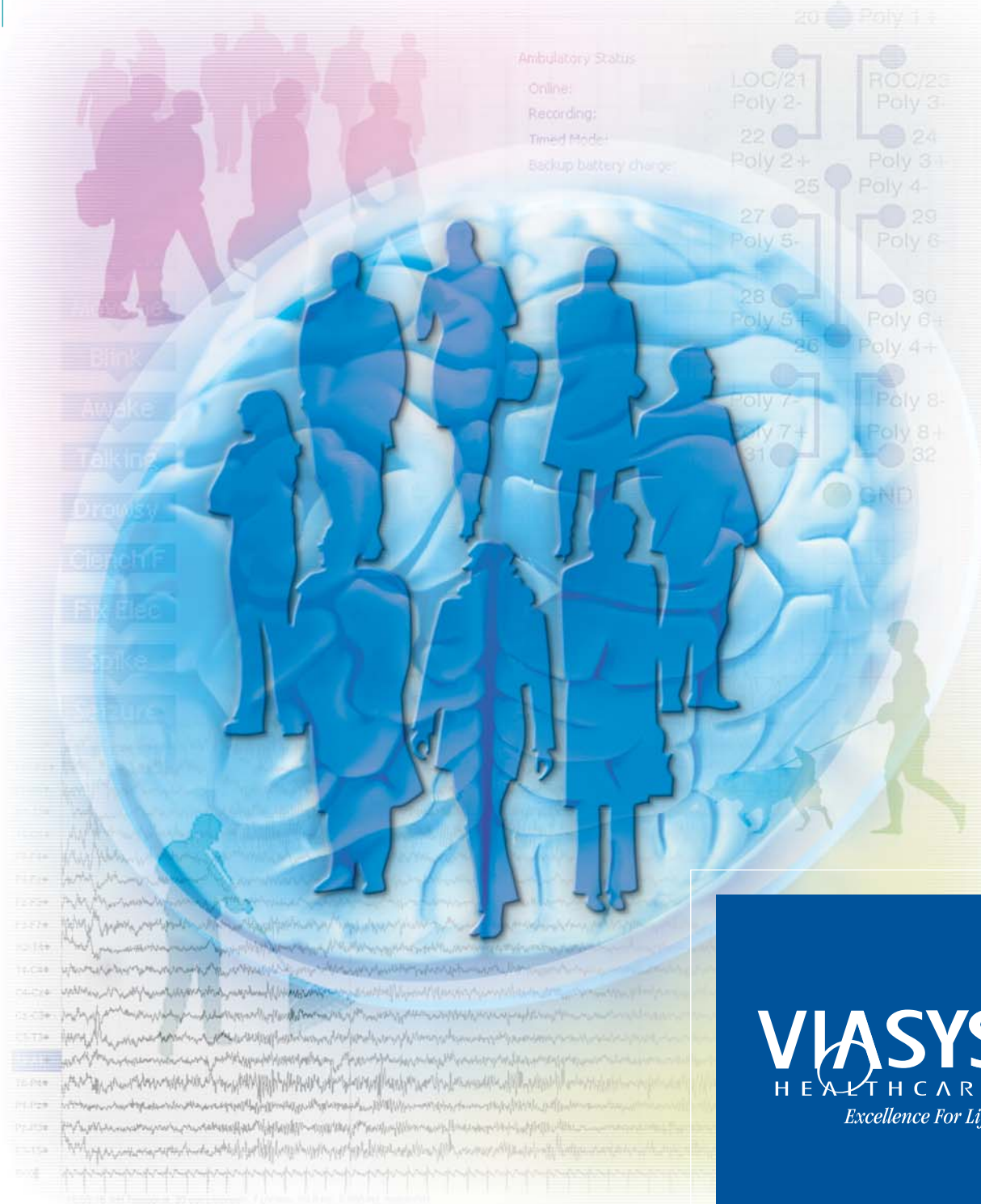# NicoletOne™ Ambulatory EEG

PORTABLE AMBULATORY SYSTEM

VIASYS®

H E A L T H C A R E

Excellence For Life

NicoletOne™ Ambulatory EEG

Shown in the carry case, the NicoletOne AEEG system provides the very best in design, mobility and digital signal processing.

UNPARALLELED PATIENT COMFORT

VIASYS Healthcare offers one of the smallest, lightest ambulatory recorders available – **NicoletOne Ambulatory**.

Ideal for patients of all ages, it combines unparalleled ease and patient comfort with robust signal quality for a wide range of recording needs. Weighing only 1.75 lbs (650 grams) including flash card and batteries, the NicoletOne Ambulatory measures only 5.6"Hx4.7"Wx1.6"D.

AMBULATORY EEG

- 34 active electrode inputs, 32 can be configured for referential recording, 16 can be configured for true bi-polar recording.

- Can record continuously for up to 72 hours, with data review directly from 2GB Flash Card, or record in EDF onto an ATA flash disk.

- Built in Impedance check, Calibration and Patient event button.

- Combined with NicoletOne's nEEG robust software for review and NicVue, VIASYS NeuroCare's patient/data management application, you can offer a complete comprehensive service to your patients.

FREEDOM OF MOVEMENT

The NicoletOne Ambulatory gives patients the flexibility to go about their daily routine while reliably recording data onto a compact flash card. A carry pouch is provided to enable patients to conveniently wear it while performing their daily activities; allowing mobile patient monitoring without costly clinic or hospital stays.
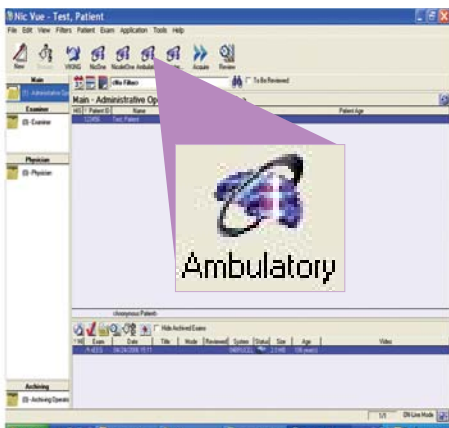
NICVUE

- VIASYS NeuroCare's patient/data management application
- Robust database utilities
- HIPPA support
- One button DVD archiving
- Global language support
- HIS Connectivity
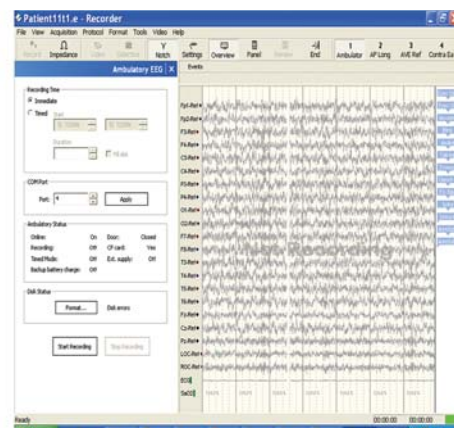
EXCELLENCE IN AEEG MONITORING

Ambulatory electroencephalography (AEEG) monitoring is a relatively recent technology that allows prolonged EEG recording in the home setting. Its ability to record continuously for up to 72 hours increases the chance of recording an ictal event or interictal epileptiform discharges. AEEG is a less expensive alternative to inpatient monitoring, with costs that are 51-65% lower than a 24 hour inpatient admission for video/EEG monitoring.

NICOLETONE AMBULATORY PACKAGES INCLUDE:

- EEG Recorder with LCD display and event button.

- 32 Channels which may be configured for referential recording of all channels, or with 24 referential plus 8 bipolar channels.

- Patient Connection Unit (PCU) and interface cable.

- Medical Grade Power Supply Unit.

- USB-Serial Converter, DB9-RJ45 converter and interface cable (for connection of Ambulatory recorder to setup PC).

- Carry Case with adult straps.

- Non-rechargeable AA Alkaline Batteries (Qty: 6)

- 2GB Compact Flash (CF) data storage memory card.

- One Year Parts Only Warranty.

COMPREHENSIVE SERVICE AND SUPPORT

Our more than 220 trained regional and in-house representatives provide you with the **best customer service in the industry**. In the rare event that problems arise, your system will be back to work with minimal downtime.

VIASYS Healthcare is committed to help you **improve your practice** with the highest-quality system, from the data you capture, manage and diagnose, to the service and expertise you will receive.

VIASYS Healthcare – *Excellence for Life*

NICOLETONE AMBULATORY RECORDER SOFTWARE

- Protocols: stored protocols can be used for multiple types of data acquisition
- Ambulatory data is recorded onto NicoletOne's robust nEEG software
- Data records in EDF format onto an ATA flashcard
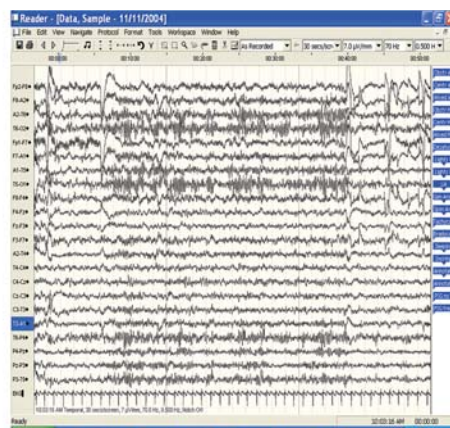
NICOLETONE AMBULATORY READER SOFTWARE

- All review functionality available
- Data can be read in all EDF compatible formats

NicoletOne™ Ambulatory EEG

GENERAL SPECIFICATIONS

Dimensions

Ambulatory EEG recorder:
5.75" H x 4.9" W x 1.6" D
(146mm H x 124mm W x 39mm D)
Patient Connection Unit (PCU):
6.4" H x 2.0" W x 1.1" D
(163mm H x 50mm W x 28mmD)

Weight

Ambulatory EEG recorder (Including batteries and flash storage card): 1lb 7oz (641g)
Patient Connection Unit (PCU): 4.3oz (122g)

Power Supply

9V DC normal operating power provided via 6 x AA batteries (Alkaline or Lithium batteries (IEC-FR6 pr IEC-LR6). Internal battery to supply power for up to 2 minutes when changing batteries. Medical Grade Power Supply for use during system set-up:
Input: 100 – 240Vac +/-10%, 50-60Hz. 0.4 – 0.3A
Output: 12.0VDC 1.25A max.

Data Storage

2GB Compact Flash (CF) Type 1 memory card supplied

Recording Time

Dependent upon media size, number of data channels collected, sample rate used and quality of batteries used, up to 72 hours.

Display

NicoletOne Ambulatory recorder features a 36mm x 9mm (1.4" x 0.4") LCD showing: Time of Day, Elapsed Time (Period of Data Recorded), Battery Level/Power Status, Recording Status, amount of storage space available.

Controls

NicoletOne Ambulatory recorder features a single push button control for dual functions of power on/off (Note: Power off requires push button to be held in for > 6 seconds) and patient event marker.

Connections

Patient Connection Unit (PCU) connector Micro-D connector for connection of external patient event push-button, 4 auxiliary high-level signals.
Host PC RJ45/Serial / Power Connection

Operating Conditions

Relative Humidity: 25% to 95% non-condensing
Temperature +10° C to + 40° C
Atmospheric Pressure range of 700hPa to 1060hPa

Storage Requirements

Relative humidity: 10% to 95%
Temperature: -10° C to +50°C%
Atmospheric Pressure range of 500hPa to 1060hPa

AMPLIFIER

Channels/Inputs

34 active electrode-level inputs, touch proof type to DIN 42 802, 32 inputs may be configured for referential recording. Alternatively, 16 of the electrode inputs can be configured (via set-up software) for true bipolar recording (e.g. for polygraphic signal acquisition as either AC or DC channels)
4 Auxiliary high-level (DC) inputs

Analog to Digital Converter

16 bit with sample and hold on all channels
ADC Resolution 0.153uV
DC Offset Tolerance
+/- 250mV (+/- 2.5V for Auxiliary high-level DC inputs)
Maximum Input Range 10mV pk-pk
Bandwidth 0.16Hz to 70Hz (-6dB)
Noise <= 3uV pk-pk @ 0.16-70Hz
Input Impedance 100 MOhm
Common Mode Rejection Ratio (CMRR) at patient inputs
>110dB (with active patient ground connected)
Input Bias Current < +/- 25nA
Sample Rate
User selectable via software from 200, 128, 64, 50, 32, 25, 16, 8, 4, 2 and 1 Hz

SOFTWARE

Setup and Review

NicoletOne™ nEEG and Reader software provides all set-up and review capabilities (Requires Windows 2000 or XP-Professional based PC with >= 3 USB 2.0 ports available) Note: 3rd party review software applications which offer compatibility with European Data Format (EDF) files may also be used for review.

Data Management

Choice of NicVue™ or Study Room patient/data management software applications

Optional review/analysis software options

Spike and Seizure Detection software option
Topographic Mapping option
Trend Analysis software option
Sleep Analysis software option

COMPLIANCE / REGULATORY STANDARDS

Designed, certified and manufactured to meet the following US, Canadian, European and International standards:

UL60601-1
Medical Electrical Safety Standard (USA)
CAN/CSA-C22.2 no. 601.1-M90
Medical Electrical Safety Standard (Canada)
EN/IEC 60601-1
Medical Electrical Safety of Medical Equipment (International and Europe)
EN/IEC 60601-2-26
Particular safety of electroencephalograph equipment
EN/IEC 60601-1-2
Collateral safety standard for EMC
European Community (CE Mark)
Medical Device Directive (MDD) product certified by N.Q.A. to comply with EC Directive 93/42/EEC

QUALITY SYSTEM

Developed for VIASYS NeuroCare Inc, by Lifelines. Designed and manufactured by G&B Electronics Ltd., United Kingdom, and marketed by VIASYS NeuroCare Inc. under ISO13485, ISO 9001 certified quality system.

The manufacturer and VIASYS NeuroCare reserve the right to change specifications in conjunction with our policy of continuous product improvement.