8G8224-01

KODAK 1500 Intraoral Camera

Safety and Regulatory Guide

Carestream HEALTH

Notice

US Federal law restricts this device to sale by or on the order of a dentist.

The Kodak 1500 intraoral camera is also marketed and sold as the STV Pro + intraoral camera.

Manual Name: *KODAK 1500 Intraoral Camera Safety and Regulatory Guide*
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CE

Authorized Representative:

EC REP

Handpiece:
FCC ID: U72KODAK1500H
IC: 7027A-KODAK1500
Docking Station
FCC ID: U72KODAK1500
IC: 7027A-KODAK 1500

Safety and Regulatory Information

Indications for Use

The KODAK 1500 intraoral camera is designed for use by health professionals in viewing and capturing intraoral or extraoral color images for the purpose of:

- Enabling practitioners to view and magnify all regions of the oral cavity to assess overall dental health.
- Assisting communications with the patient by providing a view of treatment areas before and after a procedure.
- Providing images for documentation in patient records.

There are two configurations for the camera: wired and wireless. The wired camera is composed of a camera, a docking station, and accessories. The wireless camera is composed of an additional charge station and accessories.

Regulatory Information

The KODAK 1500 intraoral camera complies with the following standards:

- 93/42/EEC European directive for medical devices including EN 60601-1-2 and collaterals
- Electrical Safety and Electromagnetic Compatibility standards (IEC) (CEM)
- Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Electromagnetic Compatibility Precautions

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Medical equipment must be installed and put into service according to the EMC information provided in this documentation.

Other equipment can interfere with communications with the intraoral camera, even if the equipment complies with CISPR emissions requirements.

Guidance and Manufacturer's Declarations

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The KODAK 1500 intraoral camera is intended for use in the electromagnetic environment specified below. The customer or user of the intraoral camera should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The intraoral camera uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	
Harmonics Emissions IEC 61000-3-2	Class A	The intraoral camera is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The KODAK 1500 intraoral camera is intended for use in the electromagnetic environment specified below. The customer or the user of the intraoral camera should assure that it is used in such an environment.

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 Kodak 1500 Intraoral camera, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.17 ÖP d = 1.17 ÖP 80 MHz to 800 MHz d = 2.33 ÖP 800MHz to 2.5GHz where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacture and is the recommended separation distance in meters (m). Field strengths from fixed RF 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 marked with the following symbol:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/M 80 MHz to 2.5GHz	3 V/M	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (Continued)

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base station for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts 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 intraoral camera system is used exceeds the applicable RF compliance level above, the intraoral camera should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Kodak 1500 intraoral camera.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/M.

EMC Standards Information

Electromagnetic Immunity for Equipment and Systems Fully Compliant with IEC 60601-2:2001+A1:2004			
The KODAK 1500 intraoral camera is intended for use in the electromagnetic environment specified below. The customer or the user of the intraoral camera should assure that it is used in such an environment.			
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 clinical environment.
Surge IEC 61000-4-5	+/- 1 kV line to line +/- 2 kV line to earth	+/- 1 kV line to line +/- 2 kV line 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 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) for25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<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) for25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. Note: Most components in the intraoral camera are powered from an uninterruptible power supply. IEC 61000-4-11 is applicable only to the intraoral camera
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.
Note: UT is the a.c. prior to application of the test level.			

Recommended Separation Distances

Recommended Separation Distance Between Portable and Mobile RF Communications Equipment and the Intraoral Camera System

The Kodak 1500 intraoral camera is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the intraoral camera can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Kodak 1500 intraoral camera as recommended below, according to the maximum output of the communications equipment.

Rated Maximum Output Power of Transmitter Watts	Separation Distance According to Frequency of Transmitter Meters		
	150 kHz to 80 MHz d = 1.17 ÖP	80 MHz to 800 MHz d = 1.17 ÖP	800 MHz to 2.5 GHz d = 2.33 ÖP
0.01	0.117	0.117	0.233
0.1	0.37	0.37	0.737
1	1.17	1.17	2.33
10	3.7	3.7	7.36
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance 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 separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

EMC Standards for Intraoral Camera

IEC 60601-1-2:2001 + A1:2004 EMC requirements and tests, Medical Electrical Equipment including CISPR11:2003 +A1: 2004 + A2:2006 Group 1, Class B.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Install the docking station in such a manner as to maintain a minimum of 20 cm (7.9 inches) separation distance between the radiating element(s) and all persons. This safety warning conforms to FCC radio frequency exposure limits.

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.

Electromagnetic Interference and Electrostatic Discharge

According to CISPR11:2003 + A1:2004 + A2:2006 Group 1, Class B.

This Class A digital device complies with Canadian ICES-003.

This device has been designed to operate with the antenna listed below, and having a maximum gain of 1.6 dB. Antennas not included in this list or having a gain greater than 1.6 dB are strictly prohibited for use with this device. The required antenna impedance is 50 ohms.

Detachable antenna:

Trade Name: Lite

Model Name: CAR-ATR-086-008

Safety Information

The Kodak 1500 intraoral camera is a Type BF device. The corresponding symbol must be visible on the camera.

Type BF Equipment

Classification in accordance with IEC 60601-1

Conforming Standards- Safety

Canada:

CSA-C22.2 #601.1-M90 (R2005) - Medical Electrical Equipment: General Requirements for Safety.

China:

GB 9706.1-2007 Medical Electrical Equipment, Part 1: General Requirements for Safety.

GB_9706.19-2000 Medical Electrical Equipment, Part 2: Particular requirements for safety -Section 2.18 Specification for endoscopic equipment. Environmental Requirements and Testing Methods of Medical Electrical Equipment.

Europe:

EN 60601-1 (1990) + A1: 1993 + A2: 1995 Medical Electrical Equipment, Part 1: General Requirements for Safety.

EN 60825-1:2001 Safety of Laser products: Equipment classification, requirements and User's Guide

EN 60601-2-18:1997 Medical electrical equipment, Part 2: Particular requirements for safety -Section 2.18 Specification for endoscopic equipment.

93/42/EEC MDD (Medical Device Directive)-Europe Only.

ISO13485: 2003 Quality Systems-Medical Devices-Particular requirements for the application of IS09001.

USA:

UL 60601-1:2003, UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety.

Other Countries:

IEC 60601-1:1988 + A1:1991+A2:1995 Medical electrical equipment; Part 1: General requirements for safety.

IEC 60601-2-18:1996 Medical Electrical Equipment, Part 2: Particular requirements for safety -Section 2.18 Specification for endoscopic equipment.

IEC 60825-1:2001 Safety of Laser products: Equipment classification, requirements and User's Guide.

Condition	Classification
Type of protection against electrical shock:	Class II Equipment
Degree of protection against electrical shock:	Type BF applied part
Degree of protection against ingress of water:	Ordinary Protection
Flammable anesthetics:	Not suitable for use in the presence of flammable anesthetics or a mixture of flammable anesthetics with air or oxygen or nitrous oxide.
Mode of operation	Continuous operation

Communications Equipment

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment EMC performance.

The wireless version of the Kodak 1500 intraoral camera operates with a 802.11g protocol in a 2.4GHz frequency band. The radio output power is 20 mW (nominal).

Accessories

The use of cables, adapters, or accessories other than those specified with the exception of those sold by the manufacturer of the equipment as replacement parts for internal components, may result in increased emissions or decreased immunity of the medical equipment.

Changes or modifications not expressly approved by the party responsible

for compliance could void the user's authority to operate the equipment

Other Equipment

The Kodak 1500 intraoral camera should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Kodak 1500 intraoral camera should be observed to verify normal operation in the configuration in which it will be used.

Cabling

Interface	Max. Cable Length	Shielded/ Unshielded	Number of interfaces with identical electrical character-istics	Cable Classifications
AC Docking Station - Camera	2.5 m	Unshielded	1	AC - DC Adapter
Docking Station - Camera	2.5 m	Shielded	1	Signal, DC Power (USB)
Docking Station - Charge Station	2.5 m	Unshielded	1	DC Power
Docking Station - Computer	1.5 m	Shielded	1	Signal
Docking Station - Monitor	1.5 m	Shielded	1	Signal
Footpedal - Docking Station	5.0 m	Shielded	1	Signal
Docking Station - S-Video Monitor	1.5 m	Shielded	1	Signal

Cautions for Safe Operation

CAUTIONS

- **Before using the camera, check the outer surfaces of the camera and any accessories to ensure there are no rough surfaces, sharp edges, or protrusions which may cause a safety hazard.**
- **Do not pull or twist the cable.**
- **Do not drop the camera.**
- **Never place the camera or accessories in a sterilizer or autoclave.**

- **Do not expose the camera to water spray or submerge it in water.**
- **Do not expose the camera to high vibrations.**
- **Do not replace the USB cable that is provided with the Kodak 1500 intraoral camera with any other USB cable.**
- **Do not replace the power adaptor that is provided with the Kodak 1500 intraoral camera with any other power adaptor. Substitutes may not provide the required electric shock protection.**

Labels

Figure 1 Charge Station

Figure 2 Wired Camera

Figure 3 Wireless Camera

Figure 4 Camera Label Wired

Figure 5 Camera Label Wireless

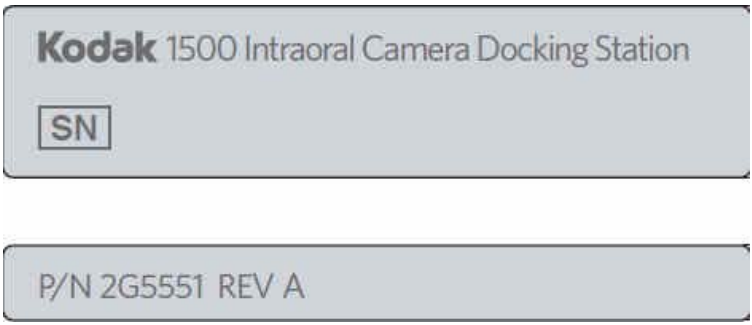

Figure 6 Docking Station

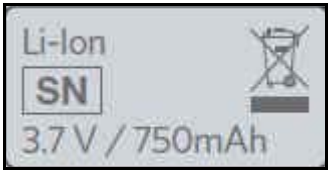

Figure 7 Battery

This Class A digital device complies with Canadian ICES-003.

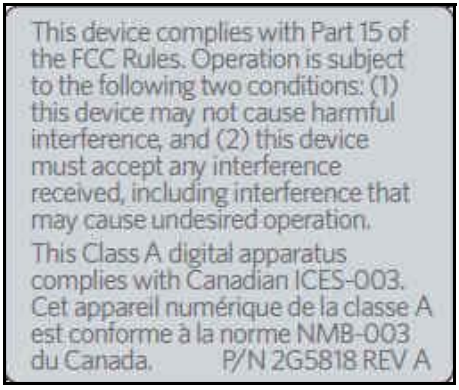

Figure 8 Class A Apparatus

Figure 9 FCC ID Label