K063113

EPMedSystems

510(k) Summary

Summary preparation date: 10/10/06

1.0 Device Trade Name

Device Trade Name	Device Classification
EP-WorkMate®	Programmable Diagnostic Computer

2.0 Establishment Address and Registration

EP MedSystems Inc.
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 USA

Larry Picciano
Telephone: 856-753-8533
Fax: 856-753-8544
E-mail: lpicciano@epmedsystems.com

US Food and Drug Administration Establishment Registration No.: 2248049

3.0 Device Classification

Programmable diagnostic computers have been classified as Class II, 74 DQK. No performance standards have been established under CFR 21 Part 870.1425 or Section 514 of the Food, Drug, and Cosmetic Act for programmable diagnostic computers.

4.0 *Predicate Devices / Technology

Product Description	510 (k) No.	Date
EP-WorkMate®	K994011	03/23/00

* This application describes a modification to the EP-WorkMate® called NurseMate™.

5.0 Labeling and Intended Use

The following labeling is contained within **Appendix 4**.

5.1 Proposed Product Labeling
5.2 Proposed Marketing Literature
5.3 Proposed Instructions for Use Manual

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5.4 **Intended Use**

The EP-WorkMate® with an EP-3 (K935590) or EP-4 (K041442) stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachy-arrhythmias measurements of electrical conduction. The addition of NurseMate™ does not change intended use of the EP-WorkMate®.

6.0 Indications for Use

Indications for Use Statement

EP-WorkMate® is indicated for use during clinical electrophysiology procedures.

The addition of NurseMate™ does not change the indications for use.

7.0 Device Description

7.1 **Background description of EP-WorkMate®:** Cardiac EP studies are diagnostic tests that enable physicians to look at electrical signals from within the heart in detail to determine if an abnormality (arrhythmia) exists. The cardiac EP laboratory is typically staffed with one or more physicians, nurses, and technologists thus making the lab a busy and sometimes crowded workspace. A physician directs the EP study and the operation of the EP-WorkMate® system; some physicians operate the system, others direct a member of the clinical staff on the system operation. The EP-WorkMate® system is illustrated in **Figure 1**. Under the direction of a physician, the cardiac stimulator delivers diagnostic stimuli to the heart through the EP catheter(s). The heart's electrical response to the diagnostic signals is returned through the catheter(s) to the amplifier/signal conditioning unit. The amplified and conditioned signals are displayed as waveforms and tabular EP data on the EP-WorkMate® real-time display monitor for diagnosis by the physician. A physician may also choose to record/store the signals using the EP-WorkMate®.

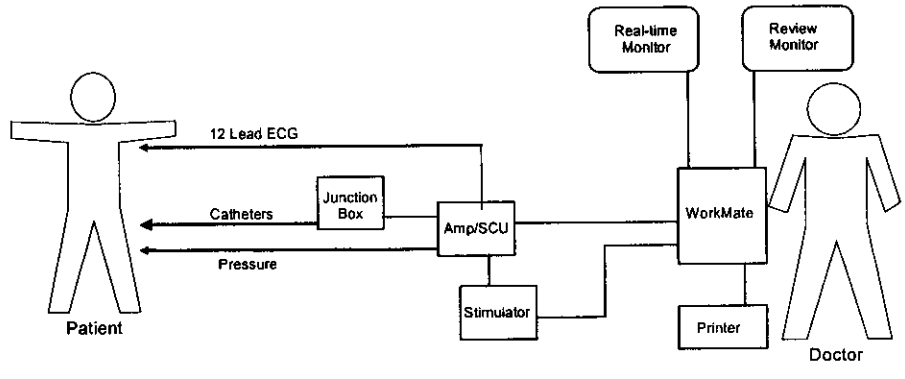


Figure 1: EP-WorkMate® System Block Diagram

7.2 **General description of NurseMate™:** This application describes a modification to the EP-WorkMate® computer that will be offered as an option to customers under the name NurseMate™. NurseMate™ is a PC (Personal Computer) workstation that when connected to the EP-WorkMate® system can be used for real-time patient charting, physiologic monitoring, and data analysis during electrophysiology (EP) studies. The interconnection of NurseMate™ to EP-WorkMate® is illustrated in **Figure 2**. Expanding the EP-WorkMate® system with the optional NurseMate™ creates an additional workstation for a member of the EP team such as a nurse. The additional workstation reduces crowding at the main EP-WorkMate® station and eases workflow congestion in the busy cardiac EP laboratory. Using NurseMate™ an EP lab staff member can perform patient charting (e.g., event titles, medications, comments) and monitor physiologic data including heart rate (HR) and blood pressure (BP) on their own display separate from the physician who is controlling the EP study using EP-WorkMate® workstation. **Figure 3** illustrates NurseMate's™ graphical user interface (GUI) displaying HR and BP.

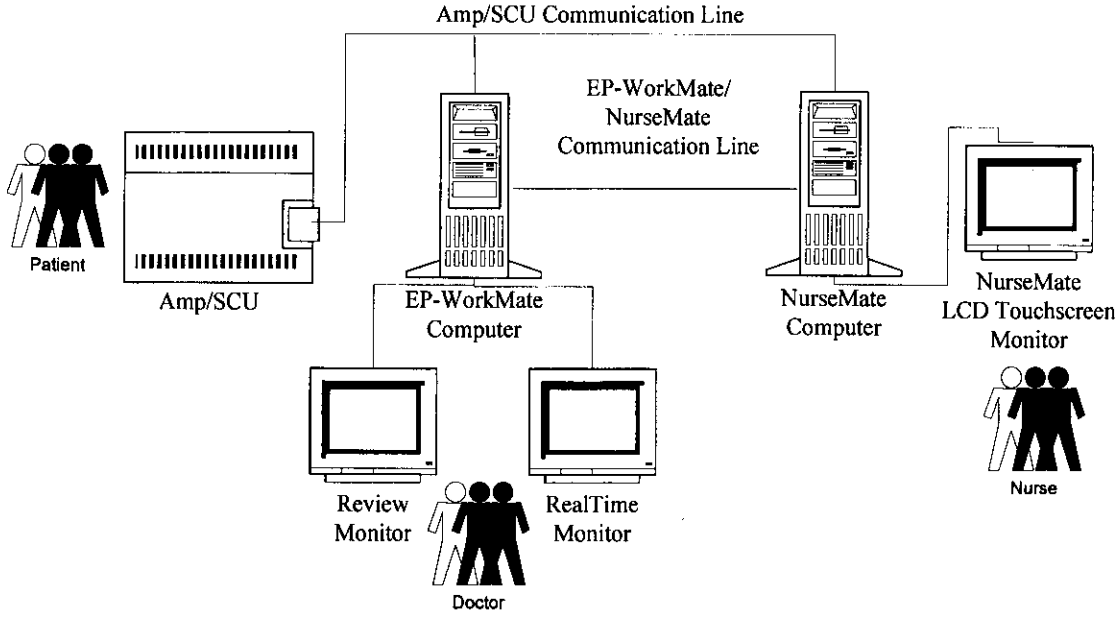


Figure 2: EP-WorkMate® with NurseMate™ Block Diagram

7.3 **NurseMate™ software description:** The NurseMate™ for EP-WorkMate® software installed on NurseMate™ is simply a modified version of the EP-WorkMate® application software. The EP-WorkMate® software was modified using the same Microsoft Visual C++ 6.0 Integrated Development Environment (with Visual Studio Service Pack

6.0) within which it was developed. The NurseMate™ for EP-WorkMate® program code is taken directly from the WorkMate's® C++ program code; hence, the software applications are highly similar. The important exception between EP-WorkMate® and NurseMate™ is that the EP-WorkMate® controls the cardiac stimulator while NurseMate™ does not. A list comprising a functional software comparison between EP-WorkMate® and NurseMate™ is presented in **Table 1**.

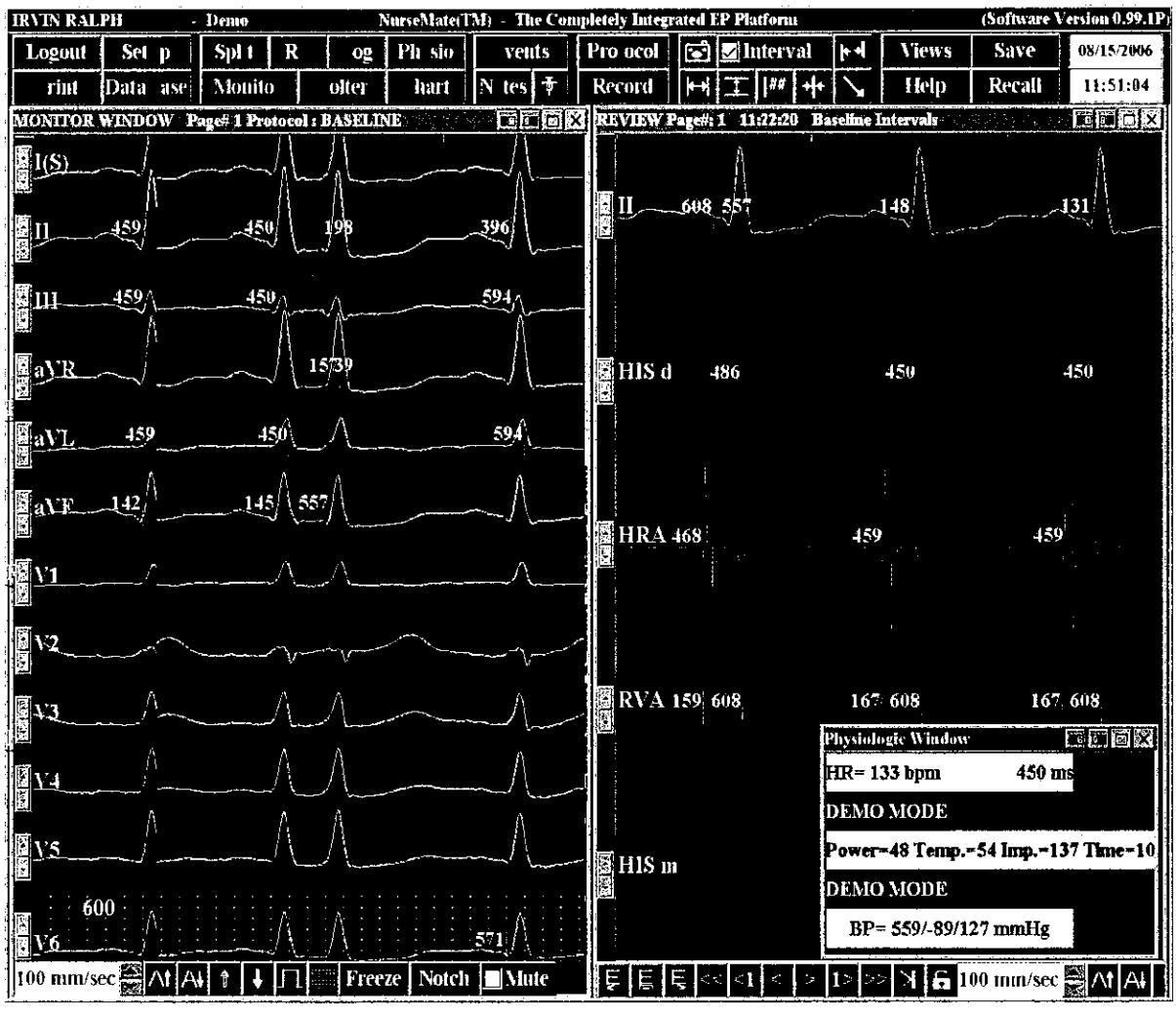


Figure 3: NurseMate™ Graphical User Interface with Physiologic Data

7.4 **NurseMate™ hardware description:** NurseMate™ hardware is designed and built using similar PC technology employed in the EP-WorkMate®. NurseMate™ comprises a: PC, touch screen LCD monitor, Central Processing Unit (CPU), mouse, keyboard, and an equipment cart. The CPU is an off-the-shelf Pentium® microprocessor based personal computer running Microsoft Windows® Operating System (OS), with on board Random Access Memory (RAM), a Hard Disk Drive (HDD), a Read/Writable (R/W) Compact Disk (CD), multiple Universal Serial Bus

(USB) ports, and a Network Interface Controller (NIC). The NurseMate™ station has a smaller, more movable, form factor than EP-WorkMate®; it has a single display monitor and a smaller footprint cart with castors. **Figure 4** illustrates the NurseMate™ station form factor.

Figure 4: NurseMate™ Work Station

7.5 **EP-WorkMate® with NurseMate™ connection:** To use NurseMate™ as intended, it must be connected to the EP-WorkMate® through two basic electronic interconnections.

7.5.1 **PC-to-PC connection:** The first interconnection between the two computers illustrated in **Figure 5** is required for the client-server operation. The EP-WorkMate® acts as the server and the NurseMate™ acts as the client via handshaking signals. The client is passive except in that NurseMate™ can issue commands to the WorkMate® to start/stop data recording. The hardware interconnection between the computers is comprised of off-the-shelf category five (CAT 5) network cabling; the connections are terminated with standard data communication connectors (RJ-45). LAN connectivity is established using standard networking software protocol, Telecommunications Protocol/Internet Protocol (TCP/IP).

7.5.2 **PC-to-Amp/SCU connection:** The second interconnection between the NurseMate™ computer and the EP-WorkMate®

amplifier uses the same hardware as a LAN connection. Communication is accomplished using a common software protocol known as Packet Driver which is similar to TCP/IP. This connection enables the NurseMate™ user to independently configure and view real time patient EP waveforms from the amplifier (Amp/SCU) during an EP study.

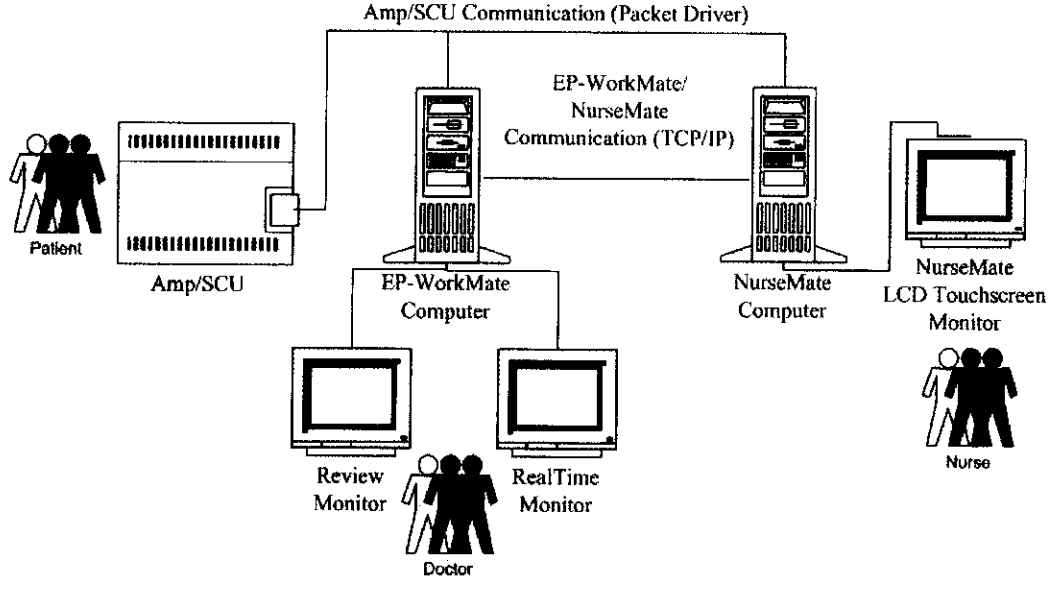


Figure 5: EP-WorkMate® with NurseMate™ Interconnection Diagram

Data is received by the NurseMate™ from the EP-WorkMate® via the two interconnections. The NurseMate™ user can only view clinical data (e.g., intracardiac ECG waveforms); this data can not be modified or deleted. NurseMate™ users may independently enter tabular data regarding the case (e.g., event identification, medication, and nurses' or doctors' comments). Tabular data entries are stored as part of the patient file on the EP-WorkMate® as if the data were entered on the EP-WorkMate®. NurseMate™ controls only start/stop recording in the EP-WorkMate®; it does not control any aspect of other devices interconnected with the EP-WorkMate®.

End of document

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2006

EPMed Systems
c/o Larry Picciano
Directory of Regulatory Affairs
Cooper Run Executive Park
575Route 73 N. Bldg. D
West Berlin, NY 08091

Re: K063113
Trade/Device Name: NurseMate™
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: October 10, 2006
Received: October 11, 2006

Dear Mr. Picciano:

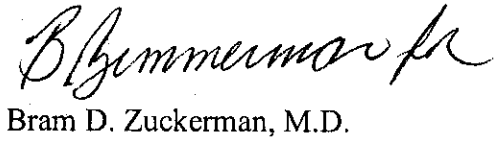
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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Enclosure

K063113

EPMedSystems

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Indications for Use

Device Name: NurseMate™

Indications for Use: NurseMate™ is indicated for use during clinical electrophysiology procedures.

Prescription Use ____√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K063113

File: Indcations for Use FDA Response 102406.doc