

Section 01

K972991

510(k) SUMMARY**Monitor One nDx®****510(k) SUMMARY AS REQUIRED BY ¶807.92(c)**

Prepared by	Joseph Hanna, Director of Quality Assurance
Date of Preparation	July 1997
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Device Name	monitor one nDx®
Common Name	ECG monitor and respiration pacer
Classification	Class II

Section 01**510(k) SUMMARY****Table of Contents**

1. DEVICE IDENTITY	3
1.1. TRADE NAME	3
1.2. COMMON NAME	3
1.3. CLASSIFICATION NAME	3
2. DESCRIPTION OF THE DEVICE	3
3. SPECIFICATIONS	5
3.1. ELECTRODES	5
3.2. ELECTRODE CABLE	5
3.3. COMMUNICATIONS INTERFACE	6
4. INTENDED USE/INDICATIONS FOR USE	6
5. PREDICATE DEVICE	6
6. SAFETY SUMMARY	7

Section 01

510(k) SUMMARY

1. DEVICE IDENTITY

1.1. TRADE NAME

monitor one nDx®

1.2. COMMON NAME

ECG monitor and respiration pacer

1.3. CLASSIFICATION NAME

Electrocardiograph (Product code DPS)

2. DESCRIPTION OF THE DEVICE

monitor one nDx® is a microprocessor based, real-time, hand-held, battery powered, ECG monitor and respiration pacer.

It identifies, classifies, analyzes, stores and retrieves from memory electrocardiographic (ECG) signals for the purpose of measuring and providing statistical analysis of heart rate variability. These signals, along with associated numerical data, are provided to the user in printed or electronic form for over-reading by competent medical professionals.

The monitor one nDX ® system consists of a pacing and recording device, a set of skin electrodes with associated cable and an optically coupled interface for transmitting stored data to compatible devices such as printers or modems

The hand-held monitor weighs 16 oz. and measures 7.5 x 3.5 x 1.4 inches. It is powered by four AA alkaline batteries.

monitor one nDx® senses changes in the electrical potential of the skin caused by successive depolarization and repolarization of the heart as it beats. These electrocardiographic (ECG) signals are picked up by electrodes applied to the skin in three locations representing two poles of the V5 lead (recommended) and a reference or "ground" lead. The resulting signal is fed to a series of operational amplifiers, comprising a precision instrumentation amplifier. The signal is conditioned, by means of filters to minimize the effect of noise and artifact. Protection circuits shunt destructive overvoltage to ground to prevent damage to the circuitry.

Section 01

510(k) SUMMARY

An analog-to-digital converter samples the amplified signal at specific intervals timed by the system master clock and converts the instantaneous voltage to a numeric value. This value is passed to the microprocessor.

Measurements of signal features, the instantaneous value of the signal for each time sample, results of algorithm operations and information about the state of the monitor and its subsystems are stored continuously.

A clock and calendar timer provides the processor with the actual time and date.

The microprocessor has been programmed to apply statistical analysis to the list of stored beat times. The results are both displayed and/or printed out for review by the attending physician.

A buffered interface can receive data from the monitor and pass the data to either a local printer or a modem.

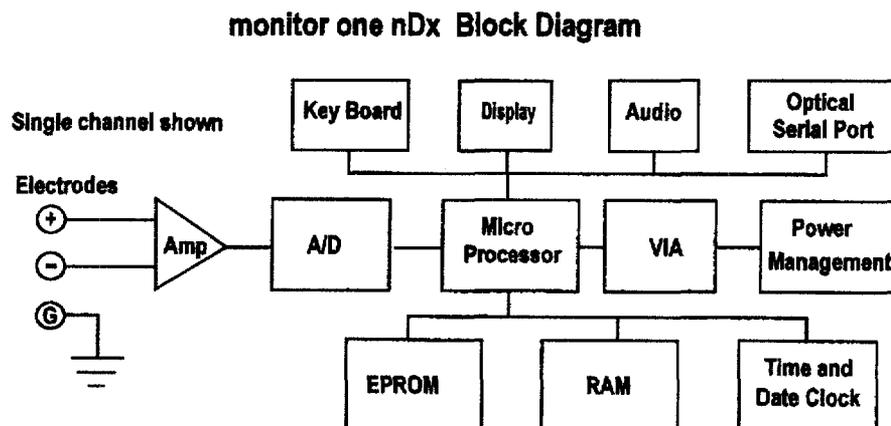


Figure 1-A

Section 01

510(k) SUMMARY

3. SPECIFICATIONS

monitor one nDx® is a portable ECG monitor that has been programmed to provide timing cues to enable a patient to synchronize both respiration cycles and other exercises to a standard regimen used to assess heart rate variability.

The device weighs slightly less than a pound. It has three controls operated by the user: an on/off switch, a twelve (12) button key pad and a pushbutton.

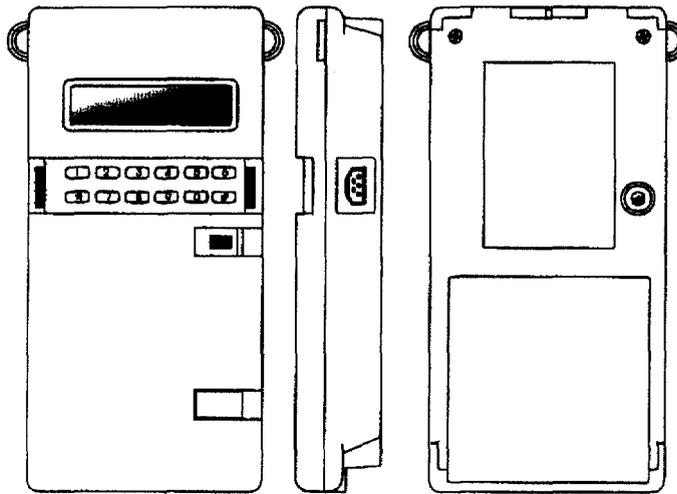


Figure 1-B

The device includes a tone generator and a liquid crystal display (LCD). It uses an infrared optical link to transmit data to the interface, providing complete electrical isolation for the patient.

The device is programmed with three different protocols to aid in assessing heart rate variability: paced breathing, the Valsalva maneuver and a posture test.

The device stores a complete test series composed of a single paced breathing test, three Valsalva results and a posture response for each patient. The data may be erased after review or stored in memory indefinitely. All data must be erased before a new patient is tested.

The digital sampling rate is 256 samples per second. The digital resolution is 10 bits @ 256 Hz. The range of normal QRS is between 50-120 milliseconds.

3.1. ELECTRODES

Electrodes supplied with the device are 510(k)-cleared. These are pre-gelled, self-adhesive electrodes.

3.2. ELECTRODE CABLE

The cable is a plastic-jacketed, shielded cable terminated at one end by a mechanically polarized connector with recessed pins and terminated at the other end by a plastic break-out from which radiate individual shielded lead wires which themselves are terminated by standard medical snap connectors for attachment to electrodes.

Section 01

510(k) SUMMARY

3.3. COMMUNICATIONS INTERFACE

A device which receives formatted serial data from the monitor, and which has the capability to store the data or convert it to parallel data format for redirection to a printer or modem. The communications interface consists of the following components:

- Plastic case with folding support;
- 6 labeled keys;
- 3 bi-color enunciator LEDs (labeled);
- Serial optical link;
- Low voltage power jack;
- Nicad battery memory back-up;
- 6552 microprocessor;
- 25 pin D connector;
- Printed circuit board; and
- Assorted electronic parts.

4. INTENDED USE/INDICATIONS FOR USE

The monitor one nDx® is intended to measure time domain heart rate variability (HRV) in response to a series of standardized, controlled exercises on the part of the patient. While the monitor one nDx® has been shown to be safe and effective for the measurement of heart rate variability, it is not intended to be used as the basis for a specific clinical diagnosis. The clinical significance of HRV should be determined by the physician.

5. PREDICATE DEVICE

For statistical analysis of heart rate variability, the monitor one nDx® is substantially equivalent to the SpaceLabs Heart Rate Variability Software Option (K950779) that was determined to be SE April 25, 1995.

Section 01

510(k) SUMMARY

6. SAFETY SUMMARY

qmed is not aware of any adverse safety information pertaining to the use of the monitor one nDx®. The following points are relevant.

- There are no plausible conditions in which the device could immediately threaten a patient's life. The device itself operates on four penlight batteries. The combination of high resistance input and passive protection circuitry insures that potentially harmful electrical current cannot be applied to the patient even in the event of system failure or physical damage.
- The device cannot directly cause irreversible illness or permanent injury under any plausible conditions. The device is non-invasive, and does not directly control any life sustaining systems or functions.
- The device does not directly control the delivery of energy, or the administration of parenteral drugs.
- The device is a diagnostic aid that presents information the physician uses, along with other important indications, to assess certain aspects of cardiac function.
- No special skills are needed to operate the device.
- The quality of the data is not dependent on operator skills.
- The controls (keypad, power switch and pushbutton) do not initiate any mechanical action, do not mediate the delivery of any substance or energy, and are not associated with any alarm condition that could plausibly create a hazard of harm or injury to either the user or the patient due to malfunction or misuse.
- The electrode cable is terminated at the monitor end with a polarized unique plug assembly in which the male contact pins are shrouded by nonconductive material. The design is such that the pins are not exposed to accidental contact with voltage sources. The form and dimensions of the plug are unique. The plug cannot be inserted in devices other than the intended device. The polarized design eliminates the possibility of inserting the plug in an improper orientation.
- The device is solid state throughout. There are no motors, actuators, transport mechanisms, fluid or pneumatic storage systems.
- The device weighs less than a pound, is easily held in the hand, has no protruding or abrasive surfaces, will not create hazardous particles when dropped, and may be stored indefinitely.
- The device makes computations that are verified by a health care professional and does not provide a diagnosis.

End of section



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 1998

Mr. Joseph Hanna
qmed, Inc.
60 Bay Street
Sag Harbor, NY 11963

Re: K972991
Monitor One nDx®
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: September 10, 1998
Received: September 10, 1998

Dear Mr. Hanna:

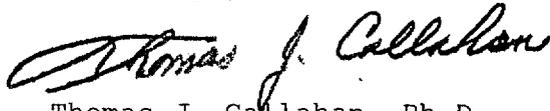
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972991

Device Name: monitor one nDx

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

mark *name*
Division Sign-Off
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____