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K952315

Innovators of medical software solutions



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510(k) Summary

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Device Name "SatMaster," Computerized Pulse Oximetry Software
510(k) File Number K952315

1. *The Device*

SatMaster is the name of EMG Scientific's Computerized Pulse Oximetry Software product. This product consists of a Program Diskette, a Software License, a User Manual, and a Test Cable. Thus, *SatMaster* is a software-only "device," intended for use with an MS-DOS, PC-type computer provided by the end-user.

Briefly, the *SatMaster* software provides a PC computer user the capability of transferring Pulse Oximetry data from a Pulse Oximeter, storing the data on the computer, displaying the data in various forms, annotating the data, calculating statistics, and printing the results.

SatMaster has been in use outside the US for over 5 years. Prominent foreign users include the Queen Mary Hospital at the University of Hong Kong, Osaka Medical & Health Center for Mothers & Children, Adelaide Children's Hospital, Royal University Hospital, National University of Singapore, Helsingborgs Lasarett (Sweden), Royal Brisbane Hospital (Australia), University of Malaysia - Department of Anaesthesiology, Universitair Ziekenhuis Antwerpen, University of Calgary, Forschungsinstitut für klinische Medizintechnik (Germany), Broadgreen Hospital NHS Trust (United Kingdom).

2. *An Accessory*

SatMaster is designed to be an accessory to enhance a caregiver's use of Pulse Oximeters. Pulse Oximeters, approved, Class II devices manufactured by several companies, are used to measure a patient's Oxygen Saturation (SaO₂) and Pulse Rate. The current values of these clinical parameters are displayed on the Pulse Oximeter's front panel. Many Pulse Oximeters contain a memory to store numerous hours of oximetry trend data.

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Likewise, many Pulse Oximeters contain a Serial Communications Port, so that the Pulse Oximeter may transfer data to a computer, a printer, or some other device. SatMaster would only be useful in conjunction with an oximeter having a Serial Communications Port, since SatMaster receives data from the Pulse Oximeter via a connection between the computer and the Pulse Oximeter's Serial Communications Port.

Some Pulse Oximeter's can be connected to various types of printing devices. These Pulse Oximeters, when connected to a printer, can produce graphs of SaO2 vs. time, histograms, and certain statistics.

Here is a list of the Pulse Oximeters that SatMaster has been designed to work with:

Manufacturer	Model	FDA 510(k) Number	Clearance Date
Nellcor	N-200 Pulse Oximeter	K863784	21 November 1986
Nellcor	Symphony N-3000 Pulse Oximeter	K942347	12 May 1995
Ohmeda	Biox 3700 Pulse Oximeter	K850494	28 March 1985
Ohmeda	Biox 3740 Pulse Oximeter	K872772	7 October 1987

3. *The Predicate Device*

The Predicate Device that SatMaster resembles is a Nellcor N-250 Pulse Oximeter. The Nellcor N-250 Pulse Oximeter is actually a composite device obtained by connecting a Nellcor N-200 Pulse Oximeter to the Nellcor N-50 Powerbase. The combination of these two devices is known as the N-250 Pulse Oximeter.

The FDA 510(k) clearances for these two Nellcor products are:

Nellcor N-200 Pulse Oximeter	K863784 (21 November 1986)
Nellcor N-50 Powerbase	K901399 (12 June 1990)

The features of these two devices that are relevant to this discussion are as follows. The Nellcor N-200 Pulse Oximeter performs Pulse Oximetry monitoring on the patient, displays instantaneous values of the SaO2 and Pulse Rate, and stores the Pulse Oximetry data in its trend memory at 5 second intervals. The N-200 also produces audible alarms for conditions such as high and low SaO2, high and low Pulse Rate, etc.

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The Nellcor N-50 Powerbase contains an LCD screen, and a strip-chart printer. The unit can access the connected Nellcor N-200's trend memory and display a graph of SaO2 vs. time on the LCD screen. Using the N-50's built-in printer, the following graphs and statistics can be output:

1. Trend Graph of SaO2 and Pulse Rate vs. time
2. A histogram showing percent of time at various SaO2 levels
3. A Tabular list of SaO2 values at 30 second intervals

Here is an example of the graphs and statistics produced by the Nellcor N-50:

Tabular printout (see Figure 11) provides a histogram for SaO2 and other tabular data for saturation and pulse rate.

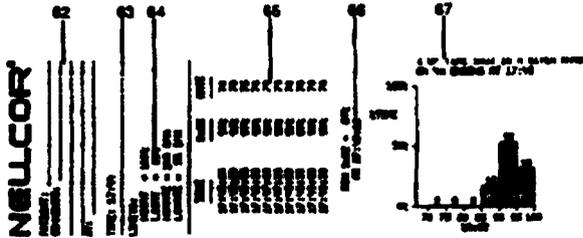


Figure 11: N-50 Tabular Printout Example

Trend (see Figure 12), shows SaO2 levels and pulse rate trends.

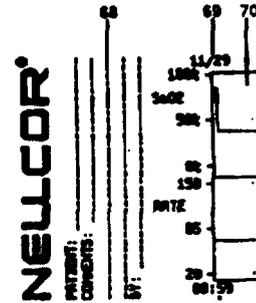


Figure 12: N-50 Trend Printout Example

Histogram (see Figure 13), shows a maximum of 12 hours of trend data

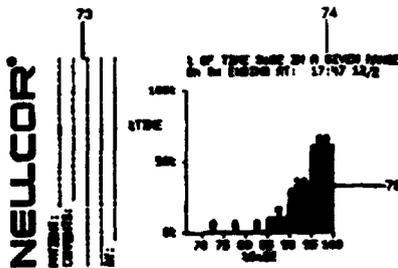


Figure 13: N-50 Histogram Printout Example

From the Nellcor N-50 Operator Manual
(Reproduced with permission from Nellcor)

4. **SatMaster's Equivalence to Predicate Device**

SatMaster is substantially equivalent to the Predicate Device in the following areas:

1. The ability to extract Pulse Oximetry data from a Pulse Oximeter and to display Pulse Oximetry trend information on the screen and in printed reports
2. The ability to produce a tabular list of Pulse Oximetry data values at various time intervals
3. The ability to generate histograms showing percent of time at various SaO2 levels

SatMaster is not intended to be a patient monitor. Therefore, SatMaster does not perform the functions of the Nellcor N-200 Pulse Oximeter. Rather, a computer running the SatMaster software performs some of the same functions a Nellcor N-50 Powerbase. Thus, a computer running the SatMaster software, when used with a Pulse Oximeter, provides some of the capabilities of the Nellcor N-250.

5. **Differences between SatMaster and the Predicate Device**

Although SatMaster is substantially equivalent to the Predicate Device, certain important differences should be noted:

1. Whereas the N-250 combination serves as a patient oxygenation monitor, SatMaster performs no monitoring of the patient. Rather, SatMaster presents the user with reports based on the data

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that has been collected by the Pulse Oximeter, which is, of course, an approved monitoring device. Thus, by design, SatMaster does not perform the functions of the Nellcor N-200 Pulse Oximeter.

2. Since SatMaster is not intended to be a patient monitor, SatMaster has no provisions for reporting of the Pulse Oximeter's alarms.
3. Although the Nellcor N-250 can be connected to an external ECG synchronization source, SatMaster does not produce an ECG or Pleth waveform output, as the N-250 does.
4. The Nellcor N-50 Powerbase acts as a dock into which the Nellcor N-200 Pulse Oximeter is inserted. The N-50 provides electrical power to the Nellcor N-200 Pulse oximeter. Likewise, several connectors are present in the N-50 to allow connection of the composite N-250 device to a variety of external devices.

Since SatMaster is a software system, SatMaster does not provide the Pulse Oximeter with electrical power, nor does it provide the Pulse Oximeter with any connections to external devices. Rather, the user's computer is connected to the Pulse Oximeter's Serial Data Port via a simple RS-232 cable.

5. SatMaster generates additional reports not provided by the N-250. Moreover, SatMaster-generated versions of the N-250's reports contain various enhancements.
6. SatMaster performs various data-management functions to aid in storing and organizing the Pulse Oximetry data that has been obtained from the Pulse Oximeter. These data management functions are designed to be easy for the user to use, and at the same time to increase patient safety.

6. *Intended Use of SatMaster*

SatMaster is intended for use as an adjunct to traditional Pulse Oximetry, in which the caregiver observes instantaneous Pulse Oximetry values as displayed on a Pulse Oximeter's face. SatMaster produces graphs and statistics describing a patient's Pulse Oximetry data trends over relatively long periods of time, including those times when the caregiver is not directly observing the Pulse Oximeter's display.

In a hospital setting, SatMaster would be used in association with ICU's, Operating and Recovery Rooms, Pulmonary Function Labs, Sleep Labs, and research.

In home-care settings, SatMaster would be used for sleep studies and home-oxygen evaluations.

It is expected that the Pulse Oximeter itself will be operated by competent personnel in accordance with the Pulse Oximeter manufacturer's FDA-approved instructions.

Once the patient monitoring process is complete, either in the hospital or home setting, the Pulse Oximeter unit would normally be brought to the office where the computer resides. (Alternatively, a portable computer would be brought to the Pulse Oximeter.) After connecting the serial oximeter-to-computer data cable and invoking the SatMaster software, the accumulated Pulse Oximetry data would be transferred from the Pulse Oximeter to the computer. Once the data transfer is complete, it is no longer necessary for the computer to be connected to the Pulse Oximeter. The caregiver may now view the Pulse Oximetry data and statistics on the computer screen, annotate the data, and print various reports.

7. *Safety and Effectiveness of SatMaster Compared to the Predicate Device*

As noted above, SatMaster is not a patient monitor. Rather, SatMaster is intended to be an Accessory to the use of Pulse Oximeters. It is expected that the Pulse Oximeter itself will be operated by competent personnel in accordance with the Pulse Oximeter manufacturer's FDA-approved instructions.

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The safe and effective monitoring of a patient by a Pulse Oximeter while connected to an external device, such as a computer running SatMaster, is a documented feature of an approved Pulse Oximeter. Thus, the Pulse Oximeter-to-patient connection, and the Pulse Oximetry monitoring process, is unaffected by whether or not SatMaster will be used to display or calculate statistics on the data. Therefore, using SatMaster should have no impact on the safety of the Pulse Oximetry monitoring process.

The SatMaster software has been designed and extensively tested to insure the correctness and accuracy of SatMaster's data retrieval, data management, data storage, statistical calculations, and reports.

As mentioned above, certain features of SatMaster represent enhancements of safety and effectiveness when compared with the predicate device. For example, a strip chart generated by the predicate device does not bear the patient's name or ID number; the possibility exists that it could be mixed up with that of another patient. When using SatMaster, however, before any oximetry data is transferred to the computer, the operator must enter the patient's name and ID number into SatMaster's Patient Data Management facility. This identification information is then prominently shown on every subsequent screen and report.

Another example: the extensive reports and statistics generated by SatMaster can provide additional information to the caregiver over that produced by the predicate device.

SatMaster serves to enhance the usage of Pulse Oximeters. Provided that a Pulse Oximeter is operated in accordance with the Pulse Oximeter's Manufacturer's instructions, SatMaster reports and statistics provide a convenient "picture" of the data collected by Pulse Oximeters. In the opinion of a number of researchers, SatMaster's functionality may have clinical value in several areas, as can be seen from the following list of published articles describing research performed using SatMaster:

Durand M, McEvoy C, MacDonald K: Spontaneous desaturations in intubated very low birth weight infants (<1000 grams) with acute and chronic lung disease. *Pediatric Pulmonology* July 1992; 13: 136-142.

Durand M, McEvoy C, MacDonald K: Computerized pulse oximetry and pulmonary resistance in preterm ventilator dependent infants (<1000g) with chronic lung disease. *Intensive Care Medicine* June 1990; 16, Supplement 1: Abstract 265.

McEvoy C, Sardesai S, Macri C, Paul R, Durand M: Neonatal pulmonary mechanics and oxygenation following amniocentesis in labor: a randomized clinical trial. *Pediatric Research* April 1991; 29: 226A.

McEvoy C, Hewlett V, Sardesai S, Mendoza E, Durand M: Prone positioning decreases episodes of desaturation in infants with chronic lung disease. *Journal of Pediatric Research* April 1992; 31: 211A.

Durand M, McEvoy C, MacDonald K: Computerized pulse oximetry and pulmonary mechanics in intubated low birth weight infants with acute and chronic lung disease. *Pediatric Research* April 1990; 27: 300A.

Jones R, Lawson A, Gunawardene W, Roulson C, Brown A, Smith I: An evaluation of prolonged oximetric data acquisition. *Anaesthesia and Intensive Care* 1992; 20: 303-307.

MacDonald KD, Salaz E, Franceschini RE: Neonatal synchronous intermittent mandatory ventilation (SIMV) improves oxygenation. *Respiratory Care* 1991; 36: 811.

MacDonald KD, Salaz E, Wirtschafter DD: Effect of patient flow triggered ventilation (PFTV) on neonatal pulmonary mechanics. *Respiratory Care* 1991; 36: 810.

Thus SatMaster can be seen to be both safe and effective when used in accordance with its instructions.