

OLYMPIC CFM 6000

aEEG infant brain monitor



Sales Guide

Contents



This sales guide will familiarize you with the features of the Olympic CFM 6000, and outline the marketing support available to you at each phase of the sales process.

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The Olympic CFM 6000



Overview

The Olympic CFM 6000 can be used in the neonatal intensive care unit (NICU), pediatric intensive care unit (PICU), operating room (OR) or emergency room (ER), and other acute-care departments as a short-term screen to detect brain abnormalities or as a long-term monitor to observe changes. It enables clinical staff to assess the neurological status of the brain as an aid to both diagnosis and treatment.

Intended Use

The Olympic CFM 6000 is intended to be used for:

- Continuous monitoring and recording of brain activity.
- Aiding in the detection and treatment of seizures.
- Monitoring the effects of drugs and other therapies on the brain.
- Aiding in identifying HIE and predicting long-term outcome.
- Improving the accuracy of newborn neurological exams.
- Determining the need for further neurological examination or transport.

What is CFM?

The cerebral function monitor (CFM) provides a global view of the brain. This view is fundamentally different than EEG, which provides localized views.

The CFM can be used for either short-term screening or long-term continuous monitoring, while an EEG is generally used only for short-term examination — typically 20–30 minutes at a time.

Reading the CFM is a pattern-recognition technique that can be quickly mastered by clinical staff, enabling them to make on-the-spot care decisions. EEG interpretation, by contrast, generally requires years of training.

CFM is not a replacement for EEG. In fact, successful use of the CFM often leads to increased requests for EEG exams. While EEG provides good visibility into localized events over short periods of time, the CFM completes the picture, showing overall brain activity over a long period of time. In fact, CFM can be used to continuously record brain activity, for days or even weeks (in 72-hour periods). While neurologists initially approached this device with skepticism, concerned that it would erode the boundary between their world and that of the neonatologist — this is changing now as more neurologists are discovering what a valuable insight CFM provides into the global brain picture as they start their patient examination.

The Olympic CFM 6000



History

The CFM was first developed in the late 1960s for use in monitoring adults undergoing surgery, suffering head trauma, or in a coma. In the mid 1980s research groups in Sweden and the Netherlands began investigating its use in neonates. Since that time there have been a number of studies of the CFM in neonates in both Europe and the United States. These studies have shown that the CFM has a high sensitivity, specificity, and predictive value for long-term severity of HIE if recordings are taken within 6–12 hours of a perinatal asphyxial event. More recently, the CFM has been shown to be useful in the detection of seizures in neonates when compared to regular EEG. Currently, a number of studies are being conducted in Europe and the United States, investigating its use in premature infants and other intensive care applications.

Because of its simplicity and ease of training, the CFM is increasing in use within the NICU. The CFM allows clinical personnel without in-depth knowledge of EEG to quickly determine global neurologic status — and provides the ability to monitor this status long-term. This is similar to the use of pulse oximetry and EKG to evaluate oxygenation and cardiac status.

CFM and Olympic Medical

In 1998, Olympic Medical was invited to collaborate on a study involving the early detection and treatment of infants with HIE, which led to our sponsoring the first international trial on the use of selective head cooling. The success of this study depended on our ability to rapidly and accurately identify infants at risk for HIE using CFM technology. Throughout the two-and-half years of trials, the Olympic/Lectromed CFM 5330 surpassed our expectations for its ease of interpretation and accuracy of prediction.

The 5330 has been used clinically for more than 25 years in leading neonatal research centers. In 2003, Olympic Medical received FDA and CE approval for the world's first fully digital CFM — the Olympic CFM 6000.

The Olympic CFM 6000



Features & Benefits

Long-Term Monitoring

The Olympic CFM 6000 is designed for long-term monitoring, whether for hours or for days. It provides continuous real-time display of cerebral electrical activity to assist the clinician in making immediate decisions and to identify patients in need of closer attention.

Improves Patient Care

The Olympic CFM 6000 improves the accuracy of newborn neurological examinations, aids in detecting and treating seizures, monitors the effects of drugs and other therapies on the brain, aids in identifying HIE and predicting long-term outcome, along with assisting in determining the need for further neurological examination or transport.

Ease of Use & Interpretation

Simply attach three electrodes to the patient's head, then touch the Record button. The device automatically calibrates. The bright color screen of the Olympic CFM 6000 is easy to read under all lighting conditions. Most importantly, the recordings are easy to interpret. Basic trace analysis, based on well-established pattern recognition techniques, can be mastered quickly and does not require the support staff to possess an in-depth knowledge of EEG or neurophysiology.

Access Raw EEG

Clinical staff can view raw EEG signal on demand for any segment of a tracing. EEG is an important aid to confirming seizures and other electrocortical events.

View Any Time

The Olympic CFM 6000 allows instant playback of the entire patient file or for a selected time period, allowing evaluation of long-term changes in the patient's neurological status. Data can be reviewed at any time without interrupting active recording.

Obtain Reliable Data

The continuous impedance display indicates the contact between the electrode and the patient, confirming data reliability and alerting clinical staff of poor electrode contact.

The Olympic CFM 6000



Mark Important Events

Clinical staff can add time-stamped markers and information about important events, such as possible seizures and medications given, for later review. And if the clinician chooses to temporarily suspend recording, the Olympic CFM 6000 automatically inserts a time-stamp when the recording is resumed.

Review Files Remotely

Patient files can be sent to the physician's desktop, or be shared between neonatologists, for additional analysis or for report creation using the *CFM Windows Viewer* program (beta version available; not for commercial distribution). Patient name and ID can be suppressed to protect patient identity.

The Olympic CFM 6000



Hardware Description



Specifications

Data Storage	Hard drive stores up to 8,000 hours of data, CD-RW drive
User Interface	Liquid-crystal display (LCD) touch screen; full color, 800 x 600 pixels, minimum viewing angle of 120°; CFM, Impedance, and EEG displays, English and 13 other languages
Printer	Internal thermal printer
Computer	P5-266-MHz processor or equivalent, 256-MB RAM, 40-GB hard drive capacity (minimum)
Portable	Built-in handle for easy carrying
Electrode Compatibility	Hydrogel, Disk, Needle
Power Requirements	100–240V~, 1.0A, 47–63 Hz
External Connections	RS-232 I/O port, RJ-45 (10/100) Ethernet port, USB port for IEC 60601-1-approved devices, PS2 standard keyboard/mouse serial ports, hospital-grade power cord
Dimensions	13.70 W x 12.25 H x 11.25 D in.; 34.8 W x 31.1 H x 28.6 D cm
Weight	17.5 lb; 7.9 kg
Operating Temperature	75–85°F; 21–29°C
Regulatory Status	FDA 510(k), CSA C-US and CB Scheme, CE – EC Certificate DGM-407

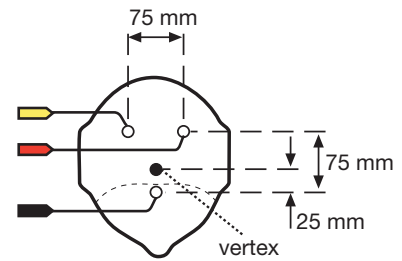


Electrodes Description

Clinicians can choose the type of electrodes to use — hydrogel, disk, or needle — and the positioning method:

Biparietal Position

Hydrogel, Disk or Needle Electrodes



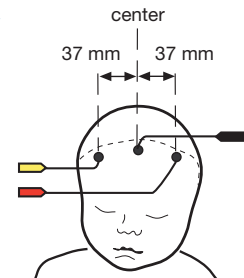
- A. Locate the vertex and place the **BLACK** electrode 25 mm anterior.
- B. Locate a point approximately 50 mm posterior to the vertex. Place the **RED** electrode approximately 37 mm to the left of this point, then place the **YELLOW** electrode approximately 37 mm to the right of this point.

Frontal Position

Hydrogel or Disk Electrodes



Alternate electrode placement method; use if hair interferes with electrode placement.



- A. Place the **BLACK** electrode on the center of the patient's forehead, as close to the hairline as possible.
- B. Place the **RED** electrode approximately 37 mm to the left of the center electrode.
- C. Place the **YELLOW** electrode approximately 37 mm to the right of the center electrode.



Product Strategy

The Olympic CFM 6000 is designed for long-term monitoring, whether for hours or for days. It provides continuous real-time display of cerebral electrical activity to assist the clinician in making immediate decisions and to identify patients in need of closer attention.

The CFM has proven itself, both in clinical and research use, as a valuable complement to traditional neurological assessment. The Olympic CFM 6000 is the only aEEG brain monitor that precisely duplicates the CFM algorithm that has been used since the 1960s.

Like the continuous monitoring of vital signs and oxygen saturation, the Olympic CFM 6000 provides critical information — revealing important transient events as well as long-term changes in the patient's overall brain activity.



The CFM 6000 is well suited for use by the NICU, PICU, OR, ER, and other acute-care departments who have a need to continuously monitor brain activity, and to assess the neurological status of the brain as an aid to both diagnosis and treatment.

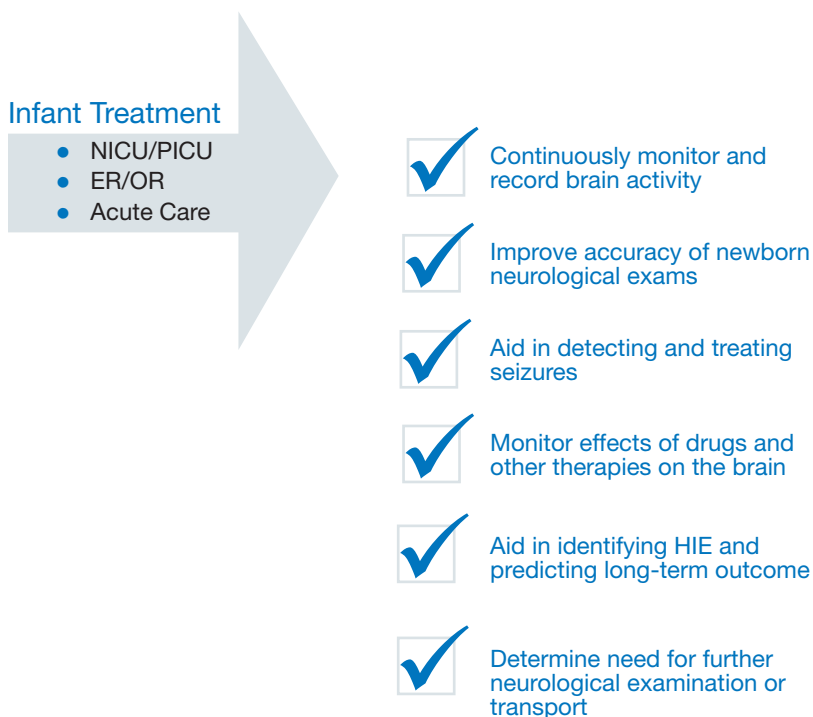
The Olympic CFM 6000 provides neonatologists and pediatric neurologists with an easy-to-read record of overall brain activity and abnormality, and its intuitive interface allows all clinical staff to use the device with minimal training.

Available Languages

The Olympic CFM 6000 is currently available in: English, Danish, Dutch, Finnish, French, German, Greek, Italian, Norwegian, Polish, Portuguese, Spanish, Swedish, and Turkish. Czechoslovakian and Hungarian will be available in Q1 2005.

Qualifying Customers

Any customers with the following needs should consider the Olympic CFM 6000:





Phase 1. Introduction to Brain Monitoring/CFM

Topics

- CFM History, Science, and Technology
- Basic CFM Data Interpretation

Support Tools

- Olympic CFM 6000 Brochure
- Cerebral Function Monitoring (CFM) Abridged Bibliography
- Bibliography: Cerebral Function Monitor (aEEG)
- Guidelines for Basic CFM Tracing Interpretation
- Cerebral Function Monitor White Paper
- “What is CFM?” Presentation (PowerPoint)
- Olympic CFM 6000 Clinical Guide
- *An Atlas of Amplitude-Integrated EEGs in the Newborn*



Phase 2. Introduction to the Olympic CFM 6000

Topics

- Olympic CFM 6000 Operation
- Basic CFM Data Interpretation

Support Tools

- Olympic CFM 6000 Quick Start Card (hang card)
- *Olympic CFM Operator's Manual*
- Guidelines for Basic CFM Tracing Interpretation
- *Olympic CFM 6000 Clinical Guide*
- *An Atlas of Amplitude-Integrated EEGs in the Newborn*



Phase 3. Support & Education

During the support phase, you will be responsible for maintaining customer contact and ensuring that their system is functional. Olympic Medical will assist you with ongoing customer support and education by providing you with:

- Bibliographies of new articles relating to aEEG/CFM
- CFM continued learning through conferences/seminars and videos
- CFM case history library and demo disks
- Service bulletins and updates
- Software upgrade disks and instructions

Support Tools

- *Olympic CFM 6000 Service Manual*
- *An Atlas of Amplitude-Integrated EEGs in the Newborn*
- *Olympic CFM 6000 Clinical Guide, Level 2*
- New-release materials, disks, and videos

Ordering Information



Product Catalog Numbers

Olympic CFM 6000	62000
Complete with power cord, amplifier module, printer paper, hydrogel electrodes, skin prep gel, and instruction manuals.	
Olympic CFM Cart	62080
Paper, thermal, 50-mm wide	62066
Electrodes, hydrogel, bag of 20	62050
Electrodes, hydrogel, box of 100	62051
NuPrep™ Skin Prep Gel, 4-oz tube	62060
Electrode Cream, 3.5-oz tube	60119
Amplifier Module Clips, bag of 5	62065
<i>An Atlas of Amplitude-Integrated EEGs in the Newborn</i>	62070

Service Part Numbers

Amplifier Module w/Clip	401260
Battery, PCB Isolation	200118
CD Drive	302202
Fan Assembly	401221
Foot Assembly	401232
Front Panel Touch-screen Assembly	401194
Fuse (two 3AG 2.5A S/B 250V~)	200021
Hard Drive (unprogrammed)	200286
PCB, Back-light Inverter	200291
PCB, Isolation	401254
PCB, Power Distribution	401185
Power Supply Assembly	200294
Power Switch Assembly (fuses not included)	401239
Printer Door Assembly	302155
Processor Assembly (embedded)	200290
Rear Enclosure Assembly	401195
Thermal Printer Assembly (includes paper)	200288

Appendix: Glossary of Terms



aEEG	Abbreviation for amplitude-integrated electroencephalogram. See also CFM.
Amplitude	Refers to the magnitude of the CFM or EEG trace.
Band of activity	Refers to the width of background activity measured from the upper margin to the lower margin of the CFM. The margins are defined as the edges of the majority of activity (darkest area) of the CFM trace and do not include spikes. The band of activity indicates the variability of the electrocortical activity.
CFM	Abbreviation for cerebral function monitor, a device used for monitoring overall electrocortical background neurological activity by recording the amplitude of the EEG at a very slow speed. It uses a single biparietal or frontal lead (three wires) to obtain an EEG signal, which is filtered, rectified, and semi-logarithmically compressed. The CFM output displays at 1 mm/minute.
HIE	Abbreviation for hypoxic-ischemic encephalopathy, an acquired syndrome characterized by clinical and laboratory evidence of acute brain injury due to asphyxia (i.e., hypoxia, acidosis). In the United States and Western Europe, severe (stage 3–4) HIE accounts for 2–4 cases per 1,000 births reported. In developing nations the incidence of HIE is likely to be higher. Severe HIE can cause mental retardation, epilepsy, cerebral palsy, and death.