FccID: H9PLA3021-100 WLAN PC Card, 2 Mbps, Proj.

Conf Num: EA97674 Class II Permissive Change

Corespondence # 18245 Date Emailed: 3/1/01

Question 1

Latest reply indicates the monitor terminal containing the Micropaq antenna is to be worn around the neck of an adult or a pediatric patient. The previous reply indicates there is a WARNING that directs the trained professional to the page of the manual for correct INSTALLATION. It appears that the installation or setup requirements are clinical procedures, which has be mis-interpreted as transmitter installation procedures in the previous correspondence. In the "Connect a New Patient" Section, which this warning refers to, there is no info on what the trained professional should do to ensure RF exposure compliance. It mentions about how to maximize transmission range; please clarify and revise the instruction to ensure RF exposure compliance. This should also be a Warning statement.

Answer:

To ensure RF Exposure requirments the internal antenna is never allowed to be within 0.9 cm of the patient. That is the distance from body to antenna with the pouch twisted backwards on the patient. Also the duty cycle is limited to %8. With the limited duty cycle the EIRP is 13.7 mW max.

See the Micropaq Duty Cycle exhibit uploaded as RF Exposure Info.

Question 2

The information in the "Connect New Patient" Section, item 12, indicates putting the device into a carrying pouch. The photo provided earlier indicates this device is carried with straps connected directly to the device. Would the carrying pouch indicated in the manual allow other operating or carrying configurations besides in front of a patient's chest ? How can the trained professional ensure that the device will always be carried by the patient with its front facing away from the patient's body so that the antenna is at least 2.2 cm (indicated in earlier reply) from the patient's body instead of having the antenna facing the patient's body at a closer distance.

Answer:

See the attached photo of the device in the pouch. The device can not be guaranteed to be in the face forward position. That is why the duty cycle was limited.

Question 3

The instructions indicates the device may be used for adult or pediatric patients. Please clarify the health and medical conditions of patients who would be qualified for using this medical monitor. It is the grantee's responsibility to alert medical professional the circumstances where the RF energy from this monitor may not be appropriate for specific patients or medical conditions. The exposure requirements for this transmitter are generally intended for health persons.

Answer:

The Micropaq* monitor is intended to be used by clinicians for single or multiparameter vital signs monitoring of ambulatory and non-ambulatory pediatric and adult patients in health care facilities. It is also intended for intra-facility transport. Micropaq is intended to operate with an Acuity * Central Station through wireless communication over Welch Allyn Protocol's FlexNet* network. FlexNet connects multiple devices to the Acuity Central Station through hardwired Ethernet networks and Wireless Local Area Networks (WLANs). If the Micropaq is moved out of range or loses communication with the FlexNet network, it continues to monitor the patient, display patient data, and generate local patient alarms or alert messages.

All patients regardless of health and medical conditions are qualified for monitoring with this medical monitor. The following Warnings are stated in the Micropaq Directions for Use:

"Exposure to Radio Frequency (RF) radiation. To comply with Federal Communications Commission (FCC) RF exposure requirements, this device shall be used in accordance with the operating conditions and instructions provided in this manual, including the section "Connect a New Patient".

For patients with a pacemaker, position the monitor to maintain a minimum 6-inch distance between the monitor and pacemaker. Immediately turn the monitor off and provide appropriate patient care if you have any reason to suspect that the monitor is interfering with the pacemaker. The Health Industry Manufacturers Association recommends this minimum 6-inch distance between a handheld wireless

	radio and a pacemaker, which is consistent with the independent research by, and recommendations of, Wireless Technology Research."