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# **Cisco HealthPresence Specifications, Warnings and Precautions**

Do NOT Discard: This document is to be kept with the Cisco HealthPresence equipment at all times.

V 2.0 for AMD Telemedicine Medical Devices August 9, 2011

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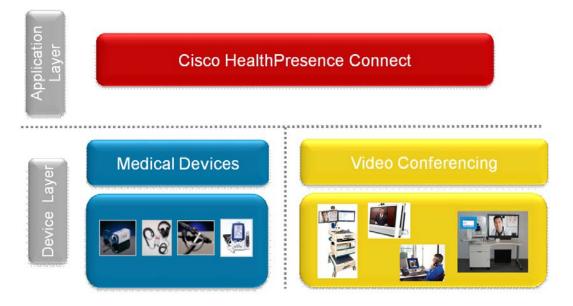
# Cisco HealthPresence Intended Use and Contraindications

Revised: August 9, 2011

# **CHP Device Components**

The Cisco HealthPresence<sup>TM</sup> Device consists of a number of components, as illustrated in 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 the medical devices allow remote measurement and reporting of medical
  information including vitals, video imaging from examination cameras and medical scopes, 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-25211-01.

For complete instructions on the use of the Cisco HealthPresence Device refer to the *Cisco HealthPresence User Guide*, OL-25041-01. For assembly, use, servicing, care and maintenance of interoperable or compatible devices, see the instructions for use supplied with each device.

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 Systems for further support:

http://www.cisco.com/en/US/support/tsd\_cisco\_worldwide\_contacts.html

# For Use By Licensed Health Care Professionals Only

The Cisco HealthPresence Device is a Class 1 medical device<sup>1</sup> 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 State (for example, California) 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 below:

digital stethoscope (AMD-3700)

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

- camera and illumination system (AMD-400/500) and supported scopes:
  - digital ear, nose, and throat (ENT) video scope (AMD-2015)
  - digital direct ophthalmoscope (AMD-2020)
  - digital dermascope (AMD-2030)
- digital examination camera (AMD-2500)
- vital sign capture and measurement device (Welch Allyn Spot Vital Signs LXi, also known as the AMD-8221).

These devices connect to the Cisco HealthPresence Attendant Appliance.

For assembly, use, servicing, care and maintenance of interoperable devices, see the third party instructions for use supplied with each device. For proper disposal of materials provided with each interoperable device, see the instructions for use supplied with the materials.

# For Use with Compatible Video Endpoints Only

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

- Cisco TelePresence System 500 (CTS 500)
- Cisco TelePresence Codec C20 with LCD 100L Pro 32N monitor
- Cisco TelePresence Codec C40<sup>2</sup>
- Cisco TelePresence System EX60
- Cisco TelePresence System EX90
- Cisco Unified VideoAdvantage
- 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 video, audio and vitals from attached medical devices. The Cisco HealthPresence Provider Appliance enables a provider to participate in appointments and conferences.



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.)

The Codec C40 is only supported when used in conjunction with the Cisco TelePresence Clinical Presence System.



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

The software listed in Table 1-1 is installed in the Cisco HealthPresence Attendant Appliance.

#### Table 1-1 Cisco HealthPresence Attendant Appliance Configuration

Cisco HealthPresence Appliance Component	Specification	
Cisco HealthPresence Attendant Appliance	CHP-ATTNDAPPL-W7	
Cisco HealthPresence Display	Viewsonic VA926	
Operating System	Windows 7 Version 6.1 Professional 64 bit Service Pack 1	
Cisco HealthPresence Connect Client	V2.0.0	
Device Aggregation software	AMD Agnes V2.0.7	
PC Browser version/type	Internet Explorer Version 8 (8.0.7601.17514), 32 bit	
Audio Driver	Realtek Audio Driver 6.0.1.6083	
Video Chipset	Mobile Intel® 45 Series Express Chipset Family 8.15.10.1749	

# For Use with Specific Multiple Portable Socket Outlets (MPSOs) Only

Only the following MPSOs are supported and they must remain as configured during the installation process:

- 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. The rating for this isolation transformer is 115/230 Vac, 5.0A/2.5A. The number required depends on the video conferencing system.
- American Power Conversion (APC) 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 circuits used by the Cisco HealthPresence Device:

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



If the user plugs the video conferencing components, Cisco HealthPresence Attendant Appliance or Cisco HealthPresence Attendant Appliance display directly into a wall outlet (rather than going through the isolation transformer) then the leakage current will exceed the allowable limits in IEC 60601-1-1. Excess leakage current can cause electric shock.

Using a different MPSO or isolation transformer could increase the risk of fire or shock and void the safety certification.

To meet the compliance as per UL 60601-1, EN 60601-1 and CSA C22.2 601.1, at Attendant Stations with AMD medical devices, the Cisco HealthPresence system must be configured as illustrated in Figure 1-2 when using a CTS-500 or Figure 1-3 when using any other video endpoint.

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 Figure 1-2.

Figure 1-2 Power Distribution for the Cisco HealthPresence Attendant Station when Used wtih a CTS-500

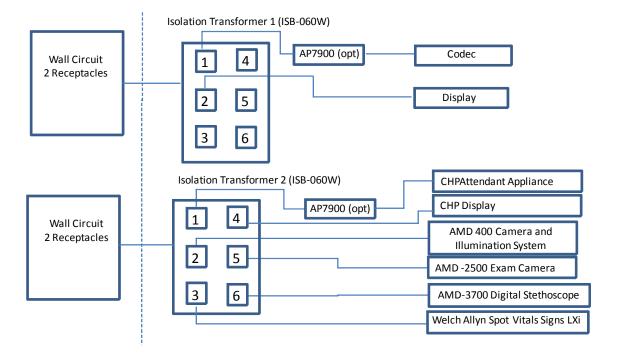
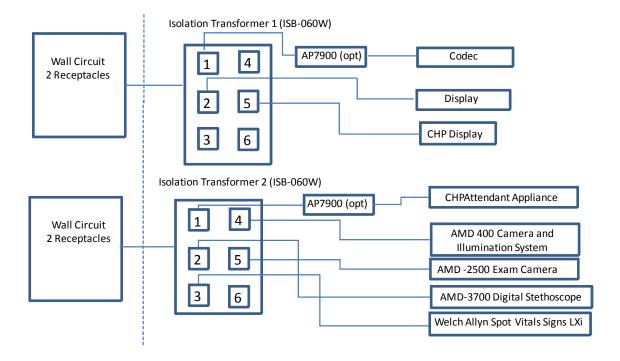


Figure 1-3 Power Distribution for the Cisco HealthPresence Attendant Station when Used wtih a non-CTS-500 Video Endpoint

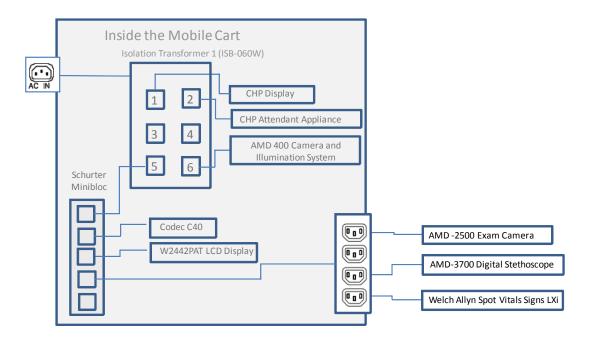


# The Optional Cisco TelePresence Clinical Presence System

If using the optional Cisco TelePresence Clinical Presence mobile cart, refer to the warnings and precautions document supplied with that device in addition to the warnings and precautions in this document. Cisco HealthPresence only uses the dual monitor AC powered system (product SKU CTS-CPS-DM-K9). Cisco HealthPresence does not use the mobile cart with the battery option.

Three medical devices, the digital examination camera (AMD-2500), the Welch Allyn Spot Vital Signs LXi and digital stethoscope (AMD-3700) plug into three of the four power plugs on the back of the cart. All other wiring is not accessible to the end user. Figure 1-4 illustrates the power distribution for the Cisco TelePresence Clinical Presence System.

Power Distribution for the Cisco TelePresence Clinical Presence System.



### 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**

Figure 1-4

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 (for example, 911) or for any other calls outside of the Cisco HealthPresence system.



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 911, 9.911 or any modification of a dial-plan for a 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.

### **Excessive Movement May Increase Delay**

Excessive movement of either the digital examination camera (AMD-2500) or the scopes attached to the camera and illumination system (AMD-400/500) may increase the delay between the device position and the image shown on the video screen.

#### **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 or Video Transmission Can Be Lost**

The Cisco HealthPresence Attendant Appliance can experience intermittent or complete loss of audio or video transmission. This can result from a power outage, a failure in the stethoscope, a failure in the Cisco HealthPresence Attendant Appliance or other causes. Typically this means a health care professional may not be able to obtain or transmit audio or video from an interoperable medical device such as the AMD-3700 digital stethoscope or the AMD-2500 digital examination camera.

#### **Delay or Choppiness of Audio or Video Transmission is Possible**

Cisco HealthPresence can experience audio delays or choppiness (jitter) from one of its interoperable medical devices. 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 and video stream. Delays or jitter 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, user's network traffic, and the motion of the examination camera if the examination attendant places the camera in a frequently changing position or state of motion.

### 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.

### AMD-2500 or AMD-400/500 May Not Focus Properly

There may be times when the AMD-2500 digital examination camera or the AMD-400/500 camera and illumination system does not properly focus when being used on a patient. This problem can result from equipment malfunction, improper use of the camera or other reasons such as an improper configuration. An improperly configured or poorly focused camera may reduce the quality of the image. If an image is not of sufficient visual quality for the intended use of Cisco HealthPresence, refer to the instructions for use for Interoperable Devices and the appropriate Cisco HealthPresence User Guide.

#### **Audio Distortions Possible**

Cisco HealthPresence can experience audio distortions from the digital stethoscope to the Cisco HealthPresence Attendant Appliance. 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.



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

## **Precautions**

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

**Use Care with ENT Scope:** Do not use the video image to position the ENT scope. The ENT scope should be manually positioned and the video image should be allowed to stabilize.



Placing the ENT scope / speculum too far in an ear canal may cause serious injury.

**Test Devices Regularly:** Prior to using the Cisco HealthPresence Device, the attendant should ensure that all components at the Attendant Station 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

#### AMD-2500 or AMD-400/500

To maximize the effectiveness of the AMD-2500 digital examination camera or the AMD-400/500 camera and illumination system with its attached scopes, do not move the examination camera or the scopes rapidly. Use slow movements and allow time for the doctor to view the image in the new location before you move the camera or scopes.

### Telephonic 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.



# **Cisco HealthPresence Specifications**

# **Environmental**



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.

<b>Operating Temperature</b>	50° to 104° (10° to 40° C) <sup>1</sup>	
Relative Humidity	15 to 95% (non-condensing)	
Operating Altitude	-557 to 6561 ft. (170 to 2000 m)	

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

# Safety

The Cisco HealthPresence Device meets the following Safety standards:

UL 60601-1

EN60601-1

EN60601-1-1

CAN/CSA C22.1 No. 60601-1

# **Emissions and Immunity Information**

The Cisco HealthPresence Device is intended for use in the electromagnetic environment specified below. The customer or user of the Cisco HealthPresence Device 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 Device uses RF energy only for its internal function.  Therefore, its RF emissions are very low an are not likely to cause any interference in nearby electronic equipment.	
EN 60601-1-2			
RF emissions CISPR 11	Class A	The Cisco HealthPresence Device is suitable	
Harmonic emissions IEC 61000-3-2	Class A	for use in all establishments other than domestic and those directly connected to the	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	public low-voltage power supply network that supplies buildings used for domestic purposes.	

#### 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	$<5\%\ U_{\rm T}$ (> 95 % dip in $U_{\rm T}$ ) for 0.5 cycle 40 % $U_{\rm T}$ (60% dip in $U_{\rm T}$ ) for 5 cycles	$<5\%\ U_{\rm T}$ (> 95 % dip in $U_{\rm T}$ ) for 0.5 cycle 40 % $U_{\rm T}$ (60% dip in $U_{\rm T}$ ) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cisco HealthPresence Device requires continued operation during power mains interruptions, it is recommended that the Cisco HealthPresence Device be powered from an uninterruptible power supply or a	
	70 % $U_{\rm T}$ (30% dip in $U_{\rm T}$ ) for 25 cycles < 5% $U_{\rm T}$ (> 95% dip in $U_{\rm T}$ ) for 5 s	70 % $U_{\rm T}$ (30% dip in $U_{\rm T}$ ) for 25 cycles < 5% $U_{\rm T}$ (> 95% dip in $U_{\rm T}$ ) for 5 s	battery.	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or
IEC 61000-4-8			hospital environment.

Note:  $U_{\rm T}$  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 Device for Cisco HealthPresence Devices that are not life-supporting

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Cisco HealthPresence Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = [1.17]\sqrt{P}$
Dadiesal DE	2 1/1	3 V/m	$d = [1.17]\sqrt{P} 80 \text{ MHz to } 800 \text{ MHz}$
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 <b>P</b> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>1</sup> should be less than the compliance level in each frequency range <sup>2</sup> .
			Interference may occur in the vicinity of equipment marked with the following:

#### Recommended separation distances between portable and mobile RF communications equipment and the Cisco HealthPresence Device for Cisco HealthPresence Devices that are not life-supporting

Immunity Test IEC 60601 Test L	evel   Compliance Level	Electromagnetic Environment Guidance
--------------------------------	-------------------------	--------------------------------------

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 Device issued exceeds the applicable RF compliance level above, the Cisco HealthPresence Device 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 Device.
- 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 Device

The Cisco HealthPresence Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cisco HealthPresence Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cisco HealthPresence Device 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.



# **Cisco HealthPresence Maintenance and Service**

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# **Cleaning**

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

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*.

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".