Achieving Effective Process Monitoring Through Detailed Process Development

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When it comes to molding for medical devices, effective process monitoring isn't just about getting a part correct, but rather, it could be a matter of life or death. Ensuring product is produced within defined limits is critical. This article highlights the considerations required to be certain effective process monitoring has been established for medical molding.

Effective process monitoring is achieved through proper process development. To effectively monitor, a manufacturer must ensure that the process is optimal and repeatable. Without repeatability, effective process monitoring will never be achieved.

Effective process monitoring does not mean setting upper and lower limits—or "defect limits"—just before defects are created. Although it is important to know the defect limits of any process, these limits are not typically tight enough to be considered effective. Effective process monitoring limits should be set so that if *any* abnormality is discovered outside of the normal process variation of the machine, it is segregated from good product. This will be well within the thresholds of the defect limits.

When establishing process limits, the goal should be to monitor a process that has been proven to produce acceptable product. Large process limits that attempt to achieve process windows so that process adjustments can be made often cause more harm than good. The thousands of interactions taking place in a molding process make it very difficult to prove every process combination or scenario that the process windows can produce. For this reason, it makes more sense to establish a robust process and use process monitoring to ensure that the optimal process is run each and every time and to ensure that abnormalities are caught and

segregated. The process to identify what are considered normal variations may differ depending on the product line, but three, eight-hour runs with complete shut downs between each run is a great start. It is extremely important to ensure no process changes are made during these runs, and manufacturers may want to run at least one version with an alternate resin lot number. Process outputs should be recorded every 15 minutes, and the parts should be collected for that recorded process. Using this data, the effective process limits can be calculated as long as all the parts collected are within specification.

Manufacturers could set up stages of process monitoring so that any shot that is segregated would be considered suspect, as long as it is within the defect limits, until further review of that product can take place. This may not be necessary as long as monitoring is set up in such a way that the machine will alert when scrap thresholds are reached. If so, the amount of product at risk will be minimal and focus can be placed on troubleshooting the issue at hand.

Process monitoring can be accomplished using the machine’s monitoring software, but to ensure effective process monitoring, third-party hardware is required. This will allow for third-party verification of the machine outputs as well as in-mold monitoring in the form of pressure transducers and thermocouples. The ability to monitor the plastic and ensure that it reacts the same in the cavity, shot to shot, is the ultimate form of effective process monitoring. Manufacturers should use the same methods of establishing the effective upper and lower limits for peak cavity pressure, pack rate, and cooling rate. This establishes machine-independent effective process monitoring and, regardless of the machine outputs, can ensure the plastic was within established limits.

To effectively monitor a process, manufacturers must have an effective means of part discrimination when out-of-process conditions arise. Automation options, such as robots, reversing conveyors, and diverters, can be used to accomplish this. If these are not an option, the machine must be set up to shut down when any out-of-process condition is identified, and ejection must be prohibited to ensure that the suspect parts are left in the mold. This is undesirable for several reasons, and in particular because interruption can cause instabilities in the process. Automation is the best option and will allow manufacturers to continue to run while keeping the process stable. It is also key to ensuring that manufacturers have built in excessive reject logic in the monitoring process to prevent the machine from running excessive scrap rates.

Regardless of how tight monitoring limits are set, the first step in effective process monitoring is process development. Merely establishing limits for unstable processing or tooling conditions will ultimately prove ineffective in preventing unacceptable product from escaping. Once manufacturers have mastered process development, effective process monitoring ensures that the process always runs effectively.

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