

Patient monitors for HIT and transfer of know-how to Siemens-Med

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Abstract

At the therapy facility CaveM of GSI a set of two Multi-Wire Proportional Chambers (MWPC) (see fig.1) and three Ionization Chambers (IC) known as ‘patient-monitor detectors’ [1] serve to steer and control the irradiation of human patients with heavy ions. They measure the beam position, direction and intensity in front of the patient in a redundant and diverse way. Lacking an industrial supplier, the detector laboratory of GSI was charged in 2003 with the delivery of this system for the Heavy-Ion Therapy facility HIT which is currently under construction in Heidelberg.

Developments

In the framework of a hospital surrounding, the detectors have to be categorized as class ‘II b’ medical devices. Therefore their design and the respective manufacturing processes for a small series production have been adapted to be in accordance with the medical-device directive 93/42/EWG accomplishing the ‘basic requirements’ of the ‘Act on Medical Devices’ MPG. Besides already well established procedures involved in detector development additional tasks like e.g. ‘risk assessment’ and ‘quality-controlled production’ had to be implemented. Research effort and investments were made to build up knowledge, procedures and infrastructure. Especially the need for a detailed documentation and the composition of a ‘technical file’ was a challenge accepted. In some cases this led to the discovery of more general findings other projects [3] could benefit from.

Know-How Transfer

The developments were promoted up to the milestone of a possible type approval of the detector system according to addendum IV/MDD 93/42. This was the moment when the medical division of the Siemens-AG (SAG) joined the HIT project and was entrusted with the further development of all products concerning radiation techniques. Consequently, in 2004 the decision was made to transfer all required knowledge to this company. An iterative four-step process was implemented: a) theoretical and practical training and demonstration by GSI, b) action of SAG with guidance and supervision by GSI, c) single handed production by SAG with follow up control and finally d) fully autonomous production by SAG to gain experience and validate the processes. The whole procedure was successfully completed during 2005. Considerable efforts have been made to enable SAG to self-responsible produce parts of the beam-monitoring system using the infrastructure which has been set up in the detector laboratory of GSI in the framework of this project. The outcome of this work was successfully verified during beam times at CaveM.

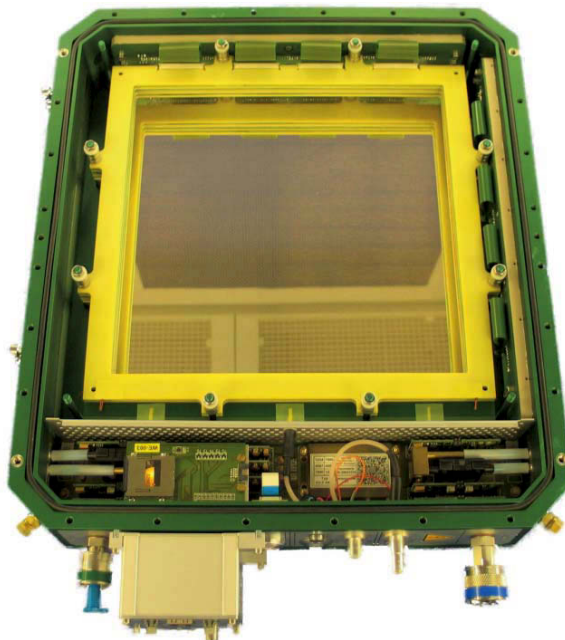


Figure 1: Picture of a MWPC with one of the chamber windows removed. The modular design is composed of the functional unit which forms either a parallel-plate ionization chamber or a multi-wire proportional chamber mounted on a carrier which serves as the exit window. The design also incorporated a set of sensors and a controller monitoring the operation conditions [2].

Outlook

Support and advisory service with respects to improvement in details, the risk assessment and the development of advanced concepts are still under way. The wire-winding machine DWM 2000 developed at GSI and sold to SAG as part of a technology transfer may be taken as an example. Here the adaptation to the special needs of the batched-flow production according to the CE and FDA certification is still ongoing.

References

- [1] B. Voss et al., The Monitor System of the Therapy Project, GSI Scientific report 1997, Volume 98-1, March 1998, page 187
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- [3] Ch. J. Schmidt et al., Surface electrical conductivity of cured Araldite 2011 Epoxy, a study initiated during ALICE TRD production, contribution to this report

