

Foolproof automated inspection transforms medical manufacturer's quality control



High process capability supported in plastic injection moulding



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Peter Makosa, Quality Manager, Alltrista Plastics

The two CNC coordinate measuring machines (CMMs) Alltrista Plastics had been using 24/7 for more than 10 years at its Christchurch, UK factory had become inefficient. The accuracy and repeatability of touch-trigger probing were becoming compromised due to the age of the machines. The software would sometimes crash, risking a physical collision, damage to the probe and perhaps even to the component being checked.

As the plastic medical parts and assemblies produced had become more complex over time, an angled stylus was often required in an inspection cycle, so an operator had to choose from half a dozen pre-set probe configurations, mount one manually and calibrate it. Additionally, the person would have to sort through different programs on a computer screen to identify and load the correct one.

This whole process has been streamlined and automated with the installation of two new Altera S 10.7.6 CMMs manufactured by LK Metrology in Castle Donington, UK. The supplier's CAMIO 3-axis scanning and reporting software was also provided along with a Renishaw

SP25M scanning probe and PH10M motorised indexing head. It is in effect two sensors in one, enabling continuous path tactile scanning as well as touch-trigger probing of discrete points. Together with a Renishaw matrix plate to allow accurate placement of parts for inspection, the set-up has resulted in a vast improvement in metrology productivity by facilitating fixturing of samples, speeding measuring cycles and virtually eliminating human intervention and the attendant risk of errors. It would not have been feasible to retrofit scanning capability to the older CMMs, as the cost would have been prohibitive and in any case the machines were becoming obsolete.

Alltrista's quality manager Peter Makosa said, "I operated LK CMMs for several years when working for an aerospace manufacturer, which had standardised on their use. When Alltrista decided to upgrade its quality room, we approached four potential machine providers including the incumbent supplier. LK's response was by far the most comprehensive.

"It carried out an online demo on one of our parts and another trial when we visited Castle Donington. It was the only company to initiate a

comprehensive on-site survey at our factory to check the feasibility of machine installation.

“On the basis of the measurements taken, bearing in mind that LK machines are taller than our previous CMMs, the manufacturer offered to reduce the height of the Altera S models during their build so they would fit comfortably through

our doorways and in our refurbished inspection room.

“What finally clinched our decision to opt for this supplier were the favourable price of the equipment, the knowledgeable engineers that dealt with us throughout the entire sales process and the company’s reputation for good after-sales service.”

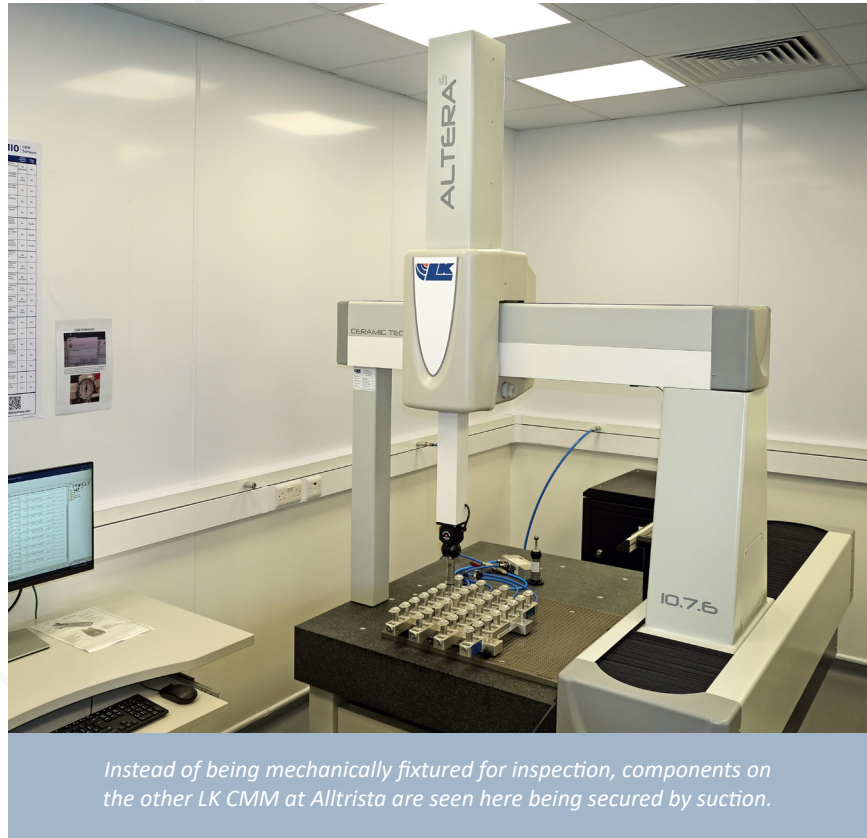


Peter Makosa setting up one of the reduced-height LK Altera S CMMs in the temperature controlled inspection room at Alltrista’s Christchurch factory in the UK.

The Christchurch site is one of five Alltrista manufacturing locations, notable for being the first facility within the holding Jadex group to be powered entirely by renewable electricity. The ISO13485-accredited firm specialises in plastic injection moulding of devices such as drug delivery systems, and packaging such as contact lens blisters, for the medical, pharmaceutical and nutraceutical industries.

The injection moulding machines are mainly housed in one Class 7 and two Class 8 clean rooms. Medical devices are increasing as a proportion of turnover as well as in variety and production volume, climbing over the past decade from 30 to 50 percent of throughput and still rising. Another trend is towards ever tighter drawing tolerances on newly designed products and more stringent GD&T (geometric dimensioning and tolerancing) requirements.

A rigorous validation process underpins the manufacture of all products at the Christchurch facility. Typically at the outset of a new production run, 30 shots containing, say, 15 components each will be run off and checked, with customers requesting a process capability of at least Cpk 1.33 and often 1.67 or 2 (six sigma). Tolerances are generally fairly open on plastic items, normally in the range 50 to 100 microns, but any inaccuracy of measurement is undesirable, as it would consume part of the tolerance band. Even more important for validation is a high level of repeatability.



Required also by Alltrista was more data to better understand certain features on mouldings, such as the flatness of sealing faces, freeform profiles and chamfers. The use of a Renishaw scanning probe has resulted in an order of magnitude more information to feed back to the production department for fine-tuning toolmaking and manufacturing.

It also makes for a much richer report for customers to understand in more detail the manufacture that is being carried out on their behalf. Furthermore, the layout of the reports is much better now, as the previous open Excel spreadsheets have been replaced by locked PDFs generated in CAMIO. They include a colour-coded part-to-CAD comparison showing product conformance, with all the accompanying data, Alltrista logo, date and time.

When the CMMs were installed, LK wrote core programs for inspecting components for four major Alltrista customers and also devised a PC screen dashboard so the whole process is menu-driven. The first screen displays an icon for each customer, which when clicked reveals every part that is injection moulded for that company. Clicking on the appropriate icon automatically sends the program to the CMM, whereupon the operator keys in their name, whether it is a standard or first article inspection report that is needed and clicks start.

Before the program can be run, however, an array of components has to be placed in a known position on the granite table. To facilitate and speed the procedure, LK supplied a Renishaw matrix plate with each Altera S 10.7.6. At no extra cost, anchor bolt holes were drilled into

the granite at non-standard centres so the plates could be secured from underneath, avoiding retaining clamps projecting from the table surface. Included on-screen in the dashboard, alongside the relevant inspection program, is an SOP (standard operating procedure) showing the operator the exact location across the numbered grid of holes on the matrix plate that the batch of fixtured samples should occupy.

Nobody will ever say that human fallibility can be removed entirely, but this system of positioning components correctly and accurately coupled with LK's CAMIO system for program instigation, CNC

inspection and automatic reporting comes very close to eliminating all potential errors. Having used the new quality control process since March 2022, Mr Makosa describes it as "foolproof".

The Altera S controllers and CAMIO software were supplied to accept data input from a laser scanning sensor in the future should Alltrista decide that the increasing complexity of its plastic devices requires this further upgrade. For now, though, tactile scanning and touch probing, including with a multi-tip stylus to access the underside of components without probe change, provides sufficient capability and capacity.



About LK Metrology

LK Metrology is renowned for innovative metrology solutions and services. The company's products, including coordinate measuring machines (CMM), portable measuring arms and metrology software, are used worldwide to control and improve the quality of manufactured components. Its precision technology underpins the process chain from design, development, production and assembly through to quality assurance in global industries such as automotive, aerospace, defence, motorsport, energy, medical and contract inspection.

Established in England in 1963, LK Metrology has an impressive heritage in metrology dating back to the birth of CMM technology. Founded by CMM pioneer Norman Key and his father-in-law Jim Lowther, LK Metrology is credited with many of the CMM industry's firsts including the first bridge-type design, first OEM to integrate computers, first to use a touch trigger probe, first to develop inspection software, first to use all air bearings and granite guideways, first to use carbon fibre composite spindles, first to use microprocessor-controlled drive systems, first to produce a truly thermally stable CMM and first to produce a high-accuracy horizontal-spindle CMM.

In 2018, LK Metrology was relaunched as an independent CMM manufacturer after several years as a division of Nikon Metrology. Headquartered in the UK, LK's CMM development and production are at the company's facility in Castle Donington. Sales and support offices are located in the UK, North America, Belgium, France, Germany, Italy and China, supplemented by a worldwide distributor network.