDD and 140 HC) and 84.16% on the independent test set (60 MDD and 60 HC). This paper was published in biosensors in December 2021.



applied sciences

MDPI

Article

Depression Detection Using Relative EEG Power Induced by Emotionally Positive Images and a Conformal Kernel Support Vector Machine

Chien-Te Wu [1,2,†], Daniel G. Dillon [3,4,†], Hao-Chun Hsu [5], Shiuan Huang [5], Elyssa Barrick [3] and Yi-Hung Liu [5,*]

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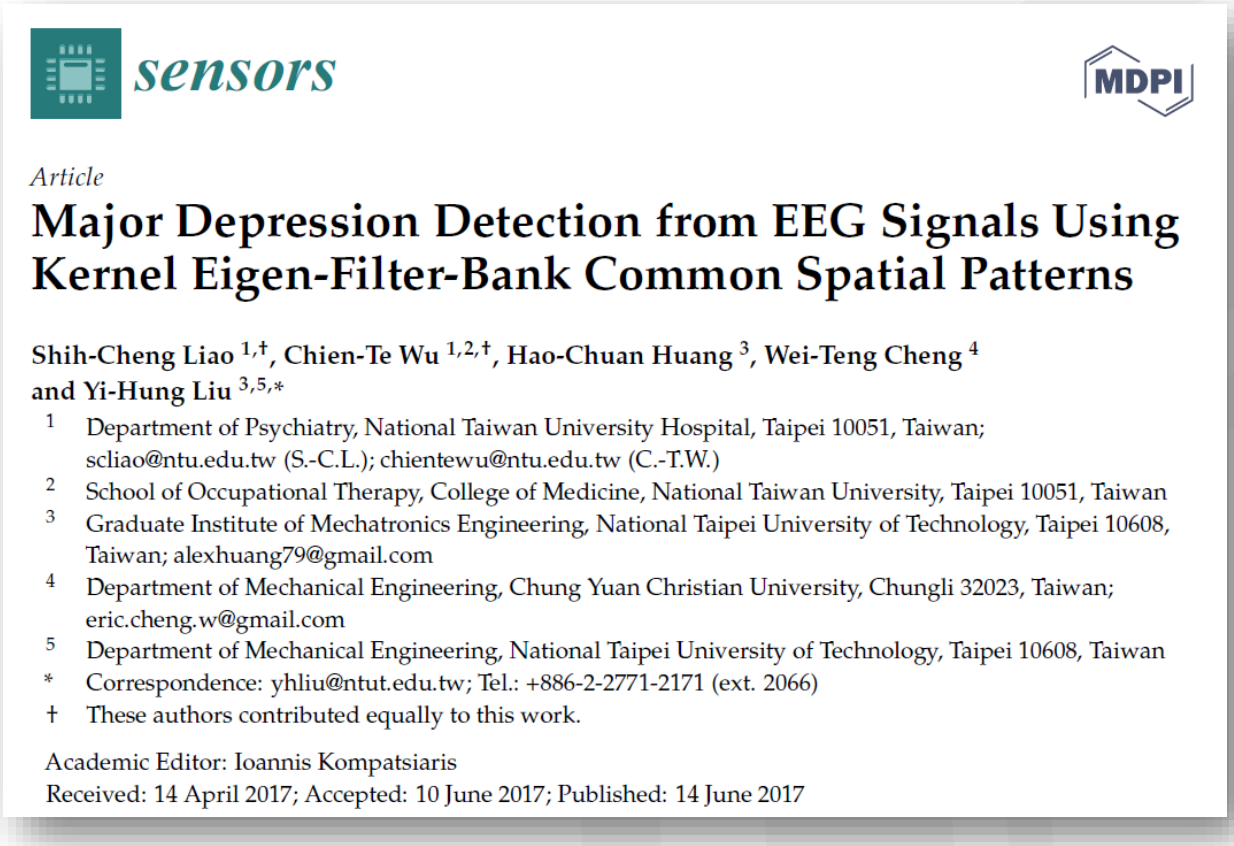
Collaboration with Dr. Daniel G. Dillon (Harvard Medical School & McLean Hospital) on depression detection from EEG signals. The experiment result (Sensitivity = 87.50%, Specificity = 80.65%) was published in applied sciences in July 2018.



sensors

MDPI

Article

Major Depression Detection from EEG Signals Using Kernel Eigen-Filter-Bank Common Spatial Patterns

Shih-Cheng Liao [1,†], Chien-Te Wu [1,2,†], Hao-Chuan Huang [3], Wei-Teng Cheng [4] and Yi-Hung Liu [3,5,*]

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Collaboration with Dr. Shih-Cheng Liao (Department of Psychiatry, National Taiwan University Hospital) on depression detection from EEG signals. The experiment result achieved 81.23% accuracy (Sensitivity = 83%, Specificity = 81%) and was published in Sensors.