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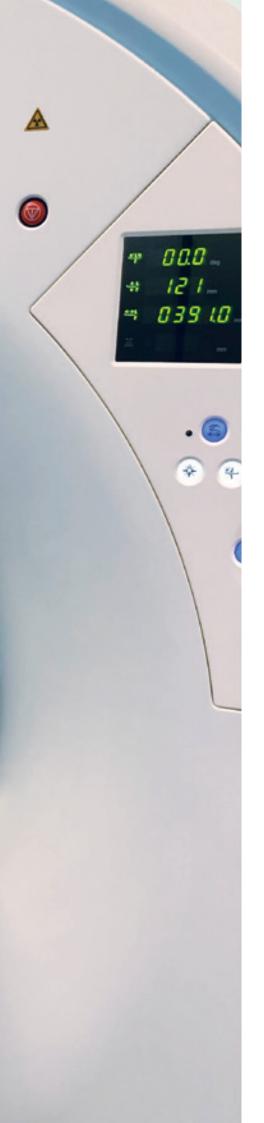
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Canon





## How Hygienic Positioning Aids are Simplifying Work Processes during the Pandemic

Extraordinary times demand extraordinary special measures. It is no accident, therefore, that Canon Medical Systems Europe entered into a partnership with Pearl Technology AG early in 2019 to make sustained improvements to important aspects of hygiene in their positioning aids – no accident, but rather a mix of fortunate coincidence and wise forethought. And then suddenly, along came COVID-19 and speed was of the essence!

ince the start of COVID-19 and even before then, hygiene has been vitally important in protecting colleagues and patients in the field of medical radiology. Radiology is different from almost any other hospital department in terms of daily visitor numbers, with very large numbers of both in-patients and out-patients attending. This fact presents enormous challenges for the specialist medical staff, and the tools and aids used are under a great deal of pressure in the effort to ensure ideal hygienic standards at all times. With up to 80 patients passing through a CT scanner on any given day, the intervals available for appropriate cleaning and disinfection are very short indeed. On top of that, the sheer number of cleaning procedures and the ever more aggressive disinfectants place the surfaces of the tools and aids under a massive strain. To make matters even worse, the nature of some of the commonly

available positioning aids is simply not compatible with economical and hygienic working practices.

Conscious of all of this, back in January 2019, the CT team at Canon Medical made a plan with Pearl Technology AG to work together, with the close involvement of customers and users, to set new standards in the area of patient positioning and with a particular focus on hygiene. After more than ten years in this market, Pearl Technology AG has become a leading provider in Europe for patient positioning equipment in radiology. Using high quality materials and a range of technologies, it covers the entire spectrum with products that can withstand the demands of modern and highly maybe "busy" radiology departments. Today, Pearl Technology's product range comprises six product lines including, for example, the PearlFit positioning aids for MR, CT and other fields.

## "We no longer have to make compromises between secure patient positioning and the hygiene guidelines."

Dr. Sascha Alexander Pietruschka, Head Physician at the Dietrich-Bonhoeffer Klinikum (Clinic for Radiology and Neuroradiology), Germany

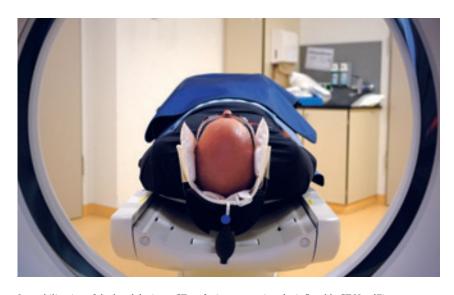


In an initial stage, several expert interviews were conducted. These confirmed very clearly that with existing positioning aids, the issues of hygiene and patient safety were in urgent need of sustained improvement.

Dr. Sascha Alexander Pietruschka, Head Physician at the Dietrich-Bonhoeffer Klinikum (Clinic for Radiology and Neuroradiology) in Germany, commented: "Hygiene is of particular importance in patient examinations. Even in the past, the fact that we were dealing with multiresistant pathogens made it necessary to stick closely to guidelines on hygiene. Regrettably, with the tools and aids generally supplied by the manufacturers, this was and is impossible. The belts that are necessary to ensure that patients are securely positioned were made of fabric, with hook and loop fasteners. It is impossible to prevent contamination of these fabric belts and then to return them before re-use to a condition in which it can be determined that pathogen thresholds are not exceeded. Given that we have 10-15 minutes between examinations and that the necessary disinfection of the belts by immersion and drying takes 24 hours, you would

need to keep a stock of 40 belts in a department such as mine, and having your own logistics for preparing the belts would be a must." In addition to this, it rapidly became clear that a perfectly fitted cover for the table mattresses was required, with wings to prevent fluids passing from the table onto the base and with material properties to prevent it from getting caught as the table passed through the gantry.

Once CT belts and mattress protectors had been identified by customers as the top priority, Pearl Technology AG immediately launched into development of the first prototypes. In consultation with Daniel Barion, CT Product Manager for Germany, these were distributed to key customers back in March 2019 for testing in their daily routine. The improvements and design adjustments that emerged from this testing were discussed with a number of experienced, knowledgeable, application specialists at Canon Medical. Allowing the enormous technical knowledge gained from decades of application experience at Canon to be brought together. In addition, direct dialogue was sought with other Canon customers during the German user meeting in Berlin in November 2019, and this was used for an intensive exchange of thoughts and ideas.



 $Immobilisation\ of\ the\ head\ during\ a\ CT\ perfusion\ scan\ using\ the\ inflatable\ CT\ Head\ Fix.$ 



Arms-over-head positioning for thoracic/abdominal examination using ProBelt on the Aquilion Lightning.

To conclude this process, revised prototypes were being used by customers for 'real life stress-testing' by the end of 2019; these fully lived up to requirements in terms of hygiene, handling and durability, while the materials selected ensured that they did not affect image quality in any way.

Then, in January 2020, the world began to turn upside down and by March 2020, it was obvious to everyone in Europe that COVID-19 would change everyday life, including life at the radiology departments. At the early stages, computerised tomography came sharply into focus for the diagnosis and therapeutic monitoring of COVID-19 patients. Exceptionally strict disinfection processes (some involving 70% alcohol), long 'blocking periods' (up to 90 minutes in cases where COVID was suspected) and more explicit zero tolerance with regard to cleanliness and hygiene all pushed the equipment and staff to their limits.

Thanks to this timely collaboration, as COVID-19 reached its peak all that was needed was to turbocharge regulatory approval and production. The instructions for use included with the products, for example, were translated into some 20 languages and approved in a very short space of time, to ensure that customers in all the countries from Portugal to Georgia had access to the newly developed solutions. In early September 2020, the first of the ProBelt and CT Table Covers were delivered to customers.

"Within eighteen months, we had gone from a product idea to the Europe-wide launch of the products. For medical devices – even if only in Class 1 – that is something like the speed of light. This was only possible thanks to our years of specific experience in patient positioning as well as the huge support of and reliable collaboration with Canon. Direct access to Canon users during development and very detailed feedback about the daily routine allowed us to develop

a very high quality and tailor-made product incredibly quickly. So the 'voice of the customer' was ever-present," said Dr. Thomas Müller, co-founder and General Manager of Pearl Technology AG, reflecting on the development work.

The ProBelts and CT Table Covers, like all products from Pearl Technology AG, are made from polyurethane film, which allows regular wipe-down disinfection even with 90% alcohol without the surface of the material becoming brittle or porous.

The ProBelts allow the patient to be secured in a stable position using eyelets and hooks, without the use of hook and loop fasteners, and raise cleanliness and hygiene to a totally new level. All six of the CT Table Cover versions for the various CT tables were developed in colours matching the Canon CT units, making the close collaboration immediately visible and ensuring that for the customer, everything is visually from the same mould.

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## "Direct access to Canon's users allowed us to develop a very high quality and tailor-made product incredibly quickly."

Dr. Thomas Müller, co-founder and General Manager of Pearl Technology AG, Switzerland.



Moreover, various features, such as the marking of the scan range and the breadth of the wings, are all matched to the characteristics of the individual CT tables.

In manufacturing the products, Pearl Technology AG meets the high quality requirements for medical devices and those of Canon Medical. From the point at which it leaves the factory, each product is individually subjected to a comprehensive quality control process to identify any weak points in the PU films or in the high frequency welded seams. All products are 100%

manufactured in Switzerland and in accordance with ISO 13485.

Close to twelve months have passed since the first delivery, and on more and more CT devices, Pearltec products are helping to simplify patient positioning in a way that guarantees ideally hygienic conditions. Across Europe, initial feedback has been thoroughly positive.

Dr. Sascha Pietruschka is delighted with the materials chosen and with their hygienic properties. "Through regular direct contact tests and microbiological analysis during validation of the ProBelt, we were able to demonstrate that with commercially available disinfectants it was possible to return the equipment to an ideal hygienic condition for immediate re-use. By performing a wipe-down disinfection of the ProBelt at the same time as that of the CT Table Cover, we managed to reduce the germ load on the surfaces to the extent that thresholds were never exceeded. The ProBelt system solves the hygiene problem. It is made of easy to clean, hygienically ideal materials and it dries quickly. According to my team of radiographers or radiology technologists, handling and secure positioning are at least as good as with previous belts. We no longer have to make compromises between secure patient positioning and the hygiene guidelines."

"It is fantastic to see how even in the complex world of medical devices a dynamic, constructive collaboration between two companies, alongside close dialogue with customers and users, can rapidly improve outcomes for patients and users with simple, innovative solutions. For everyone involved, of course, it makes sense to follow up on a success story such as this. So intensive work has already started on additional solutions in various different fields of application. We look to the future with excitement," Dr. Pietruschka concluded. //



 $CT\ Table\ Cover, ProBelt\ and\ Pearl Fit\ positioning\ aids\ from\ Pearl\ Technology\ at\ the\ Aquilion\ Lightning.$