Olympic Brainz Monitor

RecogniZe™ User Guide

Publisher's Notice

REF

007389 RevG
Natus Olympic Brainz Monitor
RecogniZe User Guide

Revision Date: November 2021

Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario
L6H 5S1 Canada
Telephone: 1-800-303-0306 (US/CAN)
Worldwide: +1-650-802-0400

Technical Service: +1 800 303 0306
Technical Service Fax: +1 650 802 8680
Technical Service Email: technical_service@natus.com
Customer Service: +1 800 303 0306
Customer Service Fax: +650 802 6620
Customer Service Email: customer_service@natus.com

International Support – Please contact your local Distributor
Distributor locations can be found at www.natus.com

EC REP

EU REPRESENTATIVE:
Natus Manufacturing Limited
IDA Business Park
Gort Co. Galway, Ireland

CE
2797

Rx only

natus

At the time of printing / transfer to the CD-ROM/DVD, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read before using the system.

The following situation voids any guarantee(s) and obligations for Natus Medical Inc.
-The device is not used according to the enclosed manuals and other accompanying documentation.

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

The proper use of this device for its intended purpose can only be assured once all instructions have been read and understood. If there are any questions regarding the operation of this device, please contact your Natus Medical Inc. representative.

Olympic Brainz Monitor - RecogniZe User Guide

The Olympic Brainz Monitor RecogniZe module incorporates a patented, proprietary seizure detection algorithm that detects events that may correspond with seizure activity in a patient. The algorithm is based on wave-sequence analysis and operates by marking sections of the recording containing events that may correspond with seizure activity.

This software has been designed to mark areas of EEG which require review. A trained clinician can then review marked sections of the EEG trace and quickly confirm or disregard the marked activity that may be interpreted as a seizure.

The Olympic Brainz Monitor RecogniZe product does not provide any diagnostic indication of the patient's condition.

Intended use

The Olympic Brainz Monitor (OBM) is a three channel electroencephalograph (EEG) acquisition system intended to be used in a hospital environment to record, collect, display and facilitate manual marking of aEEG recordings.

- The signals acquired from P3-P4, C3-P3 and C4-P4 channels are intended for use only with neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a postconceptual age of 24 to 46 weeks) to display aEEG for monitoring the state of the brain.
- The signals acquired from P3-P4 channel is intended to assist in the assessment of Hypoxic-Ischemic Encephalopathy severity and long-term outcome, in full term neonates (post-conceptual age of 37-46 weeks) who have suffered a hypoxic-ischemic event.
- The RecogniZe seizure detection algorithm is intended to mark sections of EEG/aEEG that may correspond to electrographic seizures in only the centro-parietal regions of full term neonates (defined as from birth to 28 days post-delivery and corresponding to a postconceptual age of 37 to 46 weeks). EEG recordings should be obtained from centro-parietal electrodes (located at P3, P4, C3 and C4 according to 10/20 system). The output of the Recognize algorithm is intended to assist in post hoc assessment of EEG/aEEG traces by qualified clinical practitioners, who will exercise professional judgment in using the information.

The Olympic Brainz Monitor does not provide any diagnostic conclusion about the patient's condition.

Manual Conventions

Various symbols and typographical conventions are used throughout the manual. The following table illustrates them and describes their meanings and functions.

Symbol / Convention	Description / Function
	This symbol denotes a warning or important information that should not be missed. Read all warnings and cautions carefully before starting the system for the first time.
Bold	Names of control keys, function keys, options, and labels are shown in bold. Bold text is also used to emphasize important names or ideas.
Italic	Italic text is used for captions.

Authorized service centers

For service advice, contact your Natus distributor or a local Authorized Service Center before contacting Natus Medical Incorporated directly.

United States

Natus Medical Incorporated Customer Service

Email: Customer_Service@natus.com

Telephone: +1-800-303-0306 Worldwide: +1-650-802-6620

Natus Medical Technical Service

Tel: +1-800-303-0306 (US/CAN) Worldwide: +1-650-802-0400

Fax: +1-650-802-8680

Email: Technical_service@natus.com

Website: www.natus.com

For outside of the US, please contact your local Distribution Partner for Technical Service-related issues.

Brief Summary of Non-Clinical and Clinical Performance Tests

All functionalities and performance of the Olympic Brainz Monitor have been verify/validated through Bench and clinical performance tests according to the intended use and user of the device.

Non-Clinical: The OBM device is compliant with all currently accepted safety standards for medical devices of its class which was demonstrated through testing, verification and validation of all components.

Clinical: Natus conducted an extensive clinical test to: 1) Evaluate the positive percent agreement (i.e., detection sensitivity) and false detection rate of RecogniZe, seizure detection algorithm, and to 2) Demonstrate equivalence of the seizure detection performance, in terms of positive percent agreement and false detection rates of RecogniZe as compared to the gold standard defined as seizures detected by a panel of 3 EEG board certified medical professionals.

RecogniZe Clinical Validation

Testing Dataset

All EEGs used for validation were collected from neonatal patients seen for routine clinical evaluation at the Neonatal Intensive Care Unit of St. Louis Children's Hospital, USA. An independent physician not taking part on the subsequent review/scoring of the data conducted database query and study inclusion from a patient database of consecutive recordings.

All studies consisted on EEGs recorded using the Stellate Harmonie for multichannel EEG recordings obtained from scalp locations according to the International 10-20 system, and Olympic Brainz Monitor for limited channel (3 channels) montage. All recordings meeting inclusion criteria were included independently of EEG patterns and technical quality.

Dataset Description:

Number of Events: 421

Total Number of Patients: 82

Number of Hours: 621

AGE (Mean ± SD)	38.3 (± 1.9)
GENDER (Female/Male)	44/38

All subjects involved in this study were neonates (defined as from birth to 28 days post-delivery, and corresponding to a post-conceptual age of 37 to 46 weeks). The demographic characteristics of the population included for this study are shown below:

To avoid over-weighting recordings containing many events, a maximum of 13 events per limited channel recording were permitted.

Analysis Method

EEG studies were de-identified, randomized and provided to board certified neurophysiologists that independently, blindly and manually marked seizures (no seizure detection algorithm was allowed) in the same manner they would normally do in clinical practice. Experts initially reviewed the full cohort of standard montage recordings (157) marking seizure onset and noting the topography of seizures. To annotate topography experts were asked to classify seizures as occurring in one of the following zones:

1. Frontal (Left/Right)
2. Centro-Parietal (Left/Right)
3. Central Midline
4. Temporal (Left/Right)
5. Occipital (Left/Right)

After a 4 weeks wash-out period implemented to avoid any possible recognition of individual recordings, reviewers were provided with the limited-channel (C3-P3, C4-P4 and P3-P4) recordings for marking. Once EEGs were marked by the expert raters same limited channel studies were submitted for analysis using RecogniZe.

Detection Parameters

To conduct the analysis, the marked studies were played back and fed into the RecogniZe, with detection threshold at 5µV (default value), 7.5µV and 10µV. Measurements of event-based Positive Percent Agreement (PPA) and False Detection Rate (FDR) of the proposed detection system were assessed.

The event-based 'any-overlap' method1 was used. An Event of Interest (EOI) detected by the algorithm was considered to match an EOI marked by the expert rater if there was any intersection between their two time periods. The any-overlap positive percent agreement was calculated by dividing the number of matched events by the total number of events.

All studies were annotated by the event detection algorithm. Notes were stored in time order in an annotation file for each study and were used for comparison against the annotated EEG files generated by the expert readers. PPA and FDR were calculated on the same dataset of recordings which combined seizure and non-seizure recordings.

1 Wilson SB, Scheuer ML, Plumber C, Young B, Pacia S. Seizure detection: correlation of human experts. Clin Neurophysiol. 2003 Nov;114(11):2156-64.

Results

Electrographic Seizure Topography

The table below describes the topographical distribution of seizures detected with standard montage on conventional EEG recordings. According to majority rule, there were a total of 635 seizures in all recordings.

Zone	% visible seizures
Frontal (Left+Right)	17.1% (109)
Central Midline	19.6% (125)
Centro-Parietal (Left+Right)	54% (340)
Temporal (Left+Right)	6.7% (43)
Occipital (Left+Right)	2.8% (18)
Total	635

We have collapsed seizures from homologous zones (i.e temporal left + temporal right, and so on). The most common location of seizures was the centro-parietal zones where 73% (465/635) of seizures occurred followed by the frontal zones (17%, 109/635). Seizures visible in the occipital zones were the less frequent.

Seizure topography as described in this study is in line with that reported by others. Tekgul et al. (2005) published a study comparing a “reduced electrode montage (9 electrodes) with the full 10/20 electrode montage for the ability to detect and characterize neonatal seizures”. A total of 151 neonatal EEG records from 139 infants, between 29 and 48 weeks conceptional age were retrospectively and blindly analyzed for seizure number, topography, duration by two expert EEG readers. According to the authors, 73% of the total number of seizures was detected in central and parietal channels.

This was also the finding reported by Lawrence and coworkers as part of their research on limited channel encephalography in term neonates. Lawrence et al (2009) studied 40 infants ≥36 weeks’ gestation admitted to St Louis Children’s Hospital with the major diagnosis of the studied group being hypoxic-ischemic encephalopathy (28/40). Other diagnoses included cortical stroke, meningitis, congenital hydrocephalus with hypoxic injury, intraparenchymal bleed with sepsis, and brainstem hemorrhage. The authors simultaneously recorded conventional EEG and limited channel aEEG/EEG (using BRM2) in 34 patients and found that 76% of the total number of seizures detected with conventional EEG were visible in centro-parietal channels (C3, C4, P3 and P4).

A well-powered, large sample size study conducted by Shellhass and coworkers (2007) also support Tekgul (2005) and Lawrence (2008) findings. Studying125 conventional EEGs from 121 neonates (conceptional age 34-50 weeks) accepted at the Children’s Hospital of Philadelphia, they found that 56% of the total 851 seizures, originated in central areas. According to the 2 experienced pediatric electroencephalographers taking part of the Shellhass et al study (2007) 78% of all neonatal seizures appeared in the C3-C4 channel.

Inter Rater Performance

1. Conventional EEG (cEEG)

Inter-rater Positive Percent Agreement and False Detection / hour with cEGG

	EVENTS					
	Rater 1		Rater 2		Rater 3	
	PPA%	FD/h	PPA%	FD/h	PPA%	FD/h
Rater 1			81	0.2	81	0.2
Rater 2	78	0.2			57	0.2
Rater 3	78	0.2	80	0.2		

The inter-rater agreement reported in our study varies between 78 % and 81% for seizure detection while FDR (false detection per hour (FD/h) was same for all three raters (0.2 FD/h).

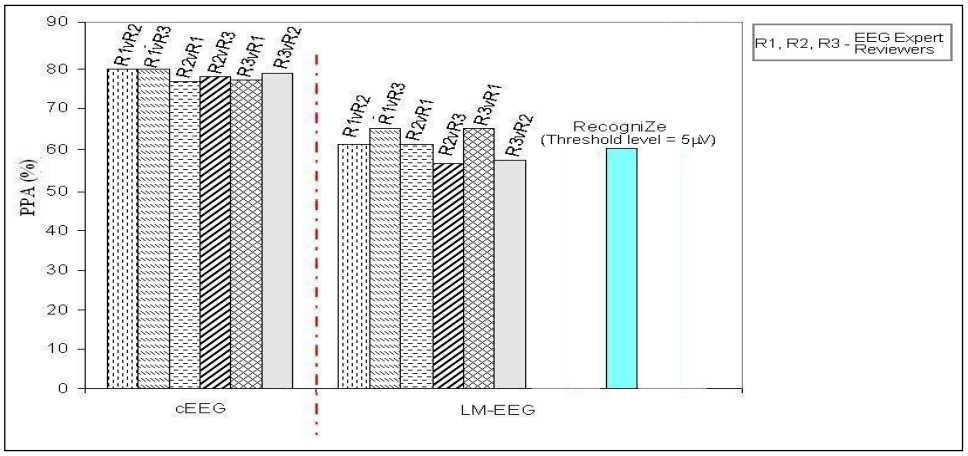
2. Limited Channel EEG (LM-EEG)

Inter-rater PPA for scorer to scorer ranged between 58 and 66%, while FDR (false detection per hour (FD/h) was very close for all three raters (0.3 FD/h).

Inter-rater Positive Percent Agreement and False Detection / hour with OBM

	EVENTS					
	Rater 1		Rater 2		Rater 3	
	PPA%	FD/h	PPA%	FD/h	PPA%	FD/h
Rater 1			62	0.3	66	0.3
Rater 2	62	0.3			57	0.3
Rater 3	66	0.2	58	0.2		

The inter-rater agreement reported in our study varies between 58 % and 66% for seizure detection on LM-EEG. Evaluating inter-rater agreement for seizure detection Walczak et al (1992) reported that seizure onset was correctly determined by 3 independent electroencephalograpers in 47% to 65% of extratemporal seizures like is the case for the study reported here where information available to electroencephalograpers was recorded at extratemporal (i.e. centro-parietal) sites.

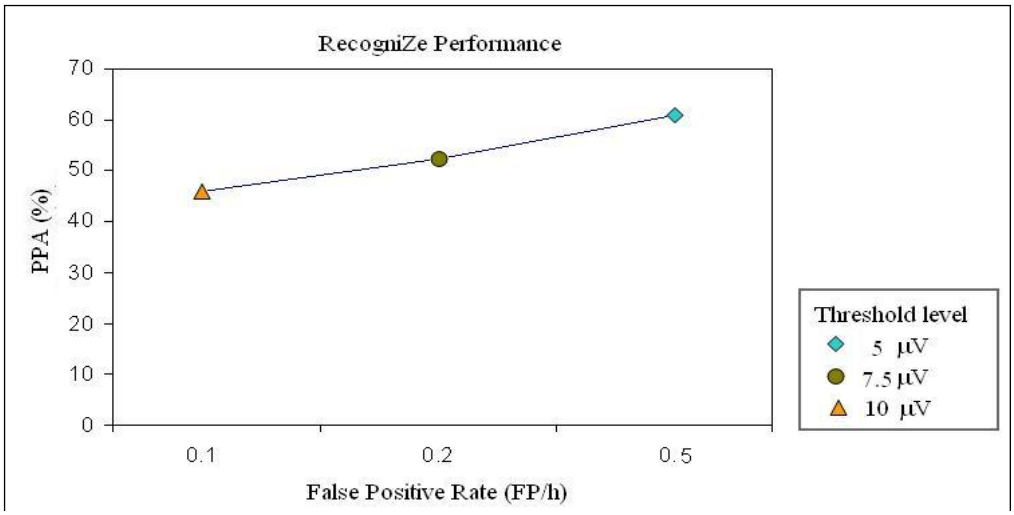


As seen in the graph above seizure recognition by expert reviewers is better when conventional EEG (cEEG) is used as compare to same task but with a Limited Channel Montage (LM-EEG). Using cEEG, expert reviewers detected a total of 635 seizures versus 424 seizures in the LM-EEG. RecogniZe detected 258 seizures in the LM-EEG. With the limited number of channels, there are less visual cues available to

perform the patter-recognition task necessary for seizure identification. This however, does not prevent seizure recognition, but somehow increases the difficulty of the task at hand. In spite of reducing the number of channels, seizure recognition on LM-EEG remains well above chance levels.

Algorithm Performance

The picture below presents RecogniZe performance using the full range of detection thresholds: 5µV, 7.5 µV and 10 µV.



The results revealed that as detection threshold increases the False Positive Rate improves (less False Positives per hour) at the expense of deterioration in the algorithm Positive Percent Agreement (PPA). With detection threshold set at 10 µV PPA drops to 47% and FDR decrease to 0.1 FP/h. With the default settings (detection threshold at 5 µV) Recognized achieved 61% positive percent agreement and a false detection rate of 0.5/hr, comparable to the range of inter-rater false detection rate of 0.3/hr.

Threshold level (µV)	**PPA (95% CI)***	**FDR (FP/h) (95% CI)***
5	61% (52 – 68)	0.5 (0.4 – 0.7)
7.5	53% (39 – 55)	0.2 (0.1 – 0.3)
10	47% (33 – 49)	0.1 (0.07 – 0.1)

PPA (95% CI)*	**FDR (FP/h) (95% CI)***
61% (52 – 68)	0.5 (0.4 – 0.7)

*Bootstrap 95% CI

When confronted with 3 channels raw EEGs the average rater PPA was 62%. That is, any given expert EEGer positively agreed 62% on average with any of its peers for seizure identification in a limited channel montage. With a 61% PPA and an FDR of 0.5 FD/hr RecogniZe is substantially equivalent to the performance of medical experts confronted with similar task and amount of data, RecogniZe is substantially equivalent to predicates in intended use, user, and all other technological characteristics.

References

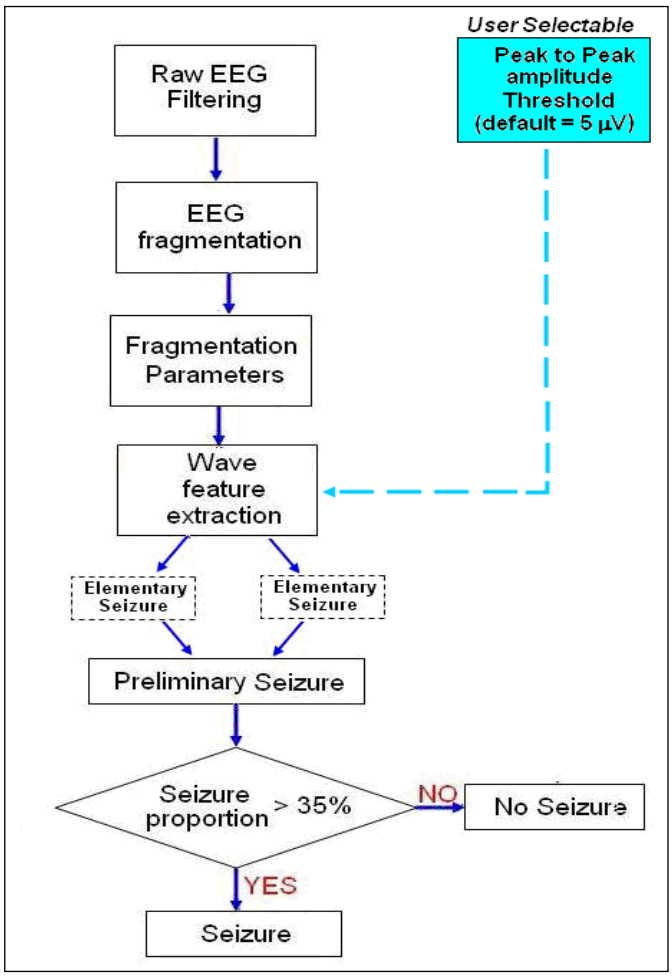
1. Tekgul H, Bourgeois BF, Gauvreau K, Bergin AM. Electroencephalography in neonatal seizures: comparison of a reduced and a full 10/20 montage. Pediatr. Neurol. 2005 Mar;32(3):155-61.

2. Shellhaas RA, Soaita AI, Clancy RR. Sensitivity of amplitude-integrated electroencephalography for neonatal seizure detection. Pediatrics. 2007 Oct;120(4):770-7.

3. Lawrence R, Mathur A, Nguyen The Tich S, Zempel J, Inder T. A pilot study of continuous limited-channel aEEG in term infants with encephalopathy. J. Pediatr. 2009 Jun;154(6):835-41.e1.

RecogniZe algorithm description

The main principle of operation of the RecogniZe algorithm (Navakatikyan et al., 2006)[2] is the detection of heightened regularity in EEG wave sequences, using wave intervals, amplitudes and shapes. Heightened regularity is the major distinguishing feature of seizure discharges, and the most significant indicator used in seizure identification by a trained neurologist.



RecogniZe Algorithm flowchart

The algorithm comprises filtering of the raw EEG signal, parallel fragmentation of the signal into wave sequences, wave-feature extraction and averaging, then elementary, preliminary and final detection. The Cross, Left and Right channels of the Olympic Brainz Monitor are used for event detection. Event detection criteria are applied to these stages as identified below.

[2] Navakatikyan MA, Colditz PB, Burke CJ, Inder TE, Richmond J, Williams CE. Seizure detection algorithm for neonates based on wave-sequence analysis. Clin Neurophysiol. 2006;117(6):1190-203.

Detection criteria

The RecogniZe algorithm detects areas of regularity in an EEG waveform, using the following criteria:

- at least five similar consecutive waves
- wavelengths that are equivalent to a frequency of 14 Hz or less
- peak-to-peak amplitude greater than 5 µV
- at least 21 seconds of continuous detection, or 26 seconds of discontinuous detection, in one minute of EEG signal

The algorithm then indicates the most probable location (in the recording) of events that may correspond with seizure activity in the patient.

Limitations

The RecogniZe algorithm is limited to analysis of the EEG data channels recorded by the Olympic Brainz Monitor, and will not detect events corresponding to seizures occurring in regions other than the central-parietal regions where the sensors are placed (see. Electrographic Seizure Topography on page 7, this Manual).

The RecogniZe algorithm might not detect a proportion of events corresponding to genuine seizure activity, particularly those events made up of complex, irregular waves, or of very short duration. As with any other seizure detection algorithm, artifacts (physiological or otherwise) might cause false detections.

Good sensor application technique, and vigilance on the part of care-givers (to avoid creating artifacts by rhythmically patting or moving the baby while RecogniZe monitoring is taking place) may help minimize spurious detections. As with any other seizure detection algorithm however, false detections might occur. According to clinical study results RecogniZe has a False Detection Rate of 0.5 FP/h.

Safety warnings

RecogniZe IS:

- Intended for review of EEG waves by qualified medical practitioners.

RecogniZe IS NOT:

- A seizure alarm system.
- Intended as a replacement of clinical surveillance of patient wellbeing.
- Intended to provide any diagnostic conclusion about patient's health.

If a medical professional qualified in EEG interpretation is NOT AVAILABLE, you might take note of RecogniZe output and communicate with an EEG qualified professional.

DO NOT use RecogniZe output as the basis to modify patient care until a medical professional qualified on EEG interpretation has reviewed the device output.

In no way, and despite any medical terminology used, do any of the RecogniZe functions represent a diagnostic indication of the patient's condition.

Sections of EEG or aEEG trace marked by RecogniZe ***must*** be reviewed by a qualified medical professional to confirm the presence of seizure activity (from examination of the relevant EEG Waveform trace). Do not perform this review unless you are qualified to recognize seizure activity from raw EEG Waveform traces.

The RecogniZe module is designed for neonatal use only (defined as from birth to 28 days post-delivery and corresponding to a post-conceptual age of 37 to 46 weeks) and is not intended for use outside this patient population.

Do not rely on RecogniZe event detection for monitoring of patient safety.

Activating the RecogniZe detector

The RecogniZe newborn seizure detector is purchased under a separate license agreement and must be activated before it can be used. Complete the activation letter and send it to Natus Technical Services in order to receive a RecogniZe Product Key and Activation Key. Note that you'll need to provide Technical Services with your machine ID (found in the maintenance utility described below).

To activate the detector, go to the Tools/System overlay and press **Exit to Maintenance**.

The RecogniZe detector is only available in jurisdictions for which it has been fully cleared. Contact Natus Technical Services for further details.

To activate RecogniZe:

1. Touch the **Detectors** sidebar button and then press the **RecogniZe** tab.
2. Enter your *Product Key* and *Activation Key* into the corresponding fields. These keys are case sensitive.
3. Take note of the machine ID on this activation screen. It should agree with the ID provided to Technical Services (as noted above).
4. Once the keys are entered, the Activate button should be enabled (a red dot beside either the Product Key or Activation Key indicates that the entered key is *incorrect*)
5. Touch **Activate**.

   Result: The RecogniZe detector is activated. A RecogniZe icon on the activation screen appears:

   (orange for a trial license)  (trial period is described in terms of days remaining)

Updating a Trial License

The RecogniZe newborn seizure detector is purchased under a separate license agreement and must be activated before it can be used. Complete the activation letter and send it to Natus Technical Services in order to receive a RecogniZe Product Key and Activation Key. Once the full license is received, proceed as follows:

To activate the detector with a *full* license, go to the Tools/System overlay and press **Exit to Maintenance**.

The RecogniZe detector is only available in jurisdictions for which it has been fully cleared. Contact Natus Technical Services for further details.

To activate RecogniZe:

1. Touch the **Detectors** sidebar button and then press the **RecogniZe** tab.
2. If the Trial license has not yet expired, press **Change License**.
3. Enter your (new) *Product Key* and *Activation Key* into the corresponding fields. These keys are case sensitive.
4. Once the keys are entered, the **Activate** button should be enabled (a red dot beside either the Product Key or Activation Key indicates that the entered key is *incorrect*)
5. Touch **Activate**.

Result: The RecogniZe detector is activated. A RecogniZe icon on the activation screen appears  ***(If a problem occurs during activation, press the***  ***button to restore the balance of the trial period)***

Note that once the trial period expires, the icon on the main UI will change to  ***(*** **RecogniZe** ***detection will not be available until a full license is purchased and activated)***

Enabling and disabling the RecogniZe module

From the main User Interface, go to the Tools/System overlay and press **Exit to Maintenance**.

If the RecogniZe module is enabled or disabled, it will remain that way for all recorded sessions until the setting is changed.

To enable RecogniZe:

1. In the ***Maintenance Utility***, press the Detectors sidebar button. Select the ***Enable Detector*** check box to enable the RecogniZe module.
2. Touch **Accept**.

   Result: The RecogniZe module is enabled. The RecogniZe icon in the main UI is purple 

   (orange for a trial license) 

To disable RecogniZe:

1. In the ***Maintenance Utility***, press the Detectors sidebar button. De-select the ***Enable detector*** check box to disable the RecogniZe module.
2. Touch **Accept**.

   Result: The RecogniZe module is disabled and the RecogniZe icon in the main UI is dimmed:

Using RecogniZe

Begin a session as normal. Refer to the ***Olympic Brainz Monitor Reference Manual*** or ***OBM Onscreen Help System*** for detailed instructions on beginning a patient session.

The RecogniZe *module operates by marking sections of the recording that contain events which may correspond with seizure activity. Event detections must always be reviewed and confirmed against the EEG recording by a qualified medical professional. The purpose of the* RecogniZe *module is to aid the qualified medical professional in the review of sections of the trace that may be clinically significant.*

RecogniZe marking of aEEG and EEG

Sections of the recording containing detections are marked with an orange bar that appears on the aEEG graph(s) (only in scoring mode when the 'automatic seizures' track is visible), and in both EEG and

aEEG graphs in review mode. The marking is applied independently to the Left, Right and Cross-cerebral channels, based on the origin of the suspect activity.

RecogniZe alerts (non-U.S.A. licenses, only)

RecogniZe alerts are not available for customers operating in the U.S.A. See the 'RecogniZe Review Indicator', below, for customers operating in the U.S.A.

During session recording, a RecogniZe alert appears in the Status Bar (via the Clinical LED located between the Signal LED and the System LED), indicating events that may correspond to seizure activity in the patient. The Clinical LED flashes amber until the event ends. Once the event has ended, the Clinical LED remains a solid amber color until the LED is touched to reset it to its normal green color (see *Acknowledging alerts*, below).

Note 1: RecogniZe events are only visible on the aEEG graph(s) when in scoring mode, and then, only if one of the visible scoring tracks is configured to display 'automatic seizures'.

Note 2: When RecogniZe alerts are disabled, the flashing and auditory beeping of the Clinical LED is suppressed even though its color changes to either green or amber as noted above.

Acknowledging a RecogniZe alert (non-U.S.A. licenses, only)

To acknowledge a RecogniZe alert:

A solid amber Clinical LED indicates that the RecogniZe module has detected an event that may be related to seizure activity. A flashing amber Clinical LED indicates that RecogniZe is in the process of detecting an event that may be related to ongoing seizure activity.

RecogniZe alerts are not available for customers operating in the U.S.A.

Touch the Clinical LED.

Result: A dialog appears allowing the user to snooze or dismiss the event. Snoozing or dismissing an active event changes the Clinical LED to a solid amber color and silences the auditory tone, if one is present.

Snooze: A snoozed event will return to the flashing alert state after several minutes. If, during the snooze period, the event ends, the alert will clear from the system, returning the LED to its green color.

Dismissed: A dismissed event will change to solid amber. Once the event ends, the alert will clear from the system, returning the LED to its green color.

If an event ends before having been dismissed by the user, the LED will change to a solid amber color and the auditory tone will silence. The LED will remain solid amber until either the alert is dismissed by the user or a subsequent clinical alert is detected.

RecogniZe Review Indicator (U.S.A. licenses only)

For licensed devices operating in the U.S.A. the 'Clinical LED' is replaced by a 'Review' indicator. The 'Review' indicator will turn solid blue when RecogniZe has detected activity that may correspond with seizure in the patient. This serves the purpose of a review reminder. Once the algorithm has detected

possible seizure activity, the Review LED remains a solid blue color until the LED is touched to reset it to its normal dark grey color (see below).

A solid blue indictor acts as a reminder. It does not flash, nor does it produce an auditory chime.

Touch the 'Review' indicator (when the indicator turns a solid blue).

Result: A dialog appears allowing the user to mark the indicator as 'Reviewed'. To clear the 'Review' indicator, select the RecogniZe item in the list and press the button labeled 'Reviewed'.

Note: If the 'Reviewed' button is pressed during an active event, the 'Review' indicator will remain dark blue until the event subsides.

Reviewing a patient session

Enter review mode by either scrolling backwards in time using one of the navigation tools or by opening a previously recorded session.

To review the displayed session:

1. Activate scoring mode by touching the scoring mode button located to the left of the aEEG display.
2. Check the Markers/Scoring/Tracks overlay to ensure that a track is configured to display 'automatic seizures' (i.e., those detected by RecogniZe)
3. Scan the aEEG graphs to identify an area of trace that is marked with an orange bar, using the scoring **navigation controls** as necessary.
4. Touch one of the *aEEG* graphs in the area of the orange bar to view the associated EEG.
5. Scan the area of the *EEG* Cross, *Left* and *Right* graphs marked with an orange bar, to identify areas that may represent seizure activity, using the navigation controls or by pressing and dragging the EEG display area.

Sections of EEG or aEEG trace marked by RecogniZe ***must*** be reviewed by a qualified medical professional to confirm the presence of seizure activity. Do not perform this review unless you are qualified to recognize seizure activity from raw EEG traces.

The section of the recording marked with an orange bar by RecogniZe represents the most likely location of the suspicious activity detected by the module. Close observation of the unmarked sections of the recording may reveal some additional areas of repetitive EEG activity, particularly where these are short (less than 10 seconds) or made up of complex repeating waveforms.

Changing the low amplitude detection threshold

The RecogniZe algorithm has been factory-set to a default low amplitude detection threshold of 5 µV p-p. This setting provides the best balance of artifact.

In individual cases, however, **clinicians may choose to raise the detection threshold in order to make the algorithm less sensitive to low-amplitude artifacts (for example, EKG interference and high-frequency ventilator artifact).**

RecogniZe sensitivity as reported in this manual (*see* RecogniZe *seizure detection Validation Study - Summary*) was obtained using the default detection threshold value (i.e. 5 µV). Sensitivity of the software at detection threshold other than default might be different.

To change the low amplitude detection threshold:

1. From the main UI, touch **Tools**, then **Settings** and then **Detectors**.

2. In the RecogniZe detector settings group, select 5.0, 7.5, or 10.0 µV p-p, depending on the sensitivity you require.
3. Touch **Accept** to confirm the setting.
4. If recording is active, a warning dialog will appear indicating recording will be briefly interrupted while the new amplitude detection threshold is applied. Touch **Yes** to proceed, else **Cancel**.

Once the detection threshold is changed, it remains fixed until it is changed again (for all subsequent recordings). A marker is automatically added to the session once recording resumes to document the *active low amplitude detection threshold*. See RecogniZe *start of recording marker*, below.

Hiding the RecogniZe marking

The RecogniZe marking may be hidden, causing the RecogniZe indication to disappear from the current aEEG display in both "review" and "live monitoring" modes. Hiding RecogniZe marking does not disable the algorithm. The algorithm will continue to detect events and will record them into the patient data file (see Disabling RecogniZe alerts, below).

To hide the RecogniZe marking:

1. Touch **Markers/Scoring/Tracks** to display the *Tracks* overlay.
2. Set the track configured to display 'automatic seizures' to 'none'.

   Result: The scoring track containing the RecogniZe marking is hidden.

To show the RecogniZe marking:

1. Touch **Markers/Scoring/Tracks** to display the *Tracks* overlay.
2. Configure one of the tracks to display 'automatic seizures'.

   Result: RecogniZe markings are displayed in the aEEG when in scoring mode.

Disabling RecogniZe alerts (non-U.S.A. licenses, only)

RecogniZe alerts are not available for customers operating in the U.S.A.

RecogniZe alerts are generated during active recording.

To disable RecogniZe auditory alerts:

1. Exit to the Maintenance Utility.
2. Touch the Detectors sidebar button.
3. Clear the checkbox beside 'Enable auditory alerts'. Touch **Accept**.

   Result: Visual RecogniZe alerts will not be accompanied by an audible chime.

   Note: This option is only available when 'Enable clinical alerts' is selected (see below)

To disable RecogniZe auditory **and** visual alerts:

1. Exit to the Maintenance Utility.
2. Touch the Detectors sidebar button.
3. Clear the checkbox beside 'Enable clinical alerts'. Touch **Accept.**

   Result: Both auditory and visual alerts are disabled (no indicator on the Status bar).

Detecting poor impedance

Poor impedance can lead to a heightened sensitivity to various artifacts as described below in *Helpful hints*. The Olympic Brainz Monitor automatically disables RecogniZe during periods of high impedance. This option can be enabled / disabled as follows:

To disable detection of poor impedance:

1. Exit to the Maintenance Utility.
2. Touch the Detectors sidebar button.
3. Clear the checkbox beside 'Detect poor impedance'. Touch **Accept**.

To enable detection of poor impedance (recommended):

1. Exit to the Maintenance Utility.
2. Touch the Detectors sidebar button.
3. Select the checkbox beside 'Detect poor impedance'. Touch **Accept**.

High impedance is determined by the lower of the two impedance alert thresholds (default: **10000 Ω**). Impedance values below 5000 Ω are recommended for superior signal quality.

Setting the correct line frequency filter

In order to reduce the effects of electrical noise and the possibility that it may affect the RecogniZe detector, the local AC line frequency must be specified. This setting is shared between the various detectors and is found in the top-right corner of each Detector tab:

Touch the button to the left of the line frequency applicable to your region to reduce the effects of electrical noise (e.g., 60 Hz in North America (as illustrated above), 50 Hz in Europe).

RecogniZe start of recording marker

With the RecogniZe detector activated, a special 'start of recording' marker is automatically placed into the session to document the following:

1. Whether or not RecogniZe is enabled
2. The current low amplitude detection threshold
3. The current 'poor impedance' threshold above which RecogniZe will be disabled

This marker is called 'RZe'. The marker description reads as follow:

RecogniZe™ - *ENABLED* / *5.0* µV p-p / *10000* Ω

The first term ('ENABLED/DISABLED') indicates whether or not the detector is enabled. The µV p-p value indicates the low amplitude detection threshold and the Ω value indicates the impedance threshold above which the detector will be disabled. Note that if the '*Detect poor impedance*' option is disabled, this impedance value will read 'DISABLED'.

Note: This special 'start of recording' marker is only included in the session when the RecogniZe detector is activated according the licensing mechanism described earlier.

Helpful hints

Periodic artifacts may trigger RecogniZe detections, particularly those within the 2 – 14 Hz range. Avoidance of these artifacts is not always possible, particularly when using a high frequency oscillating ventilator. Other artifact sources that could cause RecogniZe detections include patting the infant, chest percussion therapy and cardiac (EKG) artifact.

In these circumstances, comprehensive event marking by the attending medical professional can help the qualified clinician when reviewing the recording. It is advised to mark events whenever they occur, particularly the presence of:

- clinical seizures
- potential artifact sources (as described above)

Maintaining good contact quality of all sensors will ensure a good quality signal, by minimizing artifact, and help the qualified clinician in reviewing the recording. Sensor impedances should be kept below 5 kΩ to ensure a good quality signal.