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Preliminary Risk Analysis of a Superconducting Gantry for Hadron Therapy

Roberto Filippini

PhD, Ind. Cons. Medical device safety and regulatory affairs, Italy: filippini.consulting@gmail.com

Enrico Felcini

CNAO, Italy. E-mail: enrico.felcini@cnao.it

Mauro Pivi

MedAustron, Austria. E-mail: mauro.pivi@medaustron.at

Marco Pullia

CNAO, Italy. E-mail: marco.pullia@cnao.it

Hadron therapy offers one of the most advanced options for cancer treatment. If compared with conventional photon radiotherapy, its advantage resides in the properties of hadrons, as protons and heavier ions, to treat deep-seated tumors with precise dose deposition, while sparing the surrounding healthy tissues. An effective implementation of hadron therapy is the use of a beamline rotating around the patient, namely a gantry. A gantry irradiates the tumor from different angles with advantages with respect to fixed beamlines. The use of the gantry in combination with heavy ions such as carbon allows for even superior treatment capabilities. At present, this solution is a considerable engineering challenge, because of the size, weight, and cost of the magnets, as well as of the overall infrastructure. In the context of the European project HITRIplus, several research institutes and clinical centers are studying and developing a compact and affordable gantry for hadron therapy with carbon ions by using superconducting magnets. The superconducting technology allows for a significant reduction in magnet size and weight with respect to normal-conducting magnets. Nonetheless, it suffers from the risk of quenching, i.e. the loss of the superconductive state, with potential damage to beamline components and consequent treatment disruption. This paper presents the results of a preliminary risk analysis of the superconducting gantry technology aiming to define design requirements for mitigating the risks and limiting their consequences by adopting several risk controls measures. An additional goal of the paper is to identify and address the design trade-offs that concern patient safety and operability. Finally, superconducting and normal-conducting gantry technologies are compared with the intent of summarizing benefits and risks.

Keywords: risk analysis, safety, medical devices, particle therapy accelerators technology.

1. Introduction

Hadron therapy is a branch of radiotherapy that uses accelerated protons and heavier ion beams for cancer treatment. The main advantage of hadron therapy with respect to conventional radiotherapy relies on the precise delivery of the dose in the tumor area while preserving the surrounding healthy tissues, thanks to the Bragg's peak energy distribution (Kraft 1990).

Hadron therapy makes use of different combinations of particle species, such as protons and carbon ions, and beamline orientations, either fixed or movable. One of the most advanced application of hadron therapy is the use of carbon ions in a particle accelerator with a gantry beamline. Gantries are rotating structures that enable targeting the tumor from various angles, thus enhancing dose conformity and treatment robustness, while minimizing at the same time radiation exposure to surrounding organs at risk.

While proton gantries are commercially available solutions, the realization of a superconducting carbon ion gantry is challenging because of the novel technology and the costs. The use of this technology would allow to maintain the same performance of conventional gantry, while significantly reducing the size of the magnets.

Two international collaborations, EuroSIG and HITRIplus (HITRIplus 2025), are advancing the design of superconducting carbon ion gantries for clinical use (Pullia 2024). The EuroSIG project is a collaboration between CERN, INFN, MedAustron, and CNAO. It aims to develop enabling technologies to demonstrate the feasibility of the most challenging elements of the design, like the superconducting magnets (Rossi 2022, Prioli 2023) and the scanning system (Felcini 2023). The HITRIplus (Heavy Ion Therapy Research Integration plus) project is a much wider international collaboration aimed at advancing biophysics and medical research in cancer treatment using heavy ion beams, while simultaneously developing cutting-edge instrumentation.

Within the HITRIplus framework, one of the work packages contains the risk analysis of the gantry, the result of which will define the requirements of the risk control measures. The risk analysis of particle therapy accelerators for clinical use is a time-consuming activity and it is mandatory for the manufacturers of medical devices to obtain conformity with the Medical Device Regulation MDR 2017/745 (Filippini, 2018). Having this future obligation in mind, the paper addresses the preliminary risk analysis of the superconducting gantry and discusses the results with respect to the expected benefits, the risks, and the operability.

The paper consists of seven sections. After this introduction, the system description is given in section 2. Section 3 introduces the risk-based design principles for medical devices. The results of the preliminary analysis and the design requirements are respectively in section 4 and section 5. The comparative analysis between the superconducting gantry and the conventional gantry is in section 6, before the conclusions in section 7.

2. System description and clinical use

The gantry is a moveable, mechanical structure that houses the beamline of the particle therapy accelerator before the nozzle. The gantry receives the beam from the high-energy beam transfer line of the accelerator and steers it along the beamline, while maintaining the required beam position and width. The beam reaches the scanning magnets, which paint the pencil beam into the target area, according to the treatment plan.

The layout of the gantry is shown in Figure 1. The most relevant gantry magnets and systems are listed below together with their functions:

- Four identical 45-degree 4 Tesla superconducting dipole magnets bend the beam.
- Spool-piece superconducting quadrupole magnets, (Baynham 1994) focus the beam, maintaining it within the magnets' aperture.
- Cryostat and Cryogenic systems maintain the temperature of the superconducting magnets below a prescribed threshold.
- Cold mass suspension system mechanically supports and aligns the superconducting magnets inside the cryostats.

The gantry beamline also includes the scanning magnets (Felcini 2024) and the orbit correctors, which are not superconducting elements.

The superconducting gantry is able to deliver beams from a minimum proton energy of 60 MeV to a maximum carbon ions energy of 430 MeV/u. The mechanical structure is designed to perform a complete 360° rotation around the patient (Piacentini 2024) and it is controlled and supervised during clinical use.

Safety is guaranteed by several safety related systems each of which has a different scope. Patient safety is guaranteed by the Patient Safety System during clinical use, and the Anti-Collision System (for moving parts of the gantry) protects medical personnel and the patient during the preparatory tasks.

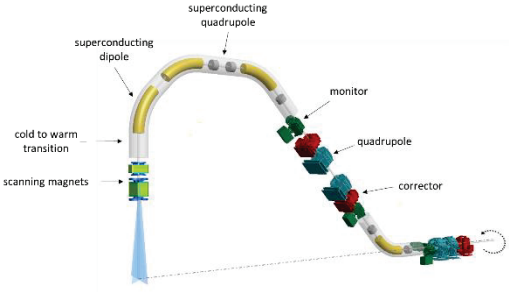

Figure 1. Layout of the superconducting gantry.

Another safety system is the Quench Protection System (QPS), which guarantees the integrity of

superconducting magnets against quenches. A quench is a sudden loss of the superconducting state of the magnet, and it may occur for several reasons. Hereafter in the paper, we define a quench as *primary* if the cause is within the magnet or the cryogenic system, and *secondary*, if the cause is external, for example beam losses onto the surface of the superconducting magnets.

The clinical use of the gantry for a patient treatment session consists of several activities that are performed by medical personnel, according to the clinical workflow. The first activity is the accommodation of the patient on the couch of the robotic table, in front of the nozzle. After the patient is accommodated, the gantry rotates to reach the required angle and position for the administration of treatment. Then the user shall wait until all checks have passed before starting treatment. During treatment the accelerator produces the beam of the required intensity and energy, according to the treatment plan. The delivery of the prescribed dose, spot by spot, into the target volume is executed by the dose delivery system by actuating and controlling the scanning magnets. At the same time, the patient safety system monitors the beam width, position, and intensity and in case of errors it triggers an interlock. The dose delivery continues until completion of all energy layers for the specific gantry angle, and then the gantry rotates to the next angle. This process ends when the treatment plan has been delivered or failures occur, which impar the treatment to be resumed for safety reasons.

3. Risk based design of medical devices

A medical device is safe for clinical use if it meets conformity with the General Safety Performance Requirements (GSPR) in Annex I of Medical Device Regulation, MDR 2017/745. Conformity is obtained by verification of the design requirements of the medical device and, where this is possible, it requires compliance with applicable standards. These standards define the state-of-the-art that the manufacturer of the medical device shall be aware of and master proficiently. This section recalls some of the activities and design principle that come from the applicable standards and particularly the risk management standard EN ISO 14971:2021.

3.1. *Preliminary Risk Analysis*

The Preliminary Risk Analysis (PRA) is one of the risk analysis methods of ISO 14971. It applies in the early design stage of a project, when to identify the hazardous situations and estimate their severities is more important than to estimate their likelihood.

Severity in radiotherapy is associated to the harm to the patient, which in turn reflects the consequence of the hazardous situation. The estimate of the harm severity is based on experimental evidence and clinical follow-ups (AAPM 1993 and ICRP 1996). In order to be used in the risk analysis, the severity is categorized into severity intervals, negligible, minor, moderate, severe, and life-threatening.

The following is the taxonomy of the possible consequences of hazardous situations in hadron therapy, for which severity of harm is estimated:

- Overdosage in the target (single or multiple spots). Harm severity is estimated from moderate to severe.
- Underdosage in the target (single or multiple spots). Harm severity is estimated as moderate.
- Dosage outside the target. Harm severity is estimated severe or life-threatening if close to vital organs.

The combination of the different consequences is possible and may lead to dosage homogeneity error in the whole treatment volume.

Another consequence or which harm severity shall be assessed is the residual extra dose that goes off target after a beam error is detected by the patient safety system. The extra dose limits are defined in the standard IEC 60601-2-64.

A different category of severity is associated to the downtime of the accelerator. Because radiotherapy requires to administer the dose in daily sessions, a long downtime may drastically compromise the treatment effectiveness. Severity categories for downtime are minor (less than one day), moderate (less than one week), and severe (more than one week).

The applicable hazardous situations for clinical use of the superconducting gantry are underdosages and dosage outside the target caused by beam position errors (dipole failures) and beam width errors (quadrupole failures). Downtime is also applicable especially for magnet quench failures.

3.2. *Risk control options and safety principles*

Risk control measures are chosen within the three risk control options of ISO 14971. They are

- Inherent safety by design.
- Preventive/protective.
- Organizational measures.

Inherent safety by design is the most effective risk control option. It includes fault avoidance and fail-safe behavior, which are embedded in the system. Preventive and protective risk control measures are also designed to protect the medical device, but as external systems. They consist of fault detection, beam monitors and beam stop devices. Organizational measures are the least effective risk control options. These include instructions for use, information for safety (e.g., labels, warnings) and quality assurance checks.

Risk control measures mitigate the risk of a hazardous situation, for the originating cause, the effects and the consequences. The risk control responds to the "As Far As Possible" principle (AFAP), which takes into account the severity of the risk. If more risk control measures apply to mitigate a risk, then they can be organized in layers, according to the "defense in depth" safety principle. Using the metaphor of a castle, each risk control measure represents a wall protecting the medical device, while the amount of risk control measures (layers) is determined by the AFAP principle.

3.3. *Operability*

Operability is defined as the ability to maintain the medical device in safe and functioning conditions for its clinical use. For what concerns the superconducting gantry, operability is mainly affected by the downtime caused by magnet quenches, which may disrupt clinical operations for days or weeks. The analysis of operability is out of the scope of this paper. However, the gantry components with the largest impact on the downtime shall be identified. The same holds for design requirements for reliability and prompt recovery from failures, such as fault tolerance, predictive maintenance and spare parts policy.

4. Results of the Preliminary Risk Analysis

The scope of the preliminary risk analysis is the superconducting gantry beamline. The results are summarized in the following sections.

4.1. *Risks distribution*

The PRA has identified and analyzed 25 hazardous situations. Each hazardous situation may have up to four consequences (patient safety, primary and secondary quenches, others) for a total of 54 individual risks. They are:

- 5 hazardous situations concern patient safety and primary quench.
- 8 hazardous situations concern patient safety, primary and secondary quenches.
- 8 hazardous situations concern patient safety and secondary quenches.
- 1 hazardous situation triggers only secondary quench.
- 3 hazardous situations cause downtime because of other reasons.

The results are shown in Figure 2. In total, 21 over 25 hazardous situations concern patient safety. The harm is damage to healthy tissue caused by the beam dose outside the target area and dose homogeneity errors, that is estimated to be severe. Primary quenches with long and severe downtime (weeks) are 7 in total. Secondary quenches affect 17 hazardous situations with moderate downtime (DT) of a few days and 8 hazardous situations with minor downtime, less than one day.

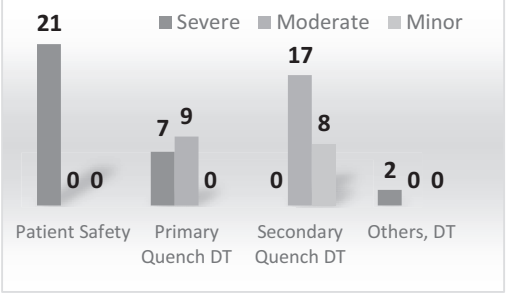

Figure 2. Risks distribution bar chart.

Among the risks that concern patient safety, beam position error at the isocenter has the highest severity if it occurs in the proximity of the nozzle and in the worst case, it is life-threatening for the patient.

Regarding risks related to downtime, an uncontrolled primary quench in the superconducting dipoles may disrupt clinical operations for several weeks or months. Treatment is compromised if patients are not

transferred to another radiotherapy center. Downtime by secondary quenches may also disrupt treatment, especially if the beam loss hits the first superconducting components of the gantry beamline, and from there it propagates to the other superconducting magnets along the beamline.

4.2. *Identification of the causes*

The causes of the hazardous situations are classified into 1) single causes if they affect one component at a time and 2) common causes if they affect multiple components at a time. Single and common causes can be random (r) or systematic (s).

Single causes of the superconducting gantry are:

- Local inefficient heat dissipation (r, s)
- Local material degradation (r)
- Fault of cold mass suspension system inside the cryostat (r),

while common causes are:

- Cryogenic system failure (r)
- Vacuum system failure (r)
- Rotating mechanical structure failure (r)
- Mechanical vibrations/stress to superconducting cables (s)
- Beam losses (r)
- Beam halo (s)
- Fault of gantry and HEBT resistive magnets leading to beam losses (r)
- Electrical system failure with subsequent magnet warm-up (r).

All these causes belong to the superconducting technology. Because they sum up to the causes of a conventional gantry, which remain valid and applicable, it is possible to conclude that the risks of a superconducting gantry are higher than the risks of a conventional gantry. Another important remark is about the contribution of common causes of failures, which again, affect only superconducting magnets and systems.

4.3. *Risk control measures*

In total 19 risk control measures are needed to mitigate the 54 individual risks of which 4 are inherent safety by design (In.S.), 4 are preventive measures (Pre), 3 protective measures (Pro), and 8 organizational measures (Org). The protective measures are the most demanded, being required to mitigate 43 of the 54 risks, followed by 25 instances of inherent safety measures, 20 organizational and 10 preventive measures.

Figure 3 shows how the risk control measures combine together to mitigate the risk, according to the "defense in depth" principle. The most frequent combination of risk control measures is "inherent safety and protective measures", with 19 occurrences, followed by 13 occurrences of "organizational and protective measures". Only 9 risks require the implementation of more than two risk control measures, namely three or four. There are also risks that are mitigated by one risk control measure, inherent safety or protective measures. This is acceptable provided that the single fault safety principle of IEC 60601-1 is met, namely a single fault never directly results into harm for the patient. It is also important to remark that there are no risks mitigated by organizational measures only, because this would not be acceptable.

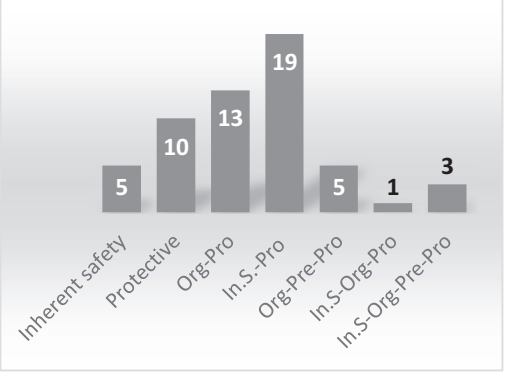

Figure 3. Combination of the risk control measures according to the *defense in depth* principle.

5. Inputs for the HITRIplus project

The results of the preliminary risk analysis are an essential input to the design requirements of the HITRIplus project. A few design requirements shall be traded-off with respect to conflicting targets, while others need further investigations.

5.1. *Design requirements*

The following requirements mitigate the risks by removing the root causes or by limiting their negative effects:

- Choice of the materials for superconducting magnet components in order counteract aging and wearing factors within normal use.
- Design of the superconducting magnets in order to tolerate mechanical vibration and rotation of the mechanical structure that might deteriorate the superconducting state of the magnets and their efficiency.
- Design of the suspension system in order to tolerate stress and sudden breaking of the mechanical stands of the magnets inside the cryostat.
- Design of beam collimators installed along the beamline to prevent beam losses at the entrance of a superconducting magnet.

Another set of requirements apply to systems that maintain the superconducting state of the magnets under normal conditions and protect their integrity from quenches under fault conditions. They are:

- Design of the cooling system in order to maintain the temperature in the superconducting magnets and guarantee margin of tolerance against local degradation of materials that might initiate a quench.
- Design of the heat dissipation components to quickly remove extra-heat in case of a triggered quench both to reduce the increase of temperature of the magnet and to shorten the cooling system, with benefits for recovery and operability.
- Design of the Quench Protection System to trigger an interlock as soon as the voltage exceeds a given threshold, thus reducing the consequences of primary quenches.

Finally, a few requirements apply to the monitoring of graceful degradation processes and precursors of quenches in superconducting magnets. They are:

- Monitoring of temperature, pressure, power of the cooling system, voltage, and current of the superconducting magnets.
- Diagnostics software to predict precursors of quenches from the collected data like e.g., abnormal operating conditions, degradation of materials, inefficient cooling, etc.

These requirements shall be coupled with an efficient spare parts policy. Spare parts make it possible the replacement of the damaged component and recovery back to operation. In this respect, the gantry has identical superconducting dipoles and quadrupoles components, thus allowing for the sharing of spare parts.

5.2. *Design trade-offs*

Design requirements cannot be always be freely assigned, especially if there are conflicting targets. This is case of safety versus operability (Filippini 2022) for which the design requirement shall be traded off. The following are some of the trade-offs that shall be taken into account for the design of the superconducting gantry:

- Trade-off of QPS thresholds: higher sensitivity to quenches reduces the severity and shortens the time to resume from a quench but, at the same time, it may disrupt more often clinical operation to the detriment of operability. Lower sensitivity has the opposite effect: it improves operability but if a quench develops, the likelihood that this may cause a long downtime is higher.
- Trade-off of collimator aperture: it reduces the aperture available to the beam, but it intercepts beam losses and it reduces the likelihood of secondary quenches.
- Trade-off of the suspension system inside the cryostat: the mechanical robustness of the stands causes, at the same time, a lower thermal insulation, with higher risk of quenches as well as higher demand for the cooling system.

5.3. *Unknowns and topics to investigate*

During the preparation of this paper, accelerator physicists, superconducting magnet experts, and cryogenic engineers provided clarifications for several hazardous situations. Still, at present, the knowledge on root causes of a few failure scenarios and their effects remains vague. These are “known unknowns”, according to the definition given in Flage and Aven (2015).

Within the known unknowns there is the degradation of superconducting magnets’ components (such as resin, insulation, and related thermal contacts) after thousands of electrical and mechanical cycles during the gantry operation. Another known unknown is the consequence of beam losses on the superconducting magnet and especially the condition after which a quench

develops. Among the technical unknown it is still to decide if cryogenics system will be based on liquid/gas helium or cryocoolers, and this may have consequence on the risk analysis.

6. Benefits and risks evaluation

6.1. *Comparative analysis*

The comparative analysis evaluates risks (safety and operability), performance, design complexity, costs and benefits of the superconducting gantry versus a conventional normal-conducting gantry. The results of the comparative analysis are shown in Table 1.

Table 1. Comparative analysis of the superconducting gantry versus the conventional gantry.

Attribute	Evaluation
Risks (patient safety)	Higher risks
Risks (operability)	Higher risks
Performance	Equal
Design complexity	More complex
Costs and savings	Equal
Clinical benefits	Equal

In terms of patient safety, the risk of a superconducting gantry is higher than a conventional gantry because of the new hazardous situations related to the superconducting technology. The same holds for operability risks, because of the longer downtime caused by magnet quenches.

In terms of performance, the superconducting gantry guarantees the same beam quality and reproducibility at the isocenter as required by the treatment plans.

In terms of complexity, the design of a superconducting gantry is more complex and certainly more demanding for maintenance than a conventional gantry. New costs shall also be accounted for the superconducting magnets, cryogenic system, and quench protection system. For sake of truth, cost savings exist for the superconducting gantry beamline because of the more compact design, the mechanics and the infrastructure.

In terms of clinical benefits, the superior capabilities of carbon ions with radioresistant tumors, is combined with the capability of the gantry to irradiate the target from different angles. This increases the treatment robustness together with the sparing of healthy organs at risk. Same benefits are achievable by conventional gantries.

6.2. Benefits and risks assessment

The comparative analysis of the two gantries has returned that a conventional gantry is able to guarantee the same performance and benefits, with lower risks and higher operability. Costs of the two gantries are comparable. Nonetheless, not all attributes have the same relevance, and if one takes feasibility into account, then it is unquestionable that the construction of a conventional gantry for the clinical use with carbon ions is very problematic because of the much bigger infrastructure for housing and maneuvering the heavier dipole magnets. This is a feasibility issue in face of which the lower risks lose a bit of significance.

Summing up, the development of hadron therapy to expand cancer treatment indications is feasible by the superconducting gantry, provided that the higher risks are acceptable in comparison with the clinical benefits, which is the goal of the benefits and risks assessment. The previous section has analyzed the risks of the superconducting gantry, and it has demonstrated that they can be mitigated, so that it is technically conceivable to guarantee patient safety and operability. In conclusion, it is possible to state that:

"the benefits of using superconducting gantry beamline with carbon ions outweigh the risks, with an improvement of the benefits-risks ratio for the intended clinical use".

This statement is the necessary and sufficient condition in favor of the continuation of the project, from the risk management point of view.

7. Conclusions

Hadron therapy offers precise cancer treatment using ionizing radiation, especially for deep seated tumors that are resistant to conventional radiotherapy. To expand the possibility of treatment indications by hadron therapy, one of most advanced application relies on developing compact, cost-effective gantries for carbon ions.

This is the objective of the HITRIplus and EuroSIG projects.

Superconducting magnets allow for a significant reduction in size for gantry beamlines, but they introduce new risks of magnet quenching, which have a detrimental effect on the clinical use of the particle therapy accelerator. This paper has analyzed the failure scenarios in the superconducting gantry that lead to beam errors at the isocenter and concern patient safety, as well as primary and secondary quenches that cause downtime and reduce operability. While beam errors at the isocenter are comparable to room-temperature normal-conducting systems, magnet quenches are unique to superconducting technologies. The preliminary risk analysis has also provided insights on the principal causes of the failure scenarios, the risk control measures related to the superconducting technology, and a few design trade-offs that concern safety and operability. Several areas of uncertainty and known unknowns in scope of the risk analysis have also been discussed.

A comparative analysis has evaluated benefits, risks, performance, design complexity and costs of the superconducting gantry versus the conventional gantry. In spite of higher risks, a superconducting gantry guarantees the same performance and clinical benefits of a conventional gantry but without feasibility issues, thus representing the accessible solution for future clinical use in hadron therapy. These results encourage the continuation of the design and development of the superconducting gantry according to the HITRIplus project objectives. The next step consists of the realization of technological demonstrators for the superconducting magnets and scanning system in the framework of the EuroSIG project.

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