OPERATOR'S MANUAL FOR DT- 4500

CAUTION

This instrument is intended for use in a hospital or clinical setting by trained and authorized personnel who are acting on the orders of a physician. Its purpose is the real-time monitoring of patients over an extended period of time.

The operator should be thoroughly familiar with the information in this manual before using the instrument. As with all monitors, the system cannot replace skilled nursing care and proper surveillance. The transmitter power is limited as required by the Federal Communications Commission and thus has limited range. To insure continuous monitoring, instruct the patient to remain within the area covered by the antenna system.

WARNING

DO NOT USE THE OUTPUT OF THIS DEVICE AS A SYNCHONIZATION SOURCE FOR CARDIAC DEFIBRILLATION. DELAYS IN PRESENTATION OF THE R-WAVE MAY BE AS MUCH AS 40 MILLISECONDS.

Information to User

WARNING

This equipment has been tested and found to comply with the limits for a CLASS B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with the instructions contained in this manual, may cause harmful interference to radio and television communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, then the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and the receiver
- Connect the equipment into an outlet on a circuit different from that of the receiver
- Consult the dealer or an experienced audio television technician

NOTE: Connecting this device to peripheral devices that do not comply with the CLASS B requirement or using an unshielded peripheral data cable could also result in harmful interference to radio or television reception.

Any changes or modifications to the device that are not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

To ensure that the use of this product does not contribute to interference, it is necessary to use shielded I/O cables.

Overview

The DT-4500 Ambulatory Transceiver provides two-way wireless communication between analog ECG circuitry and the hospital's data distribution network. The DT-4500 is connected to the patient through the ECG lead circuitry and is carried on the patient in a gown or disposable paper pouch. The ambulatory transceiver converts the analog ECG patient parameters to a digital format, which is then transmitted to an Access Point transceiver. The Access Point transceiver distributes the digital data to the hospital's data distribution network. The transceiver system includes 6 ECG leads, accurate waveform notification, data port activity, notification of radio frequency (RF) link to Access Point, battery status, attendant present switch, nurse call switch, and two I/O ports for attachment to external medical devices.

Equipment Site Selection/Location

The transceiver is worn by the patient and is carried either in a gown pocket or disposable paper pouch. The typical orientation is against the chest with the front facing out, which minimizes body attenuation losses.

The DT-4500 is IPX7 compliant and can be submerged in 1m of water for 30 minutes without seepage, while remaining in operating condition

Operating Instructions

The DT-4500 ambulatory transceiver is attached to the patient through the ECG lead system. The ECG circuitry, based on the previous DT-4000 front-end circuitry, consists of 6 lead wires and 2 I/O interfaces for external medical devices. The battery-powered transceiver enclosure is carried in a gown pocket or disposable paper pouch. The digital ECG patient parameters are transmitted to the Access Point Transceiver, which then transmits the data via Ethernet network system (cable and hub) to the hospital's data distribution network. The 9V replaceable battery, or rechargeable battery, should last at least 48 hours.

Antenna Installation

The DT-4500 transmits in the 608-614 MHz frequency range. The omnidirectional antenna is a part of the lead set system, with each lead wire paired with an antenna wire. Transceiver output power and system operation requirements are defined by the FCC. <u>Therefore, it is essential that the antenna provided not be modified or altered in any way by the end user.</u>