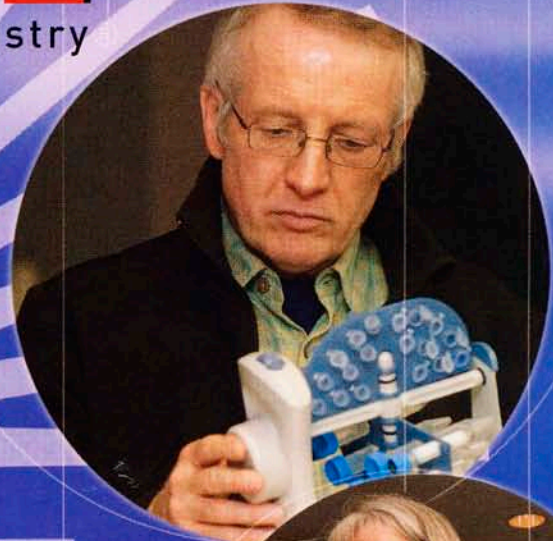


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Staying in Control of the Extrusion Process

Many tools and techniques help extruders meet demanding requirements.

William Leventon

As medical devices get smaller and tolerances get tighter, it has become more important than ever for tubing manufacturers to maintain good control over the extrusion process. But smaller dimensions and tighter tolerances also make process control more difficult than ever for extruders.

How are manufacturers meeting today's process-control challenge? Strategies include a complex mix of factors involving extrusion equipment, practices, and personnel. Potential solutions can come into play before, during, and after the extrusion process, both on and off the production line. Not surprisingly, however, all of the extras that help ensure tight control can also run up the price of extrusion, so medical device firms should be sure that they're not buying more process control than they really need.

Elements of Process Control

The first thing to consider about process control is the setting in which extrusion is performed. Extruders can't expect to achieve tight and reproducible process control if they don't have control of the extrusion environment, says Keith Andrews, director of business development for Upchurch Scientific (Oak Harbor, WA), which extrudes tubing for medical device companies. Upchurch controls the extrusion environment by performing the process in a Class 100,000 cleanroom. Among other things, the cleanroom setting prevents large variations in temperature and humidity that could be detrimental to the extrusion process, Andrews notes.

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When setting up a new process, extruders can often get help by reviewing data from old processes, according to Don Centell, general manager of ExtruMed LLC (Placentia, CA), which provides custom extrusions to the medical

device industry. ExtruMed's database contains information about almost 14,000 extrusion runs over the last 10 years. Company personnel tap this database for information that can be applied to a new job, Centell says.

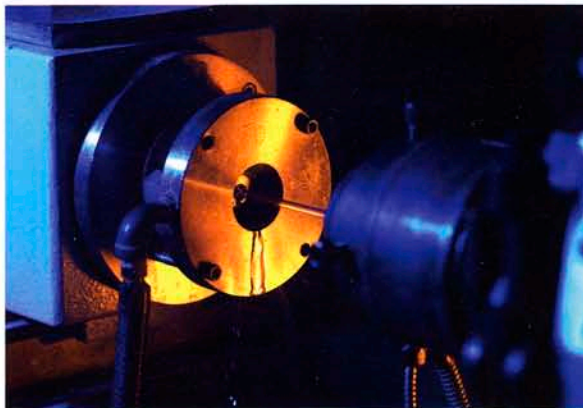
Particularly important is information about the material used to make the tubing. But device companies can't go to their databases for information about the many new resins being introduced. Before using a new resin, Andrews says, manufacturers must test the material to

obtain data on its characteristics that will help determine a successful, well controlled process for extruding it.

The material should determine what screw design is chosen for the extrusion process. "If a screw isn't properly designed for a particular material, then you typically won't get consistent output from that screw," says Mark Saab, president of Advanced Polymers Inc. (Salem, NH), which manufactures plastic tubing and medical balloons for dilation procedures. "This means you'll have a lot of dimensional and temperature fluctuations in your process."

At Advanced Polymers, the first step in finding the right screw for a particular material is evaluating various in-house screw designs. If none of these provides consistent output, the company sometimes turns to an outside manufacturer to produce a new screw for the material. But this can be a lengthy and expensive process, so it's best only when it can be justified by sufficient product volume.

In addition to the screw and other basic equipment, extruders sometimes add a melt pump to their lines. Melt



Increasingly smaller medical devices require tighter tolerances that make extrusion process control more difficult.

pumps can provide a more consistent flow of material than the extruder itself, which stabilizes the process and improves control, says Bob Asam. He is a senior process engineer at Teel Plastics Inc. (Baraboo, WI), which specializes in manufacturing close-tolerance plastic tubing.

In some cases, melt pumps reduce pressure fluctuations that can cause dimensional inconsistencies during the extrusion process. For example, Centell says, pressure on the inlet side of the melt pump might be fluctuating by 20 or 30 psi, but by less than 5 psi on the discharge side.

On the downside, Saab notes, a melt pump is a costly piece of equipment and is expensive to maintain. It also exposes the extruded material to additional heat, which can cause thermal degradation. For these reasons, he says, most extruders either don't use melt pumps at all or only use them when necessary to meet customer requirements.

Beneficial Advances

All up-to-date extrusion lines have benefited from advances in motors and drives, which allow manufacturers to tightly control the speed of screws and other equipment along the line. "When you set the machine to 46 rpm, the speed is exactly 46 rpm," says Guy Schultz, a process engineer for Filtrona Extrusion (Athol, MA), which manufactures plastic tubing. "There's no variation over time, which allows us to hold tighter tolerances."

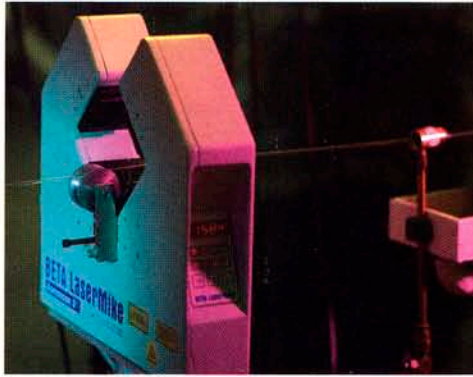
In addition to precise speed regulation, state-of-the-art extrusion lines feature improved temperature control. In the past, Schultz says, the temperature of the extrusion process "could bounce around a little bit." Now, however, temperature controllers on the machines maintain process temperatures within a range of $\pm 1^\circ\text{F}$.

According to Saab, most new extruders include high-end proportional integral derivative (PID) temperature controllers. But many older extruders that lack these temperature controllers are still in operation. Such extruders are "something you really want to avoid if you're in the medical industry," Saab says. "In extrusion, being able to control the temperature in your line is fundamental. But that doesn't mean everybody does it or does it well."

Besides temperature controllers, Advanced Polymers uses data-acquisition systems to collect temperature and pressure information from different points along the line during an extrusion run. These data help plant personnel pinpoint production problems and determine their cause.

In-Line Measurement

Perhaps the most common and useful process-control tools are devices that perform in-line measurement of critical tubing dimensions. At Filtrona, tubing outer diameter (OD) is checked by a high-speed in-line monitoring system. The system features a dual-axis laser micrometer



Process control systems can include screw designs, diameter measurement equipment, and melt pumps, which can be expensive.

that measures tubing from two angles 90° apart, to catch any ovality in tube cross sections. Also included is a large LED readout that displays tubing ODs to the fourth decimal place.

Some commercially available laser gauges add a third axis to the measurement process, increasing the likelihood of catching tubes that aren't perfectly round, according to Saab.

On Filtrona's extrusion lines as well as others, laser gauges that measure tube OD are joined by ultrasonic devices that can determine the thickness of tube walls. With a tube's OD and wall thickness known, a system

can calculate the inner diameter (ID) to the fourth decimal place, Schultz says.

In-line measuring devices make it possible for tube manufacturers to set up feedback loops that operate during the extrusion process. For example, ExtruMed engages feedback loops based on the tube OD readings taken by a laser micrometer. If the OD readings are moving toward the high end of the allowable range, the system removes a little air from the extrusion process and then takes more readings to see the results of that action, Centell explains. Then, if necessary, the system can remove more air to further adjust the process.

Because feedback loops introduce another variable into the extrusion process, ExtruMed uses them only when absolutely necessary. "One rule of thumb is that if you've got a real slow drift, go ahead and engage the feedback loop. It will help you out," Centell says. "But if [the process] is running stable on its own, keep it manual."

ExtruMed's database of information from past extrusion runs can alert operators to situations that might require a feedback loop. For example, Centell says, data from previous runs may show that a pressure feedback loop is usually engaged when extruding a certain material. In a case like this, the feedback loop may not be engaged to begin with, but the operator won't hesitate to do so if run data indicate that it can help solve a control problem.

Though it can be a useful tool in many cases, closed-loop control has significant limitations. "It can only adjust what it's set up to adjust," Saab notes. "So if you have another problem, it's not going to correct for that." It can make matters worse by repeatedly making adjustments in an effort to solve a problem that it hasn't been set up to solve.

Saab says a better control system is one that involves a trained operator. In such a system, a drifting process sets off an alarm that alerts the operator, who can then assess the situation and decide on a course of action.

Advantages of SPC

Filtrona's monitoring system prints out quality-control reports during the extrusion process, when they can be used to make any necessary process adjustments. "Once the job is done, it's too late" to get this information, Schultz says. "We [get] real-time quality control information."

At Teel, computerized statistical process control (SPC) makes it easy for operators and quality control personnel to access process data. "I can just go to my computer and pull up a run to see if we were in control or out of control," says Rachell Bainbridge, the company's director of quality.

Before SPC was computerized at Teel, operators wrote process information on paper control charts. In addition to plotting data points on the charts, they had to calculate ranges and averages. Now, operators enter measurements

Computerized statistical process control makes it easy for operators and quality control personnel to access process data.

into the system and it produces process information at the press of a button, speeding up data analysis and eliminating the possibility of human error in the calculations.

Like the Teel system, ExtruMed's process provides real-time data in chart form that allow plant personnel to spot trends. "It's visual, so you can very quickly see whether you're running stable or experiencing very slow fluctuation," says Centell.

Most of ExtruMed's customers don't ask the company to provide SPC data, but the company still gathers the information for its own purposes. "We use it to find out whether the current run is similar to the other runs we've done for the customer in recent years, so we know whether we're consistent," Centell explains.

Other Factors

Another factor affecting process control is the caliber of an extruder's engineering and quality teams. At Teel, an engineer is always present for the initial run of a material in order to optimize the process, according to Chris O'Connor, a senior product development engineer at the company. In addition, Saab says, operators who can't get a process to run within specifications call in an engineer, who looks at factors such as tooling, temperature, and screw design. And if a number of recent extrusion runs have produced tubes that are rejected for the same reason, manufacturing engineers and the quality team at ExtruMed get together to try to pinpoint the cause of the problem.

Then there are the operators. Has the extruder established effective training programs for them? In many cases, operators aren't trained well enough to take full advantage of the latest extrusion equipment, Centell says.

In addition to training their operators, companies concerned about process control should make sure they follow standard work procedures. Examples include the steps established by a company for starting up an extrusion line and calibrating gauges. "We don't want five different operators to be doing five different things," Andrews says. "We want all the operators to follow a proceduralized process that will help us get consistent results."

Process control also depends on how well extrusion

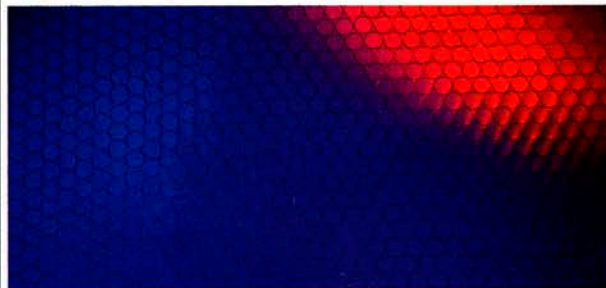
personnel maintain equipment. "The process can drift over time because of equipment wear," Saab says. "As a result, what you make this year can be significantly different from what you made two years ago."

No equipment is more important to the process than the screw and barrel. "As these components wear over time, your process will change," Andrews says. "So it's crucial to keep track of the wear of the screw and barrel—and to know when you have to repair or replace them."

In addition to checking for wear, Saab says, extrusion personnel should make sure that their equipment is properly calibrated. Consider, for example, the temperature controller on an extrusion line, which could "very easily" be off by 5°F, Saab says. Although that may seem like a small amount, it can have an effect on the properties of tubing made on that line.

The Importance of Inspection

To ensure that an extrusion process remains in control, no job is more important than inspection. At ExtruMed, technicians constantly check their products and fill out in-process inspection sheets. Depending on what data a



customer wants, technicians record measurements of tube OD, ID, and wall thickness. If multilumen tubing is being extruded, inspectors also record all lumen dimensions.

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Once every half-hour during the extrusion process, Filtrona personnel cut a cross section out of the tubing and inspect it using an optical comparator. This device magnifies the cross section 20 times, making it easier for inspectors to examine tubing and check critical dimensions.

Vision systems are crucial tools at Molded Rubber and Plastic Corp. (MRPC; Butler, WI), which extrudes silicone tubing for the medical industry. These elastomeric products can't be measured with a touch probe because contact with the measuring device can cause deformation of the soft material, explains Greg Riemer, MRPC's vice president of sales and marketing.

But measurement using a vision system doesn't require any contact with the product. These systems put a magnified color image of a tube cross section on a computer monitor, allowing inspectors to manually take dimensions such as OD, ID, and wall thickness. Because the systems can "see" dark and light, they can also locate the edges of a tube for an inspector, notes Mark Tesch, MRPC's engineering manager.

Plant personnel certainly need help in meeting today's greatest inspection challenges. For example, studies done by Advanced Polymers have found that inspectors simply can't measure tubing with the supertight tolerances now being specified by many medical device firms. So the company is working with Lumetrics Inc. (West Henrietta, NY) to develop a noncontact optical gauging system that will be used offline to measure tubing. An operator will set up the system and load tubing into it, but the system automatically takes measurements without operator involvement, thereby freeing the measurement process from human error and limitations. In addition to providing greater accuracy, Saab hopes that the system will also be faster than manual measurement.

Customers and Control

How much inspection is necessary? That's ultimately up to the customer. ExtruMed can show customers a year's worth of in-line measurement data to statistically prove that an extrusion process is under tight control—and, therefore, that costly inspections can be reduced. But if a customer still insists on frequent inspections to check critical tube dimensions, "then that's part of the price that the customer is willing to pay," says Brandon Gosiengfiao, ExtruMed's senior quality engineer.

ExtruMed makes several different tubing products for Spectranetics Corp., a medical device firm in Colorado Springs, CO. These include three sizes of bump tubing made of high-density polyethylene, which is a very difficult material to extrude, according to Jamie Fearing, the company's purchasing supervisor. Adding to the difficulty of the job are the tolerances, which, in one case, are as tight as ± 0.0001 in., Fearing notes.

To help ensure that ExtruMed's processes are up to the job, Fearing's firm conducts regular audits at the extruder's facility. During these audits, Spectranetics personnel look for the following:

- Quality systems that are ISO or FDA certified.
- Records showing that operators are properly trained.
- Evidence that processes are in control. This is obtained by watching production runs and reviewing inspection data from past runs.

Of course, the evidence that would satisfy Spectranetics might be different from the evidence that would satisfy another medical device firm. So the quality plan for an extrusion job may be more or less demanding, depending on customer requirements. "Some of our stringent customers want an ID, OD, wall, and concentricity measurement for every 20 pieces we run," Tesch reports.

The price paid by these customers for their stringent requirements can be very high. According to Saab, process-control equipment and personnel can easily double or triple the cost of an extrusion run. "There's a huge difference between what we charge a customer who has broader tolerances and specs and a customer with tight tolerances and specs." ■