

Description of Wireless Feature

Table of Contents

1. Performance of Wireless Functions 2

 1.1. Wireless Functions 2

 1.2. Communications Protocol 2

 1.3. Wireless network mode 2

2. Wireless Co-existence 2

 2.1. RF Spectrum Selection: 2

3. Wireless Quality of Service 2

 3.1. Wireless Connectivity 3

 3.2. Message Latency 3

 3.3. Transfer Time 3

4. Integrity of Data 3

5. Security of Transmitted Data 3

6. Electromagnetic Compatibility (EMC) 4

7. Design Validation 4

8. Description of How Users Will Interact with the Wireless System 4

9. Description of Wireless Network Access 4

10. Limitation for Proper Operation and RF Wireless Communications 4

11. Description of Applicable EMC and Telecommunication Standards 4

12. Description of Wireless Performance and Specifications 5

13. Description of Software Program’s Ability to Handle Device Responses and Failures under EMI Conditions (outside of co-channel interference) 5

14. Description of EMC-related Device Shielding and Filtering to Protect against EMI from Other Devices* 6

15. Description of Environmental Requirements 6

16. Design and Development Verification (summary of RF Wireless and EMC testing) <Attached later> 6

17. Design and Development Verification (verification testing of RF wireless medical device communication, control functions and EMC) <Attached later> 7

APPENDIX A 7

1. Performance of Wireless Functions

1.1. Wireless Functions

The wireless version of Kodak K1500 intra-oral camera has 2 parts: dock and handpiece. Both dock and handpiece have a built-in Wifi device. Functions performed by the Kodak K1500 dock and handpiece consist of Control Messages as well as visual live video and visual still image Transmission.

* Control Messages consist of the following types of messages:

- User input actions: In response to user input (from either handpiece or dock), compose a message to transmit to the receiving device (either dock or handpiece)
- Still image arrive notification: Once a new still image is captured, handpiece composes a message to tell dock a new image has arrived.

* Visual live video Transmission

- Transmission of mpeg4 video stream from handpiece to dock. The video is for view finder to help user to capture a still image

* Visual still image Transmission

- Transmission of visual still image from handpiece to dock

1.2. Communications Protocol

The K1500 wireless system uses the IEEE 802.11g standard in the 2.4GHz band as its wireless communications medium. TCP/IP (Transmission Control Protocol/Internet Protocol) was chosen because it is a connection-oriented communications protocol that provides reliable and error-corrected data delivery.

1.3. Wireless network mode

Every set of K1500, dock and handpiece create a private wireless ad-hoc network differentiated by a unique SSID.

2. Wireless Co-existence

2.1. RF Spectrum Selection:

The K1500 uses a randomly selected channel to communicate between handpiece and dock. Thus avoid potential interference from other K1500 or wifi devices. Even if another network is using the same channel, the built-in wifi devices continue to operate.

(Question/Comment from RL Cain – Does the dock act as an access point by initiating communication with the handpiece? Does the handpiece act as a station by responding, but not initiating communication with the dock?)

Answer from Tiger Liu: No, neither dock or handpiece acts as an access point, they both work in Ad-Hoc mode.

Both handpiece and dock may initiate a communication session

3. Wireless Quality of Service

There are two quality metrics for the wireless system: transfer time and command message latency. Before wireless service begins, connectivity needs to be established and reestablished if the connection is dropped.

3.1. Wireless Connectivity

The K1500 handpiece or dock is designed to automatically associate with the service set identifier (SSID) stored in its internal register when the battery is inserted or any time the association is lost, for example, the handpiece was out of range of the dock and was brought again back to its dock.

3.2. Message Latency

The live video stream transmission has about 200-300ms latency; it's normal for video stream transmission.

Kodak K1500 is not using wireless for:

- Critical medical device alarms
- Continuous physiological data
- Real-time control data
- Time-critical data - The K1500 wireless function does not communicate real time patient waveforms or alarms. A live video stream is transmitted to function as viewfinder to assist the operator to select still images for capture.
- Control of therapeutic devices

3.3. Transfer Time

The K1500 wireless system transmits live video and still images captured by the handpiece. The K1500 using TCP/IP over an 802.11g link is capable of a data rate of 8 Mbits/sec under typical installed conditions. At 8 Mbits/sec data rate a full K1500 image will be transmitted in approx. 1 seconds. Transfer times up to 2 seconds have been measured in the presence of very strong co-channel interference.

4. Integrity of Data

The TCP/IP standard provides for error detection and correction, which guarantees data delivery. This is important for both control message and video/image data transfer. Under conditions of high RF noise and/or low signal strength, individual packets may be lost or corrupted but these are detected and the protocol automatically re-transmits those packets until a complete, non-corrupted set of packets are received. The conditions of high RF noise and/or low signal strength will affect the transfer time of the image data, but not the data integrity itself.

If the wireless communications fail, K1500 handpiece will hold the image in memory, and try 3 times. If still can't be transmitted, the image is discarded, and there will be a no "image stored" directive on the display screen. The wireless connection is under control, it'll try to re-connect if out-of-connection is detected.

(Question/Comment from RL Cain – Please provide the message that appears on the display screen when the image is successfully transmitted and when the image cannot be transmitted.)

Answer from Tiger Liu: There are 2 icons for "image successfully stored" and "image store failed" respectively. They are displayed on the screen according to the result. But these icons are not finalized yet, we are on process of the artworks design.

(Question/Comment from RL Cain – Please explain the requirements for the wireless connection to be under control so that a re-connection attempt will be made.)

Answer from Tiger Liu: We must keep the camera in normal working mode, if there is an accident that cause a temporary out-of-connection, the camera must be able to recover from this status.

5. Security of Transmitted Data

The K1500 transmits only still and video images of the mouth and teeth of the patient. No other patient data or information is transmitted, and data encryption is not needed.

6. Electromagnetic Compatibility (EMC)

EMC test report showing compliance with IEC 60601-1-2:2004 (See **Attachment 4**)

7. Design Validation

Design validation of the Carestream K1500 System wireless feature can be found in Carestream K1500 System Test Plan and Carestream K1500 System Test Report, see **Attachment 1**.

8. Description of How Users Will Interact with the Wireless System

The K1500 wireless system is active when the docking station system is powered on and the USB cable between the handpiece and dock is disconnected. The wireless function is disabled when the USB cable is connected between the handpiece and dock. The only indication to the user that the wireless system is functional, is the display of an icon in the acquisition screen on the system monitor (symbol seen on page 10.)

9. Description of Wireless Network Access

The wireless devices in K1500 handpiece and dock don't connect to public wireless network, or other 3rd party wireless network. The connection only exists between K1500 handpiece and dock. So No 3rd party devices need to access the private wireless network created between any handpiece and dock.

10. Limitation for Proper Operation and RF Wireless Communications

The K1500 system is specified to work in a room 7 meters long. Testing in the lab showed the handpiece was capable of communicating over 8 meters away from the dock.

The K1500 was able to tolerate another network access point on the same channel as close as 7 meters from the access point installed in the exam room.

11. Description of Applicable EMC and Telecommunication Standards

K1500 System complies with the following standards:
47 CFR part 15.247 (a), (b), (d),(e)
47 CFR part 15.203 (antenna requirement)
47 CFR part 15.109 (spurious emissions)
47 CFR part 15.209 (radiated emissions)
IEC 60601-1-2:2004 (EMC for medical equipment)

(Question/Comment from RL Cain – My understanding is that a SAR (Specific Absorption Rate) test is not required for the K1500. If so, the references to the SAR report must be removed. The Telecommunication Certification Body –TCB- or TUVV will provide RF exposure calculations for the K1500 radio)

(Question/Comment from RL Cain – Please compare the FCC standards in 11 above carefully with the standards in the K1500 FCC radio certification report. The above standards appear to be duplicated from the DRX-1 FDA Wireless Guidance document. Since the radios are different, some of the FCC standards may be different also.)

[SAR is not required for K1500](#)

12. Description of Wireless Performance and Specifications

Technical Specifications	
Network Protocol	TCP/IP
Network Type	Isolated Private Wireless LAN (WLAN)
Wireless Protocol	802.11g
Frequency Band	2.412 – 2.462 GHz
Available Channels (fixed at installation)	6, 9, 12, 18, 24, 36, 48, 54 for USA and Europe
Maximum Power of Detector Radio	20 mW
Number of Antennas on Handpiece	One pair each
IP Addressing	Static Private IP addresses for handpiece and dock
Agency approvals	FCC Part 15
Typical Data Size	One 8 MB file per image
Dual Homed PC (two NIC cards)	Hospital network connection, Private Network connection

Security	
WPA-PSK	Factory loaded key
SSID	Hidden Non Broadcast
Private Patient Identification Data	No patient ID data transmitted
Username and Password	Non-default username and password

Other	
Device Location	Handpiece and dock confined to Exam Rooms

The K1500 System uses IEEE 802.11g protocol for wireless communication in peer to peer configuration. The maximum transmission rate for a peer to peer implementation with 50MHz channel bandwidth is 12Mbit/second. The K1500 handpiece using TCP/IP over an 802.11g link is capable of a data rate of 8Mbits/sec. At 8Mbits/sec data rate a full K1500 image will be transmitted in approximately 1 second. Transfer times up to 5 seconds have been measured in the presence of very strong co-channel interference. An image from the K1500 Detector is 8Mb, which requires 1 second for transmission at the 8Mbps rate. Operating frequency for the K1500 radio is 2.412-2.462 GHz. The radio is authorized as a U-NII device by the FCC with output power at 20 mW (maximum).

The antennas for the K1500 HP radio are surface mounted on a circuit board (chip antennas) with maximum gains of approximately 1.0 dBi at 2.45 GHz. And the antennas for the DK radio are SMA antennas with maximum gains of approximately 1.6dBi at 2.45GHz. RF cable with SMA connectors soldered to wifi circuit board in DK is provided for SMA antenna connection.

13. Description of Software Program's Ability to Handle Device Responses and Failures under EMI Conditions (outside of co-channel interference)

If any communications failures occur between the handpiece and the dock an error message is displayed on the screen indicating that an operation has failed. The

handpiece will hold the image memory until it can be successfully transferred to the host computer using the wired USB connection.

See the tables in K1500 System performance in the presence of Electromagnetic Disturbances (EMD) in Appendix A of this document.

14. Description of EMC-related Device Shielding and Filtering to Protect against EMI from Other Devices*

*includes medical devices, consumer products, commercial and private radio transmissions, power line disturbances & other sources of EMD

The Carestream K1500 System was designed using the EMC techniques recommended in section 4.3.6 of the AAMI Technical Information Report 18-1997 (Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers –Part 1: Radiated Radio –Frequency Electromagnetic Energy).

Note: Application of ETSI EN 320 195-1 as referenced in the FDA Wireless Guidance is not applicable to K1500 system because the standard deals with devices that operate on much lower frequencies than the K1500 System.

Reference EMC report showing compliance to IEC 60601-1-2 especially the immunity data.

See the tables in K1500 System performance in the presence of Electromagnetic Disturbances (EMD) in Appendix A of this document.

15. Description of Environmental Requirements

The K1500 handpiece should be no more than 7 meters away from the dock, and no wall or other thick obstacle between the handset and the dock.

Main power quality for the K1500 System should be that of a typical commercial or hospital environment.

Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment. The recommended ambient temperature range for the K1500 System is from +5 to +25 degrees C, and relative humidity is less than 90%.

16. Design and Development Verification (summary of RF Wireless and EMC testing)

See RF wireless standards in item 11 above (Description of applicable EMC and telecommunications standards). The K1500 system is also compliant with IEC 60601-1-2:2004, collateral standard: Electromagnetic Compatibility, requirements and tests.

The K1500 continuously transmitted live video or still images during EMC tests. Images were evaluated for live video halt or lost data during the test. The deviations from a baseline of live video halt were the acceptability criteria for K1500 performance when electromagnetic disturbances were present.

No system modifications were required for the K1500 to meet the requirements of IEC 60601-1-2:2004.

17. Design and Development Verification (verification testing of RF wireless medical device communication, control functions and EMC)


Verification testing of RF wireless medical device communication, control functions and EMC can be found in several areas of the Carestream K1500 System. RF wireless medical device communication compliance standards to which the Carestream K1500 System complies can be found in Section 11 of this document (**Attachment 2** Description of Wireless Feature). **Attachment 4** contains the EMC report showing compliance to IEC 60601-1-2:2004. Immunity data are included in the results from the EMC report. Control functions and RF wireless medical device communications test results are also found in **Attachment 1** in Carestream K1500 System QA Test Report.

APPENDIX A

K1500 Performance in Presence of Electromagnetic Disturbances (EMD)

electromagnetic immunity			
The <i>Carestream K1500 System</i> is intended for use in the electromagnetic environment specified below.			
EMD Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-6 kV contact +/-8 kV air	+/-6 kV contact +/-8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment.

IEC 61000-4-11	<5% UT (>95% dip in UT)	<5% UT (>95% dip in UT)	
Power frequency (50/60Hz) 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.

Electromagnetic immunity			
The Carestream K1500 System is intended for use in the Radio Frequency (RF) electromagnetic environment specified below.			
Rf 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 <i>Carestream K1500 System</i> , 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 $d = 2.33 \sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacture and d is recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 v/m 80 MHz to 2.5GHz	3 v/m	
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.			