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Digital X-Ray System
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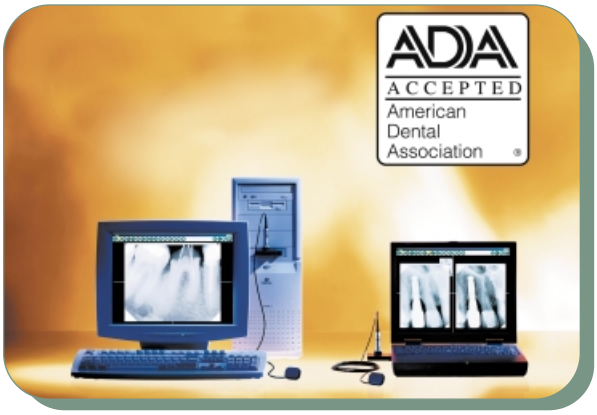
Product name: DEXIS® Digital X-Ray System
Manufacturer: ProVision Dental Systems, Inc., 4117 El Camino Real, Palo Alto, Calif. 94306; 1-888-88-DEXIS (1-888-883-3947)
ADA Acceptance: Received ADA Seal of Acceptance February 2001
Other ADA-Accepted products in this category: None



Description: Digital X-ray systems offer a valid alternative to conventional dental radiographic film. DEXIS® Digital X-Ray System was introduced in Germany in 1995 and has been available in the United States since 1997. The system consists of a sensor (which substitutes for film), an image capture PCMCIA card, and software for image display, enhancement and storage. The DEXIS® system can be used on desktop or laptop computers, whether stand-alone or networked.

Considerations for Acceptance: The DEXIS® Digital X-Ray System was evaluated at the January 2001 Council on Scientific Affairs (CSA) meeting using the ADA Provisions for Acceptance as a guide. The Council also elicited comments and recommendations from CSA consultants.

Efficacy Data: ProVision submitted four studies demonstrating that the diagnostic quality of the DEXIS® system is substantially equivalent to that of conventional dental film. In the first study, extracted human teeth with fabricated mechanical lesions were inspected for the presence of lesions using conventional and digital radiography. This study found no statistical differences in identifying lesions using these different methods. A second study evaluated the accuracy of treatment decisions using different radiographic systems. The gold standard was set by clinical evaluation. Extracted human teeth were examined for the presence of caries using conventional and digital radiography. Again, there was no difference in identifying caries between groups. The third and fourth studies compared conventional and digital X-ray systems for endodontic file length determination. Accuracy of measurement was found to be similar between the systems (Eikenberg and Vandre, 2000; Vandre and colleagues, 2000). The DEXIS® sensor is more sensitive than X-ray film. This allows usable images to be recovered with 60 percent to 80 percent less than the usual exposure for X-ray film.

Quality Control: Image integrity is maintained with the DEXIS® system. DEXIS® always saves the original image, prior to use of any enhancement tools, so the original image data cannot be modified. Clicking the "Home" button in the DEXIS® software undoes all processing. In addition, DEXIS® stores a digital signature computed from the image data. This signature is only given to images acquired directly from acquisition hardware, not to imported images. This allows detection of images that have been modified by other image-processing software.

Images can be routinely tested for quality in the dental office using an X-ray phantom.

Safety Data and Toxicity: The DEXIS® sensor was shown to be safe for use in the oral cavity. The sensor is watertight so that it can be disinfected between patients. The sensor cannot be autoclaved or soaked overnight. For additional protection, the sensor may be covered with a plastic sheath that is disposed of between patients. These disinfection practices meet the Centers for Disease Control and Prevention recommendations for infection-control practices in dentistry (1993).
The DEXIS® system has been tested to meet a number of worldwide standards demonstrating safety, including FDA classification as a Class II Medical Device, the European Union Declaration of Conformity, Pulver Laboratories Product Certification Label and Checklist Essential Requirements Medical Devices Directive.

Benefits of Use: Images are seen instantly. Chemical disposal is eliminated. No X-ray film is required. Darkroom space no longer is required. Patients can participate better in codiscovery. Radiation is reduced.

Other Considerations: There are currently no standards with which digital X-ray systems can conform to guarantee interoperability. Contact ProVision to determine if DEXIS® is compatible with other digital X-ray file formats.

References: Haak R, Noack MJ. Treatment decision making in approximal sites with digital radiology. Abstract 1981. Paper presented at: 78th General Session of the International Association for Dental Research; April 5-8, 2000; Washington.

Vandre RH, Pajak JC, Farman T, Farman AG. Comparison of digital radiographic systems and film in the evaluation of endodontic instrument placement. Dentomaxillofac Radiol 2000;29:216-22.

Eikenberg S, Vandre R. Comparison of digital dental X-ray systems with self-developing film and manual processing for endodontic file length determination. J Endodont 2000;26:65-7.