

**Nomination for SARTA's Claire Pomeroy Award 2010
for the Prior to 1990 Time Period**

Nominee: Richard K Wertz, M.D.

Nominator: Warren D. Smith, Ph.D.

Product Name: MicroScan Automated Microbiology Diagnostic System

Background of Invention and Impact on Patient Care

When patients have bacterial infections, it is vital that physicians know what type of bacteria are infecting the patient and how sensitive those bacteria are to different antibiotics. Prior to the development of MicroScan, clinical laboratories could only test for sensitivity to antibiotic drugs by plating bacteria on a semisolid growth medium, placing paper discs impregnated with different antibiotics, and noting whether or not there was inhibition of bacterial growth next to the discs. If bacteria could not grow next to the antibiotic impregnated disc, they were considered to be sensitive to the antibiotic. Conversely, if there was no inhibition of growth, the bacteria were considered to be resistant to that antibiotic. For many reasons, this lab test was a very rough approximation easily be subject to error, leading the doctor to sometimes prescribe the incorrect drug or use the wrong dosage. What was needed was a more precise quantitative method to determine antibiotic sensitivity, and this could only be achieved by testing growth of bacteria in many tubes containing serial dilutions of antibiotics. As many as 96 tubes would be necessary to test a full battery of different antibiotics at different dilutions. If bacterial growth was stopped by a certain dilution of antibiotic, the tube would be clear; however, if the bacteria were resistant to the drug, they would continue to grow, and that tube would become cloudy. Such testing with 96 tubes per specimen was far too cumbersome and time-consuming for the average clinical lab to perform. Dr. Wertz teamed up with a new company, MicroScan, which introduced small molded plastic plates, approximately 4" x 5", that contained 96 miniature optically clear molded tubes all in one unit (microtiter plates). The tubes were pre-loaded with different antibiotics at different concentrations, and bacteria could be introduced by a simple prong device in one motion. After incubation, the tubes could be read manually. The MicroScan system improved accuracy, but was still very time consuming, since the results of each of the 96 micro test tubes had to be read by a technician, written down, and then interpreted. What was needed was an instrument that could read the tubes and integrate the results at the push of a button.

In the late 1970's, Dr. Wertz enlisted the assistance of biomedical engineering professor Dr. Albert Cook and student Mr. James Hathaway at Sacramento State University to develop such an instrument. Computers were in their infancy, but after two years of work financed by Dr. Wertz, a working prototype was produced. The new device was one of the earliest computerized medical instruments that interacted with technicians through an LED display each step of the way. Not only were accurate quantitative antibiotic measurements now possible, but sophisticated, precise biotype identifications could be also made on the isolated bacteria. With this new type of microbial fingerprinting, hospitals could now rapidly detect cross-infection

between patients in a given nursing station. Some of these first discoveries came to light at Sutter Memorial Hospital where Dr. Wertz was chief of the department of pathology and clinical laboratories.

Road to Commercialization

Dr. Wertz formed a company called Digital Biomedical and teamed up with a New Jersey company which produced microtiter plates for bacterial diagnosis. The job was to develop a commercial product from the prototype developed at Sacramento State. U.S. patent 4,448,534 was issued, and the system of instrument working with the disposable MicroScan plates caught the attention of American Hospital Supply Corporation (AHSC) as the instrument became commercialized. The instrument was approved by the FDA on a 401K and went into production in 1981. Both MicroScan (producer of the plates) and Digital Biomedical (producer of the instrument) were acquired by American Hospital Supply Corporation (AHSC), and since the instrument, called AutoScan-3, was already being manufactured in Sacramento, the decision was made to centralize the operation of both companies in the Sacramento region.

Economic Impact on the Healthcare System and Sacramento Region

AHSC was acquired by Baxter Corporation shortly after it acquired Digital Biomedical and MicroScan, and the company decided to build its headquarters in West Sacramento. The company became a worldwide leader in microbiology instrumentation with a facility of over 200,000 sq. ft., 300 employees, and sales well over \$150 million per year in the early 1990's. Baxter joined with the German company, Behring, to consolidate all of its diagnostic instruments into one separate company called Dade Behring. Then the German electronics giant Siemens Corporation acquired Dade Behring in 2007 for \$6.3 Billion. With the MicroScan unit in West Sacramento being the crown jewel of this acquisition, the economic impact to the Sacramento community will continue to be very significant.



The Original AutoScan Instrument

1979



Siemens MicroScan Walk-Away System

2010