Cisco HealthPresence Specifications, Warnings and Precautions

Do NOT Discard: Keep this document with the Cisco HealthPresence equipment at all times.

V 2.0 for Neurosynaptic Medical Devices
August 25, 2011

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Cisco HealthPresence is intended for use by licensed health care professionals with those certain independent third party medical devices listed as compatible in the Cisco Health Presence Instructions for Use. The user is to refer to the third party instructions for use concerning any further information about the use of those certain medical devices. Cisco HealthPresence is not intended to perform real-time, active, or online patient monitoring, and does not transmit or display any real-time data that is intended to alert the user of alarms or other conditions that require immediate action or response. Cisco Systems makes no representations or warranties concerning jurisdictional requirements related to the licensed practice of medicine or health care using Cisco HealthPresence.

Cisco HealthPresence Specifications, Warnings and Precautions

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Cisco HealthPresence Specifications, Warnings and Precautions

CHAPTER 1

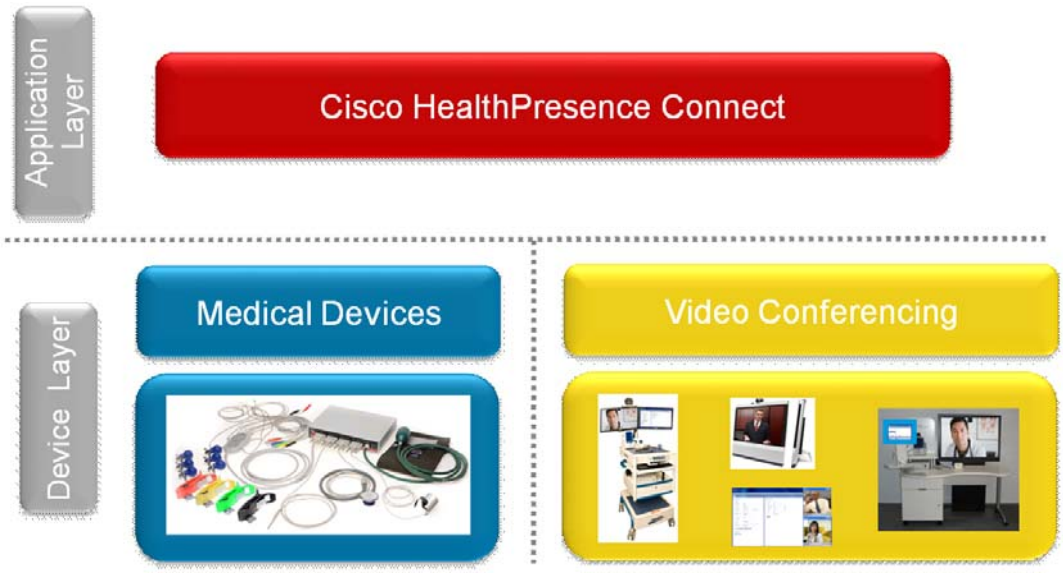
Cisco HealthPresence Intended Use and Contraindications

Revised: August 25, 2011

CHP Device Components

The Cisco HealthPresence™ Device consists of a number of components, as illustrated if Figure 1-1.

Figure 1-1 Cisco HealthPresence Device Diagram



The components include the following:

- CHP Connect software - provides a communications link between end points over secure private or virtual private network connections. Cisco HealthPresence Connect software transmits data acquired from third-party medical devices between end points.
- Medical Devices - medical devices allow remote measurement and reporting of medical information including vitals, ECG, and stethoscopic audio.
- Video Conferencing - Provides a “face-to-face” feel for the appointment.

Intended Use of Cisco HealthPresence

For information on the design of the Cisco HealthPresence Solution, refer to the ***Cisco HealthPresence Solution Design Guide***, OL-25304-01 and the ***Cisco HealthPresence Solution Design Guide Neurosynaptic Addendum***, OL-25211-01.

For complete instructions on the use of the Cisco HealthPresence Device refer to the ***Cisco HealthPresence User Guide***, OL-25427-01. For assembly, use, servicing, care and maintenance of interoperable or compatible devices, see the instructions for use supplied with each device. Refer to the ***ReMeDi MDAU Hardware Operating Manual*** for assistance with the Neurosynaptic medical devices.

If the user is unable to use Cisco HealthPresence for its intended use due to the performance or operation of Cisco HealthPresence, discontinue the patient examination using Cisco HealthPresence and refer to the Cisco HealthPresence User Guide and the instructions for use for Interoperable Devices for further information on proper operation. If a problem cannot be resolved by the user, contact Cisco as outlined in Chapter 3, “Cisco HealthPresence Maintenance and Service”.

For Use By Licensed Health Care Professionals Only

The Cisco HealthPresence Device is a Class 1 medical device[1] that is intended for use only by licensed health care professionals working in a clinical setting for examining patients. A licensed health care professional is defined as any medical practitioner licensed by law of the country in which he or she practices to use or order the use of the applicable device. The term “user” in this document refers to a licensed health care professional located at any endpoint. It is the user's obligation to provide health care services in accordance with the applicable standard of care and all other jurisdictional requirements related to user's providing of health care services when using Cisco HealthPresence.

The entire Cisco HealthPresence system is suitable for use within the patient environment.

For Use in Non-Critical Exams Only

The patient data and physician consults using Cisco HealthPresence are for use in non-critical examinations with a licensed health care professional present as an Attendant.

For Use with Interoperable Devices Only

Only certain third party medical devices are indicated as interoperable with Cisco HealthPresence (“Interoperable Devices”). Interoperable Devices are to be used according to the instructions for use prepared by the manufacturers of those Interoperable Devices.

Third party medical devices indicated by Cisco Systems as being Cisco HealthPresence Interoperable Devices are listed in Table 1-1.

1. As defined by the FDA in the Code of Federal Regulations, Title 21.

Table 1-1 Interoperable Devices

Description	Label
ReMeDi-MDAU	ReMeDi-MDAU
ReMeDi ECG Probe	ReMeDi-ECGCAB-001
ReMeDi Temperature Probe	ReMeDi-TEMPCAB-001
ReMeDi Stethoscope Probe	ReMeDi-STETHCAB-001
ReMeDi BP Probe	ReMeDiBPCAB-001-

The ReMeDi-MDAU connects to the Cisco HealthPresence Attendant Appliance and the remaining components connect to the ReMeDi-MDAU.

For assembly, use, servicing, care and maintenance of interoperable devices, see the ReMeDi-MDAU 1.10 Medical Data Acquisition Unit Hardware Operating Manual.

For warnings and precautions specific to the ReMeDi-MDAU medical devices, refer to the ReMeDi-MDAU 1.10 Medical Data Acquisition Unit Hardware Operating Manual.

For Use with Compatible Video Endpoints Only

Only the following video endpoints are indicated as compatible with Cisco HealthPresence.

- Cisco TelePresence System 500
- Cisco TelePresence Codec C20 with LCD 100L Pro 32N monitor
- Cisco TelePresence CodecC40 with LCD 100L Pro 32N monitor
- Cisco TelePresence System EX60
- Cisco TelePresence System EX90
- Cisco Unified Video Advantage
- Cisco Unified IP Phone 7985G

For assembly, use, servicing, care and maintenance of your video endpoint, see the instructions for use provided with the device.

For Use with Specific Software and Hardware

The Cisco HealthPresence solution requires specific hardware and software at the provider and attendant stations.

Cisco HealthPresence customers run the Cisco HealthPresence Connect V2.0 software on the Cisco HealthPresence Attendant or Provider Appliance. The Cisco HealthPresence Attendant Appliance enables an attendant to participate in appointments and conferences. It also aggregates audio and vitals from attached medical devices. The Cisco HealthPresence Provider Appliance enables a provider to participate in appointments and conferences.

Note The Cisco HealthPresence Attendant Appliance and the Cisco HealthPresence Provider Appliance must not be changed in any way, as this can impact the performance of the solution. No software packages may be added and existing software packages must not be modified (either by configuration changes or service level changes, except for required service upgrades to Windows and anti-virus software.)

Caution Windows Updates and anti-virus updates and scans must not be scheduled during patient appointments.

The software listed in Table 1-2 is installed in the Cisco HealthPresence Attendant and Provider Appliances in all cases except when used with the Cisco Unified Video Conferencing video endpoint. (Items listed with an * are installed on the Attendant Appliance only.)

Table 1-2 Cisco HealthPresence Attendant Appliance Configuration For Windows 7

Cisco HealthPresence Appliance Component	Specification
Cisco HealthPresence Attendant Appliance	CHP-ATTNAPPLNS-W7
Cisco HealthPresence Attendant Appliance Monitor	Viewsonic VA926
Operating System	Windows 7 Professional, Version 6.1 64 bit[1] Service Pack 1
Cisco HealthPresence Connect Client	V2.0.0
PC Browser version/type	Internet Explorer Version 8 (8.0.7601.17514), 32 bit
Audio Driver	Realtek HD Audio Driver 6.0.1.6083
Video Chipset	Mobile Intel® 45 Series Express Chipset Family 8.15.10.1749

1. Unless this is a provider endpoint running Cisco Unified Video Advantage, in which case, the operating system is Windows XP.

The software listed in Table 1-3 is installed in the Cisco HealthPresence Attendant and Provider Appliances when used with Cisco Unified Video Advantage. (Items listed with an * are installed on the Attendant Appliance only.)

Table 1-3 Cisco HealthPresence Attendant and Provider Appliance Configuration For Windows XP

Cisco HealthPresence Appliance Component	Specification
Cisco HealthPresence Attendant Appliance	CHP-NSCUVAAPPL-XP
Cisco HealthPresence Attendant Appliance Monitor	Viewsonic VA926
Operating System	Windows XP Professional, Version 5.1, Service Pack 3
Cisco HealthPresence Connect Client	V2.0.0
PC Browser version/type	Internet Explorer Version 8.0.6001.18702 (32 bit)

Cisco HealthPresence Appliance Component	Specification
Audio Driver	Realtek HD Audio 5.10.0.5730
Video Chipset	Mobile Intel® 4 Series Express Chipset Family 6.14.10.5068

Electrical Specifications of the ReMeDi-MDAU

The electrical specifications for the ReMeDi-MDAU are listed below:

- Mode of Operation: USB Powered
- Power Input: 5V, 500mA, USB Power
- Classification: Class II, Defibrillation Proof, Type BF, IPX1

For Use with Specific Power Strips and Isolation Transformers Only

Only the following Multiple Portable Socket-Outlets (MPSOs) and isolation transformers are supported and they must remain as configured during the installation process:

- Isolation Transformer: Toroid Corporation W-Series, Model ISB-060W: International / Multi-Voltage Medical Hospital Grade Isolation Transformer for attendant endpoint, to isolate and surge-protect medical devices, DA, and displays.
- Optional Power Distribution Unit: American Power Conversion AP7900 (power distribution unit [PDU] with 8 port outlets) for both the attendant and the provider endpoints, to enable remote powering of the Cisco HealthPresence Attendant/Provider Appliance.

The following rules must be followed with the MPSOs and isolation transformers:

- Do not place MPSOs and isolation transformers on the floor.
- Do not connect any additional MPSOs, isolation transformers or extension cords to the system.
- Do not connect devices other than those provided with the system to the MPSOs or isolation transformers used by the system.

Power Distribution

If the Cisco HealthPresence system is used with any supported video conferencing system other than the Cisco Unified Video Advantage, it must be configured as shown in Figure 1-2 or Figure 1-3.

The power distribution units (AP7900s) are optional, but if not present, the CTS-500 Codec and Cisco HealthPresence Attendant Appliance must plug directly into the isolation transformers in the slot indicated in the diagrams below.

Figure 1-2 Power Distribution for the Cisco HealthPresence, Neurosynaptic Medical Devices and a Cisco TelePresence System 500

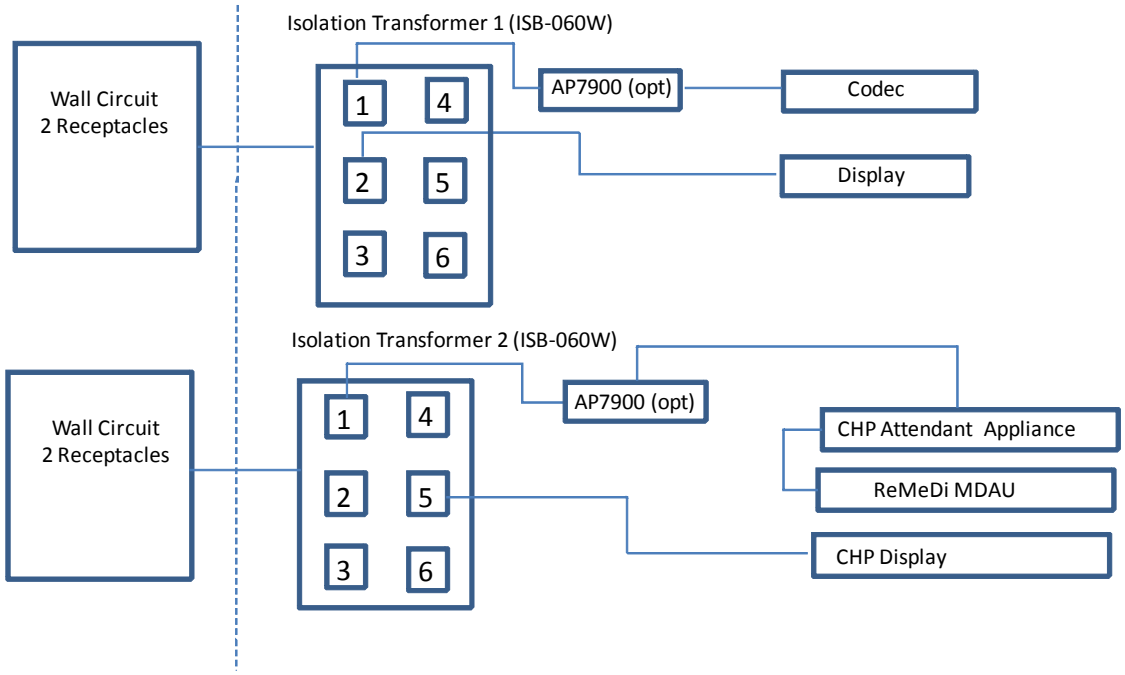
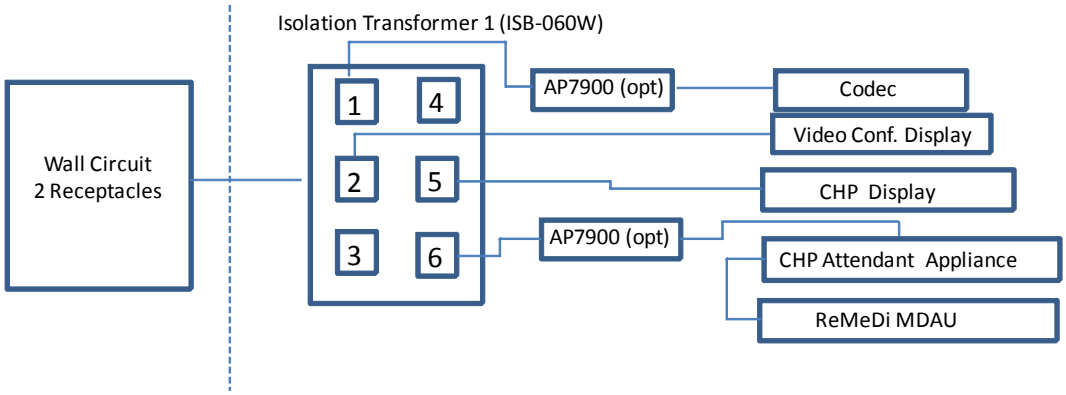


Figure 1-3 Power Distribution for the Cisco HealthPresence, Neurosynaptic Medical Devices and Other Supported Video Conferencing Systems



Foreseeable Misuse of Cisco HealthPresence Device

Cisco HealthPresence must be used with the approved medical devices only. Cisco-approved medical devices are listed in the ***Cisco HealthPresence User Guide*** and within this document.

Patient Privacy

Cisco HealthPresence employs securement for the protection of patient data. No securement can provide absolute protection against loss of privacy, unauthorized use of passwords, or corruption of data. The user is advised to employ reasonable precautions at the user's site and that the user must meet minimum network requirements as further detailed in the ***Cisco HealthPresence Solution Design Guide***.

Therapeutic Claims

Cisco does not claim that the Cisco HealthPresence Device will improve the outcome or have a therapeutic impact on patients with specific medical conditions.

Contraindications

Not for Use in Emergency Situations

The Cisco HealthPresence Device is intended for use by licensed health care professionals during examination of patients with non-life threatening illnesses and injuries. The Cisco HealthPresence Device is not a substitute examination for life-threatening emergencies or other situations where an immediate physician response is required. Cisco HealthPresence is not for use in situations involving real-time patient monitoring or alarming.

Not for Real-Time Applications

The Cisco HealthPresence-Connect software is not intended to perform real-time, active, or online patient monitoring, and does not transmit or display any real-time data that is intended to alert a physician of alarms or other conditions that require a physician's immediate action or response.

Warnings

Dialing Emergency Medical Services May Not Be Possible

Some compatible video systems (the Cisco TelePresence System 500, Cisco Unified Video Advantage or Cisco Unified IP Phone 7985G) use an integrated IP phone to connect video conference calls and to control the volume of conference calls. Depending on how your system was configured, if you have one of these Cisco Unified IP phones, outside calls may or may not be supported. Unless the Cisco

HealthPresence Solution design included special provisions to enable emergency medical services dialing, the Cisco Unified IP Phone cannot be used to dial emergency medical services or for any other calls outside of the Cisco HealthPresence system.

Note If the solution design does not enable emergency medical services dialing from the Cisco Unified IP phone, a formal communication plan should be presented to Cisco HealthPresence clients/users about what capabilities and restrictions exist if an emergency call is made. The end users assume full responsibility for emergency dialing plans once the project has been signed-off and handed over for operational use.

Loss of Connectivity is Possible

During the use of Cisco HealthPresence, a health care professional can lose connectivity with the system, a medical device or the video conferencing system. Loss of connectivity can result from power outages, network outages, failure in the Cisco HealthPresence software/hardware or other causes. Loss of connectivity can prevent a health care professional from having a HealthPresence telemedicine appointment or can limit the use of one or more of the devices interoperable with the solution.

System Components Subject to Environmental Conditions

Adverse conditions resulting from internal/external environmental forces can cause system failure or interruption of service. A system failure can prevent a health care professional from having a HealthPresence telemedicine appointment.

Audio Transmission Can Be Lost

The Cisco HealthPresence Attendant/Provider Appliance can experience intermittent or complete loss of audio transmission. This can result from a power outage, a failure in the stethoscope, a failure in the ReMeDi MDAU or other causes. Typically this means a health care professional may not be able to obtain or transmit audio from the stethoscope.

Delay or Choppiness of Audio Transmission is Possible

Cisco HealthPresence can experience audio delays from the stethoscope. A health care professional can have difficulty making adjustments if incremental delays are added or if the sound is unclear. The system normally starts transmitting with a 2–3 second delay before providing a continuous audio stream. Delays can result from network latency, software/hardware malfunction, or other causes. Typically this means a health care professional may be unable to obtain reliable data, resulting in a misreading upon initial usage.

Delays can be substantially greater than 2–3 seconds depending on user's network configuration and network traffic.

Proper Training in the Use of Cisco HealthPresence System is Required

Health care professionals using Cisco HealthPresence should be sufficiently trained and familiar with the appropriate Cisco HealthPresence User Guide and the instructions for use for Interoperable Devices before performing consultations using Cisco HealthPresence.

Audio Distortions Possible

Cisco HealthPresence can experience audio distortions from the digital stethoscope. Distortions can occur due to network latency, software/hardware malfunction or for other reasons such as an improper configuration. If the audio is not of sufficient quality for the intended use of Cisco HealthPresence, refer to the instructions for use for Interoperable Devices and the appropriate Cisco HealthPresence User Guide.

Note A ringing or pinging sound may be heard while using the digital stethoscope. If this should occur, please cease operation and immediately contact Cisco to troubleshoot the issue.

Precautions

To ensure safety and to minimize operational problems, take the following precautions:

Test Devices Regularly: Prior to using the Cisco HealthPresence Device, the attendant at the patient pod should ensure that all components are in good working order by following the procedures outlined in the Cisco HealthPresence User Guide.

Avoid Use Near Flammable Mixtures: The Cisco HealthPresence device is not suitable for use in the presence of flammable mixtures.

Maximizing the Performance of Cisco HealthPresence with Interoperable Devices

Digital Stethoscope

To maximize the effectiveness of the digital stethoscope, minimize extraneous noise in and around the Attendant Station.

TelePresence and Video Conferencing

Room lighting and noise levels can affect the quality of the TelePresence or video conference component of the Cisco HealthPresence. Refer to the ***Cisco HealthPresence Solution Design Guide*** for room design guidelines.

CHAPTER 2

Cisco HealthPresence Specifications

Environmental

Warning **This device is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. An explosion may result.**

Operating Temperature	50° to 104° (10° to 40° C)[1]
Relative Humidity	15 to 95% (non-condensing)
Operating Altitude	0 to 6561 ft. (170 to 2000 m)

1. The maximum temperature for the Cisco TelePresence Clinical Presence System mobile cart is 95° (35° C)

Emissions and Immunity Information

Both the Cisco HealthPresence Attendant Appliance and the Cisco HealthPresence Provider Appliance are intended for use in the electromagnetic environment specified below. The customer or user of the Cisco HealthPresence Attendant and Provider Appliances should assure that it is used in such an environment.

Table 2-1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Emissions
RF emissions CISPR 11	Group 1	The Cisco HealthPresence Attendant Appliance 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.
EN 60601-1-1		

Emissions Test	Compliance	Electromagnetic Emissions
RF emissions CISPR 11	Class A	The Cisco HealthPresence Attendant Appliance is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Class A	
Voltage fluctuations / flicker emissions	Complies	

Table 2-2 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%.
Electrostatic 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 commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV lines to earth	±1 kV line(s) to line(s) ±2 kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cisco HealthPresence Attendant Appliance requires continued operation during power mains interruptions, it is recommended that the Cisco HealthPresence Attendant Appliance be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Table 2-3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity (Not Life Supporting)

Recommended separation distances between portable and mobile RF communications equipment and the Cisco HealthPresence Attendant Appliance for Cisco HealthPresence Devices that are not life-supporting			
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 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Cisco HealthPresence Attendant Appliance, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [1.17]\sqrt{P}$ $d = [1.17]\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [2.33]\sqrt{P}$ 800MHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following: 

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.

1. 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 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 Cisco HealthPresence Attendant Appliance issued exceeds the applicable RF compliance level above, the Cisco HealthPresence Attendant Appliance should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cisco HealthPresence Attendant Appliance.
2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 2-4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Cisco HealthPresence Attendant Appliance

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

	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
Rated maximum output power of transmitter W	$d = [1.17]\sqrt{P}$	$d = [1.17]\sqrt{P}$	$d = [2.33]\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 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.

CHAPTER 3

Cisco HealthPresence Maintenance and Service

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Cleaning

For care and cleaning of compatible video devices, see the third party instructions for use supplied with each device.

Repair

If you have problems with the Cisco HealthPresence Device, refer to the problem solving section of the ***Cisco HealthPresence Site Administration Guide***. The Cisco HealthPresence Patient Pod has no serviceable parts.

If you are unable to resolve problems on your own, contact support. When your Cisco HealthPresence system was installed, your site was provided with the appropriate numbers to call.

If your site has a support contract with Cisco, you can contact Cisco Systems at:

http://www.cisco.com/en/US/support/tsd_cisco_worldwide_contacts.html.

Reference your Cisco HealthPresence support contract number and use the keyword “HealthPresence”.