PART

SUBJECT: PERSYST 15 QUICK REFERENCE GUIDE FOR A REDUCED SET OF ELECTRODES AND THE PROVIDED SEIZURE BURDEN TREND

This Part is a controlled document. Users are required to ensure they have the most current version by obtaining updates from the manufacturer.

SCOPE

This Quick Reference Guide refers to Persyst 15 Seizure Detection using a reduced set of electrodes and the provided Seizure Burden trend. A complete Instructions For Use is available under the information below.

SYMBOLS AND WARNINGS

SYMBOL	DEFINITION
REF	Product name
Rx Only	Prescription Use Only
	Caution, consult accompanying documents
	Consult Instructions For Use
	Manufacturer

Rx Only

Federal law restricts this device to sale by or on the order of a physician or a licensed healthcare practitioner.

REF Persyst 15 EEG Review and Analysis Software

 WARNING: Since Persyst 15 seizure detection has not been tested with patients under 18 years old, we recommend that you verify the automatic seizure detections with another method.

 Consult Instructions For Use
{Request Instructions for Use - Persyst}
https://www.persyst.com/request-instructions-for-use/


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INTENDED USE

Persyst 15 EEG Review and Analysis Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices to aid neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information.

INDICATIONS FOR USE

The Seizure Detection component of Persyst 15 is intended to mark previously acquired sections of the adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained using reduced set of electrodes including Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2, but with respect to full montage electrode set, it will have decreased sensitivity for seizures due to its limited spatial sampling.

SYSTEM REQUIREMENTS

Persyst 15 Seizure Detection using reduced set of electrodes and seizure burden shall be available as an application library on an Android platform with the following minimum requirements:

Android 8.0 (API Level 26)
Processor: Qualcomm SDA660 (up to 2.2GHz)
Memory: 4 GB LPDDR4X

PERFORMANCE DATA

{Adult seizure detection, reduced set of electrodes}

Seizure detection algorithm, designed to utilize data acquired from a reduced array of EEG electrodes (Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2), is intended to assist qualified practitioners in the assessment of the EEG. Because the use of a reduced electrode array can result in some loss of sensitivity and specificity for detecting seizures compared to full 10-20 EEG recordings, clinicians must weigh the benefits of the reduced electrode approach against its potential limitations to determine whether to utilize a reduced recording array during the care of an individual

The overall observed sensitivity (total number of true algorithm detections divided by the total number of seizures, with number of seizures per subject down sampled to six) was 0.753. 95% confidence interval of the detection sensitivity, based on 3000 bootstrap

replicates using BCa (bias corrected and accelerated) method, was [0.688,0.813].
In the test dataset, seizure detection performed with a mean false detection rate of 0.989 per 24 hours, with its bootstrap standard error equal to 0.293. The 95% BCa bootstrap confidence interval (number of bootstrap re-sampling = 3,000) of the P14 false detection rate = [0.551, 1.789].

	Probability Threshold	Duration Threshold	Sensitivity	Sensitivity -95%	Sensitivity +95%	FP/Day	FPD -95%	FPD +95%
Default	0.5	10	0.851	0.777	0.909	0.989	0.551	1.789

The table below shows sensitivity and false detection rates at the default threshold settings.

Adult seizure detection, reduced electrode set at recommended default setting:
Sensitivity = 85.1 % FP Rate = 0.99/24 hrs

{Seizure Burden Trend}

In conjunction with the reduced set of electrodes, the seizure burden trend was calculated on the previous five-minute period every ten seconds. The results were calculated and displayed 400 seconds after the end of the relevant period, or at the end of the record, whichever came first.

The results are displayed in a value from 1 to 3, where the values have the following meaning:

1) >= 30 and < 150 seconds of seizures. {Frequent}
2) >= 150 seconds and <= 270 seconds of seizures. {Abundant}
3) >= 270 seconds of seizures. {Continuous}

Event sensitivity and event positive rate for each category of Seizure Burden 1-3:

The following table was computed by averaging the sensitivity by patient. This standard methodology removes biases that can be caused by single patients having particularly high or low sensitivity, or patients having particularly high or low false positive rates.

Seizure Burden	Event Sensitivity	Number of Records	Sensitivity 95% CI	FP/hr	N	FP/hr 95% CI
1	93.8%	73	87.6-97.0%	0.192	85	0.140-0.266
2	88.7%	24	70.8-96.5%	0.255	85	0.182-0.530
3	98.7%	13	93.6-100.0%	0.075	85	0.043-0.146

where Number of Records is the number of records used for the sensitivity calculation

(only records with expert marked events were included in the calculation), all 85 records were used for the average false positive calculation.
The total duration of all records was 441.547 hours. The following table is calculated by looking at all events across all patients, and a false positive rate across all the records.

Seizure Burden	Event Sensitivity	Sensitivity 95% CI	FP/hr	FP/hr 95% CI	TP	FP	FN	NE
1	89.7%	83.9 - 93.1%	0.186	0.152 - 0.215	156	82	18	174 (94ICU, 74EMU,6AMB)
2	73.2%	58.9 - 82.1%	0.224	0.195 - 0.242	41	99	15	56 (39 ICU, 17 EMU)
3	94.7%	73.7 - 100.0%	0.057	0.039 - 0.068	18	25	1	19 (12 ICU, 7 EMU)

TP: True positive / FP: False Positive / FN: False Negative / NE: Total number of experts marked events

The Seizure Burden Trend is computed using the seizure probability output of the Persyst seizure detector. It is designed to match expert markings of the prevalence of seizure during five minute epochs. While it is highly correlated with seizure detections, which also uses the output of the seizure probability output of the Persyst seizure detector it does not use the specific cutoffs used to mark discrete seizures. The level of seizure burden in a given epoch will therefore not necessarily be equal to a simple arithmetic sum of the duration of the seizure detections that overlap or are contained within an epoch.

Note: As the seizure burden level increases, there may be increasing uncertainty in the device sensitivity at the event-level, with the lower bound of the 95% C.I. for category 2 as 58.9% and for category 3 as 73.7%, both much lower than for category 1 at 83.9%.