

K962896

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## SUMMARY OF SAFETY AND EFFECTIVENESS

### I. INTRODUCTION

The KODAK Digital Science Remote Cassette Identification Station(RCIS) is an accessory to the KESPR and the QCW. RCIS will allow the user to enter exam information and patient information at a separate RCIS terminal(s) so that the information is available to all the components of the KODAK Ektascan Image Link Model 400 System.

### II. GENERAL INFORMATION

Name of Manufacturer

EASTMAN KODAK COMPANY  
Health Imaging Division  
901 Elmgrove Road  
Rochester New York 14653

Established Registration Number

- 1319085

Device Name:

- KODAK Digital Science Remote Cassette Identification Station

Device Classification

Class II Device

### III. THE DEVICE

The general hardware configuration of the KODAK Digital Science Remote Cassette Identification Station contains the following major components,

- Touch screen monitor
- Central Processing Unit(CPU)
- Bar-code reader

### IV. INDICATION FOR USE

The user will enter Exam Information and/or display Patient information from HIS/RIS at one of the RCIS terminal(s). This

information will be transmitted via a network to the primary Quality Control Workstation of the CR-400 System. The primary QCW will update other QCW's and their respective KESPR Readers. After the phosphor cassette containing the Latent Image is scanned by a KESPR Reader the images are transmitted to a workstation which allows for the proper display of the images for diagnostic purposes. The information stored in the Readers and the will be updated by removing Exam and Patient Information. The phosphor readers are not for supporting or sustaining human life, nor do they present a potential for unreasonable risk for illness or injury.

## V. REGULATORY & CONSENSUS FOR STANDARD COMPLIANCE

### Safety:

Underwriters Laboratories Inc., #1950, Standard for Safety Of Information Technology Equipment, including Electrical Equipment.

Canadian Standards Association C22.2, 950-M89 Data Processing Equipment.

IEC Standard 950:1991 / EN 60950:8.1992 + A1:1.1993, Safety of Information Technology Equipment including Electrical Business Equipment.

IEC Standard 601-1:1988 / EN 60601-1, Medical Electrical equipment, Part

- 1: General requirements, sections
- 6. Identification, Marking and Documents
- 19. Continuous Leakage Currents
- 20. Dielectric Strength
- 44.3 Spillage
- 57.10 Creepage Distances and Air Clearances

### Electromagnetic Capability

EMC Directive (89/336/EEC) - ITE Equipment

EN 55022 (87) Class B

EN 50082-1

EN61000-3-2 Power Line Harmonics

EN61000-3-2 Flicker

IEC 801-2 (91) Electrostatic Discharge, severity level 4

IEC 801-3 (84) Radio Frequency Immunity, severity level 2

IEC 801-4 (88) Electrical Fast Transient, severity level 2

FCC 47 CFR, Part 15, Subpart B, Class A

Seismic

California Administration Code, Title 22, Division 7 and Title 24,  
Part 2.