

510(k) Summary

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Re: Protec-1024 Mobile Gamma Camera System (also referred to as Multiwire Gamma Camera)

The Protec-1024 is an imaging device utilized to determine the distribution of gamma-emitting radioactive tracers within the human body. As such, the device is a completely non-invasive tool, which is positioned near the surface of the body (the chest, for example, in heart studies) and passively acquires images based on detection of radiation emitted from the body. There is neither any contact with nor any invasion of the body. It is, therefore, inherently safe in its use to provide diagnostic information.

The device consists of a radiation detection head, containing a multiwire proportional detector, coupled to a mobile part, containing electronics utilized to process images from the detector, and a computer utilized to control image acquisition and to provide image processing and display. The Protec-1024 is substantially equivalent to the scintillation gamma camera systems, such as the SIM-400, widely marketed in the nuclear medicine field, as well as to a previous version of the multiwire camera, the Xenos Mobile Cam, marketed by Xenos Medical Systems. The detector of the Protec-1024 is essentially identical in characteristics to that of the Xenos device. In comparison with the conventional scintillation gamma cameras, this multiwire camera has an energy range of 30 keV to 90 keV as compared to 30keV to 300keV. On the other hand, the multiwire camera operates at much higher event rates than the single crystal scintillation cameras.

The multiwire camera has been extensively evaluated in human imaging applications and has been shown to be useful, particularly in blood pool imaging. The general indication for use is in imaging human organs through use of injected radiopharmaceuticals, which are separately regulated as diagnostic drugs. The device will have a wide variety of applications in planar single organ and whole body imaging.

Assessment of the provided performance data establishes the equivalence of this device to other similar systems. The bench performance data of a system substantially identical to the detector currently to be marketed by Proportional Technologies Inc. was reported in the Journal of Nuclear Medicine article "*A Gamma Camera for Medical Applications, using a Multiwire Proportional Counter*" (Lacy JL, Leblanc AD, et al.; 25:1003-1012, 1984). Further bench data in the form of collimator and detector sensitivity measurements was reported in the Journal of Nuclear Medicine Article "*First-Pass radionuclide Angiography Using a Multiwire Gamma Camera and Tantalum-178*" (Lacy JL, Verani MS, et al.; 29:293-301, 1988).

Clinical data employing this system has been reported in multiple publications by reputed cardiology investigators. The most significant of these were the previously cited Journal of Nuclear Medicine article "*First-Pass Radionuclide Angiography Using a Multiwire Gamma Camera and Tantalum-178*", and the Journal of the American College of Cardiology articles "*Quantification of Left Ventricular Performance During Transient Coronary Occlusion at Various Anatomic Sites in Humans: A Study Using Tantalum-178 and a Multiwire Gamma Camera*" (Verani MS, Lacy JL, et al.; 19:297-306, 1992) and "*Effects of Acute, Transient Coronary Occlusion on Global and Regional Right Ventricular Function in Humans*" (Verani MS, Guidry GW, et al.; 20:1490-1497, 1992). The former reported a study comparing the performance of the MWGC system to the approved Baird multicrystal device. The latter study reported the results and measurements of left and right ventricular function following balloon angioplasty intervention. Further clinical validation data obtained with the entire package as currently designed was provided in an a report to the NIH Heart, Lung and Blood Institute. This report, which includes 53 patient studies, covered evaluation of the camera at The Philadelphia Heart Institute by Ami Iskandrian, M.D., 1995 president of the American Society of Nuclear Cardiology, and discussed both imaging performance and functionality of the portable camera package.

Software validation data is provided in a report critically evaluating the static and dynamic image acquisition system (see Frame Acquisition Test Results). This study verified the proper, accurate performance of the software in controlling acquisition of image data. This is the only fully computer-controlled function of the software package. I, myself, created the analytical software package utilized in the 1988 validation study and the 1992 articles. Furthermore, a comprehensive study of the interobserver and intraobserver variability in the ejection fraction measurements was reported in the aforementioned 1992 Journal of the American College of Cardiology paper evaluating left ventricular function.

We believe that this published and test data, by some of today's most respected nuclear cardiologists, combined with our tests and evaluations provide a very thorough testament to the equivalence of the device to approved nuclear medicine systems.