AI FOR EVENT DETECTION

REMIVIGILENZ™

Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Product Description

REMI Vigilenz™ AI for Event Detection will analyze previously collected 4-channel data from patients equipped with the REMI™ Remote EEG Monitoring System for identification of discrete electrographic seizure events lasting ≥10 seconds. REMI Vigilenz AI for Event Detection will annotate these neurological events of interest within a compatible REMI EEG file and electronically annotate the start/end points of that event in such a way that it is visible to the physicians qualified to analyze and interpret EEG when viewed using a qualified EEG viewing software.

Clinical Study

EEG data from adult and pediatric patients was used to 1) train the REMI Vigilenz AI for Event Detection to identify potential electrographic seizure events in a broad patient population, and 2) validate the REMI Vigilenz AI for Event Detection's ability to identify potential electrographic seizure events within an indicated patient population.

Patients at these sites wore REMI wireless EEG sensors at bilateral frontal and temporoparietal scalp sites alongside standard-of-care 19-channel, full-montage, video-EEG for up to 7 continuous days in Epilepsy Monitoring Units (EMUs) or for up to 3 continuous days during at-home ambulatory EEG monitoring.

The REMI Vigilenz AI for Event Detection validation data set consisted of 31 patient records with 87 consensus-determined electrographic seizures lasting at least 10 seconds in duration, and 19 patient records with no consensus-determined electrographic seizures, for a total validation sample size of 50. All attempts were made to ensure diverse patient demographics. The consensus-determined electrographic seizures represented in the validation data set include:

- Focal Seizures
- Focal Evolving To Generalized Seizures
- Generalized Seizures

Clinical Reference

EEG data used to generate a reference standard for REMI Vigilenz AI for Event Detection was collected from standard 19+channel wired 10-20 montage EEG records acquired concurrently with REMI 4-channel EEG. Prior to inclusion in the validation data set, all patients' EEG records underwent panel review by 3 independent expert epileptologists. Experts consisted of a panel of 6 epileptologists, holding certification by the American Board of Psychiatry and Neurology or certification by the American Board of Clinical Neurophysiology with Special Competency in Epilepsy Monitoring. Consensus ground truth electrographic seizures and seizure negative determinations were made using the wired EEG records when at least 2 of 3 members identified the presence or absence of an electrographic seizure event.

Training and Clinical Reference Data Overview

Demographics by age are presented in Table 1 below.

Table 1. Demographics By Age. “Train” is the set of patient records used to train the algorithm, “Test” is the set of patient records used in this validation analysis. (Sz: Seizure patients; No-Sz: Non-seizure patients)

Age	Train	Train Sz	Train No-Sz	Test	Test Sz	Test No-Sz
Pediatric (≤21)	43 (40%)	31 (42%)	12 (34%)	24 (48%)	13 (42%)	11 (58%)
Adult (22+)	65 (60%)	42 (58%)	23 (66%)	26 (52%)	18 (58%)	8 (42%)
Total	108	73	35	50	31	19

Demographics by gender are presented in Table 2 below.

Table 2. Demographics By Gender. “Train” is the set of patient records used to train the algorithm, “Test” is the set of patient records used in this validation analysis. (Sz: Seizure patients; No-Sz: Non-seizure patients)

Gender	Train	Train Sz	Train No-Sz	Test	Test Sz	Test No-Sz
Male	46 (43%)	32 (44%)	14 (40%)	26 (52%)	17 (55%)	9 (47%)
Female	62 (57%)	41 (56%)	21 (60%)	24 (48%)	14 (45%)	10 (53%)
Total	108	73	35	50	31	19

Demographics by EEG monitoring environment are presented in Table 3 below.

Table 3. Demographics By Monitoring Environment. “Train” is the set of patient records used to train the algorithm, “Test” is the set of patient records used in this validation analysis. (EMU: Epilepsy Monitoring Unit environment; Ambulatory: Ambulatory environment; Sz: Seizure patients; No-Sz: Non-seizure patients)

Environment	Train	Train Sz	Train No-Sz	Test	Test Sz	Test No-Sz
EMU	85 (79%)	59 (81%)	26 (74%)	38 (76%)	27 (87%)	11 (58%)
Ambulatory	23 (21%)	14 (19%)	9 (26%)	12 (24%)	4 (13%)	8 (42%)
Total	108	73	35	50	31	19

A summary of electrographic seizure types included in REMI Vigilenz AI training and validation is presented in Table 4 below.

Table 4. Electrographic Seizure Type Count. “Train” is the set of patient records used to train the algorithm, “Test” is the set of patient records used in this validation analysis.

Seizure Type	Train	Test
Focal	254 (45%)	22 (25%)
Focal Evolving To Generalized	39 (7%)	35 (40%)
Generalized	269 (48%)	30 (34%)
Total	562	87

A summary of the duration of seizure record data, broken down by electrographic seizure type, is presented in Table 5 below.

Table 5. Duration of Seizures by Electrographic Seizure Type. “Train” is the set of patient records used to train the algorithm, “Test” is the set of patient records used in this validation analysis.

	Focal		Focal Evolving To Generalized		Generalized	
Duration (s)	**Train**	**Test**	**Train**	**Test**	**Train**	**Test**
<10	9 (4%)	0 (0%)	0 (0%)	0 (0%)	76 (28%)	0 (0%)
10-20	51 (20%)	4 (18%)	0 (0%)	0 (0%)	100 (37%)	14 (47%)
21-40	80 (31%)	1 (5%)	0 (0%)	0 (0%)	40 (15%)	7 (23%)
41-60	45 (18%)	7 (32%)	5 (13%)	2 (6%)	43 (16%)	2 (7%)
61-80	25 (10%)	7 (32%)	6 (15%)	6 (17%)	6 (2%)	3 (10%)
81-100	15 (6%)	1 (5%)	10 (26%)	5 (14%)	3 (1%)	2 (7%)
101-120	9 (4%)	1 (5%)	3 (8%)	10 (29%)	1 (0%)	1 (3%)
121+	20 (8%)	1 (5%)	15 (38%)	12 (34%)	0 (0%)	1 (3%)
Total	254	22	39	35	269	30

Product Performance

REMI Vigilenz AI for Event Detection was evaluated through validation against a combined primary endpoint of Sensitivity > 70% and of a False Alarm Rate (FAR) < 0.35 False Positives (FP)/hr. REMI Vigilenz AI for Event Detection clinical validation testing demonstrated that REMI Vigilenz AI for Event Detection achieved Event-Level Sensitivity > 70% (with a calculated 95% Confidence Interval (CI) lower bound of 79.5%) and FAR < 0.35 FP/hr (with a calculated CI upper bound of 0.221 FP/hr).

Across all 31 patients with seizures, the event-level Sensitivity was 86.2%. The Mean Per-Patient Sensitivity was determined to be 92.2%, with a 95% CI Lower Bound of 86.5%, and ranged between 50% to 100%. Per-Patient Sensitivity was 100% for 23 of the 31 patients. At least one known event was detected for all 31 patients with seizures.

Across all 50 patients, the event-level FAR was 0.162 FP/hr (with 415 FP for 2,562.5 hours of data). The Mean Per-Patient FAR was determined to be 0.176 FP/hr, with a 95% CI Upper Bound of 0.230, and ranged between 0 to 0.929 FP/hr. There were 17 patients with FARs ≤ 0.08 FP/hr, 8 patients with no more than one FP (including 4 non-seizure patients), and 4 patients with no FP, including 2 non-seizure patients.

Sensitivity by age group and FAR by age group are presented in Table 6 below.

Table 6. Sensitivity and False Alarm Rate by Age Group (pediatric vs. adult).

Parameter	Pediatric (6-21 years)	Adult (22+ years)
Sensitivity		
Subjects with Seizures	n = 13	n = 18
Event-level Sensitivity	83.0%	90.0%
95% Confidence Interval	73.1, 93.3	81.5, 100.0
Subject-level Sensitivity	87.8%	95.5%
95% Confidence Interval	77.0, 97.0	90.0, 100.0
False Alarm Rate (FAR)		
Total Subjects	n = 24	n = 26
Event-level FAR	0.227 FP/hr	0.131 FP/hr
95% Confidence Interval	0.131, 0.335	0.085, 0.197
Subject-level FAR	0.223 FP/hr	0.132 FP/hr
95% Confidence Interval	0.146, 0.316	0.088, 0.190

Sensitivity by monitoring environment and FAR by monitoring environment are presented in Table 7 below.

Table 7. Sensitivity and False Alarm Rate by Monitoring Environment (EMU vs. Ambulatory environment). (EMU: Epilepsy Monitoring Unit environment; Ambulatory: Ambulatory environment)

Parameter	EMU	Ambulatory
Sensitivity		
Subjects with Seizures	n = 27	n = 4
Event-level Sensitivity	87.5%	80.0%
95% Confidence Interval	80.0, 94.4	71.0, 100.0
Subject-level Sensitivity	92.2%	92.5%
95% Confidence Interval	85.9, 97.3	77.5, 100.0
False Alarm Rate (FAR)		
Total Subjects	n = 38	n = 12
Event-level FAR	0.136 FP/hr	0.290 FP/hr
95% Confidence Interval	0.089, 0.194	0.170, 0.434
Subject-level FAR	0.138 FP/hr	0.294 FP/hr
95% Confidence Interval	0.096, 0.187	0.184, 0.440

Authorized Predetermined Change Control Plan (Authorized PCCP)

REMI Vigilenz AI for Event Detection has been cleared by the US FDA with an Authorized PCCP. The REMI Vigilenz AI for Event Detection Authorized PCCP outlines authorized modifications intended to improve algorithm performance through expansion of the training data and/or through optimizations of the algorithm.The Authorized PCCP outlines REMI Vigilenz AI's data management practices (i.e., how data is collected, annotated, curated, stored, retained, controlled, and used), re-training practices, how and when its

performance is evaluated.

The Authorized PCCP also defines validation requirements for all algorithm updates. Prior to release, modifications are validated through testing against a previously established validation data set as well as an updated validation data set. Updates to REMI Vigilenz AI for Event Detection will be implemented per the Authorized PCCP and through the Software Update process (described below), and will be communicated through updates to this document.

Safety Information

Please read, understand, and follow all safety information contained in these instructions prior to using REMI Vigilenz AI for Event Detection. Retain these instructions for future reference.

Indications for Use

REMI Vigilenz AI for Event Detection is indicated for the analysis of REMI Remote EEG Monitoring System electroencephalogram (EEG) recordings. REMI Vigilenz AI for Event Detection is intended to be used by physicians qualified to analyze and interpret EEG who will exercise professional judgment in using the information.

As an aide to the qualified physician's REMI EEG review, REMI Vigilenz AI for Event Detection marks previously acquired sections of REMI EEG that may correspond to neurological events of interest indicative of potential electrographic seizures lasting at least 10 seconds in duration. REMI Vigilenz AI for Event Detection is indicated for use with adult and pediatric patients (6+ years).

REMI Vigilenz AI for Event Detection does not mark REMI EEG records in real time and does not provide any diagnostic conclusion about the patient's condition to the user.

Contraindications

- REMI Vigilenz AI for Event Detection is not for use with EEG records gathered by standard wired montages and should only be used with EEG data gathered by the REMI Remote EEG Monitoring System.

Warnings

- REMI Vigilenz AI for Event Detection is not meant to be used as a standalone means of identifying seizure-like events in a REMI EEG record or of diagnosing a detected potential event as a true seizure. Qualified physician oversight is required.
- REMI Vigilenz AI for Event Detection has not been trained or validated on the records of any children under 6 years of age.

Precautions

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- If REMI EEG traces are incompatible or incomplete, REMI Vigilenz for Event Detection may not provide any output.
- REMI Vigilenz AI for Event Detection is trained to detect only discrete electrographic seizures lasting a minimum of ten seconds. The following seizure modalities are not included in REMI Vigilenz AI for Event Detection training: continuous seizures (e.g., status epilepticus), seizure clusters, very short duration seizures (e.g., single myoclonic seizures). While patients experiencing these seizure types may still be appropriate candidates for use of the REMI Remote EEG Monitoring System and REMI Vigilenz AI for Event Detection, these seizure types need to be confirmed independently.

Operator Profile

REMI Vigilenz AI for Event Detection operates using previously acquired EEG traces collected by the REMI Remote EEG Monitoring System, and can assist a qualified physician (i.e. a physician qualified to analyze and interpret EEG who will exercise professional judgment in using the information) in the review of REMI EEG records.

Operating Instructions

REMI Vigilenz AI for Event Detection, if enabled, will analyze previously acquired REMI EEG traces. REMI Vigilenz AI for Event Detection can assist qualified physicians in their review of REMI EEG records by highlighting sections of REMI EEG that may correspond to neurological events of interest indicative of potential electrographic seizures lasting at least 10 seconds in duration, which qualified physicians can then review for relevance.

Viewing REMI Vigilenz AI for Event Detection Outputs

Once analysis is complete, REMI Vigilenz AI for Event Detection annotations are appended to the REMI EEG record file. The full REMI EEG record remains available to give context to the sections marked by REMI Vigilenz AI and to permit identification of other potential electrographic seizure events within the broader record. Qualified physicians using REMI Vigilenz AI for Event Detection may determine whether detected potential events constitute electrographic seizures and may assess how this information impacts patient diagnosis and care plans.

Annotations are accessible on both the Persyst Mobile Patient Views screen and via the Comments button within a Persyst Mobile EEG review screen. See Figures 1 and 2 to view how to access REMI Vigilenz AI for Event Detection outputs within Persyst Mobile.

Note that annotation duration is limited to the initial 5 minutes of any detected event, so any detected electrographic event lasting longer than 5 minutes will only be annotated across the first 5 minutes of detection.

Note that the first annotation of every REMI EEG trace that has been analyzed by REMI Vigilenz AI for Event Detection identifies that the EEG record was analyzed by REMI Vigilenz AI and provides its Unique Device Identifier (UDI) along with the duration of data analyzed.

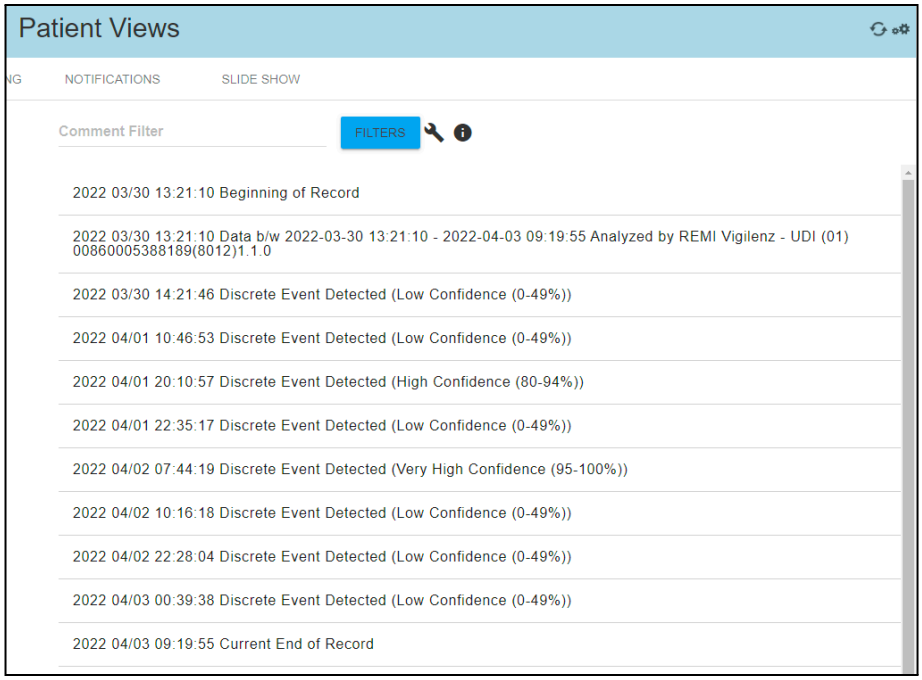

Figure 1: REMI Vigilenz AI for Event Detection Outputs as displayed in Persyst Mobile (Patient View).

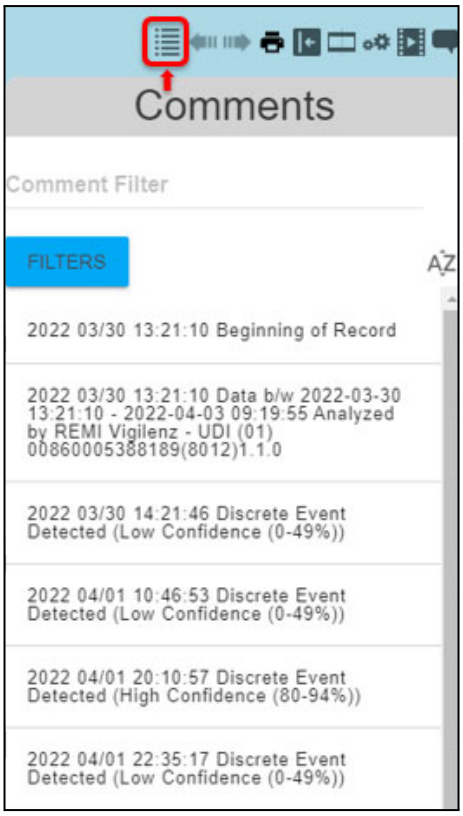

Figure 2: REMI Vigilenz AI for Event Detection Outputs as displayed in Persyst Mobile (within record comments).
Note: To display comments select the icon indicated by the red box.

Annotations of discrete electrographic seizure events detected by REMI Vigilenz AI for Event Detection are also visible at the base of the Persyst Mobile EEG review screen in the “Comment” row. See Figure 3 to view how REMI Vigilenz AI for Event Detection outputs are displayed in Persyst Mobile.

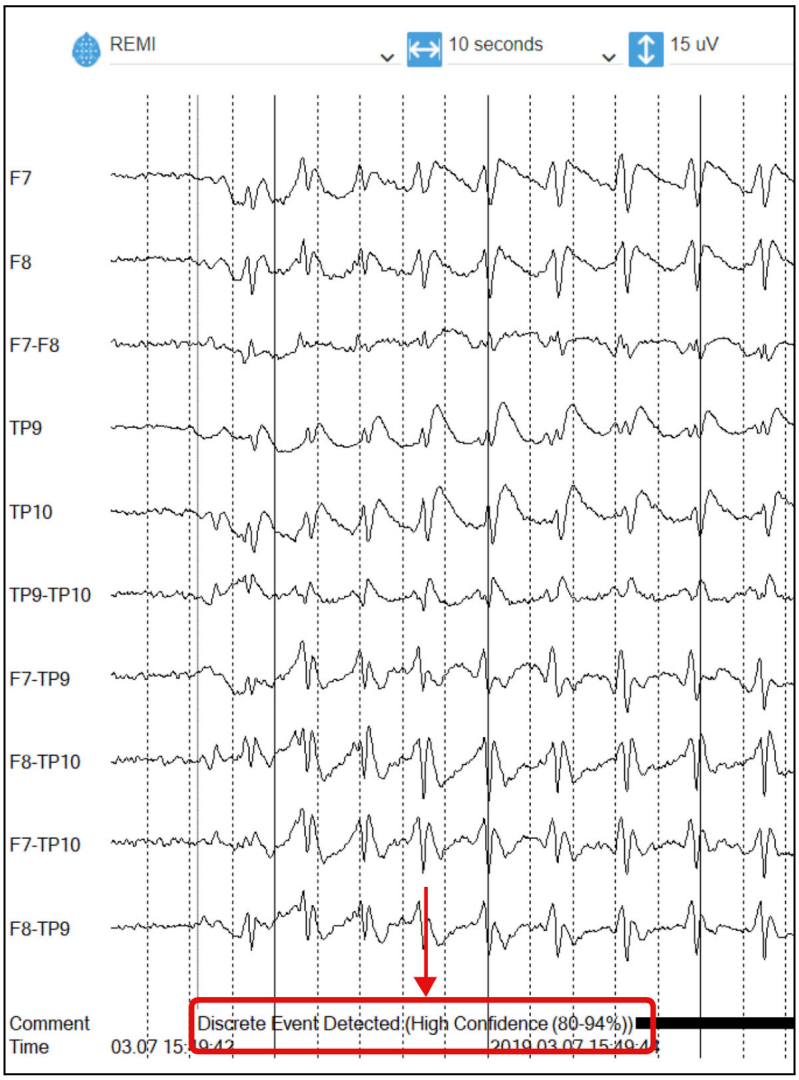

Figure 3: REMI Vigilenz AI for Event Detection Outputs as displayed in Persyst Mobile (within record annotations)

Event Confidence Labels

REMI Vigilenz AI for Event Detection has been designed to process REMI EEG records to identify potential discrete electrographic seizure events within the recording. REMI Vigilenz AI for Event Detection is designed to maximize the number of potential events that may correspond to true seizure events, but also to report its confidence that a detected potential event represents a true positive electrographic seizure event.

Review of the REMI EEG record by a qualified physician should still be conducted even after REMI Vigilenz AI processing.

> **Warning:** REMI Vigilenz AI for Event Detection is not meant to be used as a standalone means of identifying seizure-like events in a REMI EEG record or of diagnosing a detected potential event as a true seizure. Qualified physician oversight is required.

High Sensitivity Detection

Event detection occurs based on the Event Detection Model (which is represented by the gold circle in Figure 4). The Event Detection Model optimizes high Sensitivity[1] at an acceptable FAR[2]. All events identified by the Event Detection Model are annotated to the REMI EEG record.

Event Confidence Assessment

Event Confidence is determined for each event detected by the Event Detection Model through the use of additional Confidence Models that were created and evaluated during algorithm training (all gray to black markers in Figure 4). The Confidence of these models are determined by their performance on training data[3]. The increase in Confidence occurs because although fewer total events are found (and thus lower Sensitivity), the ratio of true positive to false positive events is higher.

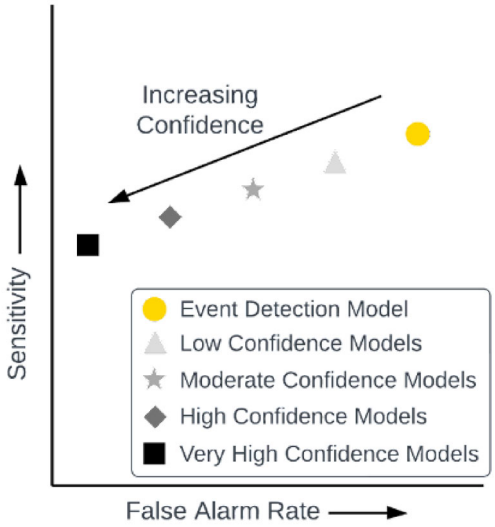

Figure 4: Event and Confidence Models of REMI Vigilenz AI for Event Detection.

[1] Sensitivity = True Positives / Total Ground Truth Events
[2] False Alarm Rate = False Positives / Duration of EEG data in hours
[3] Confidence = True Positives / (True Positives + False Positives)

Event Confidence Level Annotations

Upon processing through REMI Vigilenz AI for Event Detection, annotations are appended to the REMI EEG record that include the detected potential discrete electrographic seizure events along with a corresponding confidence level and range.

The ranges of each confidence level are described in Table 8 below:

Table 8. REMI Vigilenz AI for Event Detection Confidence Level Descriptions.

Confidence Level	Description
Very High (95-100%)	REMI Vigilenz AI for Event Detection is ≥95% confident that the identified event is not a FP, based on training data.
High (80-94%)	REMI Vigilenz AI for Event Detection is 80-94% confident that the identified event is not a FP based on training data.
Moderate (50-79%)	REMI Vigilenz AI for Event Detection is 50-79% confident that the identified event is not a FP based on training data.
Low (0-49%)	REMI Vigilenz AI for Event Detection is <50% confident that the identified event is not a FP based on training data.

Examples: 1) If a REMI Vigilenz AI detected event is found by a model with 75% confidence but not by any model with greater than 80% confidence, the confidence would be determined as “Moderate” and the text “Moderate Confidence (50-79%)” would be included in the annotation for that event.

2) If a REMI Vigilenz AI detected event is found by a model with 94% Confidence but not by any model with 95% or greater confidence, the Confidence would be determined as “High” and the text “High Confidence (80-94%)” would be included in the annotation for that event.

Troubleshooting

REMI Vigilenz AI for Event Detection annotations were expected but are not available – REMI Vigilenz AI for Event Detection analyzes previously collected REMI EEG traces. Additional time may be required before REMI Vigilenz AI for Event Detection analysis is complete. If annotations are still not available after one day, contact your Epitel representative to ensure that REMI Vigilenz AI for Event Detection is enabled and functional.

I cannot find REMI Vigilenz AI for Event Detection annotations on Persyst Mobile – Annotations are accessible within Persyst Mobile on both the Patient Views screen and the corresponding REMI EEG recording. If you cannot find these screens, consult the Persyst Mobile Instructions for Use or contact your Epitel representative.

Server and Software Information

Server Maintenance

REMI Vigilenz AI for Event Detection operates on a virtual server within Epitel's Cloud Environment. Epitel's Cloud Environment runs on the Amazon Web Services (AWS) cloud platform and follows AWS best practices for HIPAA security and compliance, including end-point protections and limited/secured user access.

In the event that server maintenance is required that would impact REMI Vigilenz AI for Event Detection, Epitel will communicate with hospital or physician practice IT administrators to notify them of the maintenance and of any expected impacts.

Software Updates

All software updates will be managed and deployed by Epitel within Epitel's Cloud Environment without the need for end user intervention. Epitel will notify customers of software updates and of any changes they may experience, and these changes will be described in release notes viewable on the Epitel website.

Software Bill of Materials (SBOM)

Access to a current machine-readable SBOM is made available to customers upon request.

User Assistance Information

This document was, as far as possible, accurate at the time of release, though subsequent changes may have been made. Epitel reserves the right to alter specifications and details as required. Late-breaking information may be supplied separately for completeness.

Medical Device
REMI Vigilenz AI for Event Detection

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Users should contact Epitel for assistance with setting up or using REMI Vigilenz AI For Event Detection, or to report unexpected operations or events. For support contact Epitel at any of the following:

Technical Support Phone Number: (801) 497-6297
Technical Support Email Address: support@epitel.com
Website: www.epitel.com

For Patent information, visit www.epitel.com/patents.

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