

Question 1

The WARNING and CAUTION statements indicated in the reply have some conflicts and inconsistencies. All proposed statements (included in text boxes) should indicate that the operating requirements are for meeting FCC RF exposure compliance; that is, "To comply with FCC ..." instead of "To confirm to ...". Please review the following and revise these statements accordingly:

Answer:

The word confirm does not appear anywhere in any of the text boxes. The word used is conform. The word conform is a synonym of the word comply.

From webster.com "conform: to be obedient or compliant -- usually used with to

b : to act in accordance with prevailing standards "

This wording was accepted in the past. The meaning is the same. Please accept it.

Question 1(a)

The CAUTION statement for the fixed mounted device is indicating a minimum separation distance of 20 cm. Please review all antennas approved under this FCC ID in the original filing to ensure that 20 cm (and not more) is appropriate. This distance could be more if high gain antennas are used. If this statement is also intended for used by multiple or different transmitters, as described by similar filings (pending) from the applicant, the separation distance should also satisfy the requirements for other transmitters.

Answer:

Our highest power transmitter is 500 mW. Our highest gain antenna has a net gain of 10 dBi with cable.

$$MPE = \text{sqr}(PxG/4x \text{ pi } xS)$$

$$S=1\text{mW}/\text{cm}^2 \quad P=500 \text{ mW} \quad G=10$$

$$MPE = 19.95 \text{ cm}$$

Question 1(b)

The CAUTION statement for antennas that are not mounted at fixed locations requires the antenna to be installed in manners that may be near hands but more than 20 cm from a person's body. Most mobile devices operating with internal antennas or detachable antennas require users to maintain a minimum separation distance because the installation procedures may not automatically provide the needed distance. These mobile devices are not intended for hand-held use. It is not always appropriate to advise users that hands may be located near the antenna. If this statement is to be used for different products, how close the hand may be from an antenna would depend on the output power and antenna configuration of the individual transmitter/product. Even for hand-held devices, the antenna are usually embedded within the device that would automatically provide several centimeters or more from the user's hands.

Question 1(c)

The reply indicates that WARNING statements will be located in the manual for the two body-worn devices and the info within these statements are referring user to follow instructions in the manual. No specific operating instructions from the manual has been submitted. In order for this warning statements to be useful, it should be placed on the final product operating with this transmitter. For users who have access to the manual info, the WARNING label should direct users to specific sections of the manual. For general use, the specific separation distance should be indicated on the label. The warning label should be located on the final product so that the RF exposure info is visible to persons requiring this info to satisfy compliance, in an easily readable and understandable format.

Answer:

For the case of non hand held mobile devices (of which there are 3 in this submission) I will change the caution to :

CAUTION: Exposure to Radio Frequency radiation. To comply with FCC RF exposure requirements this antenna shall be installed in such a manner that it will be more than 3 cm from all hands and more than 20 cm from all bodies during normal operation conditions.

$$R = \sqrt{P \cdot G / 4 \cdot \pi}$$

$$R = \sqrt{112 \cdot .64 \cdot 1.58 / 4 \cdot \pi} = 3.01 \text{ cm}$$

Answer:

There are actually three body-worn devices in this package.

#3 Vovollect which is covered by a SAR test.

#6 Oniel MMCX which I am withdrawing at this time.

#13 Micropaq - I have included the user manual which has the warning in the cautions and warning sections. The warning directs the trained professional to the page for correct installation. This should satisfy RF Safety.

Question 2

Previous info submitted for this filing indicates the antenna for the body-worn printer has less than 5 cm separation from its user's body. The most recent reply indicates 2.2 cm. There is a similar pending filings from the applicant, for another transmitter (EA 97592), using the same antenna configuration and product configuration that has indicated a separation distance of 1.5 cm. Body-worn operating configurations are required to satisfy SAR requirements. Whether SAR test data may be needed to demonstrate compliance is highly dependent on the separation distance between the antenna and its user's body. A difference of 0.5 cm could result in 50% difference in SAR. These discrepancies must be clarified in order to determine if SAR compliance could become an issue. Please provide the smallest measured distance between the antenna and the outer surface of the printer, on the side where it is carried next to the user, or its belt-clip. Please also identify the location of the WARNING label to be placed on this device. An example warning statement for general users may read -
WARNING: To comply with FCC RF exposure requirements, this device must be carried at the waist, with a belt to provide a least xx cm between the antenna installed within this device and the user's body during transmission.

Answer:

I am withdrawing antenna #6.

Question 3

The newly added body-worn device, Micropaq is described to operate with a 2 dBi antenna in a small terminal worn in front of a person's chest. The submitted info indicates a separation distance as close as 2.2 cm is possible. Please verify how this distance was determined. If the device can be worn with its front facing the person during transmission, could this separation distance be smaller than 2.2 cm. Issues on warning label and manual instruction should be addressed similar to that described for the body-worn printer above.

Question 4

The radiated measurement for one of the newly added antenna configuration, 6146, is indicating 300 mW EIRP. The MPE info is indicating 0 dBi antenna gain for this configuration. The measured field strength is substantially higher than allowed by the antenna gain described in the MPE info, please clarify.

Answer:

The 2.2 cm distance was determined from the CAD models of the device (Pro Engineer).

The device will never be installed with the front facing the wearer.

This device is only installed by trained professionals that have access to the manual.

The micropaq device also severely limits the TX duty cycle by design. The .64 DC for remote devices is the maximum that can be achieved by any device. The micropaq device only uses the transmitter in a burst mode that limits the TX DC to only 1.82%. I have attached a plot of the DC for the micropaq device.

I have attached an updated user manual.

Answer:

The 120 dBuV/m in the test report is a peak reading. The emission was measured with the transmitter in CW mode with no modulation. The peak reading is measured using a RBW of 1MHz and a VBW of 1MHz. It is very typical when measuring a CW signal with a peak measurement that the measurement will be several dB higher than the average method. Unfortunately there is no average measurement listed for the fundamental which would give a much better representation of the antenna gain.

The 6146 is a typical PIFA (Planar Inverted F Antenna) with a maximum gain of 0 dBi.

Question 5

The EIRP indicated in the antenna summary for antenna # 3 (vocollect) and #13 (Micropaq) are incorrect.

Answer:

$112 \text{ mW} * .64 = 71.68 \text{ mW}$
Cabel loss .25 dB = .94
Cabel loss .15 dB = .97
2 dBi = 1.58

$\text{EIRP \#3} = 71.68 * .94 * 1.58 = 107.25 \text{ mW}$
 $\text{EIRP \#13} = 71.68 * .97 * 1.58 = 109.86 \text{ mW}$

Question 6

FYI - For future filings, vehicle-mount terminals are considered mobile terminals, which is different from mobile transmitters operating with vehicle-mount antennas. Please do not reference vehicle-mount terminals as a vehicle-mount device, which typically refers to vehicle-mount antenna configurations.

Answer:**Question 7**

FYI - The revised antenna summary list appears to indicate the hand-held products are for occupational use. This should not be interpreted as occupational exposure limits may apply to these devices. In order for occupational limits to be applicable, persons exposed must operate such transmitters for work related use only and they must have appropriate training so that they will have the knowledge to control their exposure conditions and duration to satisfy the higher occupational exposure limit. This transmitter will require additional supporting info to qualify for occupational exposure requirements.

Answer:

General Warnings and Cautions

Familiarize yourself with all warnings and cautions before using the Micropaq monitor.



When considering a treatment protocol that involves wireless communication of patient data, be sure to recognize some limitations inherent in wireless communications. When the Micropaq is not connected to the network:

- There are no patient alarms or alerts at the Acuity Central Station.
- Acuity does not perform arrhythmia and ST analysis on the patient data and does not generate related alarms.
- Patient data is not saved.
- Pressing the Nurse Call key on the Micropaq does not cause any response at Acuity.

Do not try to monitor neonatal patients with the Micropaq monitor. The Micropaq is intended for adult or pediatric patients only.

Always check the patient mode when monitoring a new patient. The patient mode determines default alarm limits and internal algorithm settings.

The monitor may not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

Do not connect more than one patient to a monitor. Do not connect more than one monitor to a patient.

Pacemaker signals can differ from one pacemaker to the next. The Association for Advancement of Medical Instrumentation (AAMI) cautions that "in some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. All pacemaker patients should be kept under close or constant observation."

Make frequent electrical and visual checks on cables, sensors, and electrode wires. All cables, sensors, and electrode wires must be inspected and properly maintained and in proper working order to allow the equipment to function properly and protect patient safety.

Avoid electrosurgery burns at monitoring sites by ensuring proper connection of the electrosurgery return circuit so that the return paths cannot be made through monitoring electrodes and probes.

During defibrillation, keep the discharge paddles away from ECG and other electrodes, as well as other conductive parts in contact with the patient.

Do not operate this product in the presence of flammable anesthetics; explosion can result.

Electronic equipment that emits strong electromagnetic or radio frequency signals can cause electrical interference with ECG monitor operation. This interference may distort the ECG signal, thereby preventing accurate rhythm analysis. Avoid operating this device near equipment of this type.

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 "Connecting a New Patient."

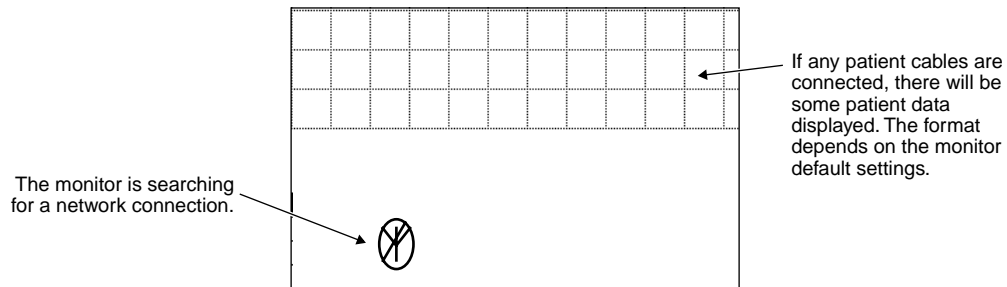
As with all medical equipment, carefully route the patient cabling to reduce the possibility of patient entanglement or strangulation.

2 – Monitoring

Connect a New Patient

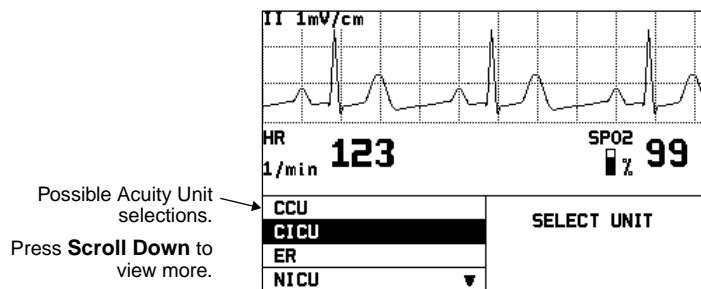
Connect to the Network

1. Insert a battery into the monitor to turn on the monitor. After a few seconds the monitor Powerup Screen is replaced by an initial monitoring screen.



Example of Initial Monitor Screen

2. After the network connection is established, the monitor may prompt you to select an Acuity Unit (if your facility has more than one Acuity unit):



Example of Acuity Unit Selection

3. Press **Scroll Down/Scroll Up** to highlight the desired Acuity unit, then press **Select**.
4. The Micropaq displays a list of possible patients.

If your patient has been pre-admitted to the selected Acuity unit, they will be included in the list.

Possible patients to select. →		
	* Select Patient at Acuity *	SELECT PATIENT
	428-02-2392, Hopkins, Bill J	
	520-29-0319, Phillips, Mary L	
	532-94-8372, Smith, Frank R ▼	

Example of Patient List

5. Scroll through the patient list to look for your patient's name.

- If your patient is NOT in the list, highlight * Select Patient at Acuity * and press **Select**. **Then go on to step 6.**

The patient name will need to be entered later at the Acuity Central Station.

- If your patient is in the list, highlight the name and press **Select**.

Within a few seconds the Micropaq displays a list of unassigned rooms.

Possible rooms to select. →		
	* Select Room at Acuity *	SELECT PATIENT
	1104A	
	1104B	
	1105A ▼	

Example of Room List

- If you want to assign the patient to a room, highlight the room and press **Select**.
- If you do not want to assign a room at this time, highlight * Select Room at Acuity * and press **Select**.



Note

If you do not select the patient name or room while connecting the patient, you will need to do that later at the Acuity Central Station. See page 35 for more information.

Connect the Patient

6. Inspect the ECG cable and replace it if it shows any signs of wear, breakage, or fraying. Plug the cable into the Micropaq.

7. Select electrode sites on the patient.

Choose flat areas; avoid fatty areas and major muscles.

8. Shave or clip hair from electrode sites, thoroughly clean skin, and lightly rub dry.

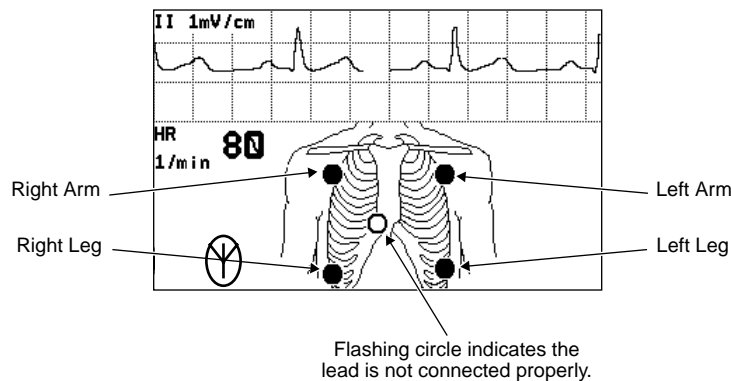
You may use soap and water, isopropyl alcohol or special skin preparation pads. To avoid allergic reactions to electrodes, refer to the electrode manufacturer's directions.

9. If you are using pre-gelled electrodes, make sure the electrode date is not expired and the gel is intact and not dried out. For best results, use only silver/silver chloride electrodes.

If you are using non-gelled electrodes, apply a 1/4 to 1/2 inch mound of gel over the electrode contact area.

For best product performance and measurement accuracy, do not use stainless steel needle electrodes, squeeze bulb electrodes, or electrodes with dissimilar metals. Do not use electrodes from more than one manufacturer on the same patient.

10. Attach lead wires to the electrodes before applying them to the patient. Apply the electrodes to the patient in the proper locations.



If the Micropaq detects that some lead wires are not properly connected, the Micropaq displays a chest diagram and indicates which leads are disconnected.

After leads are properly connected, confirm that the Micropaq displays the ECG waveform, heart rate, and other patient data.

To change the ECG lead selection, press **Select** to display the Main Menu. Then press **Scroll Down** to highlight ECG LEAD . . . , then highlight ECG 1 or ECG 2 and press **Select** to change the lead.

11. If you want to monitor SpO₂ (with Micropaq 404):

- Attach the sensor to the patient according to the manufacturer's directions for use, observing all warnings and cautions.
- Inspect the SpO₂ cable. Replace it if it shows any signs of wear, breakage, or fraying. Plug the cable into the sensor and the Micropaq.
- After the cable is connected, confirm that the Micropaq displays SpO₂ data.

12. Put the carrying pouch on the patient and insert the Micropaq.

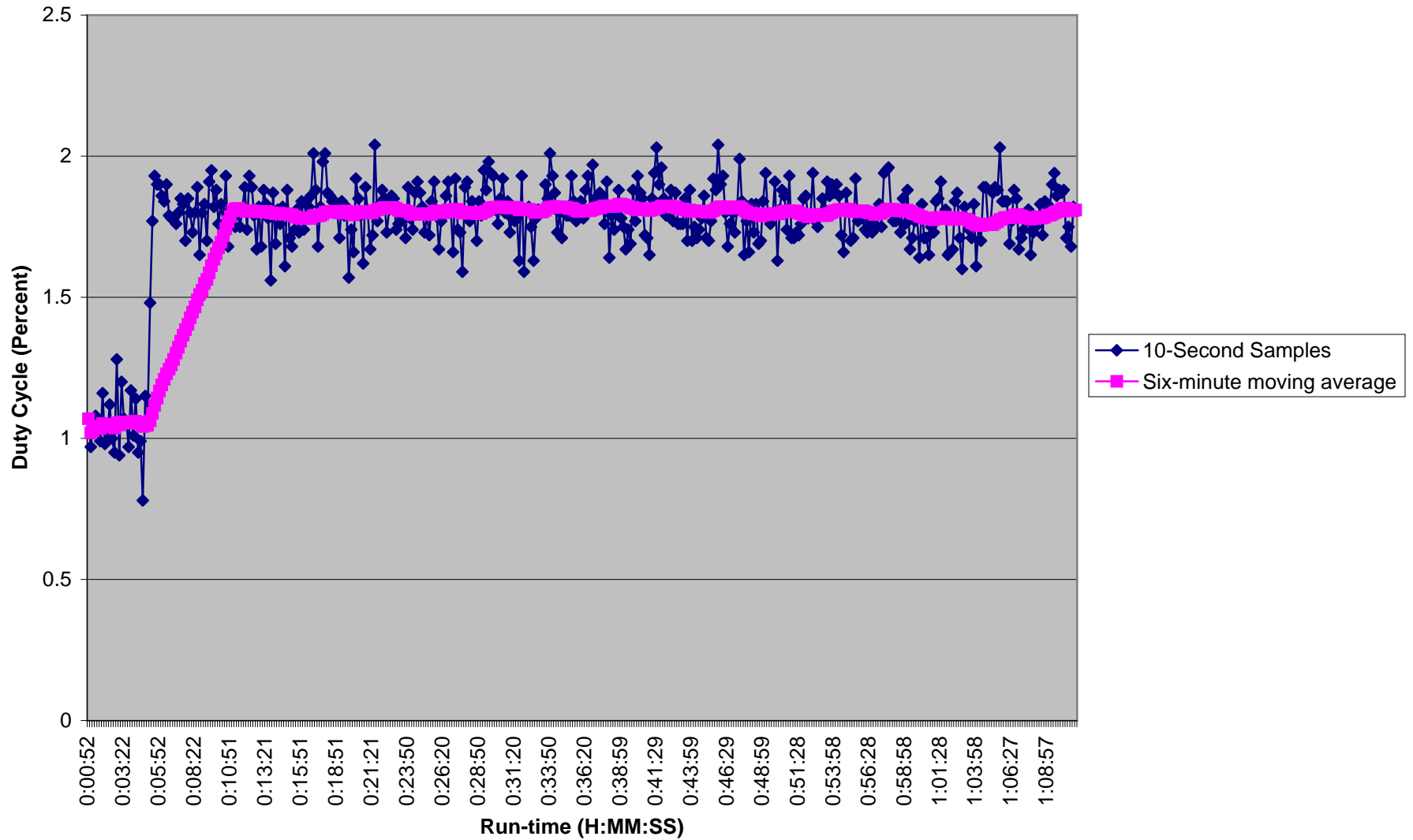
Carefully arrange the pouch and Micropaq on the patient to avoid bruising or other skin injuries.

To maximize the Micropaq's wireless transmission range, always make sure that the Micropaq display is facing out and away from the patient's body.

Customize Patient Alarms

After you confirm the patient ID, Acuity downloads the default settings and patient alarm limits for that Acuity unit. If you need to customize alarm limits for your patient, see page 31.

Micropaq Radio Interface Duty Cycle
(Includes time to transmit, receive, and initialize radio interface)





RF Exposure Antenna Summary

Network Systems Organization

FCC ID: **H9PLA3021-100**

WLAN PC Card, 2 Mbps, Proj. C, Lo Pwr

Source Based

AP DC Factor: 0.650

Output Power: 112 mW

Class II Permissive Change

Remote DC Factor: 0.640

Mobile Antennas (R>20cm)

Ant No	Model	Symbol P/N	Type	Gain (dBi)	Cabel Loss (dB)	Pout (dBm)	MPE (cm)	TR Status	Device Use
01.	XP	50-21900-024	Slot	0.0	0.58	19.92	2.2	Tested	Hand Held Ocp
02.	2742	703624-2	F-Element	0.0	0.13	20.36	2.4	Tested	Hand Held Ocp
04.	7242	10-35477-01	F-Element	0.0	0.12	20.37	2.4	Tested	Hand Held Ocp
05.	Toko	50-21900-022	Puck	0.0	0.00	20.49	2.4	Tested	Hand Held Ocp
07.	6846	10-32290-02	F-Element	0.0	0.34	20.15	2.3	See # 2	Hand Held Ocp
08.	1742	703549-2	F-Element	0.0	0.11	20.38	2.4	See # 2	Hand Held Ocp
09.	7546	10-38649-02	F-Element	0.0	0.31	20.18	2.3	See # 2	Hand Held Ocp
10.	Rubber DuckTNC	50-21900-029	Dipole	1.0	0.00	20.49	2.7	See # 3	Vehicle Mount
11.	6146	10-35305-02	F-Element	0.0	0.12	20.37	2.4	Tested	Hand Held Ocp
12.	IEC PC-LP	LA-3021-100	Patch	2.0	0.00	20.49	3.0	Tested	Laptop

Portable Antennas (R < 5cm)

Ant No	Model	Symbol P/N	Type	Gain (dBi)	Cabel Loss (dB)	Pout (dBm)	EIRP (mW)	TR Status	Device Use
03.	Vocollect MMCX	50-21900-025	Dipole	2.0	0.25	20.24	107.3	Tested + SAR	Belt Worn 5-
06.	Oniel MMCX	50-21900-031	Slot	0.0	0.37	20.12	65.8	Withdrawn	Belt Worn 5-
13.	Micropaq	50-21900-037	PCB	2.0	0.15	20.34	109.8	Tested	Belt Worn 5-

Antenna Gain listed without cable
TR Status refers to whether the antenna was tested. If not refer to the directed antenna test data

Duty Cycle Factors are applied to MPE and EIRP

Tx Limited configurations are for low power versions of the radio. See the specific antenna exhibit for

Tuesday, February 20, 2001 07:40 PM

Page 1 of 1