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Press release

New options for efficient medical device production

Kistler presents update to the process monitoring system maXYmos TL ML

Winterthur, December 2022

An update to the process monitoring system maXYmos TL ML from Kistler is now available worldwide. The new version 1.8 allows medical device manufacturers and plant builders in the sector to further simplify user management and increase measuring accuracy. Launched in 2020, the maXYmos TL ML is the first system to enable effective process monitoring that is compliant with FDA and MDR regulations. The update maintains this regulatory compliance and other proven features while offering additional advantages such as the new sensitivity correction functionality, the improved audit trail function and a master administration system.

Like few other industries, the medtech sector is subject to strict regulations, with high requirements for product safety, quality management and process validation. The introduction of the world's first FDA- and MDR-compliant process monitoring system thus met an urgent need of machine and plant builders as well as manufacturers in the medtech industry: maXYmos TL ML is used all over the world to improve the production quality of medical devices during joining and assembly processes and in testing procedures. In addition, its new features, such as the new sensitivity correction functionality, the improved audit trail function and a master administration system render it useful for other industries as well. Especially in sectors that depend on precise measurements, reproducible processes and full traceability, the system can prove its advantages.

Specifically designed for the medtech and pharma sectors

The maXYmos TL ML system is integrated directly into the production line. It allows for measurements at exceptionally low ranges and can deliver 100-percent-testing during production – a critical requirement for manufacturers of medical devices, as it can eliminate the need for mandatory process validation. A further highly appreciated feature is the direct batch release. This function allows users to quickly switch between different batches with no additional quality assessment and validation. The function is based on a library of evaluation objects (EOs), a set of predefined tolerance boxes for good parts. The system gives the user the option to pre-qualify a set of EOs for each type of part that can be selected when batches change.

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New enhancements to the FDA- and MDR compliant audit trail

The latest version of the maXYmos TL ML features a revised audit trail functionality. End-to-end traceability of each individual product is a further regulatory requirement in medtech. Via the audit trail functionality, the maXYmos TL ML monitors and records all changes to the testing device, including the indexing of time and user. The audit trail provides a standard solution in accordance with FDA and MDR regulatory demands. The feature also facilitates the mandatory archiving of the log files, as data can either be exported, for example to PDF files, or printed. Above all, the audit trail reduces audit-related efforts considerably.

The update includes a convenient search and filter function for the logged files on who changed what, when and why. The data is saved directly on the device and can thus be conveniently accessed by authorized staff. To provide a high level of security, access is restricted to users with admin rights. In addition, Kistler has optimized the system login for users. Often, several machines at a plant demand logins, which can be laborious for users. To facilitate a single sign-on to all systems, Kistler developed a master administration system.

New feature: sensitivity correction

The new version 1.8 also comes with a sensitivity correction functionality. In-line process monitoring entails the challenge that measured values tend to slightly deviate from the realistically applied forces. This can happen due to the way the sensors are mounted in the machine or interferences resulting from adjacent cables. Eventually, this can lead to a minimal offset between the indicated values and the actual forces. Obviously, these deviations are potentially relevant, especially in medical device production, where machines usually operate at lower force ranges. Sensitivity correction compensates these biasing factors: The function allows users to define up to 31 support points on a non-linear curve that represent the swing of a real force. After measuring, they can be compared to the results from the force sensors. Based on these insights, users can fine-tune the force ranges and thus match the measurement chain to its environment in an optimal way.

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The maXYmos TL ML from Kistler is the first system to enable effective process monitoring in medical device production that is compliant with FDA and MDR regulations. (Copyright: Kistler group)

The maXYmos TL ML is integrated directly into the production line to monitor and evaluate the quality of any given manufacturing step. (Copyright: Riegler)

The maXYmos TL ML visualizes process curves on a monitor and automatically separates bad from good parts. (Copyright: Kistler group)

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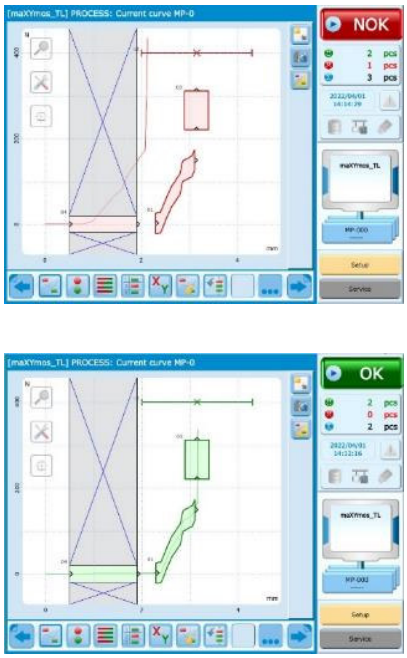

If a curve leaves an evaluation object at an undefined point, the respective part will automatically be qualified as bad part (NOK) and consequently be dismissed. A set of evaluation objects (EOs) serves as a model for good (OK) parts. The maXYmos TL ML can save a library of EOs for various types of parts to enable a release of batches with no additional validation. (Copyright: Kistler group)

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About the Kistler Group

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