Medical Automation Novelty from Waldorf Technik

Safety x 96

Injection needle head holders or canule tips, so called hubs for insulin pens, with a diameter of 10 mm and a length of 12 mm, possess only a small hole in which a needle is inserted later. For these hubs a Scandinavian customer ordered an automation system that had more to offer than available on the market to date. Not only should the medical parts be removed from the tool of the injection moulding machine but the parts should then be cavity sorted and undergo an extraordinary stringent quality control check that is divided in two sections. Especially difficult – 96 cavities each! This is a welcome challenge for Waldorf Technik GmbH & Co. KG, the specialist for high speed robots & automation for the injection moulding industry in the medical and laboratory markets, based in Engen in Southern Germany.

Follow-up order thanks to customer satisfaction

The Scandinavian order is a result of Waldorf's customer references. Already seven years ago the company received a first order from a Scandinavian customer for a sophisticated project. Since then all further projects have been concluded to the highest customer satisfaction and when the new hub project was placed the German company won the contract. The demands were extremely unusual. The hubs are manufactured with 96 cavities inside the injection tool. Therefore, Waldorf developed 96 vacuum circuits and 96 vacuum control circuits as well as two separate quality control systems. As per the slogan "Everything is possible" the performance conditions were examined as for their physical restrictions for the system and the best possible compromise was found in discussions with the customer. Christian Boos, Engineering Director, explains how the outcome of these discussions is working today on site.

Inherent quality control

„The hubs are produced in 96 cavities in the hot runner tool with a cycle time of 6.5 seconds. Our task is to remove the parts as fast as possible, to sort them in clusters and to transport them into intermediate containers. A cluster, these are sub divisions in the hot runner system, feeds six parts each via one sub divider. Subsequently a sub division contains six hot runner nozzles and there are 16 sub divisions inside the tool. That means, we remove the parts and place them in groups of six parts into corresponding temporary containers." The background for this procedure, explains Boos, is the critical hub needle location hole, which is blocked in case of a core breakage. Result: the needle can no longer be inserted, i.e. the whole production batch could not be used. However, the system of 96 cavities allows isolation of the defect cavity and to continue with the production of the other 95 cavities. In this way, the defects can be reduced within the corresponding cavity group to an absolute minimum and the shift work can continue to the end or to a scheduled stoppage without interruption.

1.3 sec time window

The servo motor driven main axis of the removal robot drives – "pre-synchronised" to tool opening time – towards the cavities in less than 0.4 sec. De-moulding is done pneumatically. Immediately afterwards the vacuum control starts. After a positive re-

sult, the gripper drives backwards; in parallel the tool closes for the next cycle. “We suck with vacuum and control with vacuum, this assures that in fact all 96 hubs end up in the gripper”, adds Boos. The speciality of this system is that each single cavity possesses a vacuum as well as vacuum control circuit. It is a novelty to be able to control each of all 96 cavities. The time window for the whole application is only 1.3 sec. The influence on the cycle time can be reduced to a minimum. This is more astonishing as the time consuming process of the ejector function of the gripper is included in that time.

Redundancy for continuous production

When all parts have been removed from the gripper, the gripper moves to the start up position in order to eject the faulty parts (if need be) over a belt, which moves these parts into special containers for further removal. The second position is set down position 1 over carriage 1; the third position is set down position 2 over carriage 2. Boos adds “Reason for this is that if position 1 reaches the desired number of parts the machine can not simply be stopped. Therefore, the gripper moves to position 2 automatically. The system tells that carriage 1 is ready for exchange. The operator can request the carriage, the carriage is unlocked, and the operator can replace the containers. This brings autonomy within the two carriages with the security of continuous production.” The carriages were specially designed for the hub project so that the operators (mostly female workers) can handle them easily. Equipped with carriage and steering wheels and a special brake locking system the removal process has been very much facilitated.

Double quality assurance

The quality assurance methods in the medical sector can never be sophisticated enough. Hence, the set down process includes already two different quality control systems. The first one is a “draw” that over rides set down position 1 and moves all 96 parts – sorted per cavity – on to a panel. Independent from the production process the operator can remove the panel and check its content for correct dimensions under a microscope. This happens in regular intervals with the last shot before the carriage exchange, reports the Waldorf Engineering Director. If all 96 parts are as expected the whole carriage content is given the all clear. If one part is faulty, the operator knows which hub requires sorting out of which group and cavity. Should a core breakage happen, the single cavity could be switched off immediately. One faulty part is acceptable in relation to whole production batch sizes of e.g. 5,000 to 10,000 parts of one generation. The second quality control system demands several shots in a row for spot checks. The “draw” over rides set down position 2 in order to remove five shots, not sorted by cavity but placed together in a separate container instead. The quality control department will check these parts according to the latest examination regulations for medical products.

Cleanroom, Ionisation and High Spec PLC control

In case of a fault, if either a cluster of 6 or only a single cavity needs switching off – the operator uses the touchscreen of the Allan Bradley control unit. The customer insisted on a control unit of this brand, as many worldwide operating companies do rely on them. A Euromap 67 interface connects the control of the injection moulding machine and the automation control. Boos explains that the material itself, the polypropylene, did not really influence the system’s engineering, however the material’s side

effects during the production process did instead. “An example is static loadings. Therefore we integrated a complete package of ionisation applications. They are placed e.g. at the drop-down chutes of the system in order to reduce the static loading of the product to a minimum”. To ionise the whole system would not have made much sense, however, cleanroom conditions do apply. The system environment is only accessible through doors with corresponding clothing and hygienic precautions for the personnel, emphasises Boos. Lubricants are only used underneath the production level or within a closed system and are always approved to FDA standards. The system is already set up on site at the customer to cleanroom standard 10,000 and is currently running only for validation purposes.

Factory acceptance test and after sales service

Before shipping and installation in October 2007 the system was running its pre factory acceptance test at the Waldorf site in the customer’s presence. The system had to run smoothly without parts for a minimum of two to three hours in order to make sure that it runs perfectly. “In this case we “married” the automation system straight afterwards with the injection moulding machine and the tool. The Swiss injection moulding machine manufacturer coordinated this process. A factory acceptance test followed in Näfels together with the customer. This enabled us to run the test under real working conditions” adds the chief engineer. “During start up when machine, tool and automation run together for the first time there is always further optimisation taking place. As all Waldorf systems are specially developed bespoke units there is nothing comparable available. Some small problems are only apparent during operating conditions however, the test enables us to eliminate them before the system leaves our plant.” Nevertheless, should questions be raised in Denmark that cannot be answered on site, the customer will profit from the after sales service. For first assistance, there is the Waldorf Technik Telephone Hotline which connects direct to experienced staff, mostly Mechatronic or Electronic Engineers. Additional, specialists are always in the position to connect direct to the system via Internet and Interface (over every distance) and to find errors, analyse the situation and even perform changes (in agreement with the customer) in remote mode. Should this not bring the desired effect, a Scandinavian cooperation partner, Saxe Hansen, is able to send out their Waldorf trained’ specialists for further assistance.

Warranty and Change of Operation

The warranty for the systems is provided in accordance with legal regulations as well as per contractual agreements. In case of the injection hub system the warranty is valid for one year respectively 5,000 operating hours. For this the customer has to comply with the maintenance regulations which are explained in the technical documentation. Only twelve months passed by from the customer’s enquiry, which was based on a 50 page long project specification requirement description, to the commissioning on site in Denmark. The assembly itself took five to six months. Should the customer wish to change the system for the production of another part in a few years, possibly a family tool, this could be realised without enormous expenditure.

Press-Information

Photos: Waldorf Technik

1 – before delivery the system is put to the acid test
2 – the automatic removal has 96 vacuum circuits for the transport of the Hubs
3/4 – the 96-cavity separation ensures that the quality of the hubs is assured and verifiable
5 - system layout
6 - 96 control circuits for single deposit

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