THE HIT ACCELERATOR AS PART OF A MEDICAL PRODUCT: IMPACTS ON THE MAINTENANCE STRATEGY

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Abstract

The HIT accelerator produces protons and carbon beams with a large variety of parameters: 255 different energies, four foci and ten intensity steps per ion are independently available at 5 iso-centres to be requested by the dose delivery system for tumour treatment. Thus the whole accelerator chain is part of a medical product, in case of HIT an in-house manufactured device. The overall risk and quality management has deep influences on the maintenance process. Not only the huge volume of necessary documentation reflects this impact but also the organizational process before, along and after the services at HIT. Especially, the comprehensive testing after the maintenance procedures follows sophisticated checklists (e.g. the ion source service). On the other hand, a high operational availability of the accelerator in a hospital is mandatory. To realize up to 8200 hours of accelerator uptime per year in case of HIT, a maintenance strategy is necessary, which interleaves the regular service of the building infrastructure, e.g. air conditioning, with the periodic maintenance of the accelerator components. In detail, this approach will be discussed along the magnets and the gantry structure.

HIT FACILITY AND OPERATION

The core of the Heidelberg Ion-Beam Therapy (HIT) Centre [1] is an accelerator facility designed to optimally support the raster scanning dose delivery method [2] by producing light ion pencil-beams having energies that allow for the treatment of deep-seated tumours.

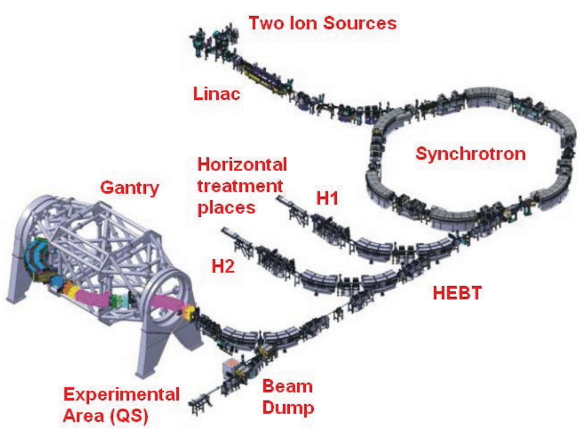

Figure 1: Layout of the HIT Accelerator Facility.

It is comprised of the following subsystems, see Fig. 1:

- Two ECR ion sources for the routine operation of proton and carbon beams at 8 keV/u; other ion species like helium and oxygen can also be produced for experiments.
- A compact 217 MHz linac consisting of an RFQ and an IH-DTL with end energy of 7 MeV/u for all ions; a foil stripper directly located behind these cavities to produce fully stripped ions.
- A synchrotron of 65m circumference capable to accelerate protons, helium, carbon and oxygen to predefined end energies e.g. for carbon ions from 89 to 430 MeV/u in 255 steps.
- A system of high energy transport lines (HEBT) to serve five destinations: the two horizontally-fixed patient treatment rooms H1 and H2, the Gantry treatment room, an experimental area (QS) and a beam dump equipped with dedicated beam diagnostics.

Since spring 2007 the HIT company, a 100% daughter of the Heidelberg University Hospital, has taken over the responsibility for the operation of the facility. In 2009 the clinical operation started at the first horizontal treatment place, all rooms are operational including the gantry since October 2012 [3]. Since the beginning about 1500 patients were treated in the facility, in 2013 around 750 patients are expected to be handled.

INTERFACE BETWEEN ACCELERATOR AND MEDICAL DEVICES

The whole accelerator chain forms an industry product as part of a medical product, which in case of HIT is certified as an in-house manufactured device. To handle the complex situation clear interfaces were defined between the accelerator devices and the medical systems, which apply the planned dose distributions in a correct and qualified manner to the patient.

At first, a secure protocol and handshake between the accelerator control system (ACS) and the therapy control system (TCS) was necessary to link both worlds by dedicated and safe interconnects. In this way it is ensured that the beam characteristics requested by the TCS are safely produced by the accelerator. In addition, the personnel safety system (PSS) has a dedicated interface to the TCS. Major components of this interconnection are secure interruptions of magnet power supplies e.g. for switching dipoles leading the beam to the treatment rooms. Furthermore the TCS reads out all position information of vacuum valves and beam diagnostic devices in the HEBT to guarantee that the correct energy is delivered to the patient treatment place, unaffected by any matter in the beam line. Interfaces like these assure that the beam can be redundantly stopped in case of emergencies. The functions of all these safety systems have to be checked regularly, especially after maintenance procedures, see examples below.

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RISK ANALYSIS AND DEDUCED MEASURES

To certify a medical product and its (industrial) subsystems, comprehensive risk analyses (RA) are necessary. For HIT several RA groups were formed along the accelerator sections (linac, synchrotron, HEBT, gantry) as well as along technical systems (PSS, detector gas supply, building infrastructure, etc.) and overall aspects like radiation safety or EMC. Several thousands of person hours were spent only to analyse all conceivable risks and find technical or organisational measures to minimize them, if evaluated to be necessary. Parts of the outcome of this process affect also the maintenance tasks. On one side this leads to an increasing amount of documentation work, on the other side additional maintenance duties have to be fulfilled.

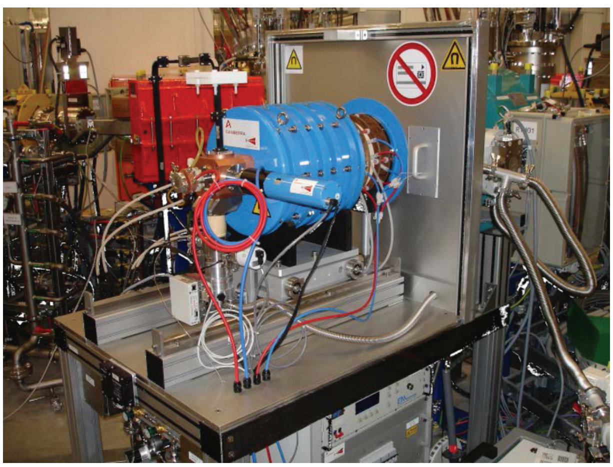

Figure 2: One of the ion sources [4] at HIT opened for maintenance tasks and intense safety checks afterwards.

As an example, the comprehensive testing after the maintenance procedures of the ion sources (see Fig. 2) will illustrate that. Summarizing all measures of the RAs a sophisticated checklist was developed, which includes the following subtasks:

- Inspection of the gas supply system
- Checking of all interlock systems
- Verification of the radiation shield (concerning microwave and X-ray sealing-off)
- Range measurement after exchange of material in the ion source (although only Mg-free materials are always used, unwanted contaminations are still possible)
- Check-up of vacuum performance and leakage control
- Inspection of hydrogen exhaust pipe concerning tightness (proton source)

The additional time needed for all these inspections has to be planned within the maintenance work packages. Additionally, the necessary infrastructure (e.g. air conditioning) must be available to perform the check-ups, oftentimes in parallel to service works of the technical building systems.

MAINTENANCE STRATEGY FOR COMPLEX ACCELERATOR SYSTEMS

Together with the medical management of HIT the following maintenance slots were defined:

- Six maintenance blocks with 4 days length (from Thursday to Sunday), two days of them reserved for service only, followed by the restart of the accelerator, retuning of ion source and beam optics, if necessary, and the comprehensive quality assurance of the medical treatment systems.
- Maintenance shifts on Monday morning every 2 – 3 weeks between the service blocks for shorter (visual) inspections, smaller repairs and update works.

Within these boundary conditions all regular maintenance tasks and deferrable repairs must be carried out to guarantee around 330–340 operation days of the HIT accelerator per year. For two accelerator systems (magnets, gantry) it will be explained how this is set-up.

Magnets

The accelerator magnets at HIT were delivered by three commercial European suppliers [5–7]. The different maintenance guide lines were reviewed by HIT and a combined version with reasonable inspection intervals for a sub- and safety systems was compiled.

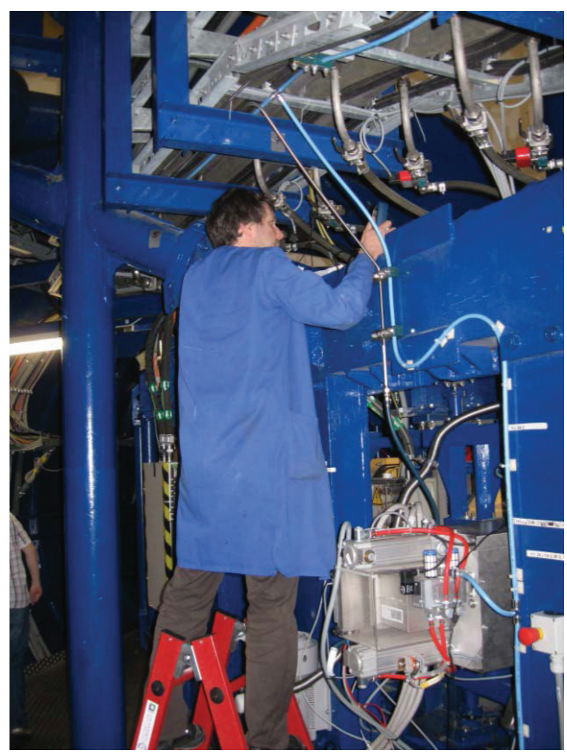

Figure 3: Inspection of water flow control units and thermo switches belonging to quadrupoles on the HIT ion gantry.

The magnet maintenance – carried out completely by HIT personnel – consists of intense visual inspection (corrosion, electrical grounding, coils, connector boxes, cooling hoses, screw fittings, hose clamps, etc.) as well as mechanical checks (retightening of screws in all cable connections using a torque key) and function testing (water flow control units, thermo switches). To test the whole interlock chain from the magnets via the power supplies to the control system, all these systems must be available in parallel with the water cooling fully functional. In case of some magnets – especially placed on the gantry – also the accessibility has to be guaranteed in coordination with other maintenance works. On this background a matrix of single work packages and linked circumstances was set up.

Gantry

As another example the gantry structure with linked control and safety electronics illustrates the complexity of maintenance planning. The checklist contains several hundred topics, from simple tasks as regular oil exchange of the drive gear to complex testing of welded connections using ultrasonic or X-ray measurement equipment. Furthermore the safety devices like laser curtains and bumper mats around the nozzle in the patient treatment room as well as numerous interlock switches have to be checked carefully.

As all these tasks are mainly carried out by the manufacturing company [8] an exact coordination is necessary. Accessibility to the gantry must be guaranteed as well as the free rotation capability for some of the work packages, which suppresses other services in the gantry hall like e.g. crane maintenance. Again a complex matrix of single maintenance tasks and linked circumstances was compiled.

SET-UP OF MAINTENANCE SCHEDULES

Until end of 2011 the HIT shutdowns take at least two weeks each in summer and winter. The new maintenance strategy starting in 2012 with "mini-shutdowns" of only 4 days (see above) demands that all service work packages do not need more than two consecutive days. This could be reached for all infrastructure systems by intense discussions with the company responsible for the facility management [9], which partly led to revised working schemes. In addition, some of maintenance plans for the accelerator systems had to be restructured, too.

In the next step a rough annual planning was made, where 4 of 6 maintenance blocks were used now to carry out infrastructure service, but the remaining two mini-shutdowns are exclusively dedicated to special accelerator work.

On this background the separate maintenance blocks are organized using project plans, where the above mentioned matrices have to be taken into account as well as other constraints like safety at work and especially the numerous checks demanded for a medical product. All degrees of freedom – separating tasks in time or distributing them in the building – are used to arrange all parallel works to be done. The resulting project plans are iterated, sometimes several times, in close cooperation with the involved persons to use all the experience gained in the recent years. Special tasks like software upgrades within the maintenance blocks need additional careful planning activities and impact analyses to deduce quality measures to be carried out afterwards.

All maintenance activities have to be documented in detail. The ones which could influence the properties of the medical product are directly checked, before the patient treatment is again released; the other documents have to be transmitted within a fixed time interval. Nearly all documents are double-checked from the technical point of view as well as on quality management aspects, e.g. completeness and hints to upcoming defects. The aim is to deduce pre-emptive maintenance measures.

In summary, the maintenance strategy for a complex facility for patient treatment like HIT needs a high degree of careful pre-organization, a good monitoring of the process and a permanent quality management. The HIT experiences result in more than 98% availability of the whole accelerator chain including infrastructure.

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