

Important Customer Information





80-KA125-2 Rev. B

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Table 4-5. IEC 60601-1-2 Recommended Separation Distance Between RF Communication Equipment and the 2net Hub

Recommended separation distances between portable and mobile RF communications equipment and the 2net Hub

The 2net Hub is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 2net Hub can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 2net Hub as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance according to frequency of transmitter (m)			
power of transmitter (W)	150 kHz to 80 MHz $d = [3,5] PV1$	80 MHz to 800 MHz [3,5] / E1 * sqrt P	800 MHz to 2,5 GHz d = [7] PE	
0.01	0.12	0.12	0.23	
0.1	0.37	0.37	0.74	
1	1.17	1.17	2.33	
10 3.69		3.69	7.38	
100	11.67	11.67	23.33	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 4-4. IEC 60601-1-2 Electromagnetic Immunity Performance Criteria – Part 2

Guidance and manufacturer's declaration - electromagnetic immunity

The 2net Hub is intended for use in the electromagnetic environment specified below. The customer or the user of

the Zhet Flob should assure that it is used in such all environment.				
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the2net Hub, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter	
		Recommended separation distance		
Radiated RF IEC			3 V/m	d = 1.2√ P 80 MHz to 800 MHz
61000-4-3			d = 2.3√ P 800 MHz to 2.5 GHz	
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). ^b	
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. ^b	
			Interference may occur in the vicinity of equipment marked with the following symbol:	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio. AM and FM radio broadcast and TV broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 2net Hub is used exceeds the applicable RF compliance level above, the 2net Hub should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the 2net Hub.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

1. How Wireless Works

Your wireless service is different from your home or business phone service. Unlike the data calls you make on a home or business wired internet service, wireless communications travel over the air and can react to the environment. Rain, snow, fog, falling leaves, water, mountains, canyons and even buildings may affect service. All wireless services are subject to "dead zones" or "no coverage" areas.

1.1 Use, Care and Maintenance

The 2net™ Hub is not intended to be:

- · A diagnostic tool
- · Used for accessing the Internet
- · Used in hospitals or emergency rooms
- Used for active patient monitoring

Operate the 2net Hub only as intended. Do not use the 2net Hub for any other purpose.

2 Important Safety Instructions

Read all instructions in this document before using the 2net Hub. When using this product, the safety precautions below must be taken to avoid possible legal liabilities and damages. Retain and follow all product safety and operating instructions. Observe all warnings in the operating instructions on the product. To reduce the risk of bodily injury, electric shock, fire and damage to the equipment observe the following precautions.

1. The 2net Hub is for indoor use only and should be kept away from water or chemical contact. Do not let the 2net Hub get wet.

- The 2net Hub is an Information Technology device and is intended for use in households and office areas only. Do not install the device in locations that may expose the product to ignitable or flammable gases or liquids.
- 3. Do not expose the 2net Hub to extreme temperatures.
- Plug the AC Adapter only into a power source in accordance with the input voltage ratings marked on the AC Adapter.
- Do not operate the 2net Hub with a damaged plug, or after the product malfunctions or is dropped or damaged in any manner. Avoid dropping the 2net Hub.
- In the event of the need for service or a replacement hub, please contact your medical device provider that initially provided your 2net Hub.
- 7. The AC Adapter for the 2net device is provided with double insulation and has no serviceable parts. In a double insulated appliance, two levels of insulation are provided instead of grounding as a means of protecting the user from risk of electric shock. Servicing of a double-insulated appliance requires extreme care and knowledge of the system and should only be done by qualified service personnel. Replacement parts for double-insulated appliances must be identical to those parts in the appliance. A double-insulated appliance is marked with the words "DOUBLE INSULATION" or "DOUBLE INSULATED", or with the symbol:



8. SAVE THESE INSTRUCTIONS.

Table 4-3. IEC 60601-1-2 Electromagnetic Immunity Performance Criteria

Guidance and manufacturer's declaration - electromagnetic immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>U</i> _T (>95 % dip in <i>U</i> _T) for 0,5 cycle	<5 % <i>U</i> _T (>95 % dip in <i>U</i> _T) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment
	40 % $U_{\rm T}$ (60 % dip in $U_{\rm T}$) for 5 cycles	40 % $U_{\rm T}$ (60 % dip in $U_{\rm T}$) for 5 cycles	
	70 % $U_{\rm T}$ (30 % dip in $U_{\rm T}$ for 25 cycles	70 % $U_{\rm T}$ (30 % dip in $U_{\rm T}$ for 25 cycles	
	$<$ 5 % $U_{\rm T}$ (>95 % dip in $U_{\rm T}$) for 5 s	$<$ 5 % $U_{\rm T}$ (>95 % dip in $U_{\rm T}$) for 5 s	
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

4.2 Medical Equipment Standards

Table 4-2. IEC 60601-1-2 Performance Criteria – Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions				
The 2net Hub is intended for use in the electromagnetic environment specified below. The customer or the user of the 2net Hub should assure that it is used in such an environment.				
Emissions test	Compliance	Electromagnetic environment – guidance		
RF emissions CISPR 11	Group 1	The 2net Hub must emit electromagnetic energy in order to perform its intended function as a communication device. Nearby electronic equipment may be affected.		
		The 2net Hub is not a Group 2 device as RF energy is not used as a form of patient treatment.		
RF emissions, CISPR 11	Class B	The 2net Hub is suitable for use in domestic establishments and those directly connected to the public low-voltage power supply network that		
Harmonic emissions, IEC 61000-3-2	Class A	supplies buildings used for domestic purposes.		
Voltage fluctuations/ flicker emissions/ IEC 61000-3-3	Complies			

3 2net Hub Regulatory Information

3.1 Food and Drug Administration (FDA) Classification

The 2net Hub is classified by the FDA under the definition of a Medical Device Data System (MDDS) Class I Device. The 2net Hub MDDS device is intended to transfer, store, convert from one format to another according to preset specifications or display medical device data. MDDSs perform all intended functions without controlling or altering the function or parameters of any connected medical devices. An MDDS is not intended to be used in connection with active patient monitoring.

The 2net Hub is not intended to be:

- · A diagnostic tool
- Used for accessing the Internet
- · Used in hospitals or emergency rooms
- · Used for active patient monitoring

Operate the 2net Hub only as intended. Do not use the 2net Hub for any other purpose.

3.2 Safety Warnings

- CAUTION: Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in section 3.4.4. Portable and mobile RF communications equipment can affect medical electrical equipment.
- CAUTION: The 2net Hub should not be used in airplanes, hospitals or locations where cellular telephones and other electronic devices are prohibited.

- Do not operate the 2net Hub in the following environments:
- In active blasting areas
- In potentially explosive environments such as refueling points, fuel depots or chemical plants
- Near life support equipment that might be susceptible to radio interference
- Cleaning
 - Unplug the product from the wall outlet before cleaning. Do not use liquid cleaners or aerosol cleaners. Use a damp cloth for cleaning, but NEVER use water to clean the 2net Hub.

3.3 Implantable Medical Devices

Persons with implantable medical devices should observe the following precautions:

- Always keep the 2net Hub more than 6 inches (15 cm) from the implantable medical device when the mobile device is turned on.
- Unplug the 2net Hub immediately if you have any reason to suspect that interference is taking place.
- Read and follow the directions from the manufacturer of your implantable medical device. If you have any questions about using your medical device with your implantable medical device, consult your healthcare provider.

4 Transmitter Information

4.1 List of Transmitters

Table 4-1. List of transmitters

Technology	Frequency Band	Transmit Frequency Range (MHz)	Receive Frequency Range (MHz)	Nominal Radiated Transmit Power
GSM/	850 MHz	824-849	869-894	3,311 mW EIRP/35.2dBm (peak power)
EDGE/ GPRS	900 MHz	880-914	925-960	3,311 mW EIRP/35.2dBm (peak power)
	1800 MHz	1710-1785	1805-1880	1,738 mW EIRP/32.4dBm (peak power)
	1900 MHz	1850-1910	1930-1990	1,738 mW EIRP/32.4dBm (peak power)
UMTS/	850 MHz (Band II)	824-849	869-894	316 mW EIRP/25dBm (±1dB) (avg. power)
HSDPA	1900 MHz (Band IV)	1850-1910	1930-1990	479 mW EIRP/26.8dBm (±1dB) (avg. power)
802.11b	2.4 GHz	2400-2484		100 mW EIRP/20dBm (±1dB) (avg. power)
802.11g	2.4 GHz	2400-2484		38 mW EIRP/15.85dBm (±1dB) (avg. power)
Bluetooth 2.1+EDR	2.4 GHz	2402-2480		13 mW EIRP/11.02dBm (±1dB) (avg. power)
ANT+	2.4 GHz			13 mW EIRP/11.02dBm (±1dB) (avg. power)

3.3.5 Industry Canada

The 2net Hub should be installed and operated with a minimum distance of 6 inches (15 cm) between the radiator (2net Hub) and your body.

Le Hub 2net doit être installé et utilisé avec une distance minimale de 8 po (20 cm) entre le radiateur (2net Hub) et votre corps.

This Class B digital apparatus complies with Canadian ICES-003. The term IC before the equipment certification number only signifies that the Industry Canada technical specifications were met.

Cet appareil numerique de la classe A est conforme a la norme NMB-003 du Canada. Le terme IC avant le numero d'homologation ne signifie seulement queles normes d'Industrie Canada ont ete respectees.

This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- 1. l'appareil ne doit pas produire de brouillage, et
- l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le onctionnement.

3.3.1 Safety and Wireless Devices

The 2net Hub contains radio transmitters and uses non-ionizing radio frequencies (RF). It works within FCC radiation exposure limits for an uncontrolled environment. It should be installed and operated with a minimum distance of 6 inches (15 cm) between the radiator (2net Hub) and your body.

Scientific research on wireless devices and radio frequency ("RF") energy has been conducted worldwide for many years, and continues. In the United States, the Food and Drug Administration ("FDA") and the Federal Communications Commission ("FCC") set policies and procedures for wireless devices. The FDA issued a website publication on health issues related to usage of cell phones where it states, "The scientific community at large believes that the weight of the scientific evidence does not show an association between exposure to RF from cell phones and adverse health outcomes." Still the scientific community does recommend conducting additional research to address gaps in knowledge. That research is being conducted around the world and the FDA continues to monitor developments in this field. You can access the FDA website at http://www.fda.gov (Under "C" in the subject index, select Cell Phones > Research.). You can also contact the FDA toll free at (888) 463-6332 or (888) INFO-FDA. The FCC issued its own website publication stating that "there is no scientific evidence that proves that wireless telephone usage can lead to cancer or other problems, including headaches, dizziness or memory loss." The publication is available at http://www.fcc.gov/cgb/cellular.html or through the FCC at (888) 225-5322 or (888) CALL-FCC. The National Cancer Institute ("NCI") states that concerns about the potential health effects of using cellular phones - "and specifically the suggestion that using a cell phone may increase a person's risk of developing brain cancer - are not supported by a growing body of research on the subject." You can access NCI's review of the research at http://www.cancer.gov/aboutnci/ ncicancerbulletin/archive/2008/092308/page7.

3.3.2 Can I minimize my RF exposure?

If you are concerned about RF, there are several simple steps you can take to minimize your RF exposure. You can, minimize usage of the device near the body. You can also place more distance between your body and the source of the RF, as the exposure level drops off dramatically with distance.

Wireless devices marketed in the United States are required to meet safety requirements regardless of whether they are used against the head or against the body.

3.3.3 Where can I obtain further information?

For further information, see the following additional resources (need to make sure all of these are still operational).

U.S. Food and Drug Administration FDA Consumer Magazine November-December, 2000 1-888-INFO-FDA http://www.fda.gov

Under "C" in the subject index, select Cell Phones > Research

American National Standards Institute 1819 L Street, N.W. Suite 600 Washington D.C., 20036 1-202-293-8020

3.3.4 Federal Communications Commission (FCC) Information

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

The 2net Hub complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause

harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

The 2net Hub has been tested to the limits for a Class B digital device, according to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The 2net Hub generates uses and radiates radio frequency energy and if not installed and used according to instructions, may cause harmful interference to radio communications or be interfered with. There is no guarantee that interference will not occur in a particular installation.

The 2net Hub should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the 2net Hub should be observed to verify normal operation in the configuration in which it will be used. If the 2net Hub does cause harmful interference to radio or television reception, which can be determined by turning the 2net Hub off and on, try to correct the interference by taking one or more of the following actions:

- Increase the distance between the 2net Hub and radio or television receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer where you bought your radio/TV or an experienced radio/TV technician.

If the 2net Hub is being interfered with try to correct the interference by taking one or more of the following actions:

- Make sure that the outlet you have plugged the 2net Hub into is no closer than 10 ft (3 m) of a Wi-Fi access point, microwave oven or 2.4 GHz cordless phone.
- Increase the distance between the 2net Hub and all other electronic equipment by moving the Hub to a different electrical wall outlet.
- Contact your medical device company that provided you with your 2net Hub.