

Forward-Looking Machine Designs in Accordance with GMP for the Production of Medical Products

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With growth rates of seven to eight percent annually, the health care sector is currently the boom branch par excellence. Medical technology is the most sensitive area in plastics processing, posing great challenges to processors and machine suppliers. On the one hand, the products require a zero-error tolerance; on the other hand, both investment costs and the operating costs of clean room production are to be kept as low as possible. Furthermore, documentation, qualification and product liability, as well as the flexibility required by the market, play an important role in the overall process. With specific measures in machine development using systematic analysis and optimisation, a large portion of the possible risk factors, as well as the running operating costs, can be significantly minimised in the end. ENGEL has been concerning itself for several years with the development of injection moulding machines to be used in medical technology. This has resulted in an economic clean room-capable machine design and a variety of accomplishments and experiences in this area.

Critical success factors

Medical products do not permit any compromises in terms of their development and production. The application itself determines the requirements for the production resources and the production environment. In the end, everything is based on two important factors: pureness and costs. The goal is to fulfil the production of 100% good parts that is demanded by the market and the authorities while still finding an economical way to carry out production. Furthermore, the required comprehensive documentation and traceability should not negatively influence flexibility in production. This results in the critical success factors that direct all production under clean room conditions. In order to satisfy this demand for quality, it is necessary to specify and eliminate all risks. In this regard, it is important that a balance be created between investment costs and operating costs from the beginning. After all, the cumulated operating costs attain the level of the investment costs as early as after three or four years (see Figure 1).

The overall investment for a clean room, including the building, technology, machines and quality control, is approximately 6500 euros per square meter for medical technological production. The annual operating costs are approx. 20-30% of the investment cost. Therefore, it is all the more important that future projects and the scope of use for the clean room be taken into account as early as the planning phase.

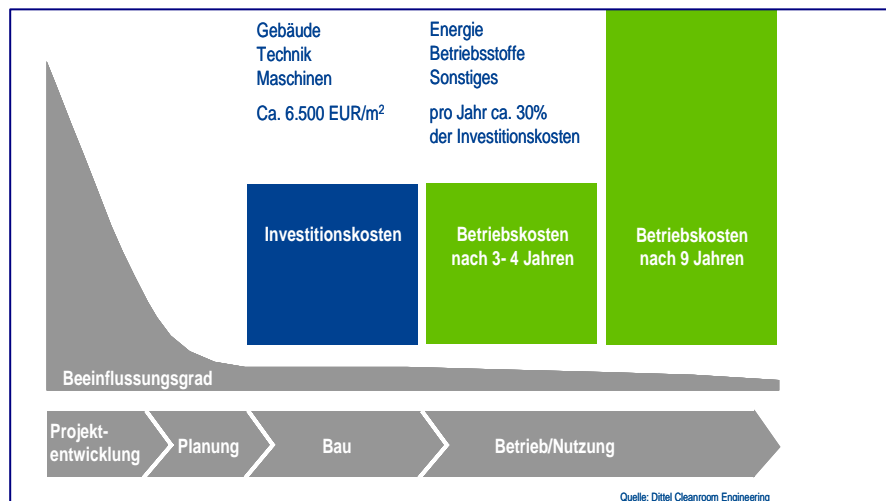


Fig 1: The operating costs reach the level of the investment costs after about 3 to 4 years.

Based on the development of injection moulding machines for clean room technologies, ENGEL can use systematic analysis and the optimisation of these factors to offer a machine design that can be used in clean room environments while being economical.

Systematic analysis and optimisation – risk analysis

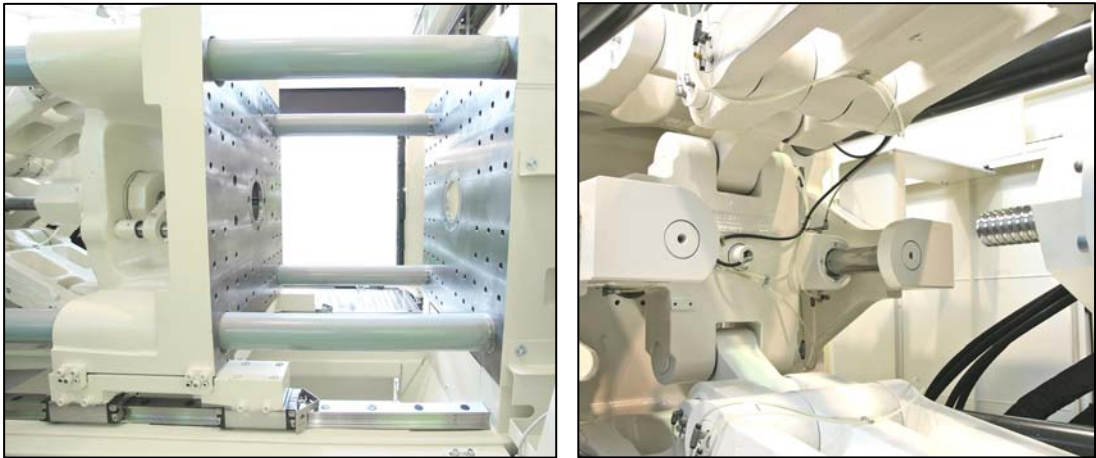
The initial position for any type of production in a clean room environment is represented by a risk analysis and the optimisation of the operating costs. The systematic recording of possible sources of errors and hotspots, as well as the definition and execution of necessary measures, lead to a solution that corresponds to the demands of the product. In addition to preventing contamination due to operating resources, minimising the heat and particle loads as well as ensuring clean-room capability play the most important roles in this regard. Within the framework of the development for using injection moulding machines in medical technology, ENGEL has defined a number of optimisation measures and then implemented them in the clean room machines:

1. Prevention of operating resource contamination

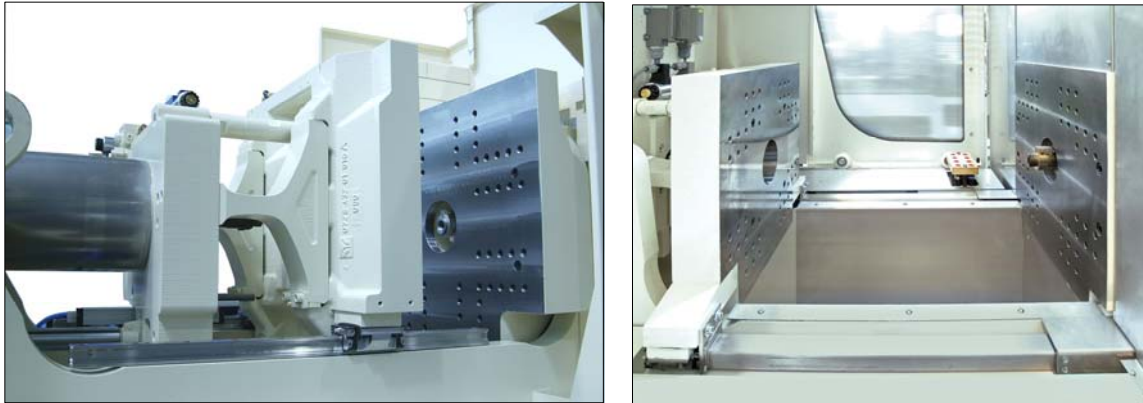
An important factor for machine development and its capability to be used in sensitive areas such as medical technology is the overall prevention of contamination by operating resources

such as greases, oils, refrigerants and so on. This is accomplished by the encapsulation and shutting off of neuralgic positions. A positive side effect of this measure is a perfectly “clean” visual appearance. An emotional component that plays a significant role in trusting the clean-room capability of the machine.

Even the basic models of ENGEL injection moulding machines, either with tie-bars or with a tie-bar-less clamping unit, offer perfect conditions for part production with minimal risk of contamination. Due to its tie-bar-less construction, the ENGEL victory machine series has decisive advantages. Tie bars, which can collect dirt, are not needed, and turbulence due to obstructive contours in the air flow are avoided. Furthermore, covered guide rails and a bulkhead to the injection unit protect the surfaces that contact and neighbour the product from contamination (Figure 2). In the case of high-performance machines with tie bars, such as the ENGEL e-motion T and the ENGEL speed, which are based on a common platform, the freestanding tie bars merely take on the function of transferring force; they run without lubrication, and therefore cleanly. Due to an oil return system on the toggle lever, any soiling due to lubricants is also prevented here, guaranteeing a clean appearance (Figure 3).



Figures 2 and 3: High-performance toggle lever machine: the tie-bars are lubrication-free and the plate contacts are large. An optional oil return system on the toggle lever prevents contamination by operating resources – the visual appearance remains perfect.



Figures 4 and 5: Tie-bar-less machine: a simple and robust concept that has been built 35,000 times. The guides of the movable plate can be displaced laterally and/or completely encapsulated, and the injection unit can be sealed off by a bulkhead.

2. Minimisation of the heat load

“Heat load” means the total energy that is emitted into the air of the clean room. Minimising the heat load in clean room machines is important as a lower cooling demand has a positive effect on the operating costs. The initial point is a qualitative analysis of the critical heat poles in a clean room using thermographs. This identifies the hotspots so that corresponding measures can be taken. In particular, the barrel is a significant source of heat (Figure 6). The heat load in a clean room can be reduced significantly using complete encapsulation. This GMP barrel extraction is supported on a dual-wall stainless steel pipe that prevents emissions from being released into the clean room. As a result, nozzle emissions and the hot air are captured without affecting the process and are passed on to an exhaust air system.

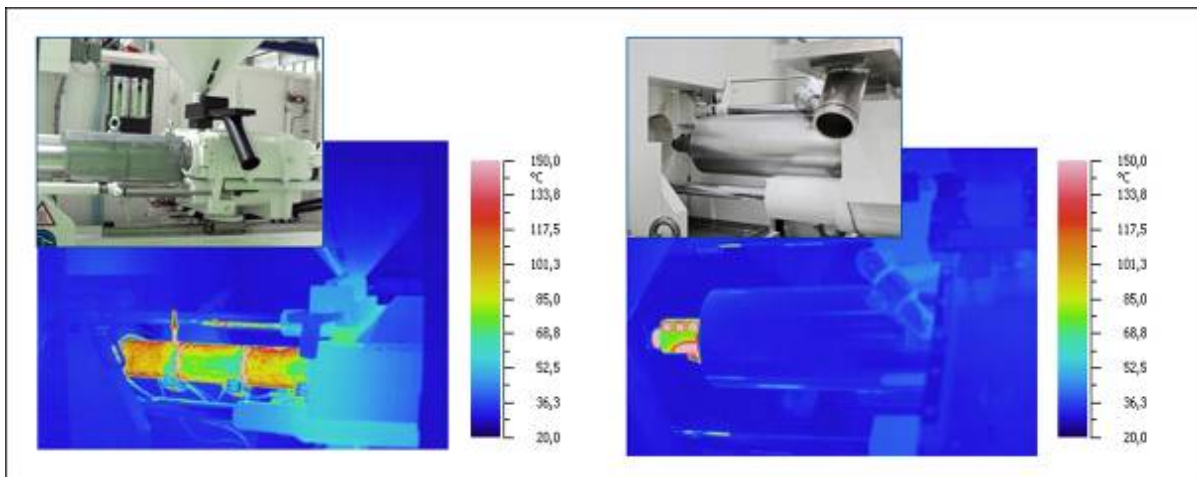


Figure 6: The GMP barrel extraction significantly reduces heat emission into the clean room.

On the other hand, a quantitative analysis such as the generation of an energy balance permits a direct comparison of the various machine designs. For example, if the energy flow

diagrams of a hydraulic ENGEL victory machine are compared to a fully electrically driven ENGEL e-motion, the difference can be clearly seen (Figures 7 and 8):

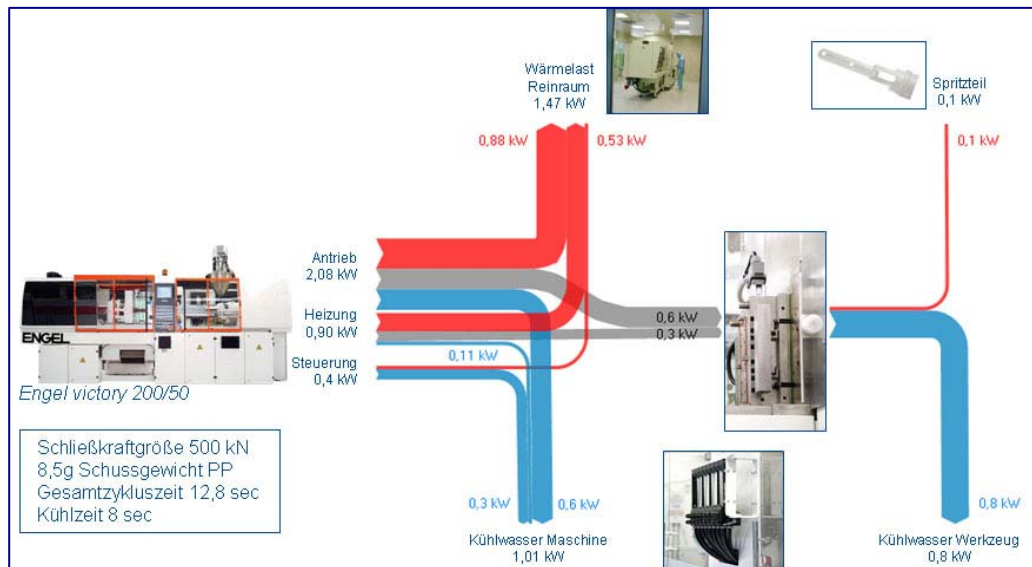


Figure 7: Energy balance for a standard fully hydraulic machine

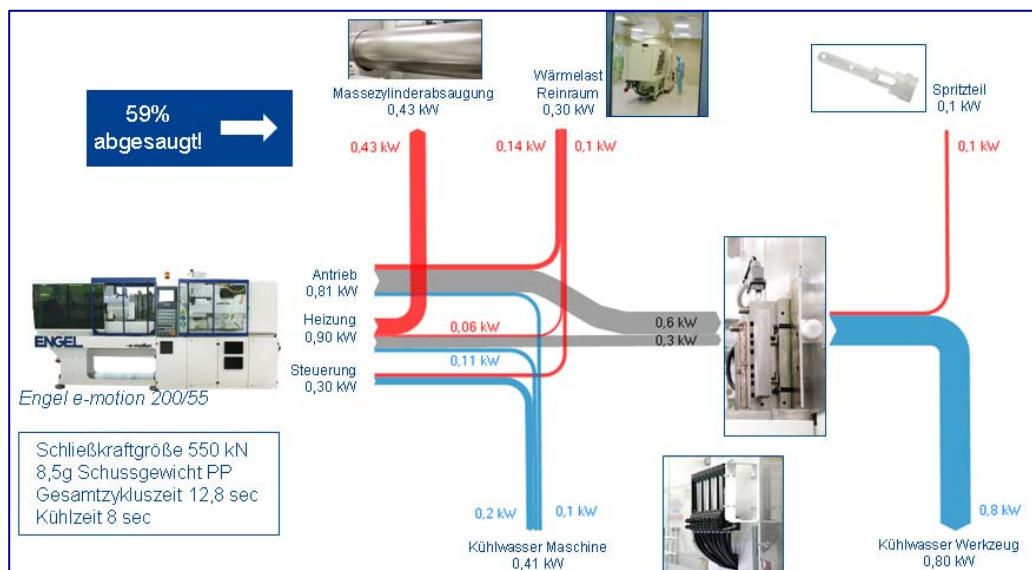


Figure 8: Significantly (approximately 0.67 kW) reduced overall heat load when using an optimised fully electrical ENGEL e-motion 200/55. Barrel extraction results in a reduction in the heat load of approx. 59% here.

This can be summarised as follows (Figure 9):

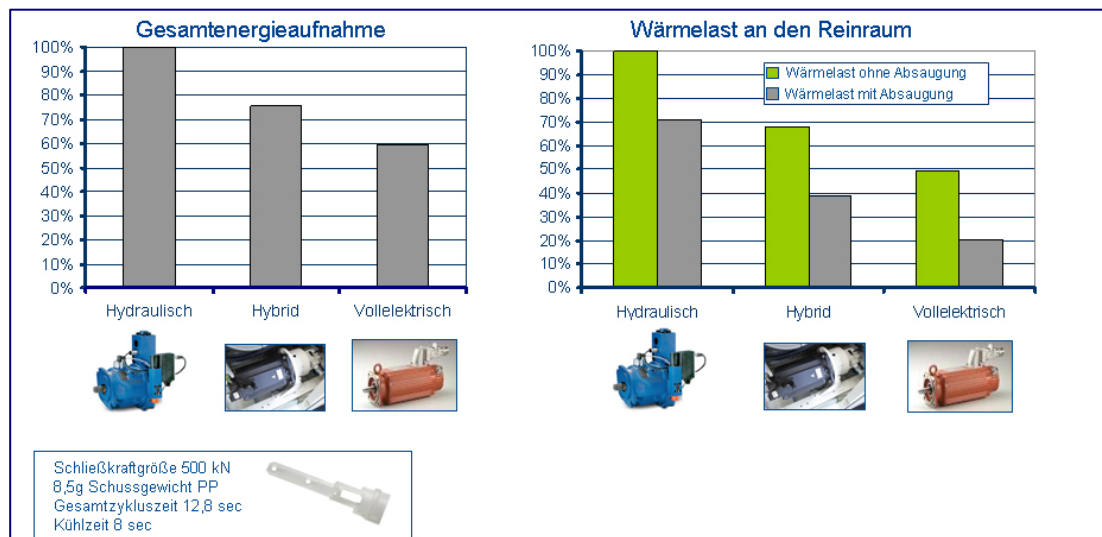


Figure 9: Energy balance in clean rooms. The selection of the drive system has a similar importance as the barrel extraction.

3. Minimisation of the particle load

What is probably the greatest challenge in clean room production is keeping the particle concentrations within the specified limit values while keeping the air exchange rate as low as possible. In clean rooms, the particle concentration is measured directly at the machine. For example, the open hydraulic tank of the standard machine represents a significant particle hotspot. The solution: encapsulating the oil tank using bellows (Figure 10). In this way, the entire hydraulics can work as a closed system. In addition the use of fan-free servomotors and GMP barrel encapsulation are important for preventing local particle emissions. The infeed of raw material to the plasticizing cylinder is also a possible source of particles due to the high proportion of dust.



Figure 10: Closed hydraulic system using a clean room-capable compensator bellows

When all these measures are implemented, the following result can be targeted in qualification measurements within the injection moulding machine (13 measuring points with

15 measurements each): in all the measurements, the maximum values relevant for satisfaction of the purity class were far below the purity class limit. Even with a comparatively low air exchange rate of 10 changes per hour preset in the clean room and with a warmed-up injection moulding machine in the dry cycle, the purity class ISO 7 was attained with ease (Figure 11).

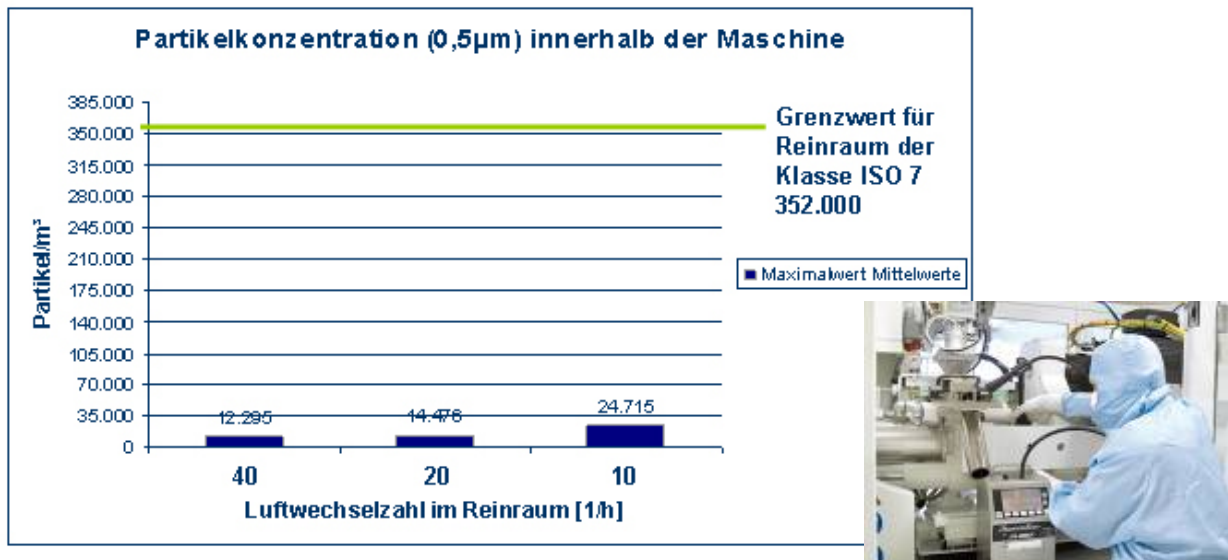


Figure 11: With a particle count of approximately 24,700 at an air exchange rate of 10 changes per hour, ENGEL clean room machines with complete optimisation are far below the permitted limit value.

In summary, it could be shown that specific analysis and optimisation could be used to identify and optimise potential risks when operating injection moulding machines. At the same time, this contributes to significantly lowering the operating costs of a clean room. A correctly optimised injection moulding machine provides a very low contribution to the overall loads of heat and particles.