

510(k) Summary
Fukuda Denshi model DS-5300
Patient Monitor

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 807.92.

The assigned 510(k) number is : K904187 .

MAY - 1 1997

Submitter:

FUKUDA DENSHI AMERICA CORP.
17725 NE 65th St., Bldg C
Redmond WA 98052
Tel: 206/881-7737
Fax: 206/869-2018

Contact Person:

David J. Geraghty
Regulatory Affairs Manager
FUKUDA DENSHI AMERICA CORP.
17725 NE 65th St., Bldg C
Redmond WA 98052
Tel: 206/881-7737
Fax: 206/869-2018

Date Prepared:

September 20, 1996

Device Name:

Proprietary Name:

model DS-5300 Patient Monitor

Common Name:

Patient Monitor

Classification Name:

Arrhythmia detector and alarm

Legally Marketed Device:

FUKUDA DENSHI model DS-3300 Patient Monitor, 510(k) number K894628. (Also references FUKUDA DENSHI model HB-310, 510(k) number K901889, and FUKUDA DENSHI model HG-302, 510(k) number K945464. These models added additional features to the DS-3300)

Description:

System

The DS-5300 Patient Monitor System is meant to acquire and monitor physiological signals from patients located within a healthcare facility. The system is designed to be used in an ICU, CCU, OR, ER, or Recovery areas of a hospital or clinic. Patient ages from neonates to adults can all be monitored. Waveforms, numeric, and trend data from these patients are available to the clinician on the system's display or it may be printed on the system's recorder.

The basic system consists of the main control unit, the display unit and the input box connected to the main unit via fiber optic cable to reduce electrical artifact and noise.

The main body of the system can be remotely located from the display unit and input box for increased flexibility. Small, lightweight, but powerful in its application of technology, the DS-5300 patient monitoring system is flexible and easy to use. Incorporation of high speed RISC (reduced instruction set computing) microprocessors, a 9.4 inch TFT color LCD display and a high quality, analog touch screen has made the DS-5300 a unique and versatile patient monitor. The die cast aluminum body eliminates the need for a cooling fan and provides a light, strong body. Use of low power, high speed, flash memory allows for easy upgradeability through a standard PCMCIA compatible IC card.

Physiological parameters are monitored through the use of flexible parameter modules that are easily inserted or removed from the input box.

Features

High performance, module type bedside monitor with an LCD panel display.

Designed to allow the main Monitor block and the LCD panel block to be separated.

A high intensity, 9.4 inch, color TFT LCD panel display.

An analog system touch screen selected for superior transparency.

A RISC type CPU for high performance.

Operates on a standard Ethernet LAN network.

A variety of physiological parameters may be added by simply plugging in additional modules.

A Super Module incorporating several typically monitored parameters in a single plug-in.

A 3 channel recorder modular.

A multiport module for accepting DATA from a peripheral device.

Patient DATA is easily moved via PCMCIA memory cards.

A high resolution patient DATA review function.

An on-line help display adds to the user friendly features.

Global version control function.

Built to comply with international standard (UL, CSA, TUV, IEC and others.)

Statement of Intended Use:

The Fukuda Denshi model DS-5300 Patient Monitor provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. These patients; neonate, pediatric, and adult; may be located in a hospital ICU, CCU, OR, ER, recovery, or other critical care unit. The DS-5300 can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician. Parameters such as ECG, respiration, non-invasive or invasive blood pressures, temperature, pulse oximetry, and cardiac output may be monitored individually or in any grouping required by the clinician. This device is not intended for home use.

Comparison to Predicate Device

In summary, the DS-5300 system is an improved version of the DS-3300 utilizing the latest technology and incorporating a color display. Changes to the system include a single multi-parameter module that replaces several of the individual modules used in the DS-3300. A change in processor technology required software changes but all algorithms are based on Fukuda Denshi algorithms that have been in use and are part of the standard Fukuda Denshi software library. The majority of the changes can be

summarized as display oriented or minor changes to alarm limit adjustment ranges.

Technological Characteristics

The DS-5300 incorporates high speed RISC (reduced instruction set computing) microprocessors as compared to the CISC (complex instruction set computing) employed in the predicate device. The DS-5300 utilizes 9.4 inch TFT color LCD display with a high quality, analog touch screen as compared to the 12 inch monochrome CRT with a similar touch screen used in the predicate device. Physiological information is acquired through modular inputs in the same manner as the predicate device. A PCMCIA card interface provides a means to temporarily store data or to update the system's flash memory.

The pulse oximetry design is licensed from Nellcor Puritan Bennett and is similar to the Nellcor design used in the predicate device.

These technological differences do not affect the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate device and are addressed in the systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify that the Fukuda Denshi model DS-5300 Patient Monitor met all design specifications and was substantially equivalent to the FUKUDA DENSHI model DS-3300. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the ANSI/AAMI standards ES1-1993, "Safe current limits for electromedical apparatus"; EC11-1991, "Diagnostic electrocardiographic devices"; and EC13-1992, "Cardiac monitors, heart rate meters, and alarms." Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation.

Testing of the non-invasive blood pressure portion of the system was conducted according to the requirements outlined in the ANSI/AAMI standards SP10-1992, "Electronic or automated sphygmomanometers." The results of this testing is presented in tabular and graphic format in the appendix.

Testing of the pulse oximetry portion of the system was conducted according to Nellcor Puritan Bennett's testing protocol. The results of this testing is presented in tabular and graphic format in the appendix. The results of this testing is presented in tabular and graphic format in the appendix.

Testing of the arrhythmia and ST Level portions of the system were conducted according to AAMI Recommended Practice ECAR-1987, "Recommended Practice for Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms. The results of this testing is presented in tabular format in the appendix.

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient.

So, the areas of risk for this device are the same as other devices in this class, and are the following:

- Electrical shock
 - Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart, and possibly leading to the onset of cardiac arrhythmias.
- Misdiagnosis
 - Inadequate design of the signal processing and measurement circuitry or program can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
 - Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
 - Inadequate design of the systems ability to alert the users through audible and visual indicators, can lead to user mistrust and/or inadequate response to the patient's condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

The design of the DS-5300 has taken into account all the above. The device is designed to meet UL 601, CSA 22.2 and AAMI standards for electrical safety for medical equipment to prevent the possibility of excessive electrical leakage current to the patient.

Conclusion:

The conclusions drawn from clinical and laboratory testing of the Fukuda Denshi model DS-5300 Patient Monitor demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Fukuda Denshi model DS-3300 Patient Monitoring System.