Polytel®
Data Transmission System

USER MANUAL
Version: R

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Table of Contents

1 Introduction

1.1 System Overview

The Polytel® Data Transmission system is designed to allow patients with chronic conditions to be monitored remotely. It consists of a series of wireless medical devices, an Access Point designed to forward data to the data center, and of a monitoring service.

The PWA-08-01 is an Access Point, or "hub" that collects information from medical devices in the home and forwards them over a regular telephone line.

The PWR-08-01 and PWR-08-02 are accessories that are incorporated into various host devices, providing a simple way for a host to transmit its data wirelessly to a receiving station.

The PWR-08-03 is an in-pouch accessory that provides a simple way for host device to transmit its data wirelessly to a receiving station, allowing remote recording or monitoring of host values.

When a measurement is taken on a compatible medical device, the radio module automatically retrieves the new measurement and tries to forward it to the Access Point. Should that Access Point be unreachable or unavailable, it will periodically retry the transmission, and eventually shut itself down automatically.

1.2 Intended Use and User

The Polytel® system is intended to be used for the home monitoring of the values of various host devices. Typical applications include remote monitoring of glucose levels in diabetic patients, or monitoring of weight and BP in congestive heart failure patients. The devices are intended to be operated by patients in their homes.

NOTE: Polymap Wireless is not responsible for the measurement, diagnosis, or electrical safety of the Host Medical Devices. The Polytel® System is a Data Transmission System only.

2 System components and accessories

The Polytel® System consists of an AC Adapter (Designated PWA-08-01-1 and PWA-08-01-2) designed to connect to the Mains, Access Point (designated the PWA-08-01), designed to gather data transmitted from the different Polytel® Remote units (accessories) located either inside of or attached to different medical devices ("Authorized Applications").

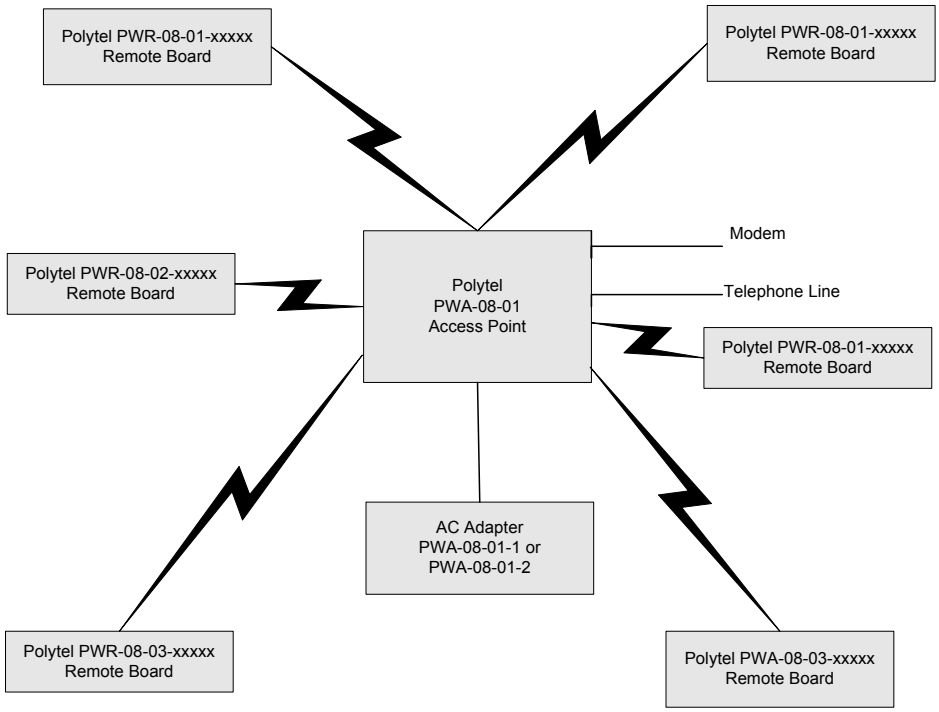


Figure 1: Polytel® Data Transmission System Block Diagram: The core of the System is the Access Point connected to the Mains through an AC Adapter and connected to the telephone line and Modem, with different accessories (Remote Boards) communicating with the Access Point through radio signal. The Remote boards are either inside of or cabled to various medical devices

2.1 PWA-08-01 Access Point

This represents the central component of the Polytel® Data Transmission System, and is used to gather data from all of the accessories. It is pictured in Figure 2.

2.2 Remote accessories

All the system accessories are built around the PWR-08 Remote module. Three different hardware configurations exist, the PWR-08-01 (board with no case, no battery, onboard antenna) the PWR-08-02 (board with no case, no battery, external antenna), and the PWR-08-03 (which includes an onboard antenna, a case and a battery and incorporates special circuitry to interface with a host). The individual accessories differ mainly in what software is loaded on them.

2.3 PWR-08-01 Remote

This accessory has an onboard antenna (see Figure 2), and is incorporated into hosts by device manufacturers.

2.4 PWR-08-02 Remote

This accessory is incorporated into hosts by device manufacturers; it incorporates an external patch antenna for use in hosts that have metal shielding.

2.5 PWR-08-03

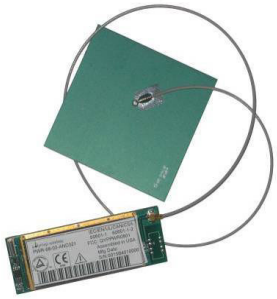
This accessory consists of a circuit board in a plastic housing intended to hold two batteries. The unit (Pictured in Figure 2) is designed to be connected by its cable to a host.

3 Identification of major parts

PWA-08-01-1 AC Adapter

Polytel® PWA-08-01 Access Point

Polytel® PWR-08-01 module



Polytel® PWR-08-02 module with antenna

Polytel® PWR-08-03 accessory

Figure 2: Polytel® System components.

The Access Point is powered by an AC Adaptor connected to the Mains Outlet, and is also connected to the household telephone line.

The Polytel® Data Transmission System consists of an Access Point (Figure 2), which acts as the "hub" or collector of information from one or more medical devices.

The PWR-08-03 accessory has a visible LED indicator, as shown in figure 3.

Figure 3: Please note the small indicator light located near the bottom right corner of the back side of the device. This allows the user to confirm whether the device is operating correctly

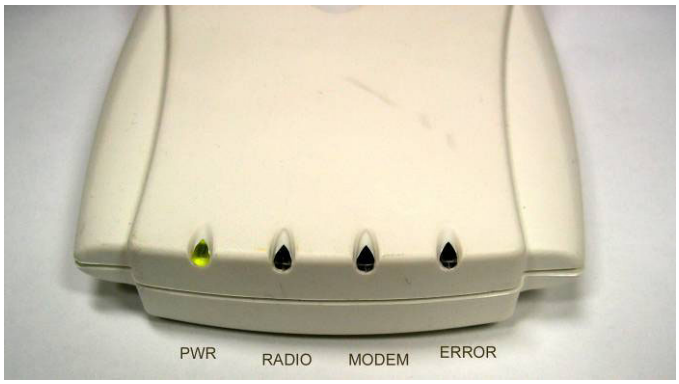


Figure 4: Indicator lights on PWA-08-01 Access Point. Leftmost indicates power, then Radio, Modem, and Error.

Figure 5: back side of PWA-08-01. This shows the power connector on the left, and the two (interchangeable) telephone connectors to the right.

Symbols:	**Meaning**
⎓	DC Input (6V)
	Modem
	Telephone line

4 Operating Instructions

4.1 Installation and setup

The effective radio range of the Access Point and the matching medical devices is around 330 feet (100 meters). Please choose a location in your house that is centrally located, or close to where the measuring devices will be used.

CAUTION – To reduce the risk of explosion or fire do not use this equipment in presence of flammable Anaesthetic mixture with Air or with Oxygen or Nitrous Oxide.

1) Connect a telephone cord between the Access Point and a telephone jack on the wall. An extra telephone outlet is provided on the back of the Access Point so you can plug a telephone into the same outlet.

2) ***CAUTION – To reduce the risk of fire, use only No. 26 AWG or larger telecommunication line cord***.
3) Connect the 6VDC power to the back of the unit, and plug the AC Adapter into a regular AC outlet. When the device is connected, expect all the front-panel LEDs to light momentarily, with the leftmost (Power) LED remaining on, and the 2nd LED (Radio) blinking at roughly one-second intervals (see Figure 4).

4) To mount the unit on the wall (OPTIONAL), two screws, mounted horizontally, on 1.5" (37mm) centers, can be used. Please use screws and anchoring systems appropriate to the wall material. The screw head size should be between ¼" and 3/8" (5-9 mm).

4.2 Location of devices

For successful use of the system, it is vital to remember that at its core, the Polytel Data Transmission System is wireless. This means that the transmitting device must be located within radio range of the Access Point, normally 330 feet. Note that various types of physical barriers, including walls, can reduce the effective range of the devices. The variety of construction methods makes predicting the effective range in a particular setting difficult.

Do not place Access Point on a metal surface or in a metal enclosure as this is likely to interfere with correct operation.

FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the equipment and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

A good rule of thumb is that the access point should be located either in the same or an adjacent room to that where the measuring device is located. You can confirm that the devices are working together correctly by looking for the blinking light patterns on the access point to change within a minute after a measurement.

4.3 A note on telephone lines

The PWA-08-01 Access Point is designed to operate over "regular" or traditional telephone lines. If you use a Voice over IP (VoIP) provider for your telephone service, you must confirm with your provider that "fax and modem support" is enabled for the telephone line you intend to use. VoIP service quality varies widely, and Polymap Wireless cannot guarantee that the device will operate correctly with every type of VoIP line.

NOTE: this device is ***not*** designed for connection to digital PBX systems, such as might be found in an office.

4.4 Batteries for the PWR-08-03

The PWR-08-03 accessory is powered by two lithium cells (CR2 size). To open the battery compartment, slide the lid in the direction indicated by the arrow labeled "OPEN" on the lid, and allow the lid to open. Please insert each battery with the negative side (–) down and its positive end (+) up, as shown in figure 6. If the two negative ends or the two positive ends of the batteries touch one another, the device will not operate. A set of batteries is expected to last several months. To close the battery compartment, bring the lid gently down against the batteries, and slide it in the direction opposite the "OPEN" arrow until the lid stops.

4.5 Usage of PWA-08-01 Access Point

In normal use, there is no intervention required by the user. Nonetheless, indicator lights are provided to give the user some sense of the correct operation of the device. There are four indicator lights on the front panel of the Access Point. These are, respectively: POWER, RADIO, TELEPHONE, and ERROR (see figure 4)

POWER (Green)	Always on in normal operation
RADIO (Green)	Blinks roughly once per second, more blinking while data is being received
TELEPHONE (Green)	Blinks when the device is connecting to the server to transfer its data. Solid while the device is connected and transferring data (usually only a few seconds)
ERROR (Red)	Comes on when data was received by the Access Point but not successfully transferred to the data center. This will occur, for example, when the telephone is in use, or there is some other congestion on the network. The Access point will keep trying, every few minutes, until it succeeds in transferring the data. Note that the forty most recent measurements are stored until they are transmitted. A rapidly flashing red light indicates that the telephone cord is not

	correctly connected.

In normal operation, the leftmost, or POWER light, will remain on, and the second light (RADIO), will blink roughly once per second. During the data transfer, the RADIO light will blink in other patterns. The PHONE light is used to indicate usage of the telephone, and the ERROR light is used to indicate a data transfer error.

Note that data transfer errors are expected to occur when phone lines or the network are congested, and should not be a concern unless they persist for more than one hour. Should the error light persist for more than an hour, please contact the agency that provided you with this equipment.

If the ERROR light comes on the first time the device is used, the most likely explanation is that it is not correctly connected to a telephone jack.

4.6 Indicator light on PWR-08-03

The device contains a small LED. This indicator will light shortly after you take a measurement on the host. It will turn itself off completely after the data is successfully transmitted. Should the data fail to transmit immediately, the device will schedule multiple retries, and the light will come on again several times for short intervals.

LED	Meaning
Solid (maximum 20 seconds)	Retrieving data from host
Fast blink (1 per second)	Looking for a receiver
Very fast blink (2 per second)	Transmitting data
Slow blink (1 every 10 seconds)	Waiting for a retry (previous attempt did not find receiver)

4.7 Retry Schedule

Immediately after a new measurement is taken, the unit will attempt to contact the receiver or access point. Should this fail, it will retry after waiting for one minute. Failing that, it will wait two minutes before retrying. Should all of these transmission attempts fail, the measurement will be stored and the device will turn itself off automatically. Stored measurements are time stamped and transmitted along with the next measurement.

If you know you have measurements stored and not yet transmitted, you can wake up the device and transmit the stored measurements without taking a new measurement. Please consult the documentation of each device for specifics instructions on how to do this.

4.8 Operation in France, Spain or Japan

The device uses a frequency hopping protocol in the 2.4GHz band. Some of the channels used are not allowed in France, though they are allowed elsewhere. Please notify Polymap Wireless of your intent to use the device in this country so that it can be reconfigured appropriately.

4.9 Troubleshooting

4.9.1 PWA-08-01 Access Point

The PWA-08-01 Access Point incorporates a red "ERROR" LED. This light indicates that the device has received data from a measuring device but has not yet been able to transmit it. This failure may be a normal occurrence (the phone number the unit dialed was busy and it's waiting to try again) or it may indicate a failure that requires user interaction.

Note that Access Points will try repeatedly to deliver the data they are holding until they are successful.

The process of troubleshooting the operation of an Access Point involves being able to watch the colored LEDs on its front panel. Troubleshooting can be made significantly easier if an ordinary telephone is plugged into the second telephone jack, allowing you to listen to the operation of the device.

Error	Cause	Corrective Action
Red LED flashes several times immediately after measurement	No dialtone	Replace telephone cord or check telephone outlet
Solid red LED after measurement	Bad telephone jack or cord	Plug a telephone into 2nd jack of Access Point. Hang up. Unplug power cord to AP and plug it in again. Wait until modem light (3rd green light) comes on, then pick up telephone and listen. If you don't a dialtone, check cord or telephone outlet
Solid red LED after measurement	Defective AP	Follow instructions above. If you hear a dialtone but do not hear a telephone number being dialed, the AP needs to be replaced.
Solid red LED after measurement	Busy signal	If this happens repeatedly, there may be a telephone company issue with 800 number access. Remove power from AP and dial 1-800-420-6565 from the telephone.
Solid red	PBX or VoIP	If you hear a modem

LED after measurement	line	answer (this sounds like a fax machine), the problem may be due to your telephone line. If you have VoIP service, ensure that "fax and modem support" is selected.
Solid red LED after measurement	Server-side configuration issues	If none of the above helps resolve your issue, please contact your service provider. A number of different service-side errors can lead to the data being retained on the Access Point.

4.9.2 PWR-08-03 accessory

Error	Cause	Corrective Action
LED does not light	Batteries missing or low	Replace batteries
LED does not light	Cable not connected to host	Connect cable to host
No "PC" indicated on host	Batteries missing or low	Replace batteries
No "PC" indicated on host	Cable not connected to host	Connect cable to host
No "PC" indicated on host	Cable not firmly plugged into host	Plug cable firmly into host
No "PC" indicated on host	Cable frayed	If visual inspection shows cable is frayed, unit must be repaired

5 Safety Information

5.1 Patient Safety

Warnings and Cautions

WARNING: "Modifications made to the product, unless expressly approved by Polymap Wireless, LLC could void the user's license for and the warranty of the device."

CAUTION: Risk of explosion if battery is replaced by an incorrect type. Dispose of used batteries according to the instructions.

5.2 Electrical Safety

Only authorized maintenance staff may remove the covers from the PWR-08-03 Remote Device. Always refer servicing to Polymap Wireless-authorized personnel.
The Polytel® Data Transmission System is classified as CLASS II equipment as per IEC60601-1 and Class II Medical Devices per 21CFR. There are no patient connected parts in the Polytel® Data Transmission System. The Host Medical Devices are approved for use by their respective manufacturers and agencies monitoring them. Polymap Wireless is not responsible for their diagnostic accuracy or their electrical safety. There are no special provisions to protect the system from flammable anesthetics or ingress of liquids

WARNING! Never operate this device in zones where there is a risk of explosion. Electrical equipment used in the presence of flammable anesthetics or oxygen may cause an explosion.

5.3 Compliance Information

This section details the telemetry system compliance requirements and the manufacturer's responsibilities.

5.3.1 Compliance Requirements

The manufacturer is responsible for the effects of safety, reliability, and performance of this equipment with the following provisions:

- The equipment is used in accordance with instructions for use
- Assembly operations, extensions, modifications, or repairs are performed by authorized persons only.

5.3.2 Compliance Statement

The manufacturer states that this device conforms to:

- FDA 21 CFR Parts 820
- IEC 60601-1: Medical Electrical Equipment – General Requirements for Safety.
- IEC 60601-1-1: Medical Electrical Equipment – Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-1-2: Medical Electrical Equipment – Collateral standard: Electromagnetic compatibility for medical electrical systems

- IEC 60601-1-4: Medical Electrical Equipment – Collateral standard: Programmable medical electrical systems
- UL 60601: Medical Electrical Equipment, Part 1 – General Requirements for Safety
- CSA: Medical Electrical Equipment, Part 1: C22.2601 No. 601.1 – M9 – General Requirements for Safety
- The manufacturer of this device complied with the following requirements applicable at time of manufacture:
    - ISO 13485:2003
    - ISO 13485/8 under Canadian Medical Device Conformity Assessment System (CMDCAS)

5.4 Label depictions and Locations

5.4.1 Label locations

Label on 120V power supply

Label on 230V power supply

Label on PWA-08-01

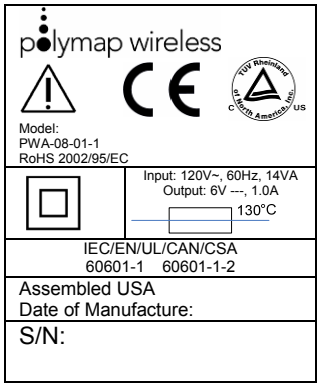
PWR-08-01 label

PWR-08-02 label

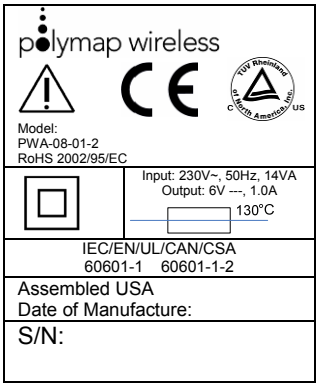
PWR-08-03 label

Figure 6 Label locations

5.4.2 Nameplate and Symbols

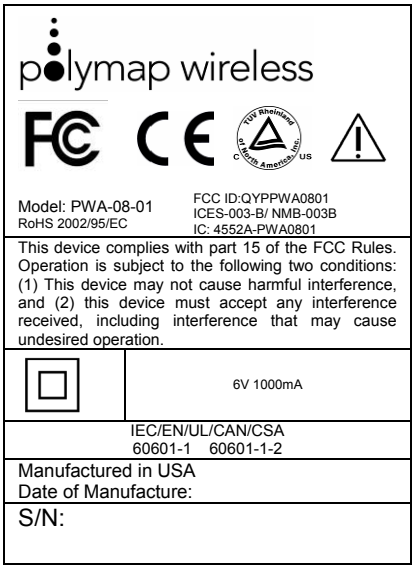


Label for 120V power supply

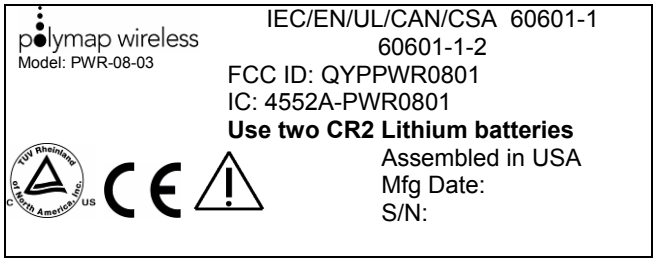


Label for 230V power supply

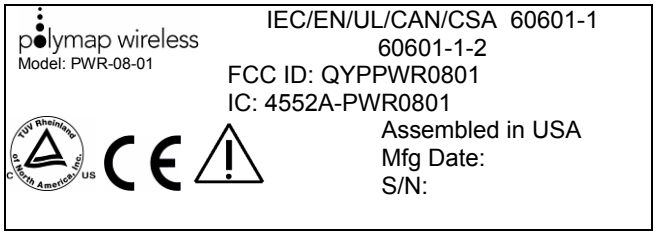
The label on the bottom of The Access Point PWA-08-01 or PWR-08-03 shows the unique radio ID of the dev
This label also shows the seals that denote the principal regulatory approvals :



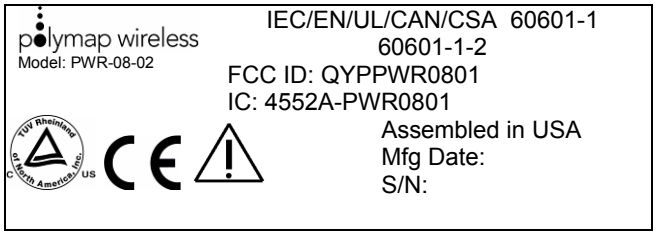
Label for PWA-08-01 Access Point



Label for PWR-08-03 accessory



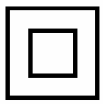
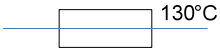
Label for PWR-08-01 wireless module



Label for PWR-08-02 Wireless Module

Figure 7: Labels.

	Indicates that the device was tested to comply with the US and Canadian safety directives.
	Indicates that the device was tested to comply with the CE MDD directive.
	Indicates that you should read accompanying documents before use.
	This device 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.
	Indicates Class II equipment under the IEC 60601-1 safety standard
	Indicates that the transformer incorporates a fuse designed to protect against temperatures in excess of 130°C
IEC/UL/CAN/CSA 60601-1 60601-1-2	Indicates that the device complies with both the safety and the radio requirements of these respective standards
FCC: QYPPWR0801	Indicates the FCC listing numbers for the device
IC: 4552A-PWR0801	Indicates the Industry Canada listing numbers for the device
S/N	Serial number

6 Operator Maintenance

6.1 Visual Inspection

The user should perform a periodic inspection (once a month) of the system to identify any component that may have become damaged or is not performing correctly.

WARNING: All parts of this System are repairable. The Repair of any damaged or incorrectly operating item should be performed ONLY by Polymap Wireless authorized personnel!

Contact Polymap Wireless promptly to maintain the equipment in the safest possible condition.

Specific attention should be paid to the cable used to connect the unit with the host.

6.2 Cleaning your PWA-08-01 and PWR-08-03:

These units should be cleaned once a year. The batteries in the PWR-08-03 should be replaced once in 6 months. Take the following steps:

1. Disconnect your PWR-08-03 from its host before cleaning.
2. Remove the batteries from your PWR-08-03, or disconnect the PWA-08-01 from the power outlet
3. Never use any spray on your units. Sprays may penetrate the unit and damage the internal electronic components.
4. Dampen a soft cloth with water, or a weak solution of household dishwashing liquid mixed with water, and wipe the unit.
5. Never immerse your units in any liquid.
6. Insert the batteries after cleaning the unit and reconnect your PWR-08-03 to its host, or reconnect your PWA-08-01 to the wall outlet, as appropriate.

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7 Technical Specifications

7.1 Electrical Input Requirements

7.1.1 PWA-08-01 Access Point

The PWA-08-01 is powered by an AC adapter. Two different adapters are available:

- 120V~ 60Hz, PWA-08-01-1
- 230V~ 50Hz. PWA-08-01-2

Both configurations have the same output rating:
6VDC, 1000ma (Maximum power, 6VA)

WARNING: There is an additional Power source inside the Access Point: 3V Lithium Battery.

7.1.2 PWR-08-03

The PWR-08-03 is powered by two CR2 Lithium cells in series (3V each). Max. Power consumption: 1W

7.1.3 PWR-08-01 and PWR-08-02

These remote boards are powered from their Host devices.
Input Voltage: 5VDC
Input current: 180mA max
Max Power consumption: 0.9W

7.2 Operating and Storing your Access Point and accessories

WARNING: Remove batteries from the equipment if not intending to use for more than 3 months!

Consult with your local Garbage Disposal Agency to dispose of used batteries

The recommended operating temperatures for your units are 10° to 40° Celsius (50° to 104° Fahrenheit).

The recommended storage temperatures are -40° to +70° Celsius (-40° to 158° Fahrenheit).

If you move your devices from a cold location to a warm location, please allow it to come up to room temperature before powering it on.

The equipment can be shipped via commercial transportation (Air and land) in packaging designed for this purpose. The recommended transportation temperatures are -40° to +70° Celsius (-40° to 158° Fahrenheit). Altitude:10,000m

7.3 Electromagnetic Compatibility

Like other electrical medical equipment, the PWA-08-01, PWR-08-01, PWR-08-02, PWR-08-03 units require special precautions to ensure electromagnetic compatibility with other

electrical medical devices. To ensure electromagnetic compatibility (EMC) the device must be installed and operated according to the information provided in this manual.

NOTE: the entire Polytel® Data Transmission System wit all its components has been tested to comply with IEC 60601-1-2:2001 requirements for EMC with other devices.

NOTE: 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, may cause harmful interference to radio 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, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or locate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

7.4 System Availability

The PWR-08-03 is designed to attempt delivery of each measurement from the host for several minutes after a measurement is taken. The system is immediately available to retrieve additional measurements in the case where they are taken before the previous measurement(s) have been transmitted.

The PWA-08-01 Access Point is always available to receive measurements from measuring devices, and will store them until it is able to forward them to your service provider

7.5 Dimensions of your PWA-08-01 Access Point

144mm x 97mm x 27mm (5.67 inches x 3.81 inches x 1.06 inches

7.6 Dimensions of your PWR-08-03 accessory:

72mm x 20mm x 45mm (2.85 inches x 0.8 inches x 1.8 inches)

8 Trademarks

Bluetooth® word mark and logos are owned by the Bluetooth SIG, Inc.
Polytel® is a registered trademark of Polymap Wireless LLC.
This product was designed solely by Polymap Wireless, independent of any of the host device manufacturers

Appendix I: IEC 60601 Section 6

8.1 PWA-08-01 Access Point

Identification, marking and documents
(per Section 6 of EN 60601-1-2:2002)

Section	Description	Complies, Does Not Comply, or N/A
6.1.201	Marking on the outside of equipment or equipment parts.	Complies
6.8.2.201	Instruction for Use	Complies
6.8.3.201a Tables 201 and 202	Technical Description (All Equipment and Systems)	Complies
6.8.3.201b Tables 203, 204, 205, and 206	Technical Description (Non-shielded Room Locations)	Complies
6.8.3.201c Tables 201, 207, and 208	Technical Description (Shielded Room)	N/A
6.8.3.201d	Equipment that intentionally applies RF Energy for Diagnosis or Treatment	N/A
6.8.3.201e	Equipment that receives RF for the purpose of operation	Complies
6.8.3.201f	Equipment that includes an RF Transmitter	Complies
6.8.3.201g	Cables, Transducers, and Accessories that could affect compliance	Complies
6.8.3.201h	Large Permanently Installed Equipment and Systems	N/A
6.8.3.201i	Equipment with no Essential Performance per Risk Analysis	N/A

Table 201- Guidance and Manufacturer's Declaration – Emissions
All Equipment and Systems

Guidance and Manufacturer's Declaration – Emissions
The PWA-08-01 Access Point is intended for use in the electromagnetic environment specified below. The customer or user of the PWA-08-01 Access Point should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF transmitter EN 300 328 EN 301 489	Bluetooth	Equipment and systems that include RF transmitter or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with the following symbol for non-ionizing radiation (EN 60417-5140) 
Other RF Emissions CISPR 11	Class B Group 1	The PWA-08-01 Access Point uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR22, FCC part 15	Subparts B and C	The PWA-08-01 Access Point is a Bluetooth device and uses RF energy to relay data to the access point. FCCID: QYPPWA0801
Harmonics EN 61000-3-2	Class A	Unit was tested for Flicker at 230VAC/50Hz, as there are no limits defined for power harmonic emissions below 220VAC or 60Hz.
Flicker EN 61000-3-3	Section 5	Unit was tested for Flicker at 230VAC/50Hz, as there are no limits defined for flicker emissions below 220VAC or 60Hz.
The PWA-08-01 Access Point is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

Notes: Unintentional Radiated Emissions were tested at 230VAC / 50Hz. The Conducted emissions were tested at 230VAC / 50 Hz and at 120VAC / 60 Hz, using the appropriate power module. The EUT complies with the EN55022 Class B, and FCC subpart B (§§15.107(a) and 15.109(g)) which has same limits as EN55011 Group 1, Class B.

The Intentional Radiated Emissions were tested using a hardwire interface board connected to a laptop computer to control frequency, frequency hopping and modulation. It complies to the requirements of EN 300 328 and EN 301 489 and FCC part 15 subpart C (§15.247).

Harmonics and Flicker was tested at 230VAC/50Hz, as there are no limits defined for flicker or harmonic emissions below 220VAC or 60Hz.

Table 202- Guidance and Manufacturer's Declaration – Immunity
All Equipment and Systems

Guidance and Manufacturer's Declaration – Immunity
The PWA-08-01 Access Point is intended for use in the electromagnetic environment specified below. The customer or user of the PWA-08-01 Access Point should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD EN 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN 61000-4-4	±2kV Mains ±1kV I/O	±2kV Mains ±1kV I/O	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency 50Hz and 60Hz Magnetic Field EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	>95% Dip for 0.5 Cycle (both polarities) 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle (both polarities) 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment.

Notes: Voltage Dips were tested at 120 VAC/ 60Hz and at 230VAC / 50Hz, using the appropriate power module. Magnetic field immunity was tested at both 50 Hz and 60 Hz.

Table 204 - Guidance and Manufacturer's Declaration – Immunity
For Equipment and systems that are not Life-Supporting (see 6.8.3.201 b) of EN60601-1-2)

Guidance and Manufacturer's Declaration – Immunity
The PWA-08-01 Access Point is intended for use in the electromagnetic environment specified below. The customer or user of the PWA-08-01 Access Point should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the EUT by no less than the distances calculated / listed below:
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	d=0.35($\sqrt{P}$)
Radiated RF EN 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	d =0.35($\sqrt{P}$) 80 to 800MHz d =0.7($\sqrt{P}$) 800MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts and d is the recommended separation distance in meters (m). Field strengths from fixed 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 containing a transmitter marked with the following symbol: 

Note 1 At 80MHz and 800MHz, 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 strength from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio 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 is which the PWA-08-01 Access Point is used exceeds the applicable RF compliance level above, the PWA-08-01 Access Point should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PWA-08-01 Access Point.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3V/m

**Table 206- Recommended Separation Distances between portable and mobile RF Communications equipment and the PWA-08-01 Access Point –
For equipment and systems that are not life-supporting (see 6.8.3.201 b) of EN60601-1-2)**

Guidance and Manufacturer's Declaration – Emissions
The PWA-08-01 Access Point is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the PWA-08-01 Access Point can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the PWA-08-01 Access Point as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz $d = (3.5/V1)(\sqrt{P})$	Separation (m) 80MHz to 800MHz $d = (3.5/E1)(\sqrt{P})$	Separation (m) 800MHz to 2.5GHz $d = (7/E1)(\sqrt{P})$
0.01	0.035	0.035	0.07
0.1	0.111	0.111	0.221
1	0.35	0.35	0.7
10	1.107	1.107	2.214
100	3.5	3.5	7.0

8.2 PWR-08-0x Remote units

Identification, marking and documents
(per Section 6 of EN 60601-1-2:2002)

Section	Description	Complies, Does Not Comply, or N/A
6.1.201	Marking on the outside of equipment or equipment parts.	Complies
6.8.2.201	Instruction for Use	Complies
6.8.3.201a Tables 201 and 202	Technical Description (All Equipment and Systems)	Complies
6.8.3.201b Tables 203, 204, 205, and 206	Technical Description (Non-shielded Room Locations)	Complies
6.8.3.201c Tables 201, 207, and 208	Technical Description (Shielded Room)	N/A
6.8.3.201d	Equipment that intentionally applies RF Energy for Diagnosis or Treatment	N/A
6.8.3.201e	Equipment that receives RF for the purpose of operation	Complies
6.8.3.201f	Equipment that includes an RF Transmitter	Complies
6.8.3.201g	Cables, Transducers, and Accessories that could affect compliance	N/A
6.8.3.201h	Large Permanently Installed Equipment and Systems	N/A
6.8.3.201i	Equipment with no Essential Performance per Risk Analysis	N/A

Table 201- Guidance and Manufacturer's Declaration – Emissions
All Equipment and Systems

Guidance and Manufacturer's Declaration – Emissions
The PWR-08-03 Remote Unit is intended for use in the electromagnetic environment specified below. The customer or user of the PWR-08-03 Remote Unit should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF transmitter EN 300 328	Bluetooth	Equipment and systems that include RF transmitter or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labeled with the following symbol for non-ionizing radiation (EN 60417-5140) 
Other RF Emissions CISPR 11	Class B Group 1	The PWR-08-03 Remote Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR22, FCC part 15	Subparts B and C	The PWR-08-03 Remote Unit is a Bluetooth device and uses RF energy to relay data to the access point. FCCID: QYPPWR0803
Harmonics EN 61000-3-2	N/A	The PWR-08-03 Remote Unit is battery operated only.
Flicker EN 61000-3-3	N/A	The PWR-08-03 Remote Unit is battery operated only.
The PWR-08-03 Remote Unit is suitable for use in all establishments, including domestic.		

Notes: Unintentional Radiated Emissions were tested using fresh batteries. It complies with the EN55022 Class B, and FCC part 15.109(g) which has same limits as EN55011 Group 1, Class B. Intentional Radiated Emissions were tested using a hardwire interface board connected to a laptop computer to control frequency, frequency hopping and modulation.

Harmonics and Flicker was not tested.
The EUT is battery operated, and is therefore beyond the scope of those standards.

Table 202- Guidance and Manufacturer's Declaration – Immunity
All Equipment and Systems

Guidance and Manufacturer's Declaration – Immunity
The PWR-08-03 Remote Unit is intended for use in the electromagnetic environment specified below. The customer or user of the PWR-08-03 Remote Unit should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD EN 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT EN 61000-4-4	Not applicable. The EUT is Battery operated. Beyond the scope of the standard.	±2kV Mains ±1kV I/O	The EUT is Battery operated. Beyond the scope of this standard.
Surge EN 61000-4-5	Not applicable. The EUT is Battery operated. Beyond the scope of the standard.	±1kV Differential ±2kV Common	The EUT is Battery operated. Beyond the scope of this standard.
Power Frequency 50Hz and 60Hz Magnetic Field EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should at levels characteristic of a typical location in a typical home, commercial, or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	Not applicable. The EUT is Battery operated. Beyond the scope of the standard.	>95% Dip for 0.5 Cycle (both polarities) 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	The EUT is battery operated. Beyond the scope of this standard.

Notes: Power-line immunity is not applicable.
The EUT is battery operated, and is therefore beyond the scope of the standard(s).

Table 204 - Guidance and Manufacturer's Declaration – Immunity
For Equipment and systems that are not Life-Supporting (see 6.8.3.201 b) of EN60601-1-2)

Guidance and Manufacturer's Declaration – Immunity
The PWR-08-03 Remote Unit is intended for use in the electromagnetic environment specified below. The customer or user of the PWR-08-03 Remote Unit should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile communications equipment should be separated from the EUT by no less than the distances calculated / listed below:
Conducted RF EN 61000-4-6	Not applicable. The EUT is Battery operated. Beyond the scope of the standard.	3 Vrms	d=0.35($\sqrt{P}$)
Radiated RF EN 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	d =0.35($\sqrt{P}$) 80 to 800MHz d =0.7($\sqrt{P}$) 800MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts and d is the recommended separation distance in meters (m).
			Field strengths from fixed 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 containing a transmitter marked with the following symbol: 

Note 1 At 80MHz and 800MHz, 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 strength from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio 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 is which the PWR-08-03 Remote Unit is used exceeds the applicable RF compliance level above, the PWR-08-03 Remote Unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PWR-08-03 Remote Unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3V/m

**Table 206- Recommended Separation Distances between portable and mobile RF Communications equipment and the PWR-08-03 Remote Unit –
For equipment and systems that are not life-supporting (see 6.8.3.201 b) of EN60601-1-2)**

Guidance and Manufacturer's Declaration – Emissions
The PWR-08-03 Remote Unit is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the PWR-08-03 Remote Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the PWR-08-03 Remote Unit as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz $d=(3.5/V1)(\sqrt{P})$	Separation (m) 80MHz to 800MHz $d=(3.5/E1)(\sqrt{P})$	Separation (m) 800MHz to 2.5GHz $d=(7/E1)(\sqrt{P})$
0.01	0.035	0.035	0.07
0.1	0.111	0.111	0.221
1	0.35	0.35	0.7
10	1.107	1.107	2.214
100	3.5	3.5	7.0

Index