



## STATISTICAL PROCESS CONTROL APPLIED TO ADDITIVE MANUFACTURING ENABLES SERIES PRODUCTION OF ORTHOPEDIC IMPLANTS

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**Abstract:** *Moving from prototyping to production is a major challenge for the Additive Manufacturing industry. It requires a robust and reliable technology with high and verifiable repeatability. The transition into production is not possible without the technology being capable of sustaining a high product quality as well as productivity at par or better than traditional manufacturing.*

*Electron Beam Melting (EBM) has since 2007 been used to manufacture CE-certified standard orthopedic implants, with more than 20.000 units produced in several EBM systems. High productivity combined with process stability have been key factors for this application to emerge. Added product value in the form of engineered surface porosity has been vital to promote the step into serial production.*

*Development of EBM has been focused on system reliability, process stability, material quality, productivity and means for process validation to reach proven requirements for production. Statistical process control (SPC) has been a very powerful tool to carry out this development in an efficient way.*

**Key words:** *EBM, production, implants, productivity, reliability*

### 1. STATISTICAL PROCESS CONTROL AND PROCESS WINDOWS

Statistical process control is the application of statistical methods to the monitoring and control of a manufacturing process, such as EBM, to ensure that it operates at its full potential. The point of statistical process control is to ensure that the resulting product reaches the required quality with the least possible scrap rate.

Statistical process control can be used to examine a process and the sources of variation in that process numerically to provide a complete understanding of the strengths and weaknesses in that process. In addition, statistical process control is a tool for increasing productivity by identifying improvements to the process so that it can become more efficient. EBM yield improvements coupled with build time reduction, has proven that statistical process control is a valuable tool for cost reduction.

Product inspection is utilized to ensure the final quality of produced parts. It is vital for maintaining the required production quality but it does not provide the necessary help for improvements. Statistical process control complements and goes beyond the scope of product inspection in that it is aimed at improving the production process, to some extent by systemizing the inspection results, but especially by linking those results to variations in the production process thereby revealing the couplings between process parameters and the quality of the product. When such links are revealed and presented in control charts, systematic improvements to the process becomes possible.

It is important to distinguish between common cause and special cause variations in a production process. All processes have inherent statistical variability which can be evaluated by statistical methods. A complex process can be under the

influence of variations of a large number of individual parameters.

Common cause variations of these parameters follow the normal distribution and it is therefore possible to determine the mean and the standard deviation of, not only each of those parameters, but also of the combined result of the parameters. This makes a process under the surveillance of statistical process control predictable in the way that it is possible to foresee quality variation and scrap rate of the produced commodity.

Special cause variations are such that are not previously observed and non-quantifiable. It can for instance be due to malfunction or degradation of the system functionality, changed skill levels when changing system operators, raw materials of lower quality or changes in peripheral conditions such as electrical power stability.

Statistical process control makes it possible not only to determine if reduced product quality has occurred but also to pinpoint the root cause in an efficient way in order to take action to rapidly bring back the process to normal conditions.

### 2. PART VERIFICATION AND PROCESS VALIDATION

For critical life-sustaining parts, such as orthopedic implants and aerospace components, the focus on parts quality is meticulous. Material quality such as tensile strength, hardness and fatigue can, in worst case, jeopardize the lifetime of an implant or the safety of air passengers. Such parts are therefore subject to scrutinous post production inspection.

Although a considerable amount of information on material quality can be determined by non-destructive testing, such part verification cannot completely cover all aspects of part quality control regardless of manufacturing method. For such critical parts it is thus necessary to conduct quality control based on the link between process stability and part quality. Such process validation, in which the process is required to comply with the process window, is accomplished by statistical process control.

A way to define and implement the method of process validation is to:

- (1) Develop optimum system parameters by optimization combined with evaluation of the product quality.
- (2) Make a statistical evaluation of the part quality variation over a sufficient amount of production runs with fixed system control parameters utilizing destructive testing of produced parts to verify that common cause variations are always well within the process window that fulfills the product specification.
- (3) Use statistical process control to ensure the absence of special cause variations in each production run.
- (4) Implement strict quality control on all conditions outside the system control parameters such as raw material quality, operator routines, system maintenance and support systems.

For additive manufacturing, geometry dependence is an important variable. Part quality in present additive

manufacturing systems is inherently dependent on part geometry and the way to ensure the required process validation for multiple geometries is in principle to perform the method of process validation defined above for each individual geometrical part in production. However, for certain variations in part geometry it is clearly possible to define classes of geometries in which the validation is valid.

To determine the validity of the process validation it is also necessary to incorporate a representative sample of various geometries under the statistical evaluation in the process validation method. As additive manufacturing technologies develops and matures, it will become possible to verify the robustness of the processes to the extent that validation will be valid for a large span of geometry variations.

### **3. EBM PROCESS STABILITY**

EBM has been developed into an additive manufacturing technology of, primarily, titanium parts. The first commercial EBM system was delivered to a customer in 2003. Initially, most EBM users were either academia or research departments in commercial organizations. Already from the start, EBM was focused on production, a high build rate combined with excellent material quality of manufactured parts have thus been main targets for EBM development. This focus is still valid.

In late 2006 the first EBM system was delivered to a manufacturing company in the implant industry for the purpose of serial production of acetabular hip implants. This delivery was soon followed by several more systems for the same market application. Since the beginning of serial production with EBM, statistical process control has been implemented to evaluate the yield and the process quality of the EBM process.

It has, furthermore, been used for continuous improvements to the EBM technology since then. Arcam's R&D Dept. has been guided by the result of statistical process control of systems in serial production, and the focus of development has been to increase system reliability to achieve an increase in system yield and to ensure that the quality requirements of the produced acetabular hip implants face up to the specification requirements without exceptions. The EBM system reliability in implant production is today above 95%.

The strongly improved system reliability enabling high system utilization and predictable production volumes have been key factors for the success in developing this additive manufacturing application into serial production. Further evidence of the reached production worthiness of EBM is that there is now also a hip stem and a spinal cage on the market. Both these products benefit from engineered surface porosity and are being implanted in patients on a routinely basis.

### **4. EBM TECHNOLOGY DEVELOPMENT PERFORMED**

Statistical log files evaluation, evaluating the main causes for system failure in production, has provided valuable insight into the main contributions to EBM system reliability. These main causes, which are typically of the special cause variation type, have been identified and largely removed by means of dedicated R&D efforts followed by system upgrades. One cause discovered in this way was repeated failures of the linear bearings in the powder distribution system.

This sub-system turned out to have a strongly elevated risk of malfunction in the vacuum environment combined with titanium powder which caused early failure of the bearings. A dedicated project found the remedy in optimizing the use of specially developed vacuum grease for the bearings and defining adequate service intervals. The occurrence of linear bearing failure has virtually disappeared since this improvement was implemented on the production systems.

This is an excellent example of a substantial improvement to EBM system reliability made possible by means of a combination of statistical process control and R&D efforts. Over the last few years a number of other special cause quality issues have been found, investigated and corrected using statistical process control.

Another development performed to increase system reliability is interesting, since it has addressed a common cause variation type. This means that it did not correct a problem directly causing a system failure but instead it corrected a variation causing a reduced process window thereby affecting system yield.

A physical effect of using an electron beam as energy source in the melting process is the creation of localized surface charges in the vicinity of the electron beam interaction region. These charges are distributed over a limited amount of metal powder particles in a highly dynamic physical process. As the charging of metal powder particles proceeds, there exists a limit to the charge density over which the repulsive force between charged particles can overcome the gravitational force normally keeping them in place in the powder bed.

As this occurs the result is a rapid re-distribution of a substantial amount of powder particles from the powder bed. This in turn creates an elevated risk of system failure due to powder contamination of the electron gun. Traditionally this effect has been avoided by sequential increase of the electron beam power while rapidly scanning the electron beam over the surface to facilitate pre-melt powder sintering, thereby increasing the electrical conductivity over the powder bed leading to avoidance of powder re-distribution when melting is initiated.

An R&D project targeting this issue developed a "controlled vacuum" functionality that allows for a controlled leak of inert gas into the vacuum build chamber of the EBM system. As the inert gas interacts with the electron beam above the powder bed, positive ions are created. These ions experience an attractive force towards the negatively charged powder particles, the strength of the force scaling with the amount of electrical charging of the powder particles.

The ions are thus accelerated towards the surface and annihilate negative charges as they come in contact with the powder bed surface. This is a repetitive process since the resulting inert gas atoms can undergo the same ionization and powder bed charge annihilation process over and over again. Since this feature was introduced on EBM systems it has not only improved productivity due to the reduced need for the time consuming gradual electron beam intensity increase, but has also provided an enlarged process window thereby improving yield in a significant way.

### **5. FUTURE IMPROVEMENTS**

Although a number of strong improvements have been made to EBM to promote serial production, there is still a focus on further improvements. Projects are ongoing to improve beam-material interaction and electron beam scanning strategies.

Another area where EBM can still improve is in process surveillance. Since EBM is a hot process, thermal dynamics in the melting strategies strongly affect the quality of the process. IR-camera integration opens up for advanced layer-wise inspection of heat distribution and defect control during build.

Extended process surveillance will further improve the ability to use statistical process control in an efficient way, making EBM an even more mature technology for serial production. As EBM is on the way to become a manufacturing technology also for turbine blades for commercial aircraft engines, the integration of extended process surveillance and statistical process control will be of the utmost importance.