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# Breathing Easy About Quality

***A Major Respirator Device Manufacturer Uses a Zeiss Accura CMM to Maintain High Quality Healthcare Products.***

*Story and photos by C. H. Bush, Editor*

**Ever see a car accident, a drowning or a fire** involving people with smoke inhalation? If you have, and paid attention to the ambulance crew, you probably saw them place a mask over the face of the victim before racing off to the hospital. That mask, in turn, was attached to a ventilation system designed to pump fresh, clean air into to the patient's lungs.

"In those cases, there's a good chance the device used to ventilate the victim was one of ours," says Marty Segari, site director, quality assurance and regulatory compliance at Palm Springs, CA's Cardinal Health (formerly Viasys Healthcare). "I believe it's safe to say that we are one of the largest manufacturers of such respiratory care products in North America. We currently produce and globally distribute more than 13,000 pieces of ventilator and diagnostic equipment each year. And, as director of quality assurance, my job is to ensure that all our products will function perfectly on the job. With lives at stake, our quality assurance program is of critical importance."

Founded in 1954 by Dr. Forest Bird, who developed the Mark 7® respirator, the company has now grown to occupy a modern 140,000 sq ft facility employing 425-450 people working 2 shifts.

"Some people are amazed to hear it, but a full 10% or more of our employees work in our quality department," Segari says. "That will give you an idea just how important quality is here. If one of our products were to fail, a patient might die. We take that responsibility very seriously."

## Major Quality Control Requirements

In the respiratory field the Cardinal Health line of products is broad and impressive.

"We make products such as the AVEATM ventilator, which is a ventilation system on



*Victor Ruiz, receiving inspector-CMM operator, sets up a part for inspection on the new Zeiss Accura CMM.*

wheels for fast and easy movement in a hospital,” Segari says. “We have ventilators for home care to transport. We make the LTV unit, which is a laptop system. Our Infant Nasal CPAP units are for infants. Although we still make Dr. Bird’s first unit, we’ve come a long way since then.”

Altogether the Palm Springs facility produces 1200 or more parts in house in a modern CNC machine shop using Hitachi Seiki and Mori Seiki vertical mills and turning systems. The company also operates grinding equipment for superfine tolerances and finishes. In addition, hundreds of components are brought in from outside. The materials machined include aluminum, stainless, titanium and others.

“We’re ISO 13485 certified,” Segari says, “which is an international standard that defines quality management system requirements for manufacturers of medical devices. The primary objective of the standard is to facilitate harmonized quality management system requirements for regulatory purposes within the medical device sector.”

When Segari arrived at Viasys three years ago, he found a quality department somewhat in confusion.

“Three different companies had been put together by Viasys,” he recalls, “so, I guess you could say there was some confusion and inefficiency in the departmental structure when I arrived. The products were all being properly tested, of course, because the testing we do is dictated by the marketplace and by the needs of the products. Still, there was some chaos, and I was brought in to get a proper organization installed to meet the company’s growing demands. So far, things have gone pretty well, I believe. We’re much more efficient now.”

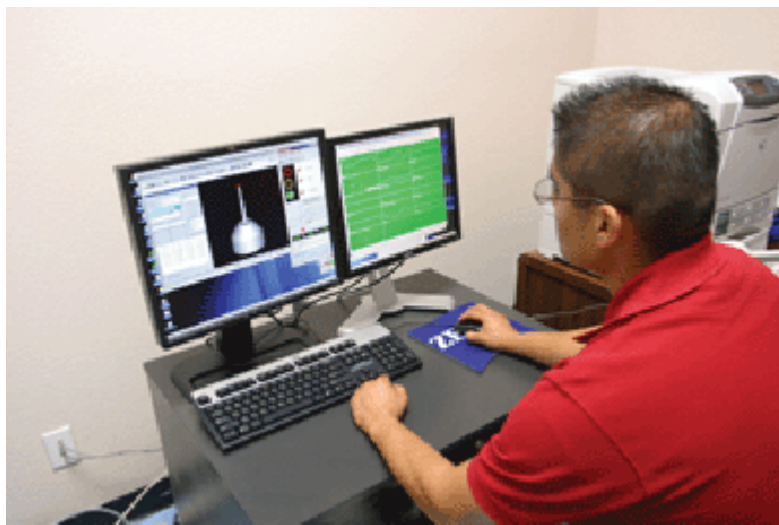
Segari’s background made him a good choice for the job. He got a bachelor’s degree in electrical engineering in Sri Lanka, and then a master’s degree at Loyola Marymount University.

“I did my Total Quality Management Certification at the University of California, San Diego,” he says, “plus I have a Six Sigma Black Belt in quality.”

In case you’ve never heard of it, Six Sigma is a set of practices originally developed by Motorola to systematically improve processes by eliminating defects. A defect is defined as nonconformity of a product or service to its specifications.



*Marty Segari, site director, quality assurance and regulatory compliance (right), and Tony Virgili, manufacturing manager, discuss ways to improve quality during production..*



*Victor Ruiz, receiving inspector, uses the Zeiss control panel to set up a part program for inspection.*

“My Six Sigma training has been very useful,” Segari says. “We have hundreds of parts needing inspection coming into receiving. And, as I said before, we needed to create a smoothly functioning department to handle the load. We now have that department, and we’re ready to grow.”

## Operations Dashboard

One of Segari’s first thrusts in the quality department was to make sure everyone rowed in the same direction.

“We clearly outlined every employee’s responsibilities,” he explains. “We set clear goals and objectives, and we trained them accordingly. Basically we put together a full set of quantified criteria needed for the operation to succeed. Most of the results are shown on a monthly operations dashboard we produce.”

The operations dashboard is like pilot’s cockpit, graphically showing the health of all the company’s instruments.

Segari: “We measure things like purchase price variance, work order variance, inventory accuracy, on-time order processing, out-of-the-box failure, and product quality first pass yield for final test. On the latter, for example, our goal is 98%. Last month we hit 97.5%. This month we’re at 98%, and we’re proud of that. If you don’t have a clear target, you don’t know what to shoot for. Producing quality is a team effort by everyone involved from manufacturing through quality and shipping.”

## Outsourcing QA

Prior to Segari’s arrival, Cardinal Health mostly used manual equipment for inhouse QA and outsourced the major, critical testing.

“We were using micrometers, and we had a manual Brown & Sharpe computer measurement machine inhouse,” he recalls. “But most of the critical quality testing was done outside. We were spending between \$100,000 and \$150,000 per year on outside quality assurance on just three parts. I found this intolerable.”

## Zeiss Accura Solution

The remedy Segari settled on was to purchase a new Zeiss Accura multi-sensor performance class CMM.

“We did a lot of analysis before we bought the



*Variety of respiratory device parts produced in Tony Virgili's machine shop at Cardinal Healthcare.*

machine,” he says. “I put together a thorough justification for the machine and it was an easy sell. One reason was that it offered a rapid, non-discounted payback. But there were a lot of other reasons for selecting the Zeiss, too.”

Some of those reasons listed on Segari’s management justification were: better resolution, advanced technology with upgradability for future vision-based measurements, multiple sensor capability, the ability to do contour measurement on curved surfaces and competitive pricing.

“The machine has outstanding reporting capability, including SPC,” he says, “plus it has a very user-friendly interface, which is easy to learn. Our people really like using the system.” Another major reason for selecting the Zeiss was the service package offered by Ellison Technologies Corporation, Segari recalls.

“We purchased programs for the first three parts from Ellison,” he says, “which worked out very well. They came in, installed the system and had it up and running in less than a month. As it turned out we didn’t need a slab for the machine, so that made things faster. They trained two of our people to run the machine, and it now does all that is required in one shift. The Zeiss has made a major impact on our department’s turnaround.”

## **Payback Big Time**

Just how much impact has the Zeiss had so far?

“It went into operation in January of 2007,” Segari says, “and though we’re only using about 10-15% of its capacity, I believe it has already paid for itself. So far, we have added three more parts programs, but my ultimate goal is to test 25 to 30 parts on the system. Now that we have been acquired by Cardinal Health we expect to leverage its world-class distribution and achieve significant growth. I believe the Zeiss easily can handle that.”