

a motionless container. All scratches, printing, or other marks on either the outer or inner surface of the container are part of the master picture. Any difference between the master and any one of the subsequent comparison pictures of the single container, therefore, would be caused only by particulate matter moving within the liquid contents, reflecting light back to the camera.

Several companies offer automated inspection equipment with the two most widely used at the time of this book publication being Eisai and Seidenader.

Eisai's inspection for particles uses static diode array sensors while Seidenader used a vision (camera) sensor system. The camera takes still images and looks for patterns that are unexpected.

Eisai System

The Eisai system uses a static diode array sensor system white light as the source of detection of particles. Its sensors detect moving shadows produced by foreign material in a container of solution and cast these images onto the diode array. Each container is spun around (thousands of revolutions per minute) and stopped so that only the liquid in the container is still rotating when the container enters the light. If any foreign matter is floating and rotating in the liquid, the light transmitted through the liquid is blocked and a shadow is cast by the moving particles. Eisai systems employ a phototransistor that converts moving shadows into electrical signals. There are 24 images obtained per inspected unit. These signals are compared with preset detection sensitivity signal standards and if the standard sensitivity is exceeded, the container is rejected. The Eisai detector does not react to scratches, stains, and colors of the container or the color of the liquid contents since these are all perceived as stationary objects.

The Eisai system checks the volume of liquid in the container and can reject overfilled, underfilled, and empty containers. The shadow cast by the liquid meniscus of a properly filled container is expected to fall within a certain preset range within the inspection field. If it falls above or below this range the container is rejected. Adjustments in the Eisai system can be easily made for different sizes, color, and viscosity of the liquid contents.

The typical number of units inspected per minute with an Eisai machine is 300 to 600. Contrast this with the average experienced human inspector inspecting four units per minute for the same defects.

The conveyance and inspection mechanism of the Eisai system is shown in Figure 22-3. Containers are conveyed by the star wheel onto the inspection table, spun at a high speed, and stopped before reaching the light beam. When the container enters the light beam, the light projector and detector follow the container while liquid is still rotating inside. After one container is inspected by two sets of projectors and receptors (thus, a double inspection system) the next container is carried through the same process. Containers are moved by the screw conveyor to the sorting pendulum, where rejected and accepted units are separated. The system automatically keeps count of the number of accepted and rejected containers and displays these numbers on the display panel.

Advantages of the Eisai system include (i) versatility, that is, ability to handle a large variety of vial sizes, products, and viscosities, (ii) the adjustable sensitivity level, (iii) attainable speeds, (iv) results of performance studies, and (v) cost. One main disadvantage is that it cannot inspect molded vials due to imperfections in the glass that inherently occur during the molding process. Only tubing vials can be inspected by the Eisai system. Also, it takes a lot of expertise to set up the Eisai system and its many "tools" (e.g., edges, regions, blob, and pixels) for proper inspection of the particular type of primary package. Syringes commonly inspected by Eisai machines.

De la Montaigne et al. (10) provide additional coverage of the sensing mechanism, capabilities, cameras, and validation of the Eisai (and other) automated inspection system.

Probabilistic Particulate Detection Model

The probabilistic inspection model is based on the finding that particulate inspection methodologies, human or robotic, are probabilistic rather than deterministic in nature. In other words, no final container of solution is acceptable or unacceptable; rather, each final container of solution possesses a probability of being rejected for whatever inspection process is being evaluated. Rejection probabilities are determined simply by recording the number of times a numbered