510(k) Summary
Lexicor NRS-2D
Date Prepared: 4/16/96

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TABLE OF CONTENTS

SUBMITTER

Lexicor Medical Technology, Inc.

5589 Arapahoe Ave. #206

Boulder, CO 80303

Telephone: 303.443.9944   FAX: 303.443.0591

CONTACT PERSON

Michael M. Shupe

Quality and Regulatory Affairs Manager

DEVICE NAME

- Proprietary Name: NRS-2D

- Common Name: Electroencephalograph with an electroencephalogram signal spectrum analyzer and biofeedback options.

- Classification Names: Electroencephalograph

  Analyzer, Spectrum, Electroencephalogram Signal

  Device, Biofeedback

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DEVICE DESCRIPTION

The NRS-2D is a two channel electrophysiological signal acquisition and biofeedback device. The product is designed for use with a standard IBM PC/AT compatible computer and associated peripheral equipment. When assembled with the computer, the NRS-2D system will acquire EEG and biofeedback data, perform signal spectral analysis and quantification and provide auditory and/or visual feedback. At the user's discretion the NRS-2D can be factory configured as a single channel device.

INTENDED USE

The NRS-2D uses Lexicor's BioLex software to perform its intended use.

BioLex Software

Description

> BioLex provides visual and/or auditory feedback based on parameters derived from spectral analysis of the electroencephalogram (EEG) signal.

Indications

> BioLex is indicated for relaxation training using alpha EEG biofeedback. In the protocol for relaxation training, BioLex provides a visual and/or auditory signal that corresponds to the patient's increase in alpha activity as an indicator of achieving a state of relaxation.

Warnings and Contraindications

> BioLex is contraindicated in patients with the following conditions:

1. Individuals who are unwilling or unable to understand the general principles and goals of the feedback used. This includes individuals with excessive behavioral problems or low IQ.

2. Individuals who experience anxiety or an unpleasant experience associated with EEG biofeedback training.

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3. In epilepsy, there may be a causal relationship between EEG training of certain EEG frequencies and incidence of seizure.

   Certain patients may be unable to learn to control the EEG through biofeedback. Therapy should be discontinued if periodic monitoring of therapeutic progress indicates that the patient is not learning despite adequate review of instructions for feedback.

Side Effects

There have been clinical reports of dizziness, drowsiness, fatigue and anxiety associated with feedback employing alpha enhancement.

Frequency and Duration of Treatment

Duration of treatment ranges from 1 to 30 sessions and frequency from 1 to 7 times weekly depending on the needs of the patient.

Operation and Usage

Please refer to the Biolex Software Manual for complete operating instructions prior to use.

PREDICATE DEVICE

Lexicor NRS-4, 510(k) K920038

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

System Block Diagram
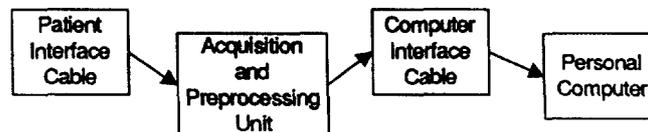
A simple software command will allow the user to check all electrode contacts at any time, while the patient is connected to the NRS-2D without having to disconnect the electrodes from the NRS-2D and check the electrode/skin contact with a separate impedance meter.

510(k) Summary
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Patient Interface

> When EEG electrodes are used and applied properly, contact impedances below 5k-10k Ohms can be obtained.

Acquisition and Preprocessing Unit

> The acquisition and preprocessing unit is a self-contained electrically isolated module which amplifies and filters the subject's EEG signals and converts them from an analog to digital form.

> Each of the NRS-2D's channels consists of a continuity checking circuit, followed by a preamplifier and then lowpass, highpass and notch filters.

> The notch filter (60 Hz USA) attenuates electrical mains interference noise entering the signal path.

> Finally the channels are scanned by a 12 bit combination multiplexer and Analog to Digital converter with Sample and Hold.

> A microprocessor in the NRS-2D controls the continuity checking and A/D conversion process, transmits data to, and receives commands from the PC through on-board optical isolators. Communication with the PC is accomplished via a 25 conductor cable which connects to the NRS-2D back panel's DB-25 connector and to any PC parallel printer port.

> A binary executable code for the microprocessor handles the communication between the Acquisition and the host software application (BioLex and NeuroLex). The code instructs the card to reset the input multiplexer, read the data into an area of dual-ported memory in the processor and set interrupt vector 7 of the host PC interrupt system. The host software's interrupt routine then reads the data form the processor memory into computer RAM. This process is repeated for each set of input samples of the digitized EEG.

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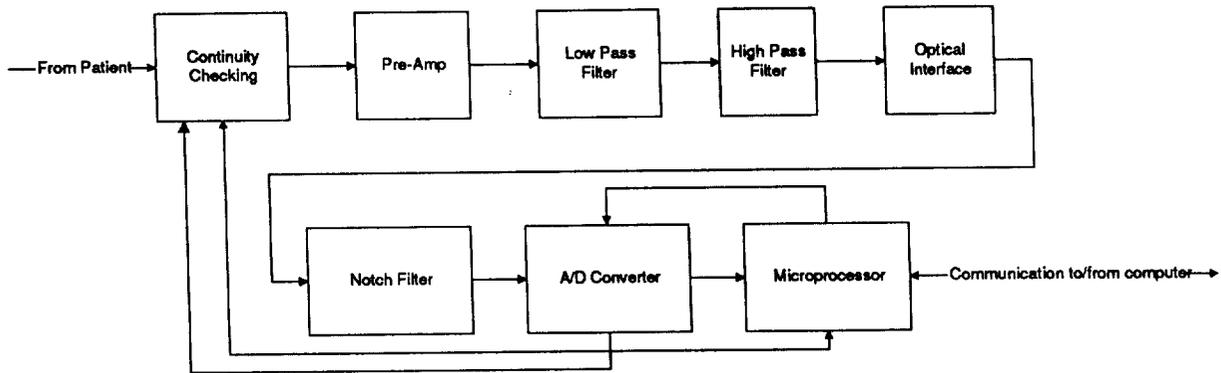
NRS-2D Functional Block Diagram

The NRS-2D has a fixed sampling rate of 128Hz, a fixed gain of 8,000 and a built in electrode continuity checking capability.

A simple software command will allow the user to check all electrode contacts at any time, while the patient is connected to the NRS-2D without having to disconnect the electrodes from the NRS-2D and check the electrode/skin contact with a separate impedance meter.

Power

The NRS-2D uses a medical grade single output switching power supply with the following features:

Universal input from 90-264VAC   Power on LED

Built-in EMI filter-class B   Overvoltage and short circuit protection

UL-544, CSA-223 and TUV-601 Safety approvals

Output-12 VDC, 2A

A 9.6 VDC rechargeable battery pack is available as an option.

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The following is a table of the NRS-2D specifications.

Physical Dimensions	6" (l) x 3" (w) x 1.125" (h)	**AC Power**	
Signal Acquisition		Voltage	100/240 volts, 30 watts, 50/60 Hz
Channels	1 or 2	Current	< 1 amp
Sampling Rate	128Hz	Leakage Current	< 20μA
Frequency Resolution	0.5 Hz	Fuses	0.8 amp, 250 volt
Noise	< 2μV pp @ 0.5-32 Hz	**Battery Power**	
Notch Filtering	60 or 50 Hz	Voltage	9.6 volts
Common Mode Rejection Ratio	> 90 db at 60 Hz	Current	600 MAH
Gain	8k	Type	Rechargeable
Artifact Rejection	manual/automatic	**Control Software**	
Low Pass Filters	32 Hz		BioLex
High Pass Filters	0.5 Hz		
Input Impedance	>1 GΩ		
A/D Resolution	12 bits		