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Application K962153

Summary of Safety and Effectiveness Information

UW LV Analysis Software assists in measuring left ventricular volume at end diastole and end systole, ejection fraction, and regional wall motion around the ventricular contour. The method comprises five main parts: a) reviewing the digital images, b) selecting the image frames to analyze, c) identifying and tracing the border of the left ventricle, d) measuring left ventricular volume from the traced border and calculating ejection fraction, and e) measuring regional wall motion. The UW LV Analysis Software allows the user to review a series of images in digital format, and manually select frames for analysis. Identifying and tracing the ventricular border is performed manually using the UW LV Analysis Software. Of the techniques developed to measure left ventricular volume from a traced border, the area length method is generally accepted as the most accurate, and is the method used by the UW LV Analysis Software. Of the techniques for measuring left ventricular wall motion, the centerline method has been proven useful for clinical trials, and is the method used by the UW LV Analysis Software. Calibration to correct for image magnification is required for volume measurement, but not for calculation of the ejection fraction or for analysis of regional wall motion.

There is no substantial hazard of death or injury to the patient associated with using this software. The intended applications of the software are: 1) to assist in evaluating a patient with suspected heart disease, 2) to measure the effectiveness of therapy, 3) to assess risk or prognosis, and 4) in clinical trials evaluating new therapies.

Although it is believed that no hazard to the patient exists from this software, considerable effort has been directed to analyzing the sources of error or variability in the measurements, and to developing methods of avoiding or minimizing them. During software development, the author frequently exercised all functions to assure proper operation. After upgrades of the software to improve performance, the data of thousands of patients were analyzed by both the new and previous versions and compared, to document that the revision had not introduced new errors or inconsistencies, or significantly altered the measurement results.

The standard of accuracy applied to validation of this software when licensed to other companies and installed on their systems, was to demonstrate the installed programs differed from the programs at the University of Washington by less than 2.5%. In internal testing of upgrade versions at the University of Washington, the measurements of volume and regional wall motion differed from those of the preceding version by less than this. The measurement variability is 8 ml for volume, 0.04 for ejection fraction, and 0.24 and 0.33 SD/chord for motion in the anterior and inferior walls, respectively.

Versions of these programs were used over the past 13 years at the University of Washington. They were also used to make endpoint measurements for a number of NIH-sponsored and agency-sponsored clinical trials. The selection of the UW LV Analysis Software programs for the NIH's TIMI trial is an indication of NIH's endorsement of their performance and accuracy.