Quality Design = Quality Product

The use of "poka-yoke" can improve medical device design and manufacturing.

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The use of mistake-proofing in the design of medical devices will reduce the quality issues during manufacturing. More inspection is not the answer to prevent defects. One approach is the use of "poka-yoke" or mistake-proofing to improve product and manufacturing quality. The earlier you get the manufacturing group involved in the design, the easier ideas can be implemented.

In 1961, a Japanese manufacturing engineer named Shigeo Shingo working at Masushita Electric developed the idea into a formal tool for achieving zero defects and eventually eliminating quality control inspections. The term poka-yoke roughly translates to "mistake-proofing" or "to avoid inadvertent errors." It is any mechanism in a Lean manufacturing process that helps an equipment operator avoid mistakes. Its purpose is to eliminate product defects by preventing, correcting or drawing attention to human errors as they occur.

The idea is to respect the intelligence of workers by taking over repetitive tasks or actions that depend on vigilance or memory, and free a worker's time and mind to pursue more creative and value-adding activities.[1] A poka-yoke device is any mechanism that either prevents a mistake from being made or makes the mistake obvious at a glance.[2]

The concept is widely used in everyday examples, though you may not have been paying attention to it in a manufacturing context.

For example:

- USB and HDMI cables for computers and electronics are designed so they can be connected only one way;
- The signal your car makes when you leave your lights on and take the keys out of your ignition might be annoying, but it beats a dead battery any day; and
- When you put together toys for your kids, the parts are designed so they can go together only one way (OK, they're not always perfect but they have gotten better over the last several years).

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Why Should I Implement It?

The value proposition to implement poka-yoke into medical device manufacturing is that it increases product yields and reduces rework and scrap. The great thing about poka-yoke is implementation can be very simple but very effective.

Here are a few facts to consider:

- Lucent Technologies reported that half of the company's 3,300 mistake-proof devices cost less than $100 while creating a net savings of $8.4 million;
- Varian Ion Implant Systems saved more than $1 million dollars on the installation, start up and warranty of its new product launch; and
- If your product is recalled from distribution, what does that cost your company?

As more products are provided in the home care setting, the need to implement this methodology is even more important given the possibility for errors. Imagine you have an insulin pump and require a 0.5-milligram bolus. Would you be shocked to know that you could give yourself 5 milligrams instead?

Where Can I Implement Poka-Yoke?

Mistake-proofing can be implemented into the manufacturing process, but it certainly is the most effective when it is incorporated into the design of the product.3 If the parts only can be assembled one way, then you've eliminated errors and time in the production area. If it can't be implemented into the design, the tooling or manufacturing aids may be another area for implementation. If it can't be integrated into the tooling, then other items such as sensors, limit switches or counters can be very effective.

Poka-yoke is most effective when a company's attitude is that it's better to have a million one-dollar improvements than a single $1 million improvement. If the company culture asks everyone to identify at least one improvement per week, this quickly can accumulate to a large cost savings.

Poka-yoke designs fall into two major categories: prevention and detection.

In a prevention approach, it is impossible to make a mistake in design. A classic example of a prevention design is the USB plug design. The connection is carefully engineered to be slightly asymmetrical so that it will not fit into the mating connection in any orientation other than the correct one. Prevention designs remove the need to correct a mistake, since the user cannot make the mistake in the first place.

A detection design signals the user when a mistake has been made, so that the user quickly can correct the problem. Line clearance methods that verify the number of components used equal the total number of finished devices completed. As an example,

the numbers of pouches are counted to be the same as the lot quantity to be shipped. When the last device is sealed in the pouch, the worker should not have any pouches left. If there are too many or not enough, this alerts the worker that something was forgotten. Detection devices typically warn the user of a problem, but they do not enforce the correction.

How Do I Implement It?

Start by picking one of these points of view: the actual user of the device, the manufacturing and assembly process, or the design. Most likely, your review will cover the other items but trying to keep it focused on one element will help you be more effective.

Get the right people together to discuss the review of the product. If it's the end-user, try to get a clinician or someone that uses your device. One recommendation is to have manufacturing technicians take part in these conversations. Once they hear how and why the device is used, they will be able to contribute great ideas for improvement.

From the design perspective, review the features of the components and how they are assembled. Are there parts that are symmetrical but have to be put together in a certain orientation? Here is a great example of looking at what assembly issues might happen and adding features into the design to prevent them.[4]

Don't wait until the end of the process to perform the inspection of a critical process or attribute. The inspection can be done with a simple template or overlay, but the most effective method is when the solution is part of the tooling. As an example, the fixture used to bond the two parts together as designed so that the part can only be put into the fixture in the correct orientation.

It also is critical to put the inspection point the closest to where the potential failure can occur.

The use of poka-yoke was implemented into our new production line at the sub-assembly level. Working with the design team from the beginning, we created a modular and easy-to-configure product. Therefore, manufacturing could create lower levels of inventory to produce finished goods quickly vs. carrying finished good levels. In order to avoid delay in the final integration and test, we needed to have assurance that the sub-assemblies were good.

When we reviewed the flex assembly of the design, we needed to verify that the wiring was correct before welding shut the units. The short-term solution was a test fixture using flying leads and a connection. We found cases where we could attach the wrong wires and reject good units and pass bad units.

The lead engineering technician looked at the test one day and told me "give me two days and I'll fix it."[5] We went over the requirements that needed to be met and, sure enough, he came back with a great solution. Notice the wires and connections are

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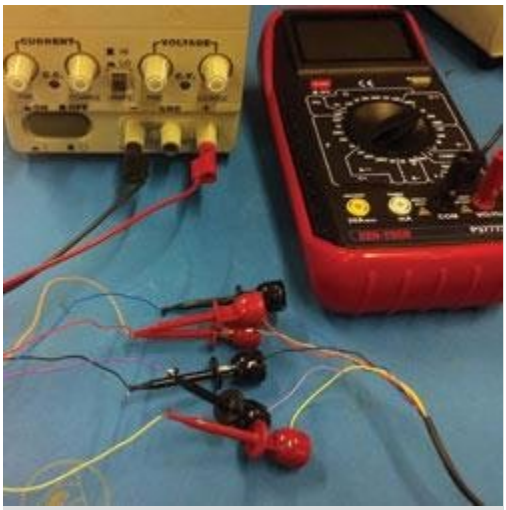
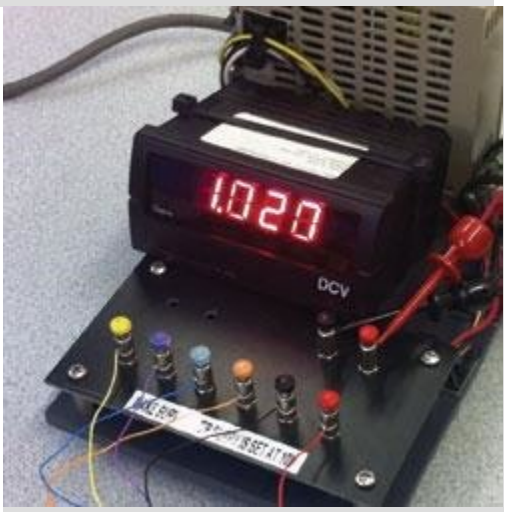
color-coded to make sure the wires are in the right positions. The total cost of the fixture was less than $20 and some of the items already were used in other parts of the manufacturing area.



Before. Quality improvement doesn't have to take hours or millions of dollars in investment. Seemingly small changes can yield significant results.



After. Here's a simple, straightforward fix that didn't waste much time or money. Photos courtesy of Dynisco.

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Poka-Yoke by the Book

"Poka-Yoke: Improving Product Quality by Preventing Defects" by Hiroyuki Hirano—also known as the "Big Red Book"—is one of my favorites. It is full of practical examples and diagrams of great ideas, showing preventative error examples as well as the poka-yoke functions (shutdown, control and warning). Sometimes these concepts are best explained with pictures and examples.

Five Examples

The idea of poka-yoke is that the workers don't go to work thinking that they are going to make a mistake. Hirano writes: "Mistakes are inevitable; people are human and cannot be expected to concentrate all the time on the work in front of them or to understand completely the instructions they are given. Defects result from allowing a mistake to reach the customer, and defects are entirely avoidable." As described in the book, here are five tools for detecting or avoiding defects caused by human error:

1. Guide pins of different sizes: These prevent the two mating parts being put together incorrectly, such as a stamping die;
2. Error detection and alarms: If a door to a CNC machining center is opened, the lights start to flash;
3. Limit switches: The worker needs to push down on a special cutter so it will cut through the material. When the cutter touches the limit switch, the light on the machine illuminates;
4. Counters: Digital counters are great tools to help employees. These devices can be attached to machines and count the repetition so the worker can cross-verify against the total output of components; and
5. Checklists: This is an easy tool to implement and very effective to highlight important items to verify.

The Bottom Line

The poka-yoke method is something that improves your daily life. Why not use it to make your product better as well? The best solutions are simple, quick to implement and 100 times more effective than 100 percent final inspection. The best ideas come from when the team can brainstorm ideas, be respectful to each other and listen. And some of the best ideas that I've seen have come from manufacturing technicians.

References:

1. "Poka-Yoke: Improving Product Quality by Preventing Defects," Hirano, Hiroyuki, Productivity Press, 1987
2. "A Brief Tutorial on Mistake-proofing, Poka-Yoke, and ZQC," John R. Grout, and Brian T. Downs, www.isixsigma.com

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3. “Poka-Yoke: Improving Product Quality by Preventing Defects,” Page 24-25, Hirano, Hiroyuki, Productivity Press, 1987
4. “Poka-yoke designs make assemblies mistake proof,” Paul Dvorak, Machine Design, Page 181-184, March 10, 1998

5. Special thanks to Canh Tang, Test Engineer, Manufacturing & R&D, my mentor.

Editor’s note: Jim Shore is a speaker during the upcoming MPO Summit in Salt Lake City, Utah, June 4-6, where he will address “Reducing Material Cost Through Kanban Material Replenishment.” To learn more, visit www.mposummit.com.

James Shore *has 25 years of quality and supplier management experience working in medical devices as well as other industries such as semiconductor capital equipment and aerospace/defense contractor (Boston Scientific, Aspect Medical, ACMI, Brooks Automation, and Raytheon). He currently is the product/process improvement leader at Dynisco in Franklin, Mass., responsible for the implementation of the global material replenishment program (eKanban) and the operations and manufacturing of a new product line (Vertex). Shore also is the regional director (New England) for the American Society for Quality, a board member of the Biomedical ASQ Division (NEDG), and a board member of American Welding Society. His professional certifications include ASQ Certified Six Sigma Black Belt, ASQ Certified Quality Manager, Certified Quality Auditor and Certified Mechanical Inspector and ASQ Senior Member. He is a veteran of Operation Desert Storm (1991), having served in the United States Marine Corps for more than 15 years and was honorably discharged at the rank of gunnery sergeant (E-7).*