MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

"Increasing Product Yields with Automated Vision Systems"

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Product quality and production yield go directly to the bottom line. Effective production line quality control inspections are essential to verify quality and detect problems that can lower production yields. Often, manual inspection processes are more effective than automated systems, for example when the product to be inspected is complex, the attributes to be inspected are more qualitative than quantitative, or the cost to develop an automated system is large.

On the other hand, a manual process can lead to inconsistencies in the inspection results, particularly where there is a certain amount of acceptable non-uniformity or variability in the finished product, or where the process relies not on specific quantitative metrics but on the judgement and training of the inspector. In cases where degrees of non-uniformity or flaws are acceptable, the experience level and training of the inspector play an important role in the effectiveness of the inspections. However, visual inspection based on judgement and experience can fall victim to habit and conditioning. Inspectors can become conditioned to expect flaws of a certain type, or in certain locations on the part or product. If the manufacturing process or materials change, flaws of a different type can appear suddenly. As a result, inspectors may fail to reject products with unacceptable flaws. Conversely, products with flaws that are acceptable may be rejected merely because the flaws are of a new and different type and perceived to be bad.

This article describes the development of a computer-based system for automated product inspection and quality control. The system was developed to improve yields and eliminate excessive variability that was observed with a manual inspection process. The key steps in developing the automated system were:

1. Identifying the critical characteristics of both the product and its possible flaws.

2. Defining the functional, performance, and quality assurance requirements for the inspection system.

3. Selecting and integrating the appropriate camera, lens, lighting, and other components.

4. Developing software to implement the measurement and decision making algorithms.

5. Validating and testing the system to ensure the requirements are satisfied.

In discussing these steps, we will highlight the key technical issues involved, with emphasis on the use of commercial off-the-shelf components where possible.

THE MANUAL PROCESS

The automated system we developed replaced a manual inspection process, in which an inspector was required to view the product (a drug delivery device) under magnification using a video monitor. The inspector accepted or rejected the product based on a visual comparison of the video image of the product to an overlay mask, or template, which showed the established dimensional tolerances for the product. Using the template, the inspector would determine whether the product was the appropriate size and whether unacceptable flaws were present.

When a change in the fabrication process unexpectedly introduced bubbles into the product, reject rates soared and yields dropped significantly. A review of the event found that most of the rejected product was in fact acceptable. Clearly, the changes in the fabrication process warranted investigation, but the event prompted rethinking of the whole inspection process. Could an automated vision system be developed that would be less sensitive to minor upsets in the fabrication process, provide reliable inspection results, and meet FDA validation requirements for software-based systems?

Fortunately, the answer was yes. With good planning, a modest amount of up-front engineering and analysis, and a well thought out validation plan, we developed a cost-effective automated vision system using commercially available components. The system improved the inspection process in three ways: (1) it provided reliable and repeatable results, (2) it reduced inspection costs, and (3) it resulted in lower product rejection rates and higher yields.

CRITICAL CHARACTERISTICS AND IMAGE ANALYSIS

Identifying the critical characteristics that need to be inspected (e.g., product dimensions, appropriate labeling, proper assembly and alignment) is fairly straightforward but essential to achieving reliable and meaningful inspection results. The critical characteristics are dictated by the product specifications and by careful observation of the types of flaws that may be the byproduct of the manufacturing process. The challenging part can be obtaining measurements of these attributes from an image or set of images. For many types of measurements, commercial vision system software is available with built-in analysis tools for tasks such as reading bar-codes, reading labels, measuring dimensions, counting parts, and inspecting part positioning. However, some applications require the development of custom image analysis algorithms.

The system described in this article was particularly challenging because one of the critical characteristics was the mass of the product located inside the delivery device. In the manual inspection process, the inspector checked the length of the drug product against an overlay, then rotated the device and checked 360° around the outside of the product for flaws including bubbles or voids. Naturally, voids in the drug product reduce its mass, but whether the product was acceptable depended on the size and number of voids. Fortunately, we found that the brightness of light passing through a translucent product is a function of the amount of material it passes through. This means that where there are flaws such as voids, the transmitted light is brighter. Dark areas with consistent brightness represent mass with no flaws.

Because of the unique characteristics, we had to develop our own image analysis algorithm. First, we collected a large library of about 10,000 images of randomly selected samples of the product. The samples included product with flaws representing the various types of defects encountered by the inspectors. The weight of each sample was also measured and entered into the library database. We set aside about half of the samples in the library for later use in validating the system. Then, we used the other half to try out various "bulk" analyses and correlate them to the known masses. Using this correlation, we were able to identify image "signatures" of good and bad product.

Through experimentation, we defined an image analysis algorithm that would correlate statistical representations of the image brightness with the mass of the drug product. This allowed us to quantify the effect of voids and infer the mass of the product so that we did not have to reject product just because a bubble is present. For example, Figure 1 shows the distribution of intensity of each pixel in the image of a typical good product sample. Notice that it has a bell-shaped curve that is slightly skewed left. The drop-off in brighter pixels on the right side of the distribution is a characteristic of good product. Figure 2 shows the pixel intensity distribution of a product that is unacceptable. Notice that the distribution is bimodal. This dual-peak distribution indicates that there are dark spots and bright spots in the image, which complement each other. Light passing through flaws is reflected near fracture surfaces, giving a dark shadow that outlines the flaws. This is what creates the bimodal distribution.

To improve the accuracy of our inspection algorithm and obtain the best mass measurement, we actually performed several statistical analyses, each using multiple images taken around the periphery of each sample. We established a voting procedure in which the results of each statistical analysis were checked in order to accept the product. We conservatively tuned this procedure to reject the borderline product in order to increase the reliability of the process, minimize the probability of accepting bad product, and maintain high product quality. Even with this conservatism, the new system recovered much of the yield lost due to inspector bias.

We identified the critical attributes, including mass, and we developed a method for measuring the attributes and their related flaws. Next, we needed an integrated, computer-based system to automate image acquisition and analysis.

SYSTEM INTEGRATION

The major components of a computer-based vision system include a computer for hardware control, image processing, and operator interface; data acquisition hardware; a camera and lens; lighting; and a product positioning system. The specific configuration and selection of components is based on the particular requirements of the application.

Our customer's requirements called for a supervised system, whereby the operator loads the product, the computer does the inspection and makes the accept/reject decision, and the operator transfers the product to the next processing step as appropriate. System performance requirements were to (1) accurately reject all product outside the acceptance range, (2) reduce the false reject rate to an acceptable value, and (3) maintain or increase the production at a rate of 30 parts per minute.

Figure 3 illustrates how the key components were integrated in our example. The process starts when the operator places the product in the fixture. Photoelectric sensors verify that the product is positioned properly and the operator's hand is out of the way. Then a stepper motor spins the fixture. The rotation is timed such that we obtain sequential images of the product every 45 degrees of rotation. Eight images are acquired and analyzed in just over _ second. The computer evaluates the data, displays an accept/reject indication to the operator, and maintains a count of accepted and rejected product for each batch.

The selection of components for a system such as this is driven by a number of important considerations relating to functionality, performance, and reliability. The rationale we used in our selection process is discussed below.

Computer Platform

When choosing a computer platform and operating system, the important issues are compatibility, reliability, and security. For safety-critical applications, a proven real-time operating system like QNX RTOS (QNX Software Systems, Ltd.) may be appropriate. For the reliability and security needed in a controlled production environment, Windows NT (Microsoft) or UNIX (Sun Microsystems) may be a good solution. We selected Windows NT for high reliability, ability to establish several levels of security, and compatibility with readily available data acquisition software.

When selecting computer hardware, the issues are processor, memory, video, storage, and communications and peripheral interfaces. For demanding video requirements, a graphics accelerator card will relieve the processor of display duties and improve performance. For storage and communication, carefully consider whether your requirements include process data archival and/or transmittal (e.g., networking). Considering maintenance issues up front is also important in providing a highly reliable system. For example, use of removable hard drives can simplify system maintenance and down time. These are very simple to install, lock in with a key, and slide out in a steel case. This way, if the hard drive fails or you want to install an upgrade, a maintenance technician can simply replace the hard-drive (fully loaded with all the software) and get the machine back in operation.

For our system, we selected a 400 MHz Dell dual-Pentium with 2 GB hard disk, 128 MB RAM, and a graphics accelerator card since our computer algorithm was computation intensive and we needed to minimize computation time. The dual processors allowed us to use a dedicated processor for image analysis while motion control, image acquisition, and operating system needs were handled on the main processor.

One of the big advantages in a computer-based system is the ability to eliminate hard-wired controls and indicators and use a video display with a mouse or keypad for the operator interface. The operator interface can be further simplified using a touch screen display. For simplicity and minimization of space, we chose a Cyber Research flat panel LCD display with a touch screen.

Data Acquisition and Control

Finding the right data acquisition hardware to satisfy the system requirements can be one of the most difficult parts of the design effort. With our automated system, we had three data acquisition and control requirements: image acquisition, motion control, and input from the photoelectric sensors. Most of the large data acquisition hardware vendors for PC-based systems, including Keithley Metrabyte and National Instruments, supply these components. To simplify system integration and minimize potential for I/O incompatibility, we chose a single supplier for the data acquisition and control hardware and for the development software. We used National Instruments and their application development software, LabVIEW.

For our system, we used three computer boards from National Instruments: an 8-bit analog monochrome image acquisition board (IMAQ PCI-1408), a two-axis, closed loop stepper motor control board (PCI-STEP-2CX), and a RS-485 serial board with distributed I/O modules. We also used a National Instruments universal motor interface in the electronics enclosure to break out the wiring to an Intelligent Motion Systems Panther-LE motor controller (see Figure 3).

Cameras

Selecting the camera type and proper shutter speeds are essential to capturing a quality image for analysis. Cameras use the Charge-Coupled-Device (CCD) to electronically collect images. A CCD sensor is a pixel-sized solid-state photosensitive element that generates and stores an electric charge when it is illuminated. A CCD imager is a rectangular array of CCD sensors upon which an image of the scene is focused.

In analog cameras, the sensor usually includes the circuitry that stores and transfers its charge to a shift register, which converts the spatial array of charges in the CCD array into a time-varying video signal (NTSC, PAL, and SECAM are standard video signal formats). Digital cameras digitize the CCD information at the camera rather than at the image acquisition board, providing a high signal-to-noise ratio and better accuracy. Standard digital cameras are available with 10 to 12-bit gray levels of resolution.

Using conventional CCDs to capture images of rapidly moving objects can often result in images that have ghosting or blurring. These CCDs use interlaced scanning across the sensor to capture the image. Interlaced scanning divides the sensor into two fields; the odd field (rows 1,3,5…) and the even field (rows 2,4,6…). Each field is read in 1/60th of a second and then combined to produce the full frame. A blurring problem can occur when the object has moved before the second field is scanned. The "progressive scan" CCD imager solves this problem by scanning the lines sequentially (rows 1,2,3,4…). For our application, we chose a Sony XC-7500 analog monochrome progressive-scan camera with a 640 x 480 pixel CCD imager.

Another topic to consider is the range of light wavelengths you wish to capture. All matter reflects and absorbs light in different ways at different wavelengths. Sometimes, you can take advantage of this if you are looking for features that are enhanced at certain wavelengths. In our case, the product itself was grayish in color. Consequently, color was not identified as critical characteristics necessary for the analysis and a monochrome camera was chosen.

Many CCD cameras come with infrared (IR) filters built-in because CCDs are sensitive to a broader range of light wavelengths outside the visible spectrum of 400 to 700 nm. For our application, light wavelengths in the infrared spectrum were not useful in the statistical analysis. Therefore, we were not concerned with the effects of the IR filters.

Lens and Image Resolution

The lens gathers the light reflected off the object and focuses that light onto the CCD sensor. To obtain adequate images, the camera and the lens must be considered together as a system. Some of the important parameters to consider are:

- Field of view – This is the area of the object that is shown on the image. The field of view establishes the magnification achieved. For example, if a field of view of 5 mm is projected onto a CCD sensor that is 10 mm in size, then the magnification is 2X.

- Focal distance – This is the distance from the lens to the object.

- Depth of field – This is the depth of the features on the object that remain in focus, or the amount by which the object can move and still remain in focus.

- F-Stop – The F-Stop refers to the lens aperture, or iris, opening. The smaller the F-Stop, the larger the aperture, allowing more light into the lens. The F-Stop affects both the resolution and the depth of field.

The resolution, or the smallest feature of the object that can be distinguished in the image, depends on the combination of the camera and the lens. Higher resolution is achieved by focussing a smaller area (smaller field of view) onto the greatest number of pixels. Most cameras have 640x480 pixel CCD imagers. Although more expensive, higher resolution cameras are available, for example with 1008 x 1018 pixel CCDs. A good resource for selecting the appropriate camera and lens for the required resolution is the Edmund Scientific catalog, which provides application notes to assist you in selecting the right components.

As an example of determining the required resolution, consider counting cell colonies in a petri dish that is 75 mm in diameter. If you use a lens that projects the whole dish onto a 640 x 480 CCD imager, then you will get a resolution of 480 pixels per 75 mm, or 6.4 pixels per mm. In order to resolve cell colonies in that dish, they would have to be at least two pixels in diameter, or 0.3 mm.

For our application, we chose a microscope lens with a 2 to 8 mm field of view and a fixed focal length of 61 mm. By experimentation, we found that setting the field of view to 7 mm was optimal. This gave us a resolution of 480 pixels/7 mm, or 68.6 pixels per mm. The magnification at this resolution allowed us to capture the entire drug product in the field of view while at the same time maintaining high enough resolution to provide meaningful statistical representations of image brightness. Since the analysis algorithms worked well at this resolution, we avoided the cost of more expensive high-resolution digital cameras.

Camera Timing

Another significant issue for automated inspection systems that capture images of moving parts (e.g., on a conveyor or turntable) is camera timing. The images used for analysis must be timed with the product positioning system, and the camera shutter speed must be set based on the speed at which the product is moving.

The controlling variable for establishing the timing is the camera frame rate, which is typically 30 frames per second. Our image analysis algorithm required eight images equally spaced around the circumference of the product. Therefore, we acquired eight sequential frames $1/30^{th}$ of a second apart as the product was rotated through each 45 degree arc.

At one revolution in $8/30^{th}$ of a second (225 rpm), a point on the object moves at about 38 mm per second. With our resolution of 68.6 pixels per mm, that speed is 2600 pixels per second. In order to snap a picture that does not blur due to movement, the shutter has to open and close before a point on the surface of the object moves more than half a pixel. Therefore, a point on the surface of the part can move half a pixel in $1/5200^{th}$ of a second. Most video cameras provide selectable shutter speeds at discrete intervals: 1/125, 1/250, 1/500, 1/1000, 1/2000, 1/4000, and 1/10,000. For our application, the shutter speed of $1/10{,}000^{th}$ of a second was used to "freeze" the image as the product fixture rotated. This relatively high shutter speed increased the lighting requirements as discussed below.

Lighting

Lighting is an integral component of an image acquisition system, and lighting design depends on the type of object to be imaged. In our application, we used backlighting since we were interested in the transmission of light through the translucent product. Many other lighting techniques are also available. Diffuse lighting minimizes shadows and glare. Ring lighting also reduces shadows and provides uniform illumination. Light emitting diodes (LEDs) are good if low light intensity is sufficient. Filters can also be used to improve contrast and enhance specific features. Often, some experimentation is needed to establish the optimal system. Resources for selecting lighting equipment include Edmund Scientific, Dolan-Jenner Industries, Fostec, Inc., and Stocker & Yale, Inc.

Getting enough light into the camera at a shutter speed of $1/10{,}000^{th}$ of a second requires relatively high intensity. We also had to prevent heating of the product which would occur with an incandescent light in close proximity. A fiber-optic light source solved these problems. Fiber-optic light sources are halogen light bulbs directed at the open end of a fiber-optic cable. The light source itself, and its associated heat load, can be mounted away from the inspection area.

We chose a Dolan-Jenner fiber-optic light source with a 25-pin parallel port connector on the back, providing computer control of the light source intensity. This proved to be extremely valuable because halogen lamp bulbs, like any other lamp bulb, degrade over time. They typically lose about 5% of initial light output in the first _ hour of operation, and another 2% over the remaining life of the bulb. Computer control of light levels allows for real-time compensation and adjustment for lamp variability. Using our CCD camera as a closed loop sensor provided full light level control at the image acquisition level. Closed loop control allows for rapid calibration to a known reference at the start of operation, eliminates errors caused by manual intensity settings, and speeds up system re-calibration when a lamp is changed.

SOFTWARE CONSIDERATIONS

Integrating the hardware described above provides the capability to acquire an image which can be displayed on a computer screen. Additional application-specific software is needed to control the hardware peripherals, capture the image, and analyze the data, and generate the graphical display for the operator.

Development Software

If you have selected your data acquisition components from one of the major vendors, you can use their data acquisition programming language to write custom software to fulfill your system requirements. In our system, we used National Instruments' LabVIEW to develop a user-friendly interface allowing the operator to configure, calibrate, and operate the equipment safely. Other software functionality included monitoring safety interlocks, controlling the moving parts of the machine, capturing images, performing image analysis, indicating part status, and logging data for batch records.

Diagnostics

Using our CCD camera, we were able to determine when the bulb should be replaced and prompt the operator to replace it, providing step-by-step instructions on the touch-screen. To calibrate the system, we designed a calibration "object" that is always in the field of view of the camera, but away from the inspected part. The object has known optical qualities and markings on it with known dimensions and orientations. In this way, we were able to check the light intensity at any time and verify the camera orientation and lens magnification. If at any time these variables were out of specifications, the software would either adjust them to specifications, or prompt the operator to take appropriate steps to correct them.

Batch Record Tracking

If the development software supports communication protocols or ODBC databases, batch record information can be transmitted to a network, the Internet, or stored it in a database. In our case, we developed a dynamic link to a database residing on the local hard drive.

SYSTEM VALIDATION

System validation is the process of determining the level of conformance between the functional operation of a system and the system requirements. Validation provides the overall assurance that the system capabilities specified by the system requirements are implemented in the hardware and software and the system is properly integrated. For the Production Manager, however, validation can be a painful process if it adds critical time to the introduction of important new equipment.

In our case, we employed a process of "concurrent validation" which shaved valuable weeks off the delivery schedule for our new system. With this approach, the customer, our engineering team, and the validation team worked together through all phases of the development process. This process was well defined at the outset with specific validation steps performed as the design progressed.

With any automated system, one of the stickiest issues is how to properly validate software. Following a formal, well-documented software development process increases the probability of error detection and removal and thus reduces the overall risk. Consequently, FDA requirements for software validation are predicated upon use of accepted software development models. Our process is based on the Institute of Electrical and Electronics Engineers Software Life Cycle Model found in IEEE Standard 1012.

Our final validation step involved testing in which the system was challenged with a subset of our 10,000-image library. The samples in the testing library were carefully selected so that a large number of samples were right on the edge of being acceptable. This testing proved that the image analysis algorithms performed as intended. We also tested the system as a whole with sample product having known flaws to make sure the hardware functioned properly.

CONCLUSIONS

In the end, we discovered that with the manual process much of what the inspectors were rejecting was actually perfectly acceptable. Because of the inspector's perception that all good product should appear identical and that all voids are bad, they were being far too conservative. Automating the inspection process made it less sensitive to minor upsets in the fabrication process, provide reliable inspection results, and cut the reject rate in half.

The lessons learned from the development of this inspection system can be applied to the development of automated systems for a variety of other products. While automated machine vision is a well established technology for many routine types of inspections, innovative image analysis techniques can expand this technology to many other applications. In particular, traditionally manual inspections for non-uniformity or flaws are subject to inspector perception and can be done more reliably by an automated system if those flaws can be quantified. In addition, with a PC-based system, properly selected off-the-shelf components can be used successfully to provide cost-effective solutions.

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For the past 13 years, the authors have worked on a variety of product development, engineering design, and system integration projects at MPR Associates in Alexandria, Virginia.

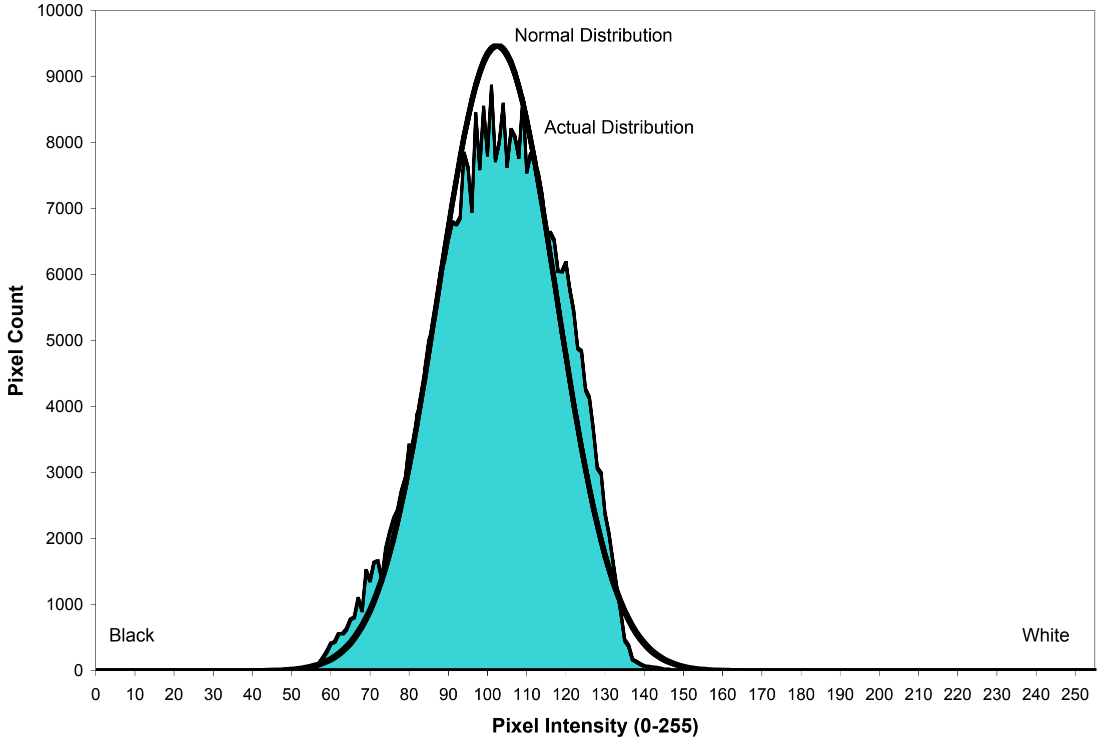

Figure 1. Typical Image Intensity for Good Product

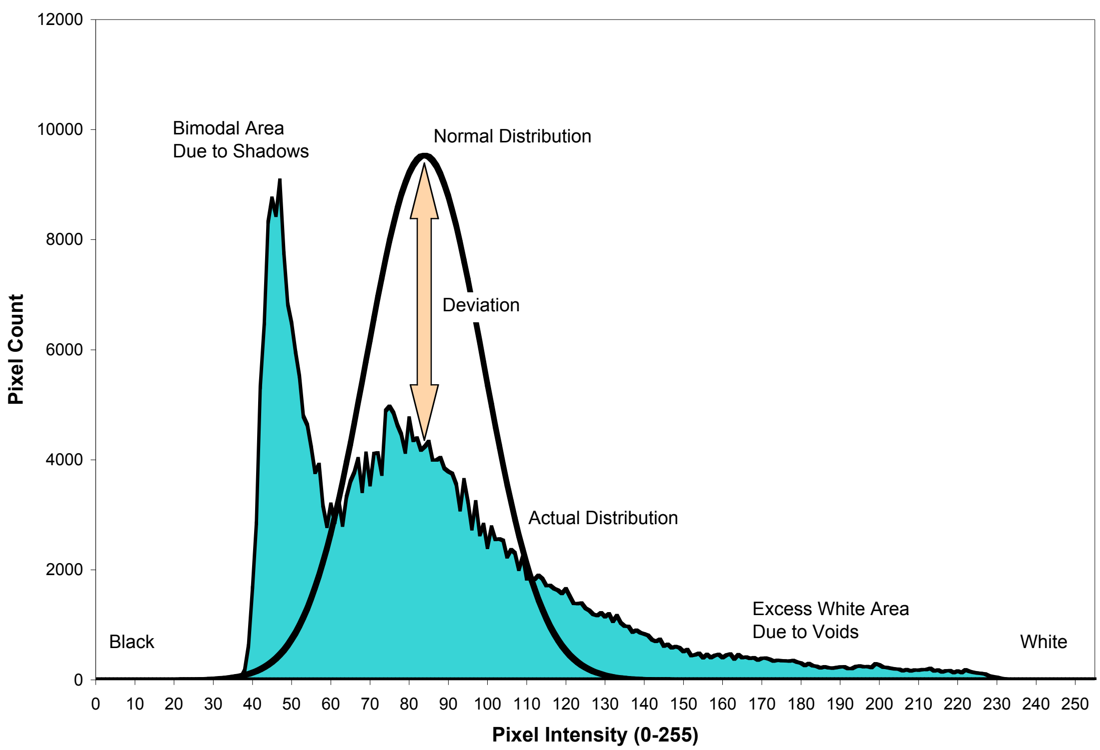

Figure 2. Typical Image Intensity for Bad Product

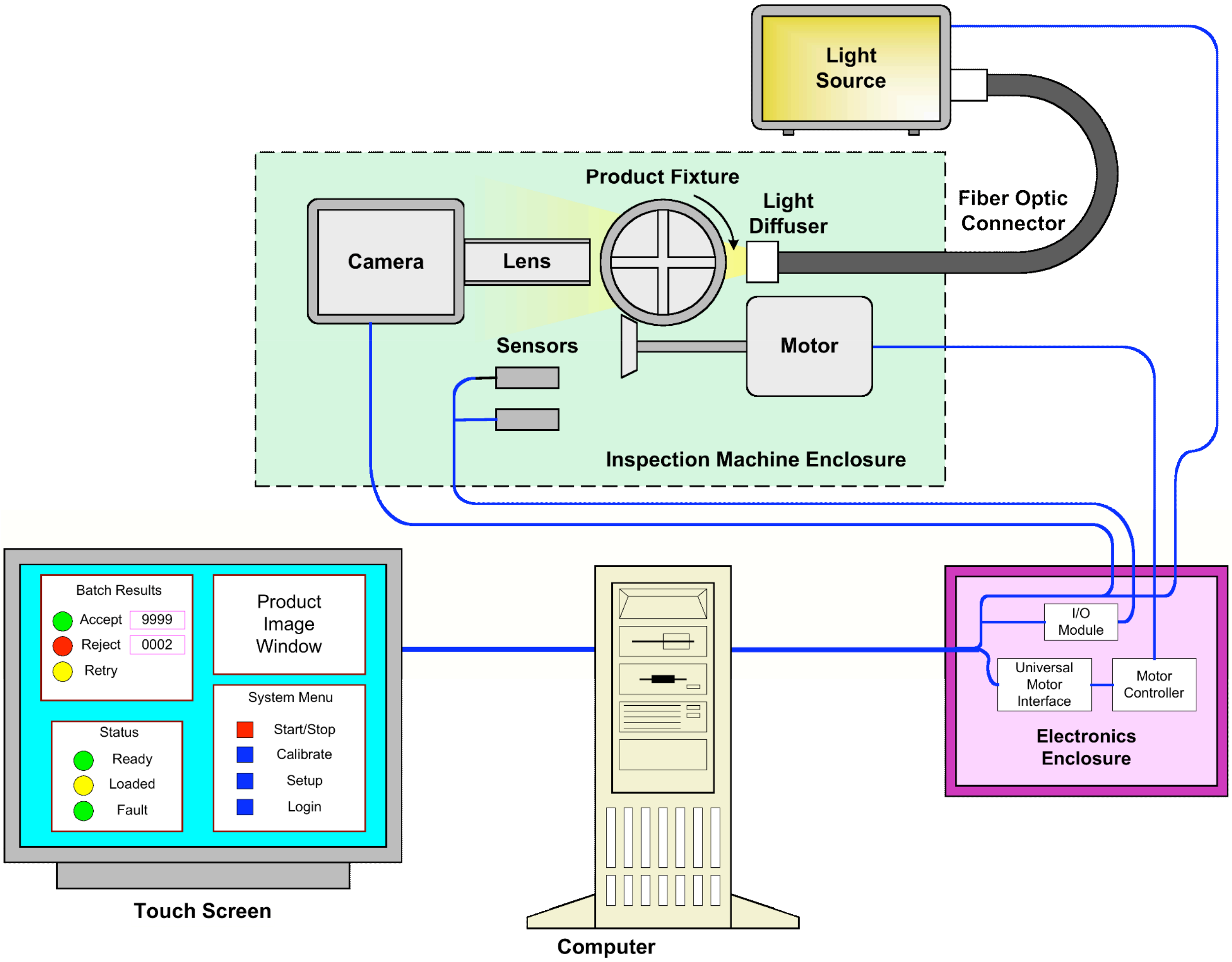

Figure 3. Vision System Components