VOLUME 1 OF A SERIES OF MEDICAL MOLDING WHITEPAPERS BY DME

Medical Molding:

The Importance of Preserving Quality Standards Through Preventative Maintenance Of The Mold Cooling System

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DME®

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The Importance of Preserving Quality Standards Through Preventative Maintenance of The Mold Cooling System

Medical and pharmaceutical companies have strict and careful process controls in place to ensure part quality and overall product compliance to meet regulatory guidelines.

Before production begins, injection molding process parameters are developed and defined through significant testing. Importantly, once the parameters are established, the original process specifications should be maintained throughout the lifetime of the part's production to minimize any variations to the process.

Thermal management of the mold is one of the most critical variables of the molding process and calculations are made to determine the thermal transfer coefficient of the part at time of mold design. However, over time, **the cooling circuit's performance may change, resulting in reduced heat transfer that can have negative effects on part quality, production efficiency, and even lead to long-term mechanical failures.**

In this whitepaper, we will explore the negative effects of expanded thermal variations over time and review methods to minimize the impact.

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Tyler Boss has a B.S. degree in Plastics Engineering at Pittsburg State University (2008) and is certified RJG Scientific Molding Master Molder I and Master Molder II. He has fifteen years of industry experience as both an educator (RJG consultant) and practitioner both in process engineering and operational management. Through his career, he has been focused on the implementation of systematic and controlled molding methodologies as well as new technologies in the injection molding industry.

Medical Injection Process Characteristics

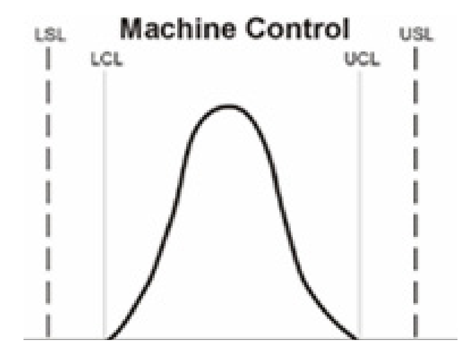
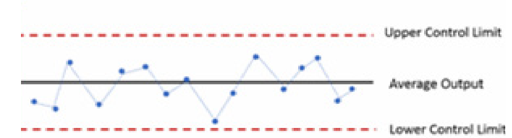


Figure 1



UCL = Upper Control Limit
LCL = Lower Control Limit
USL = Upper Specification Limit
LSL = Lower Specification Limit

Source DME

The medical and pharmaceutical industries operate to the highest regulatory standards with ISO 13485 and FDA approvals being a prerequisite. This requires companies to follow a stringent quality management system (QMS) where all the necessary processes are identified, risk assessed, measured, recorded, and controlled.

The process of molding revolves around four key parameters: melt temperature, flow, pressure, and cooling. The values of these variables are typically established by scientific molding principles that govern the part's processing specifications, most often obtained by using the design of experiments (DOEs) method.

Scientific molding involves setting defined targets and monitoring for deviations, with data being measured and recorded between upper and lower controls limits (figure. 1). The collection and scrutiny of this data ensures part quality and manufacturing output performance is properly maintained.

Monitoring technology, including the use of sensors with the process, can provide the molder an abundance of realtime data covering all the elements of scientific molding. In the case of cooling, measuring and monitoring variables like turbulent flow, water temperature, and pressure in the cooling circuit allows for the calculation of the delta T (ΔT) and delta P (ΔP), which is the difference between coolant outlet and coolant inlet. .

Among all the molding variables, cooling is recognized as the most influential factor in determining both cycle time and post mold stability. Any changes in the performance of thermal transfer will determine the effectiveness of cooling over time

Medical Injection Process Characteristics

Condition Of The Water Cooling Channel Affects The Mold's Thermal Transfer Over Time

Water is most commonly used as the coolant media in injection molding, but it has certain challenges. Water and impurities such as minerals contained within it can impact the cooling lines in different ways. The oxygen inside water attacks the metal surface of the mold, even those made from stainless steel, causing corrosion or rust. It is on these roughened surfaces of the water channels that the impurities within water are released and scale is deposited.

Heat acts as a catalyst. The higher the mold and water temperature, the greater the speed and quantity of deposit. Scale not only decreases the effective cooling diameter of the channel, but, most significantly, it acts as an insulator. With some calcium derivates exhibiting thermal conductivity more than 20 times lower than steel (Figure. 2) even slim layers can significantly impede thermal transfer and impact the molding process even though there is no perceptible restriction of flow rate.

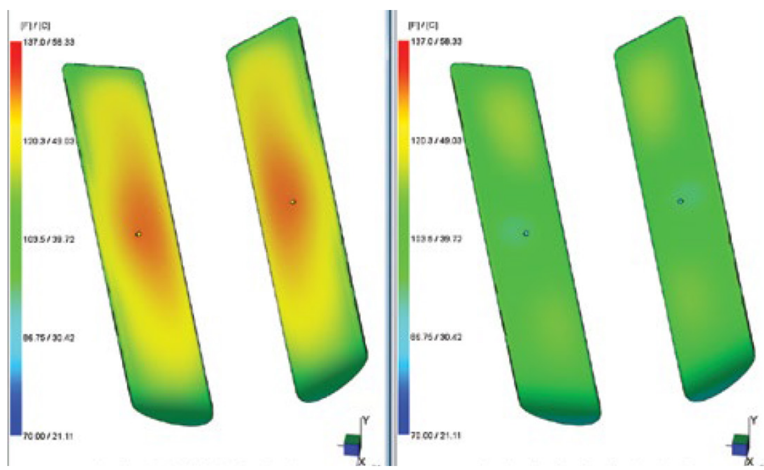
Even when water is treated to remove the calcium and other impurities that can cause deposits, the problem of scale up is not eliminated. This problem becomes more acute when the water circuitry is complex and the channels are narrow. This is often the case when conformal cooling is deployed, or micro bubblers are added to the channels.

MATERIAL	Calcium Carbonate Scale	Calcium Sulphate Scale	Calcium Silicate Scale	1.2343 Steel
HEAT CONDUCTIVITY W/mk	0.6-6	2.3	0.3	24

(source: Fado SP. z 0.0.)

"Scale not only decreases the effective cooling diameter of the channel, but it acts as an insulator."

Why Parts Quality is Affected By Deviations In Heat Transfer



Molders typically measure part quality through simple attributes such as dimensional tolerances, cosmetics, and occasionally physical testing to check functionality. Accelerated life cycle testing of the finished parts is unusual due to the volumes involved and the associated costs.

In monitoring the data and any trends that deviate from the established control limits requires the technician to not only modify process conditions but, most importantly, understand the root cause and address it with the necessary corrective actions. This often includes the need for predictive maintenance especially when it comes to the cooling of the mold.

Failure to restore the thermal transfer performance of a tool can result in rising mold temperatures, which in turn may affect the molecular structure of the polymer. This is particularly problematic when processing polymers sensitive to heat and/or where excessive temperature and dwell time can cause degradation of the polymer.

If the water-cooling channels in the mold are not regularly maintained and cleaned, the thermal transfer properties will deteriorate and the polymer will be subjected to elevated steel surface temperatures. Clearly, this is not desirable and can lead to major quality problems. Cosmetic quality problems can be easier to monitor but other issues may be difficult to identify at the time of production and may result in failures in the field.

"Elevated temperature accelerates additives migration over time."

Deviations in processing conditions, however minor, combined with normal viscosity variations can go virtually undetected with post molding inspections. These changes in the physical attributes of the material are known problems, but it is often not seen until the final part is placed into its normal service environment.

Heat can also impact the additives inside the polymer structure. Additives are added to polymers to enhance properties (e.g., UV resistance, process stability etc.) but do not attach to the polymer molecule itself. With the addition of heat, the additives tend to migrate to the surface. Elevated temperature over time accelerates this phenomenon. This can result in polymeric material building up on the surface of the core and cavity of the mold, which can then transfer to the molded part and cause unwanted surface defects and possible part contamination.

Another reported factor to consider is the generation of so-called non-intentionally added substances (NIAS*). These are chemicals that have not been added for a technical reason during the production process but are generated through the addition of excessive temperature. The NIAS can migrate from the plastic part into the contents of the medical packaging, but it is very difficult to completely understand and control such processes.

The common solution in both cases above is to incur the cost of additional and regular cleaning of the mold surface. To minimize the impact of this know problem, maintaining the steel surface temperature of the core and cavity is critical.

*The term NIAS was introduced for plastic food contact materials in Europe in legal context (Commission Regulation (EU) No 10/2011).

Preventative Maintenance of the Water-Cooling Channels

Importance of Preventive Maintenance for Cooling

A successful preventative maintenance program can help resolve challenges that develop through the production process. Active preventative maintenance for cooling requires an initial tool benchmark to be established at the time of first sample or at clean state. This baseline should be used in the IQ/OQ/PQ (Installation Qualification, Operational Qualification, Performance Qualification) validations, and later in preventative maintenance procedures, as it is needed as the set point to re-establish the process to original specified conditions.

Medical molders typically deploy extensive preventive maintenance (PM) programs, which can include mold disassembly and cleaning of predominantly the exposed surfaces. These actions do not necessarily return the thermal transfer performance of the tool to its initial state.

A comprehensive preventative maintenance program requires that the water-cooling lines are monitored, cleaned, and returned as close to the original state as possible for optimal performance. This requires the use of specialized cleaning equipment.

Common systems used for cleaning other parts of the mold, such as dry ice for cavities or complex ultrasonic baths where parts of the mold are disassembled and immersed, are not appropriate to clean deep inside of the cooling channels. Drilling clogged channels is also not an optimal solution for circuit cleaning, as it can only be done in straight steel channels and requires the tool to be removed from production for an extended period of time.

The cleaning of water circuitry within the tool requires the de-plugging of any blocked line, elimination of any debris such as rust and, most importantly, scale attached to the surface of the channel be removed.

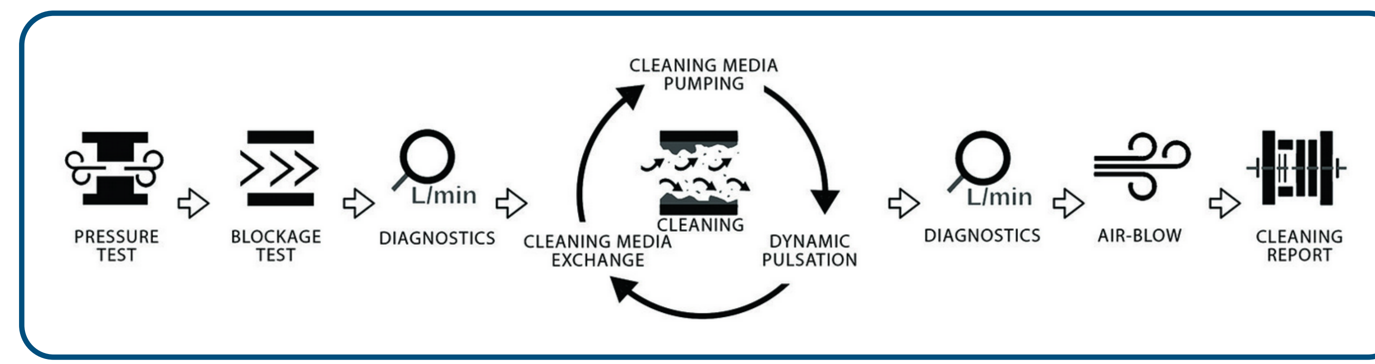
Ideally, the original baseline for flow within the individual channels should be stored and made available, so the cleaning process can be monitored and ended only when original settings have been restored. Trying to clean the channels without this data can result in unnecessary long cleaning times or, if cleaning is not fully accomplished, suboptimal molding performance.

It is important, especially in the medical sector, to use the proper cleaning agent, one which does not attack the surface of the steel or damage sensitive mold components (such as those made of copper alloys) and any exposed polymer-based seals.

To achieve the necessary cleaning, it is preferred that the cleaning media is heated to fully activate the chemicals inside it, thus accelerating the removal of any scale and rust. Of greatest importance is the application of a two-way pulsating movement of the cleaning media as this applies pressure back and forth to "scrub" the channel walls and remove any air blocks in the channels.

By cleaning each individual channel, the resulting flow and pressure data can be collected and the information stored for future traceability and possible use during an external audit.

When using cleaning equipment that includes verification steps prior to and after cleaning, such as leakage, test for clogs, flow rate, and even final air purging for drying the circuits, labor costs can be minimized as the process can run unattended. With such equipment, the cleaning of the water channels can be carried out simultaneously with the rest of the maintenance program avoiding the need for any additional labor.



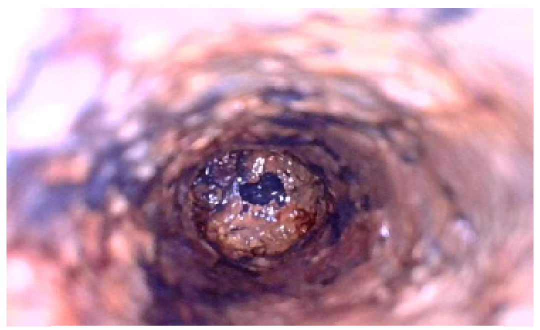
The DME CoolingCare equipment, with its unique two-way pulsating technology, has been developed for and deployed to medical molders to not only clean the mold cooling circuits but also record and store the data of the water flow for each individual channel. This unique capability creates a record so when the mold needs to be cleaned, again the CoolingCare system knows exactly what level of flow needs to be reestablished and, once this level is reached, the CoolingCare unit stops the cleaning cycle and sends a digital notification to the operator. Data on up to 3,000 tools can be stored and managed in this way.

The cleaning media is economical and can be reused for multiple cleanings, and there are several cleaning media to choose from depending on the type of contaminants to remove.

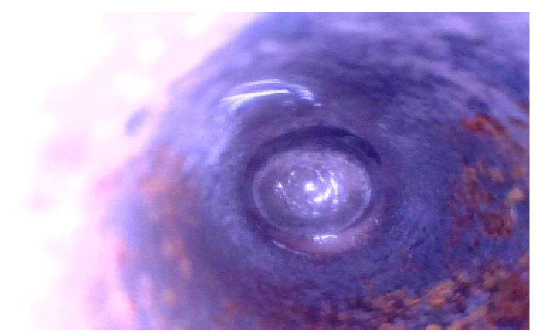
SUMMARY

Medical and pharmaceutical companies operate to strict and careful process controls to ensure part quality and overall product compliance. Significant testing is undertaken prior to the commencement of production and process parameters are defined.

However, the original mold specifications at the time of testing and approval can be difficult to maintain when process conditions change through the lifetime of manufacture, including reduction in the thermal transfer performance.



Before Maintenance



After Maintenance

Without adequately addressing this issue through preventative maintenance, output efficiency and part quality can suffer, and unnecessary costs and risk will result.

Effective and efficient circuit cleaning practices must be incorporated into preventive maintenance routines. It is important that the cleaning equipment can use both current and stored data to manage the cleaning cycle, and the cleaning is able to not only remove debris but also scale. Cleaning should be unattended and done in a non-aggressive way to protect the mold and the mold components.

The DME CoolingCare solution has proven to be ideal for the medical industry as part of a proactive mold maintenance program that helps maintain production output and part quality throughout the production lifecycle.

To learn more about how DME can assist you with establishing an active preventative maintenance program and for monitoring and controlling your cooling performance, please contact us at Cooling_Medical@DME.net.

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