

User Manual // Gen 2





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Safety Information

Save These Instructions

Read all instructions in this document before using the 2net Hub. To assure the correct and safe use of the product, retain and follow all product safety measures and operating instructions listed in this user manual. Observe all warnings in the operating instructions on the product.

The 2net Hub is not intended to be:

- A diagnostic tool
- Used in hospitals or emergency rooms
- Used for active patient monitoring nor in any situation in which a patient's physiological processes or parameters are monitored for variations that indicate harm or danger to the patient
- Used for accessing the Internet

To reduce the risk of bodily injury, electric shock, fire and damage to the equipment observe the following precautions:

- Operate the Hub only as intended. Do not use the Hub for any other purpose.
- The Hub is for indoor use only and should be kept away from water or chemical contact. Do not let the Hub get wet.
- The Hub 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.
- Plug the Hub in to an electrical wall outlet with the front label upright. Do not plug in the Hub in other orientations (e.g., upside-down, sideways, etc.).
- Do not expose the Hub to extreme temperatures.

- Plug the Hub only into a power source in accordance with the input voltage ratings marked on the back of the Hub.
- 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 Hub.
- Do not operate the Hub with a damaged plug, after the product malfunctions, or is dropped or damaged in any manner.
- In the event of the need for service or a replacement Hub, please contact the service provider that supplied your Hub.
- CAUTION: Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information in the Regulatory Information and Transmitter Information sections of this document. Portable and mobile RF communications equipment can affect medical electrical equipment.
- **CAUTION**: The Hub should not be used in airplanes or locations where cellular telephones and other electronic devices are prohibited.
- Do not operate the 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
- The Hub is provided with double insulation and therefore does not require a Protective Earth (PE) ground pin for safe use. 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. A double-insulated appliance is marked with the words "DOUBLE INSULATION" or "DOUBLE INSULATED", or with the symbol:



- The Hub has no parts that are serviceable by users. Servicing of this device requires extreme care and knowledge of the system and should only be done by qualified service personnel or by the manufacturer.
- This equipment has no applied parts.

Operating and Storage Ratings:

- Operating temperature: 0-35°C
- Storage temperature: -20°C 70°C
- Operating and storage humidity: 95%
- Operating and storage atmospheric pressure: 70.0 kPa - 106.0 kPa

Implantable Medical Devices

Persons with implantable medical devices should observe the following precautions:

- Always keep the Hub more than 6 inches (15 cm) from the implantable medical device when the Hub is plugged into electrical power.
- Unplug the 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 Hub with your implantable medical device, consult your healthcare provider.

Getting to Know Your 2net Hub

The 2net Hub securely captures medical device data in near-real time and wirelessly transmits it to cloud-based remote care applications that are offered by a range of health care providers or medical device manufacturers.



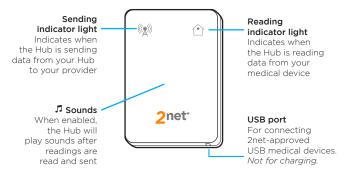
The 2net Hub is easy-to-use and is designed for use in the home. You simply plug the Hub into a standard electrical wall outlet in your home or office.

The 2net Hub does not contain any medical sensors. The Hub collects data from commercially available medical devices, including but not limited to:

- Blood pressure monitors
- Glucose meters
- Weight scales
- Pulse oximeters
- Thermometers

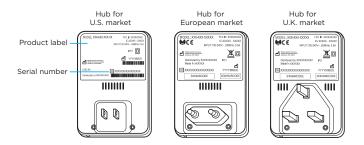
The Hub transfers the data wirelessly, via either cellular network or WiFi, to the 2net service platform for delivery to the service provider that supplied your Hub.

What does each part do?



Standard electric power wall plug

(available for U.S./Canada, European, and UK markets)



What do the lights mean?

There are two lights on the front of your Hub that light up in different colors to give you information. Each light has an accompanying symbol.



The sending light (left light)

The radio tower symbol shows you the status of the Hub's sending function. Table 1 explains what it means when the light for this symbol changes color.



Table 1. Sending status

| Sending light color (left light) | Sending status |
|-------------------------------------|--|
| Flashing GREEN | Your Hub is starting up and searching for a connection to the network. |
| | i It can take up to 5 minutes to complete the initial connection. Do not unplug the Hub while the light is flashing GREEN . |
| | • Your Hub is sending data. |
| Solid GREEN | Your Hub is connected to the network and is ready to send data. |
| (m) Solid BLUE | Your Hub successfully sent your medical device data to the service provider that supplied your Hub. Both the sending light and reading light will turn solid BLUE for 5 seconds. |
| Flashing ORANGE | Your Hub is unable to connect to the network and is not ready to send data. |
| | Wait for up to 5 minutes to see if a signal is found and the light turns solid GREEN . If not, unplug the Hub and move it to a new location with better cellular (or WiFi) coverage. Move all the medical device(s) you want to use with the Hub to the new location. |

(table continued on next page)

| Sending light color (left light) | Sending status |
|-------------------------------------|--|
| Solid ORANGE | Your Hub failed to send your medical device data. |
| | No user intervention is needed. The Hub will attempt to resend the data at a later time. |
| ((no color) | No power is being supplied to the Hub, or the Hub is not plugged in. |



The home symbol shows you the status of the Hub's reading function. Table 2 explains what it means when the light for this symbol changes color.



Table 2. Reading status

| Reading light color (right light) | Reading status |
|--------------------------------------|--|
| Solid GREEN | Your Hub is ready to read data from your medical device(s). |
| Flashing GREEN | Your Hub is communicating with your medical device(s). |
| Solid BLUE | Your Hub successfully read data from your medical device(s). Will stay solid BLUE until your Hub has successfully sent your data to the service provider that supplied your Hub. |
| Solid ORANGE | Your Hub failed to read data from your medical device(s). |
| (up to 90 seconds) | To resolve, take the reading on the medical device(s) again. If the reading light turns solid ORANGE a second time, contact the service provider that supplied your Hub. |
| ① Off (no color) | Your Hub is not ready to read data from medical devices. |
| | If this condition persists for more than 5 minutes, your Hub will automatically restart. No user intervention is needed. If your Hub does not return to the ready state within 30 minutes, contact the service provider that supplied your Hub. |

What do the sounds mean?

When sounds are enabled, the Hub plays short sounds/ melodies to indicate specific events or conditions have occurred. Table 3 explains what it means when the Hub plays sounds.

| Table 3. Sounds on the H | Hub |
|--------------------------|-----|
|--------------------------|-----|

| Title | Melody | Events/Conditions |
|----------------------|--|--|
| Hub ready | Six tone melody | After start up, your Hub is ready to wirelessly connect to your medical device(s). |
| Information received | Two short tones | Your Hub successfully received data from your medical device. |
| Success | Four short tones | Your Hub successfully transmitted your data to the service provider that supplied your Hub. |
| Alert | Long tone repeated one or more times | • Your Hub failed to receive valid data from your medical device. |
| | | Your Hub is unable to connect to the long- range network. |



Sounds are turned off by default. If you would like your Hub to play sounds, notify the service provider that supplied your Hub.

How Wireless Works

Your Hub's wireless service is different from your wired home phone service. Unlike wired services, wireless communications travel over the air and can be affected by 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.

Using Your 2net Hub

Starting Up the Hub

To start using your Hub, first, plug it into a standard electrical wall outlet in the same room as the medical device(s) with which you want to use it. There is no power switch.



To ensure the best performance, plug in the Hub in an upright position and leave it plugged in.

1. When you plug the Hub into an electrical wall outlet, the sending light in flashes GREEN. This means your Hub is starting up and searching for a connection to the cellular (or WiFi) network.



Using Your Hub



It can take up to 5 minutes to complete the initial connection. Do not unplug the Hub while the light is **flashing GREEN**. If you do unplug the Hub, just plug it back in and start up will resume.

2. The sending light (2) stops flashing and remains solid GREEN when the Hub has successfully connected to the network, and coverage is good.



 After startup, the reading light
 [∩] turns solid GREEN. When both the reading light and the sending light are solid GREEN, your Hub is ready to receive data from your medical devices.





If audio is enabled, the Hub Ready sound will play when the Hub is ready.



If the sending light ^(N) is **flashing ORANGE**, it means coverage is bad. Refer to the Troubleshooting Tips, for help.





If audio is enabled, the Alert sound will play when your Hub fails to connect.

Collecting Medical Data from Wireless Devices

First, confirm that both the sending light and reading light on your Hub are **solid GREEN**. Then, use the medical device(s) provided with your Hub to take a reading.

 Your Hub automatically receives data from your medical device(s). The reading light
 flashes GREEN while medical data is being received.





Your medical device might have a "transmit" button or function that you may need to activate to transmit data. Follow the instructions provided in the user manual for your medical device. 2. The reading light 1 turns solid BLUE for five seconds when your data has been successfully received.





If audio is enabled, the Information sound will play when your data has been successfully received.

- **3.** After receiving the medical device data, the Hub will automatically send the data to the service provider that supplied your Hub.
- 4. The sending light (2) flashes GREEN when the Hub is sending data over the cellular (or WiFi) network.



 Both the sending light and reading light turn solid BLUE for five seconds when the Hub successfully sends your medical data to the service provider that supplied your Hub.





If audio is enabled, the Success sound will play when your data has been successfully sent.

6. When the Hub has finished sending data, both the sending light and reading light turn **solid GREEN** which means the Hub is again ready to read and send medical data.





If the reading light \bigcirc turns **solid ORANGE**, it means the Hub received incomplete or invalid data. To resolve, wait 90 seconds for the Hub to return to its ready state, with the reading light \bigcirc lit **solid GREEN**, then take the reading again. If the reading light turns **solid ORANGE** a second time, contact the service provider that supplied your Hub.





If audio is enabled, the Alert sound will play when data collection is incomplete or the Hub detects invalid data.



If the sending light (2) turns **solid ORANGE**, it means the Hub failed to send your data. No user intervention is needed. The Hub will attempt to resend the data at a later time.



Alternate Configuration for Wired Devices

Most devices will connect wirelessly. The following directions apply only if your device is not wireless and was provided with a USB cable.

There is a USB port (type A) on the bottom side of the 2net Hub to connect 2net-approved USB-capable medical devices to the Hub.



The USB port is not for charging USB devices.

To collect data from a USB-capable medical device:

- 1. Confirm that both the sending light and reading light on your Hub are solid GREEN.
- 2. Take a reading on your medical device.
- Connect your medical device to the Hub using the USB cable supplied with your medical device.
 - Your Hub should automatically receive data from your medical device. If not, your medical device might have a "transmit" button or function that you may need to activate to transmit data. Follow the instructions provided in the user manual for your medical device.
 - The Hub's reading light flashes GREEN while medical data is being received.
 - The Hub's reading light 1 turns solid BLUE when your data has been successfully received.

- **4.** After receiving the medical device data, the Hub will automatically send the data to the service provider that supplied your Hub.
 - The Hub's sending light ^(A) flashes GREEN when the Hub is sending data over the cellular (or WiFi) network.
 - Both the sending light and reading light turn solid BLUE for five seconds when the Hub successfully sends your medical data.
- When the Hub has finished sending data, both the sending light and reading light turn solid GREEN which means the Hub is again ready to read and send your medical data.

Troubleshooting Tips

Long Startup Time

It can take up to 5 minutes to complete the initial start up and configuration. Do not unplug the Hub while the sending light ((R)) is **flashing GREEN**. If you do unplug the Hub, just plug it back in and start up will resume.



Insufficient Coverage

If the sending light 🖗 is **flashing ORANGE**, it means the cellular (or WiFi) coverage is inadequate. Wait for up to 5 minutes to see if the sending light turns **solid GREEN**, which means the cellular (or WiFi) signal has been found.



If the sending light continues **flashing ORANGE**, unplug the Hub and take it to another location in your home or office where the cellular (or WiFi) signal may be stronger. Replug the Hub into an electrical wall outlet there. Remember to also move your medical device(s) to the same room as the Hub.

Reading Error

If the reading light 1 turns **solid ORANGE**, it means the Hub received incomplete or invalid data. To resolve, wait 5 minutes for the Hub to return to its ready state, with the reading light 1 lit **solid GREEN**, then take the reading again. If the reading light turns **solid ORANGE** a second time, contact the service provider that supplied your Hub.



Hub Not Receiving Readings

Confirm that your medical device is powered on. If the medical device will not power on, or no display appears on the unit, you may need to replace the batteries or connect the device to power. Once your medical device is powered on, verify the 2net Hub is plugged in, has power and both the sending light and reading light are **solid GREEN**. If the reading light is **OFF**, your Hub is not ready to receive data from medical devices. (See troubleshooting for Hub Not Ready below). If the reading light is **solid GREEN**, your Hub is ready to receive data from medical devices. Then, do the following:

- 1. Ensure your medical device, and your Hub are in the same room.
- 2. Take a new reading.

The Hub's reading light \bigcirc will **flash GREEN** when receiving medical data. If your Hub does not respond to the new reading, do the following:

- 1. Restart your Hub: Unplug the Hub, wait 5 seconds, then plug it back in.
- 2. Restart your medical device: Power it off (turn it off, unplug it, or remove the batteries for 5 seconds) and then power it back on. Make sure your device has fresh batteries and, if it has a battery indicator, confirm it shows a full battery charge.
- 3. Wait for your Hub and medical device to be ready.
- 4. Take another reading with your medical device.

If, after completing the steps above, your Hub still does not receive the reading, your medical device might need to "pair" with the Hub. ("Pair/pairing" means to establish connectivity between medical devices and the Hub). Your medical device might have its own "pairing" button or function. You may need to press that button or activate that function for the device to work with the Hub. Refer to your medical device user manual for "pairing" instructions. Follow the instructions provided by the manufacturer of your medical device to "pair" your medical device to the Hub.

If, after following the pairing instructions, your Hub is still not receiving readings, contact the service provider that supplied your Hub.

Hub Not Ready

If the reading light \bigcirc is **OFF**, your Hub is not ready to receive data from medical devices. Do not unplug the Hub at this time. Your Hub may be processing an update. If this condition persists for more than 5 minutes, your Hub will automatically restart. No user intervention is needed. If you unplug the Hub during an update, just plug it back in and the update will resume at a later time.



• If your Hub does not return to the ready state (the reading light is **solid GREEN**) within 30 minutes, contact the service provider that supplied your Hub.

Hub Off / No Power

When both the reading and sending lights are **OFF**, this means no power is being supplied to the Hub. Confirm that the Hub is plugged in to an electrical wall outlet and verify that the wall outlet you are using is working correctly. If the wall outlet is controlled by a wall switch, verify the switch is in the "ON" position. Consider moving the Hub to a different wall outlet.



No Sounds

If the Hub is not playing sounds \square , contact your service provider to enable this feature.

2net Regulatory Information

Intended Use Statement

The 2net Hub is used in the 2net Platform to capture and transmit medical device data. The 2net Hub is intended to receive, convert (from one format to another), store and transfer data from a connected medical device and to act as a medical device data system (MDDS). The 2net Hub transfers the data wirelessly, via either WiFi or cellular network, to the 2net Platform. The 2net Hub performs these functions without controlling or altering the function or parameters of any connected medical devices.

The transfer of data from the 2net Hub is subject to time delays and potential data loss due to conditions in which the 2net Hub and the 2net Platform are operating, including: network or power disruptions, connectivity interruptions, medical and mobile device limitations and user error, time zone offsets, and other conditions outside the control of the 2net Hub or the 2net Platform.

The 2net Hub is not to be relied upon for transmitting data necessary to inform immediate medical decisions, for transmitting continuously (24/7 or similar), for the time-sensitive monitoring of a patient, or for connecting to emergency response systems.

Wireless Devices

The Hub contains radio transmitters and uses non-ionizing radio frequencies ("RF"). The Hub operates within the exposure limits for an uncontrolled environment as set by the U.S. Federal Communications Commission ("FCC") and Innovation and Science and Economic Development Canada ("ISED"). The 2net Hub should be installed and operated with a minimum distance of 8 inches (20 cm) between the radiator (Hub) and any person.

Scientific research on wireless devices and RF energy has been conducted worldwide for many years, and continues. In the United States, the Food and Drug Administration ("FDA") and the FCC set standards and regulations pertaining to wireless devices. The FDA issued a statement on health issues related to usage of cell phones: "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 > Health Issues). You can also contact the FDA toll free at (888) 463-6332 or (888) INFO-FDA.

The FCC has also issued the following statement: "According to the FDA and the World Health Organization (WHO), among other organizations, to date, the weight of scientific evidence has not effectively linked exposure to radio frequency energy from mobile devices with any known health problems", available at https://www.fcc.gov/consumers/guides/wireless-devices-andhealth-concerns or through the FCC at (888) 225-5322 or (888) CALL-FCC.

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 by placing more distance between your body and the source of the RF. Exposure levels drop off dramatically with distance.

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

Where can I obtain further information?

For further information, see the following additional resources.

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

In Canada: Health Canada

Address Locator 0900C2 Ottawa, Ontario K1A 0K9 Email: Info@hc-sc.gc.ca Telephone: 613-957-2991 Toll free: 1-866-225-0709 Fax: 613-941-5366 TTY: 1-800-267-1245

Safety Evaluations

The Hub has been tested by Underwriters Laboratories (UL Classified) for safety in accordance with the following safety standards:

USA

 ANSI/AAMI ES60601-1 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance

EU and CB Scheme

- IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral Standard: Usability
- IEC 60601-1-8 General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical system used in the home healthcare environment

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 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 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 Hub generates 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 Hub should not be used adjacent to or stacked with other electrical equipment. If adjacent or stacked use is necessary, then the Hub should be observed to verify normal operation in the configuration in which it will be used. If you suspect the Hub is causing harmful interference to radio or television reception, unplug the Hub from electrical power. If the interference stops, please take one or more of the following steps before attempting to use the Hub again:

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

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

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

Innovation, Science and Economic Development Canada (ISED)

The Hub should be installed and operated with a minimum distance of 8 inches (20 cm) between the radiator (Hub) and your body.

Le Hub doit être installé et utilisé avec une distance minimale de 8 po (20 cm) entre le radiateur (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 ISED technical specifications were met.

Cet appareil numerique de la classe B est conforme a la norme NMB-003 du Canada. Le terme IC avant le numero d'homologation ne signifie seulement queles normes d'Innovation, Sciences et Développement économique Canada ont ete respectees.

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

Le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique 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.

Caution:

(i) Devices operating in the 5150-5250 MHz band are only for indoor use in order to reduce the risk of harmful interference to mobile satellite systems operating on the same channels. (ii) Users should also be advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to Wireless LAN devices.

Avertissement:

- (i) les dispositifs fonctionnant dans la bande 5 150-5 250 MHz sont réservés uniquement pour une utilisation à l'intérieur afin de réduire les risques de brouillage préjudiciable aux systèmes de satellites mobiles utilisant les mêmes canaux;
- (ii) De plus, les utilisateurs devraient aussi être avisés que les utilisateurs de radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5 250-5 350 MHz et 5 650-5 850 MHz et que ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LAN-EL.

Transmitter Information

List of Transmitters

| Technology | Frequency Band | Transmit Frequency Range (MHz) | Receive Frequency Range (MHz) | Typical Radiated Transmit Power (dBm) |
|-------------------|-------------------|---|--|---------------------------------------|
| LTE | Band 2 | 1850-1910 | 1930-1990 | 23 (25.7 max.) |
| | Band 4 | 1710-1755 | 2110-2155 | 23 (25.7 max.) |
| | Band 5 | 824-849 | 869-894 | 23 (25.7 max.) |
| | Band 12 | 699-716 | 729-746 | 23 (25.7 max.) |
| WCDMA | Band 2 | 1850-1910 | 1930-1990 | 23 (25.7 max.) |
| | Band 5 | 824-849 | 869-894 | 23 (25.7 max.) |
| 802.11a | 5 GHz | 5180- | -5825 | 17.6 (31 dBm) |
| 802.11b | 2.4 GHz | 2400 | -2484 | 20.8 (31 dBm) |
| 802.11g | 2.4 GHz | 2400-2484 | | 18.8 (31 dBm) |
| Bluetooth 2.1+EDR | 2.4 GHz | 2402-2480 | | 11 (31 dBm) ¹ |
| BLE | 2.4 GHz | | | 4 (avg. pwr., 30.5 dBm) |

Table 4. List of transmitters

¹ EDR power as measured in the GFSK header.

Medical Equipment Standards

Table 5. IEC 60601-1-2 Performance Criteria Electromagnetic Emissions

| Guidance and manufacturer's declaration – electromagnetic emissions | | | | |
|--|----------|--|--|--|
| The Hub is intended for use in the electromagnetic environment specified below. The customer or the user of the Hub should ensure that it is used in such an environment. | | | | |
| Emissions test Compliance Electromagnetic environment – guidance | | | | |
| RF emissions CISPR 11 | Group 1 | The Hub must emit electromagnetic energy in order to perform its intended function as a communication device. Nearby electronic equipment may be affected. | | |
| | | The 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 Hub is suitable for use in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for | | |
| Harmonic emissions, IEC 61000-3-2 | Class A | domestic purposes. | | |
| Voltage fluctuations/ flicker emissions/ IEC 61000-3-3 | Complies | | | |

Table 6. IEC 60601-1-2 Electromagnetic Immunity Performance Criteria

| The Hub is intended for use in is used in such an environmen | | pecified below. The customer or the | e user of the Hub should ensure that it |
|--|--|--|---|
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact ± 15 kV air | ± 8 kV contact ± 15 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 | Main power quality should be that of a typical domestic or commercial 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 | Main power quality should be that of a typical domestic or commercial environment. |
| Voltage dips, short interruptions and voltage variations on power supply | <5 % U ₁ (>95 % dip in U ₁) for 0,5 cycle | <5 % $U_{\rm T}^{}$ (>95 % dip in $U_{\rm T}^{}$) for 0,5 cycle | Main power quality should be that of a typical domestic or commercial environment. |
| input lines IEC 61000-4-11 | 40 % U_{T} (60 % dip in U_{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 ₁ (>95 % dip in U ₁) for 5 s | <5 % U ₁ (>95 % dip in U ₁) 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. |

Table 7. IEC 60601-1-2 Electromagnetic ImmunityPerformance Criteria - Part 2

| Guidance and manufacturer's declaration – electromagnetic immunity The Hub is intended for use in the electromagnetic environment specified below. The customer or the user of the Hub should ensure that it is used in such an environment. | | | |
|--|-----------------------|-------------------------------|---|
| Immunity Test IEC 60601 Test Level Compliance Level Electromagnetic Environment – Guidance | | | |
| Conducted RF IEC 61000-4-6 | induced in the String | | Portable and mobile RF communications equipment should be used no closer to any part of the 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 61000-4-3 80 MHz to 2.5 GHz | 3 V/m | d = 1.2√ P 80 MHz to 800 MHz | |
| | | d = 2.3√ P 800 MHz to 6.0 GHz | |
| | 00 m 2 0 2,5 0 m | | 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, 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 PM radio broadcast and TV broadcast can on the predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the massured field strength in the location in which the Hub is used exceeds the applicable RF compliance level above, the Hub should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the Hub.

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

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

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

| Rated maximum output power | Separation distance according to frequency of transmitter (m) | | | |
|----------------------------|---|--|----------------------------------|--|
| of transmitter (W) | 150 kHz to 80 MHz d = [3,5] P V 1 | 80 MHz to 800 MHz [3,5] / E1 * sqrt P | 800 MHz to 6.0 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.

Disposal of the Hub

Dispose of the Hub according to applicable local regulations. For information about correct disposal, please contact your local authority, government agency or electronics recycling center.

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Philips North America 3000 Minuteman Road Andover, MA 01810



Manufactured by Venture Corporation Limited for Philips North America Designed by 2net



80-KA624-2 Rev. A

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