Technical Note: The Design and Function of a Horizontal Patient Rotation System for the Purposes of Fixed-Beam Cancer Radiotherapy

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Abstract

Purpose: Cancer radiation therapy treatment is performed by delivering a 3D dose distribution to the tumour via the relative rotation between beam and patient. Whilst most modern machines rotate the radiation beam around a still patient, the treatment can also be delivered by rotating the patient relative to a fixed beam. Fixed-beam, patient rotation radiotherapy machines show promise for reducing the size, surface area footprint, and shielding requirements compared with rotating gantry machines. In this Technical Note, we describe the development of a bespoke horizontal patient rotation system for the purposes of a fixed-beam cancer radiotherapy architecture.

Methods: A horizontal Patient Rotation System was designed in accordance with the appropriate standards pertaining to performance and safety of medical electrical equipment and medical linear accelerators (ISO 9001, IEC 60601-1, IEC 60601-2-1, ISO 14971, ISO 13485, 21CFR820, IEC 62304, Machinery Directive 98/37/EC). The principal criteria for the design were safety, patient comfort, real-time control and the ability to be integrated with other radiation therapy componentry (including a linear accelerator and kV imaging systems).

Results: A first of its kind device for securing, immobilizing, translating and rotating patients has been designed and built and tested against 161 different design, safety and usability specifications. The device has real-time control for all critical applications.

Conclusions: We designed and built a bespoke device which can translate and rotate patients 360 degrees around a horizontal axis. The device meets all design and safety criteria with early usability tests indicating a high degree of comfort and utility. The system has been installed in a clinical bunker, integrated with a fixed-beam linear accelerator and is currently being commissioned for the purposes of cancer radiotherapy

treatment.

Keywords: Radiotherapy, Patient Rotation, Fixed-Beam Cancer Radiotherapy

Introduction

Close to half of all cancer patients globally are indicated for radiotherapy as part of a curative or palliative treatment regime[1-3], making it a vital modality for treating the "silent crisis" of rising rates of cancer incidence and mortality[4]. Radiotherapy delivers ionising radiation by rotating the radiation beam relative to the patient, enabling a 3D conformal dose and distribution at the tumour location whilst minimizing it elsewhere along the line-of-sight. Modern radiotherapy machines rotate the radiation beam around a stationary patient. In contrast, simplified (and less expensive) designs are also reemerging[5] which deliver the 3D dose and distribution by rotating the patient relative to the radiating beam[6-12] using X-ray or MRI-guidance for photon and particle beam therapies. Fixed-beam, patient rotation radiotherapy devices show promise for significantly reducing the size, surface area footprint, and shielding requirements compared with rotating gantry machines[7].

A real-time, adaptive, horizontal patient rotation radiotherapy machine is currently under development[7-8]. This machine is a compact and real-time controlled cancer radiotherapy device based on a fixed-beam linear accelerator, a kV imaging system for intra-treatment image-guidance and a patient rotation system (PRS). In this technical note, we describe the design inputs and specification of the PRS and summarise the results of 10 volunteers rotated in the PRS for the purposes of quantifying comfort, ease and utility.

Materials and Methods

Design

A horizontal PRS was designed and built in Australia in accordance with the appropriate standards pertaining to performance and safety of medical electrical equipment and medical linear accelerators (ISO 9001, IEC 60601-1, IEC 60601-2-1, ISO 14971, ISO 13485, 21CFR820, IEC 62304, Machinery Directive 98/37/EC). The principal criteria for the design were safety, patient comfort, real-time control and the ability to be integrated with other radiation therapy componentry (including a linear accelerator and kV imaging systems). The final PRS design (shown in Figure 1-top) was based on 10 individual sub-assemblies (Figure 1-bottom) and a number of high-level input requirements (first two columns of Table 1). All design requirements were set prior to any testing or testing design. The patient restraint system is a custom-designed arrangement of secure primary Velcro strapping and multiple, interconnected, computer-controlled (Programmable Logic Controller - PLC) airbags.

Table 1: PRS Design Specifications and associated Validation/Verification Testing Descriptions.

Specification	Description	Method	Test Description	Pass Criteria
Real-Time Control	The PRS will be controllable in real-time by third party software with <100ms response time	Analysis	N/A	N/A
Patient Ingress	The patient will be secured into position in less than 60 seconds.	Test.	Assess patient simulant (test subject) size and select the most suitable retention points. Place test subject on table and restrain with straps and close the Lid.	Time from when patient begins to climb onto bed to the when the lid is closed shall be less than 60sec.
Patient Restraint	The PRS will prevent the heaviest patient from moving into any position where injury can occur (i.e. collision, strain, impingement etc).	Test	With a patient simulant (test subject) restrained in the bed via the straps only, rotate the bed to 90° at the minimum and maximum rotation speeds. Observe the position of the simulant and record potential injury hazards. Inspect the straps and fixings for signs of damage, disconnection, wear and fatigue. Repeat this for 135°, 180°, 225° and 270° positions.	The patient simulant shall be restrained in a position that does not suggest possible injury and the straps shall remain secure and in place.
Patient Egress	It shall be possible to remove the patient in less than 60s when the PRS is already at the Egress position. With the PRS at its furthest translated point and at 180° (the furthest position from Egress) engaging the Auto Egress shall move the Bed from this position to the Egress position (0° and 0mm) in less than 90s, with the heaviest patient restrained in the Bed. When at 0° Airbag deflation shall commence.	Test	A patient simulant is to be placed in the Egress position, with the lid closed and the airbags deflated. Measure the time taken to open the lid, disconnect the restraints and have the patient dismount the Bed.	Time for each patient to get off the bed is less than or equal to 60s
Rotation Speed and Range	The PRS with the heaviest expected patient shall rotate from 0° to 360° at a minimum speed of less than 1°/s (0.17rpm) and a maximum speed of more than 60°/s (10rpm) in both clockwise and anti-clockwise directions.	Test	With a patient simulant of max weight restrained in the bed with the airbags inflated, set the desired rotation speed. Initiate rotation and record the time taken to complete one revolution. Compare with set speed and record the difference. Repeat test at five different speeds one being the lowest achievable speed and the other at greater then 60°/s (10rpm), in both directions clockwise and anti-clockwise.	For each test run the Bed rotates in the desired direction and the speed is measured. The lowest speed achieved is less than 1°/s and the fastest speed achieved is above 60°/s. The accuracy of actual speed to set speed is determined. Check for any damage to the PRS.
Rotation Acceleration and Deceleration	The maximum acceleration/deceleration achievable shall be 60°/s^2 with the heaviest expected patient restrained in the	Test	With a patient simulant of max weight restrained in the bed and air bags inflated, set a desired	For each test run the Bed rotates in the desired direction and the

	PRS.		acceleration and desired speed. Initiate rotation and measure the achieved acceleration. Repeat this for five acceleration and speed combinations, one of which includes the maximum acceleration and speed, in both directions clockwise and anti-clockwise.	acceleration is measured. The maximum acceleration achieved is above $60°/s^2$. The accuracy of the actual acceleration is determined. Check for any damage to the PRS.
Rotational Resolution	The PRS shall rotate to any position with a resolution of 0.1° as measured at the encoder.	Test	A patient simulant of max weight is restrained in the Bed and all airbags are inflated. Rotate the Bed at the maximum rotation speed to a predetermined position. The final position is to be measured and compared to the programmed position. Repeat the test for three positions each at the maximum and minimum rotation speeds, in both directions clockwise and anti-clockwise.	The resolution of the movement can be set to 0.1°. The accuracy of the final position compared with the programmed position shall be determined. Check for any damage to the PRS.
Translation Speed and Range	The PRS with the heaviest expected patient shall be able to translate from the Egress position to the maximum translated position at a minimum speed not greater than 10mm/s and at a maximum speed of greater than 100mm/s.	Test	With a patient simulant of max weight restrained in the Bed and all airbags inflated, set the desired translation speed. Initiate translation and record the time taken to complete one translation from Egress to the maximum translated position. Compare with set speed and record the difference. Repeat test at five different speeds one being the lowest achievable speed and the other at greater then 100mm/s, in both directions.	For each test run the Bed translates in the desired direction and the speed is measured. The lowest speed achieved is less than 10mm/sec and the fastest speed achieved is greater than 100mm/sec. The accuracy of actual speed to set speed is determined. Check for any damage to the PRS.
Translation Acceleration and Deceleration	The rate at which the PRS can achieve a set translation speed shall be able to be set. The maximum acceleration/deceleration achievable shall be no less than $100mm/s^2$.	Test	With a patient simulant of max weight restrained in the Bed and all airbags inflated, set a desired acceleration and desired speed. Initiate translation and measure the achieved acceleration. Repeat this for five acceleration and speed combinations, one of which includes the maximum acceleration and speed, in both directions.	For each test run the Bed translates in the desired direction and the acceleration is measured. The maximum acceleration achieved is above $100mm/s^2$. The accuracy of the actual acceleration is determined. Check for any damage to the PRS.

Translational Resolution	The PRS shall translate to any position with a resolution of 1mm, measured at the encoder.	Test	A patient simulant of max weight is restrained in the Bed and all airbags inflated. Translate the Bed at the maximum speed to a predetermined position. The final position is to be measured and compared to the programmed position. Repeat the test for three positions each at the maximum and minimum translation speeds, in both directions.	The resolution of the movement can be set to 1mm. The accuracy of the final position compared with the programmed position shall be determined. Check for any damage to the PRS.
Patient Sizes & Orientation	Patients of lengths between 1.45m and 1.92m, width between 361mm and 551mm, and waist between 143mm and 349mm, lying in a supine on the bed, with legs bent shall be accommodated. Patients of weight between 42kg and 137kg shall be accommodated.	Inspection	Inspection	N/A
Integration with Radiotherapy Environment	The PRS must be able to perform all functions when exposed to radiation from a cancer radiotherapy treatment beam. The PRS shall be able to be installed in a medical radiation bunker and translate, rotate and open its lid without interfering with any other medical or linear accelerator equipment. The PRS shall be able to be connected to the bunker's power supply and have the correct connection with the user interface in the control room and air compressor in an adjacent room. All materials in the field of view of the treatment beam will be radio translucent.	Analysis	Analysis	N/A

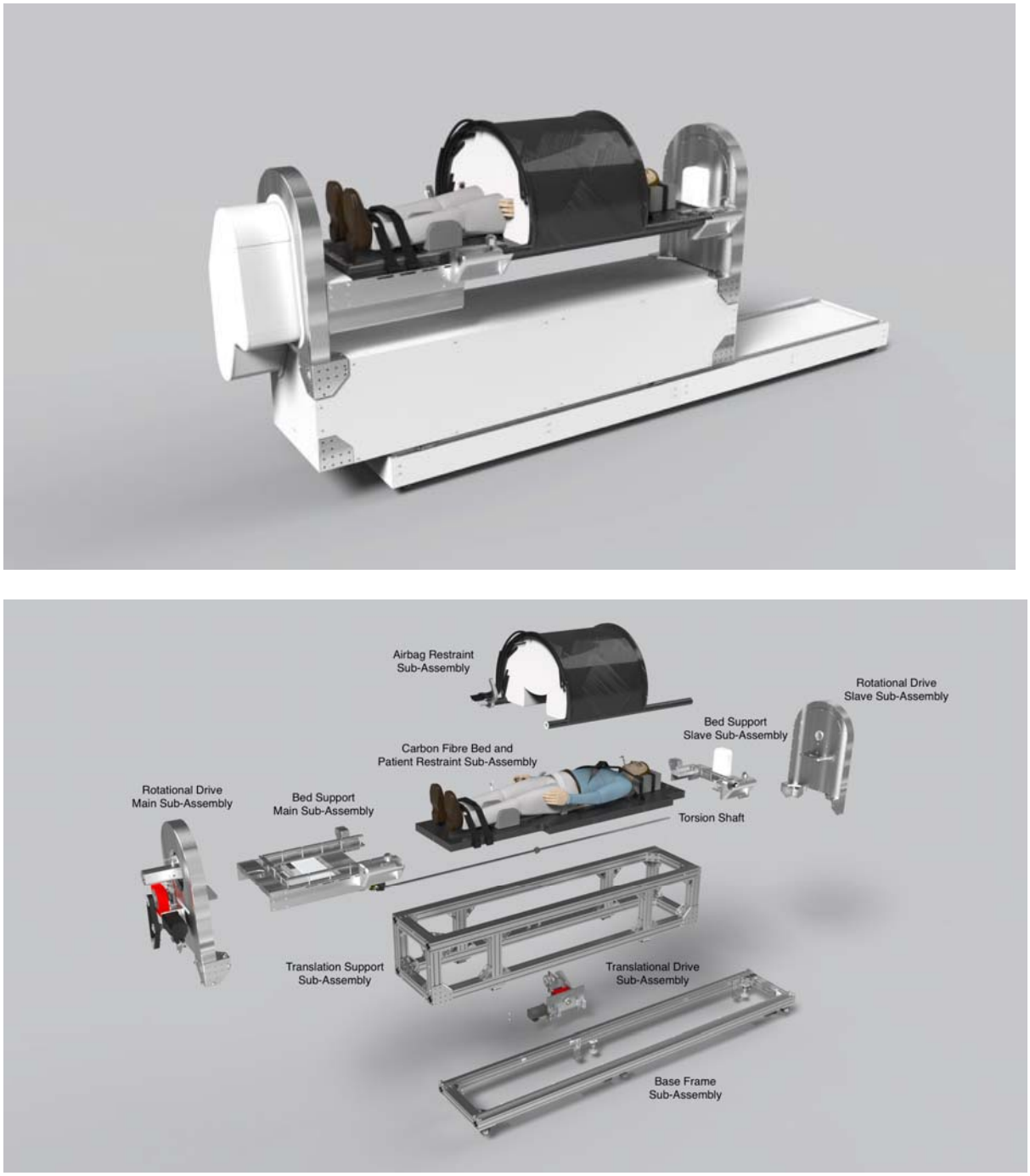

Figure 1: (Top) The final design of the patient rotation system. (Bottom) An exploded view of the 10 Sub-Assemblies.

Quality Assurance

User safety is assured through multiple redundancies in communication, sensors, switches, interlocks, emergency stops and manual override protocols. Full system and subsystem mechanical, electrical and human factor risk analyses were performed during the design phase by means of a Design Failure Mode and Effect Analysis (DFMEA) and subsequent expert review. 161 independent quality tests were identified and included as part of formal Quality Assurance Testing. The most significant PRS design and safety inputs are listed in Tables 1 and 2, respectively, along with their associated testing method and pass criteria used for validation and verification.

Table 2: PRS Safety Specifications and associated Validation/Verification Testing Descriptions.

Safety Feature	Description	Method	Test Description	Pass Criteria
Emergency CPR - Access	With lid open and bags deflated and a patient restrained, an operator can climb onto the bed and into a position where they can apply CPR.	Test	With a patient simulant loaded onto the bed and restrained with the straps, simulate positions and actions required to conduct effective CPR.	Inspection shall demonstrate that there is adequate space to perform CPR.
Emergency CPR - Loading	The total weight supported is 236kg for 5 minutes. With the bed at Egress, it supports the weight of the heaviest patient plus an operator of average male weight performing CPR. An additional 15% of the operator weight can be placed on the edge of the bed near the chest.	Test	With a patient simulant restrained within the PRS, the bed shall support 236kg without damage.	No damage to PRS when loaded as specified.
Emergency Patient Egress	An Emergency Egress switch shall be available in the treatment room that will move a restrained patient from the furthest translated and rotated position to the Egress position in less than 90 seconds.	Test	With patient simulant at the furthest translated and rotated position, trigger emergency egress. When the bed reaches egress, open lid and un-restrain the patient simulant and remove them from the bed. Record the time taken. Repeat this for other translation and rotation configurations.	The time taken from emergency egress being triggered to patient simulant off the bed is less than 90seconds.
Emergency Stop (E-Stop)	When the ESTOP is activated, the bed will cease translation within 10mm and rotation within 3°. Power to motors will be disconnected. The pressure in the Airbags will be maintained unless the ESTOP is triggered at Egress position (0mm/0°). The ESTOP will hardwired to hardware required to perform	Test	Air Bag Inflation - with a patient simulant restrained in the bed at 0°, initiate inflation via the treatment room user interface. At a time prior to completion of inflation, trigger the E-Stop, record the PRS response and measure time to initiate response.	All movement shall cease within 10mm and 3° with airbag pressure retained. If at Egress position (0mm/0°) all movements shall be prevented and airbag pressure shall be released. User must reset ESTOP button to reinitiate movement or egress patient, this must not

	above functions in both treatment and control room. User input will be required to disengage the ESTOP. User input shall be required to re-initiate movement.		Bed Motion Stop - with a patient simulant restrained in the bed, start bed rotation at maximum speed. At anytime trigger the E-Stop, record distances required for Bed motion to stop. Repeat for translation and max speed.	occur automatically.
Airbag Pressure Low - Below Min	If the airbag pressure drops below the Minimum Pressure set during treatment, the PRS shall stop all motion and a beam-hold signal will be sent to the linear accelerator. If the PRS is at Egress, bed motion will be disallowed until the Minimum Pressure is exceeded.	Test	With a patient simulant restrained in the PRS and airbags set at a defined pressure with a lower minimum pressure, commence rotation of the bed and at a point after rotation commenced, deflate a bag below min pressure setting and record the time for all Bed movement to stop and the time required for this signal to be sent to the linear accelerator. Repeat for bed during translation. With bed at the Egress position set the pressure below minimum pressure and attempt to initiate movement, record bed response.	All Bed motion stops within limits and the time to send the signal is less than 100ms. The Bed does not move from the Egress position when the pressure is below minimum.
Airbag Pressure High - Above Max	If any Airbag's pressure exceeds the set Absolute Maximum Pressure, one or more of the following occurs: - Auto shut Off Valve switches to divert air from filling Airbags - Mechanical Relief Valve opens to atmosphere - Electrical Relief valve opens to atmosphere These actions are initiated within 100ms of the maximum pressure being exceeded. The actions cease once Treatment Pressure is reached. The Electrical Relief valve is hardwired to one sensor.	Test	Create an overpressure scenario with each airbag. Then sequentially disable one of the pressure relief valves and test the remaining functions (e.g. disable mechanical and auto shutoff, to test electrical relief). Repeat for every possible configuration.	All conditions release pressure when tested. This test demonstrates that the signal path is hardwired.
Manual Enable Switch Locations & Functions	The PRS features manual Enable controls for motion (rotation/translation) and Airbag control (inflation/deflation) in treatment room and for motion only in the control room. The Enable control in the treatment room is physically attached to the PRS.	Test	Using the treatment room User Interface (UI), inflate then deflate each airbag, translate the bed the full translation distance and back. Then rotate the Bed 360° in both clockwise and anticlockwise directions. With the control room UI, translate the bed the full translation distance and	The Bed can be translated and rotated with both Enable switches. Airbags can only be inflated and deflated with the treatment room Enable switch. An inspection shows that the Enable switch located in the control room is attached but has no control for Airbag

			back. Then rotate the Bed 360° in both clockwise and anticlockwise directions. Confirm the control room user interface does not provide airbag inflation/deflation control.	inflation/deflation. The Enable switch in the treatment room is attached to the PRS.
Ready & Safe Control	The PRS has a "Ready & Safe" switch on the UI that enables control of the PRS Bed in the control room. Any event that disrupts the interlock line or if the PLC detects an unsafe state, will require Ready & Safe to be re-initiated.	Test	With the PRS Lid closed and Airbags inflated, do not engage "Ready & Safe". Attempt a movement sequence with the control system. Engage the "Ready & Safe" switch and re-attempt a movement sequence with the control system..	The Bed shall only move when the Ready & Safe switch is engaged.
Manual Enable - Motion	It shall not be possible to initiate or maintain manual rotation or translation, without the simultaneous actuation of the motion control and a hardwired enable control. When either control is removed movements will stop within 3° for rotation and 10mm for translation.	Test	Rotate PRS manually clockwise and anticlockwise, at its maximum speed, then remove the enable control. Repeat with translation in both directions at maximum speed. Record via the encoders the distance taken for motion to stop.	When enable is removed the Bed shall come to a complete stop within 3° for rotation and 10mm for translation. This tests demonstrate that the signal path is hardwired.
Enable - Airbag Inflation	Airbag inflation is only possible when the PRS meets all of the following conditions: - Lid Lock Sensors showing lock closed - Enable Control(s) - PLC & Manual engaged - LINAC stop motors engaged - E-Stop switches disengaged - Bed 0° Position sensor engaged - Bed 0mm Position sensor engaged - Inflation selected on UI - Inlet air pressure between limits - Power to PRS User input will be required to initiate/continue inflation if one of these states is not present.	Test	With each inflation prevention condition created, or combination thereof, attempt to inflate each airbag manually and to a preset pressure.	When the conditions outlined in the specification are created, no airbag should inflate, in any combination of conditions.
Enable - Airbag Deflation	Airbag deflation is only be possible when the PRS meets both of the following conditions: - Enable Control(s) - PLC engaged - Bed 0° Position sensor engaged User input will be required to initiate/continue deflation if	Test	With each deflation prevention condition created, or combination thereof, attempt to deflate each airbag manually and to a preset pressure.	When the conditions outlined in the specification are created, the no airbag should deflate, in any combination of conditions.

	one of these states is not present.			
Stop Motion - Hardwired Interlocks	The following sensors and switches will be hardwired: - Lid Lock Sensors - Enable Control(s) - PLC (PLC unit failure) & Manual - LINAC stop motors - E-Stop switches If any sensor or signal from a sensor is interrupted, all motion shall stop. If power to the PRS, or encoder signals, is lost, all motion shall stop. All movements will cease within 3° for rotation and 10mm for translation from the time the interrupt event occurs. User input is required to re-initiate motion or Egress patient.	Test	With the Bed placed into a typical sequence of movements as expected during a typical treatment, create a condition that should initiate the Stop Motion. Measure the distances the Bed took to stop. Repeat for each condition or combination thereof. The heaviest expected patient simulant is to be restrained in the PRS for this test.	When the conditions outlined in the specification are created, the Bed should come to a complete stop within the radial and translational limits of 3° for rotation and 10mm for translation from the time the interrupt event occurs. The user must act to reinitiate movement or egress patient; this must not occur automatically.
Stop/Prevent Motion - PLC Control	The PLC will prevent or stop all motion if any one of the following states of sensors and switches occurs: - There is an error between a secondary and primary encoder - Loss of signal from encoder - The interlock line is interrupted - Translation limit switch engaged - Ready & Safe switch is disengaged All movements will cease within 3° for rotation and 10mm for translation from the time the event occurs. Movement will be prevented if any of the states are as stated.	Test	With the Bed placed into a typical sequence of movements as expected during a typical treatment, create a condition that should initiate the stop all motion. Measure the distances the Bed took to stop. Repeat for each condition or combination there of. The heaviest expected patient simulant is to be restrained in the PRS for this test.	When the conditions outlined in the specification are created (all combinations), the Bed should come to a complete stop within the radial and translational limits, for all test runs. The user must act to reinitiate movement or egress patient, this must not occur automatically.
Linear Accelerator (LINAC) Beam Off	When any one of the following events occurs the LINAC will trigger a beam stop within 100ms of the event occurring: - Power loss to the PRS - PLC Failure - Encoder signal loss (any encoder) - Lid Lock Sensors indicating unlocked lid - Enable Control(s), PLC (PLC unit failure) - E-Stop is engaged - Pressure in any one Airbag drops below the Minimum Pressure set - No movement from motor	Test	With the Bed placed into a typical sequence of movements as expected during a typical treatment, create a condition that should initiate the beam off signal to be sent to the LINAC. Repeat for each condition or combination thereof. The heaviest expected patient simulant is to be restrained in the PRS for this test.	When the conditions outlined in the specification are created (all combinations), the PRS control system should send a beam off signal to the LINAC within the prescribed time limit, for all test runs.

	and corresponding secondary encoder - There is an error between a secondary and primary encoder - Ready & Safe switch is disengaged			
Stop Motions - Power Loss	When power is lost to the interlock line, the E-Stop will be triggered and all motion will cease within 3° for rotation and 10mm for translation	Test	With the Bed placed into a typical sequence of movements as expected during a typical treatment, disconnect all power from the PRS.	The Bed should stop within the radial and translational limits (3° for rotation and 10mm for translation) and the LINAC shall be triggered to switch the radiation beam off. The user must act to reinstate PRS power.
Manual Translation & Rotation – Power Loss	With complete power loss and the heaviest patient restrained in the PRS (see Table 1) it is possible to manually move the bed through 360° in both directions (clockwise and counter clockwise) and move the bed through its full translation range in both directions.	Test	With a patient simulant restrained correctly in the PRS disconnect power to the PRS. Use the manual input wheels to translate the bed to its furthest position and back, followed by rotating the bed through 360° in both directions, clockwise and anti-clockwise. The time taken to complete these actions will be measured and the difficulty in completing the actions scored by the user. Repeat this for any additional users.	The bed can be translated the full distance and back and rotated 360°, clockwise and anti-clockwise. The time taken to complete the actions shall be recorded, as well the score for difficulty in completing the movements.
Safety Relays	All relays used in the interlock chain are EN 50205 compliant	Inspection	N/A	N/A
Servo Enable	The servo has a dual enable configuration. When disconnected, it removes power to the motors.	Inspection	N/A	N/A
Servo Drive	The servo drives fails with power disconnected to the motor.	Inspection	N/A	N/A
Patient restraint - Airbag failure	In the event of a sudden airbag failure (loss of pressure) the restraining straps prevent the heaviest patient from injury, strain or collision and continue to restrain the patient until Egress is possible.	Test	With a patient simulant restrained in the bed via the straps and air bags, rotate the bed to 90° then relieve the air bag pressure and observe the position of the patient simulant, record potential injury hazards. Repeat for 135°, 180°, 225° and 270° positions. Inspect straps and fixings for signs of damage	The patient simulant shall be restrained in a position that does not suggest possible injury and the straps remain secure and in place when airbag pressure fails. The PRS can be returned safely to Egress position from each angular position.

			disconnection, wear and fatigue. The bed is to be in the furthest translated position for each test.	
Airbag Pressure - Power Loss	With complete power loss to the PRS, and when inflated and out of Egress, the air pressure in the bags will be maintained.	Test	Inflate all three airbags to max pressure, then cut all power to the PRS. Measure the pressure in each bag. Repeat for bags at min pressure	Airbag pressure shall remain unchanged for each test run.
Power Loss to PRS	User input and control is required to change or reinstate actions following a power loss event to the PRS. Ready & Safe control must be enabled prior to recommencing treatment.	Test	With the PRS in a sequence of rotation and translation, cut all power to the PRS. Reinstate power to the PRS and observe and record PRS reaction.	There shall be no movement or inflation/deflation of the airbags when power is reinstated.
UI - Manual Motion Speed Limit	The speed at which the Bed can be translated and rotated manually from the User Interface is limited (via PLC programming).	Test	With a patient simulant restrained within the PRS, select an airbag to inflate and the Inflate function. Simultaneously hold the Manual Enable switch and allow airbag to reach max pressure. Select the Deflate function and simultaneously hold the Manual Enable switch and allow the airbag to deflate. Repeat for all combinations of bag filling.	Selected airbags inflate to the maximum pressure when operated and maximum pressure is not exceeded. Selected airbags deflate when operated. Inflation/deflation ceases if Manual Enable switch of inflate/deflate command released.

User (Human Factor) Testing

Table 3: User Testing Sequence

Step	Movement	Duration (sec)	Rotation Velocity (deg/sec)	Rotation Acc/Dec (deg/sec^2)	Translation Velocity (mm/sec)	Translation Acc/Dec (mm/sec^2)
1	Hold at 0 degrees then translate 1000mm	60	N/A	N/A	100	100
2	Rotate 360 degrees	N/A	10	30	N/A	N/A
3	Rotate 360 degrees	N/A	30	30	N/A	N/A
4	Rotate 360 degrees	N/A	60	30	N/A	N/A
5	Rotate 45 degrees	60	10	30	N/A	N/A
6	Rotate 90 degrees	60	10	30	N/A	N/A
7	Rotate 135 degrees	60	10	30	N/A	N/A
8	Rotate 180 degrees	60	10	30	N/A	N/A
9	Egress	N/A	10	30	100	100

In order to demonstrate the PRS functionality from a user's perspective, 10 healthy female and male engineers and physicists from our team were tested on the PRS for human factors including comfort, experience and ease of use. Each of the 10 test subjects were loaded onto the PRS, restrained and put through the test sequence outlined in Table 3. Subjects were secured with the restraint and airbag systems and rotated 360 degrees, once each at a pre-set speed of 10 deg/sec, 30 deg/sec and 60 deg/sec. Their subjective comfort and experience was measured after each rotation on a scale of one to five with five being most comfortable and one being uncomfortable. Each user was then rotated and held for one minute at angles of 45, 90, 135 and 180 degrees, and their comfort and experience was again measured on a scale of one to five at each angle prior to being rotated and translated back to the Egress position and released from the PRS.

Results

A Horizontal Patient Rotation System with Real-Time Control

The PRS hardware has been built and verified and validated against our design and safety input requirements using the testing methods and pass/fail criteria listed in Tables 1 and 2. The PRS passed every test. Figure 2 shows the PRS open and closed with Figure 3 illustrating a typical patient ingress and Figure 4 the full range of rotational states.

The PRS control system has been developed with consideration to a fully working fixed-beam radiotherapy system wherein patient safety drives the core of the design process. In this context the control system includes a real-time system to handle/manage all critical communication with the PRS and numerous non real-time computers for tasks that are not critical, such as for User Interfaces (UI). The software on the real-time computer, which is developed in C++, communicates with the PLC controlling the PRS via CAN/CANOPEN. System errors, such as a failure to read the airbags pressure, or interlock situations, and dose related synchronization tasks, e.g. synchronizing dose delivery with the PRS rotation, are given high priority and processed in real-time in an appropriate manner (e.g. a beam hold might be issued to the linac). The primary mechanism for the PRS to handle critical errors is via hardware, which is double fault safe. As such the software control system is not relied on for patient safety and the software system simply provides a tertiary level of safety where commands are not issued when criticalities are identified. Non critical tasks, such as displaying bag pressures and PRS positions, are processed with a lower priority with the message re-packaged and sent via TCP across the network to the appropriate computer for display to the operator. As the non real-time computers on the network are used for interaction with an operator, the UI software has been developed in C#.

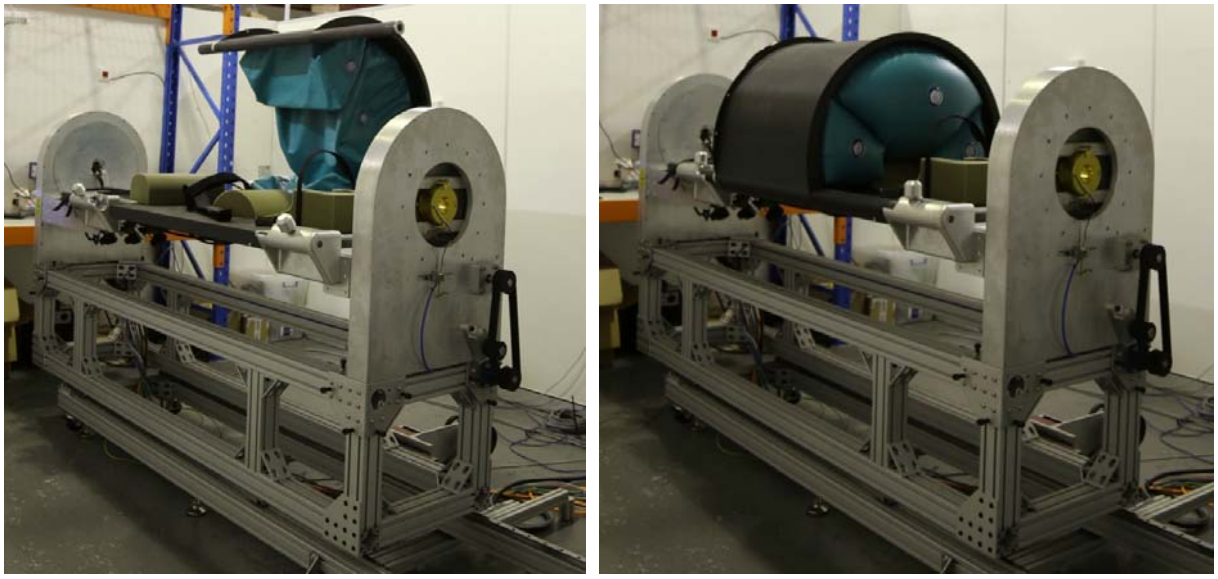

Figure 2: The PRS at Ingress Position (left) and with the lid closed and the airbags inflated (right).

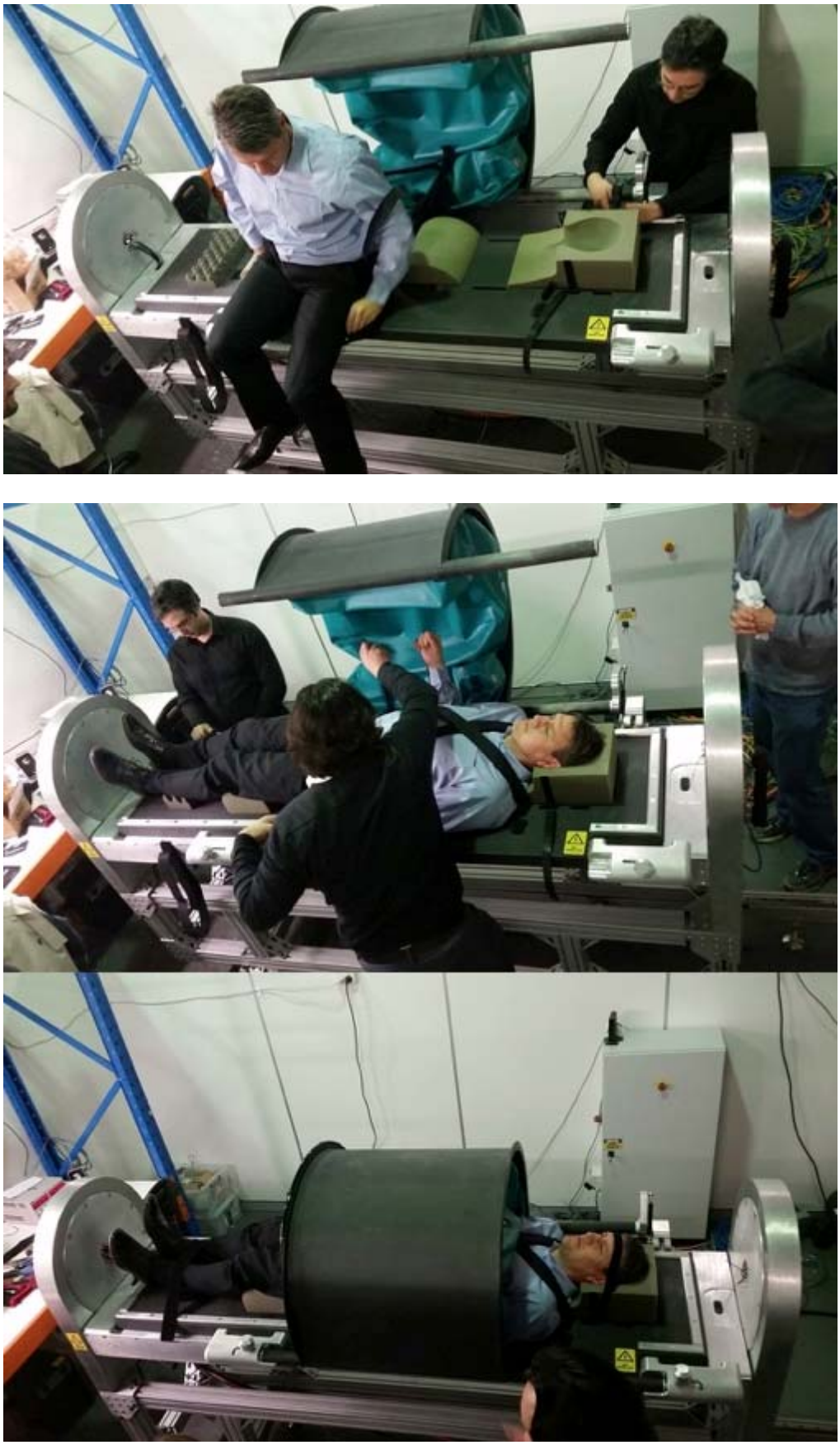

Figure 3: PRS Ingress: (top) a volunteer sits down on the bed at a comfortable sitting height, (centre) a volunteer lies down in the supine position and primary restraints are secured, (bottom) three inter-connected but independent

pneumatic airbag systems provide secondary immobilisation and comfort and security. Figure reproduced with permission from Feain et al. (2017)[16] .

Figure 4: Rotation of the PRS shown in steps of 45 degrees starting at 45 degrees. Clockwise from top left.

Quality Assurance

The PRS was subjected to 161 independent validation and verification tests grouped around the nine categories of (1) Device, Startup and Training, (2) Patient Ingress, Restraint and Egress, (3) Treatment, (4) Human Factors, (5) Safety, Regulatory and Labelling, (6) Radiation and Linear Accelerator Compatibility, (7) Software and Electrical, (8) Dimensional and Mechanical, and (9) Environmental Conditions. The design criteria (columns 1 and 2; Table 1) and Safety Inputs (columns 1 and 2; Table 2) were validated and verified using testing methods listed in Columns 3 and 4 of these Tables. Inputs relating to radiation and Linear Accelerator compatibility were tested using signals simulating related parameters. All validation and verification tests passed according the specified testing and pass/fail criteria listed in Column 5 of Tables 1 and 2. Summaries of the numerical results for some of these tests are described below.

Patient Ingress: Three test subjects were loaded onto the PRS. The times taken to strap the subject in and close the lid were 52.8s, 58.4s and 56.2s respectively.

Patient Egress: Three test subjects were unloaded from the PRS. The times taken to un-restrain the subject and remove them from the PRS was 52.15s, 56.37s and 55.13s respectively.

Rotation and Translation Speeds, Accelerations and Decelerations

For these tests, a 140kg patient simulant was loaded into the PRS and then moved using various profiles (variants) described further in Tables 5 and 6. The accuracy in time measurements is of order +/-1s.

Table 4: Results of Rotation Speed, Acceleration and Deceleration Tests

Variant	Set Rotation Position (°)	Set Rotation Speed (°/s)	Set Rotation Acc/Dec ($°/s^2$)	Expected Time (s)	ΔTime[1] (s)	Final Rotation Position (°)	ΔRotation[2] (°)
1	180	1	1	181	0.39	180.0	0
2	135	1	1	136	0.67	135.0	0
3	45	1	1	46	0.99	44.9	0.1
4	90	15	15	7	0.68	89.9	0.1
5	90	30	30	4	0.24	89.8	0.2
6	90	45	45	3	0.32	89.9	0.1
7	180	60	60	4	0.44	180.1	0.1
8	135	60	60	3.25	0.55	135.0	0
9	45	60	60	1.75	0.27	44.9	0.1

1. ΔTime: Difference between Expected and Measured Time
2. ΔRotation: Difference between Expected and Measured Rotation Position

Table 5: Results of Translation Speed, Acceleration and Deceleration Tests

Variant	Set Translation Position (mm)	Set Translation Speed (mm/sec)	Set Translation Acc/Dec (mm/sec^2)	Expected Time (s)	ΔTime (s)	Final Translation Position	ΔTranslation (mm)
1	1000	1	1	1001	-0.15	1000	0
2	500	1	1	501	0.92	500	0
3	333	1	1	334	0.79	333	0
4	1000	25	25	41	0.65	1000	0
5	1000	50	50	21	0.22	1000	0
6	1000	75	75	14.33	-0.03	1000	0
7	1000	100	100	11	-0.09	1000	0

1. ΔTime: Difference between Expected and Measured Time
2. ΔTranslation: Difference between Expected and Measured Translation Position

Patient Sizes & Orientation: The system was shown to accommodate patients between 42kg and 137kg of lengths between 1.45m and 1.92m, width between 361mm and 551mm, and waist between 143mm and 349mm.

Emergency Patient Egress: The PRS was moved to the furthest position target 1600mm, 180° and an E-Stop triggered mid movement (558mm, 68.8°). The emergency egress button was pressed and the time take to Egress the patient was recorded. The test passed with the total time to egress and remove the patient 1:16.28.

Emergency Stop (E-Stop): The E-Stop was triggered during a simulated movement of a test subject. When the E-Stop was pressed all movements ceased. As the system was not at 0° no pressure was released from the airbags. The movement from the moment of E-Stop being called was 40mm in translation and 3.2° in rotation. The E-Stop was then tested during inflation of the airbag. When the E-Stop was pressed pressure from all bags was released to atmosphere. The stopping distance caused this test to fail however the functionality worked as specified otherwise.

Airbag Pressure High - Above Max Pressure Set: The pressure was set to the maximum treatment pressure (60mbar) and an over pressure scenario was created by applying external pressure to each of the bags. When the pressure went over the treatment pressure an error appeared on the screen warning the user that the bag was outside the treatment pressure. When the pressure exceeded the absolute maximum pressure (80mbar) for each of the bags the PLC vented the airbag with over pressure and an error message was displayed on the screen. At the same time the hardware pressure switch was triggered also opening the relief valve to atmosphere. To test this functionality separately to the PLC function, the set point on each of the pressure switches was set to 70mbar to activate before the PLC. This function was found to work correctly for all bags.

Linear Accelerator (LINAC) Beam Off: An E-Stop event was triggered and monitored on an oscilloscope. The time between the event and the opening of the relay contact to terminate radiation was measured to be 20ms.

Airbag Pressure - Power Loss: With a maximum simulant load (140kg) the airbags were inflated with a treatment pressure setting of 30mbar. The PRS was then moved into a test position of 1000mm, 180°. The power was disconnected to the PRS and the reaction monitored. All valves remain in a closed state with the pressure difference before and after equal to zero.

User (Human Factor) Testing

The level of usability of the system was found to be straightforward, robust and comfortable with the majority of volunteers expressing increased comfort over time. There was little discernable difference in tolerance to rotation speeds, although 30 deg/sec was typically preferred over the faster (60 deg/sec) and slower (10 deg/sec) alternatives. Using a user comfort scale of 1-5 to measure a subject's comfort (with 1 being very uncomfortable and 5 being very comfortable), the average at each sequence step is listed in Table 6.

Table 6: Average Results of User Testing

Step	Average Comfort (Scale 1-5)	Comments
1	**3.75**	Most users experienced transient anxiety whilst airbags were filling
2	4.25	Four users noted increased comfort after becoming accustomed
3	4	
4	4	
5	4.13	Three users noted head shifting
6	3.75	
7	3.88	Two users noted lying prone more comfortable than lying supine
8	4	

Nine of the test subjects rated the ease of getting in and out of the system between four and five. One subject found it more difficult to get in as a result of not being able to adjust the lumbar support position to a comfortable position. With help from the operator a comfortable position was found.

Five of the subjects expressed a comfort level of less than four for one or more of the test sequences in Table 3. The common cause of discomfort was a feeling of numbness in the hands/arms from the airbag pressure and/or inadequate head support leading to neck discomfort. Observed subject movement was prominently in the legs. Although leg motion didn't lead to a subject's discomfort, future modifications to the PRS are required to ensure minimum patient movement. Four test subjects noted anxiety during the airbag fill sequence, which was due to unease in not knowing when the airbags would cease inflating. Half of these subjects expressed increased comfort levels once they had become accustomed to the system. Six of the subjects reported increased comfort over time in the system, with four reporting they were most comfortable when positioned 180°.

Discussion

Limitations of the current Restraint System

The user testing showed that the majority of the subjects and movement variants resulted in the subject being comfortable or very comfortable. The testing highlighted issues with the neck restraint and the leg restraint. The neck and head requires more support to ensure the neck remains aligned straight and stop the subject from remaining tense during treatment. The primary cause of test subject movement was the legs being able to move. Increased support and restraint would be required to reduce the level of torso shift in the bags. Adjustments will be made to the existing head and ankle restraints to better handle immobilization during the slowest rotation. All of the subjects expressed some level of discomfort and/or visible signs of pressure restriction in the arms at the end of the treatment sequence. Improvements to the restraint system to enable arms above the head (when possible) would alleviate this discomfort and allow for higher pressure in the side bags. This would lead to a greater level of patient restraint and reduced patient movement.

Intended Function in a Fixed Beam Radiotherapy Treatment Workflow

Modern radiotherapy machines utilise rotating gantries to deliver differential 3D motion between the patient and the kV and MV beams for imaging and treatment, respectively. Simplified designs that replace the rotating treatment gantries with rotating patient systems may offer an equivalent solution[6-12] with the potential for more compact footprint and affordable designs[7].

The fixed-beam radiotherapy machine we are developing utilises real-time control to treat the dynamic patient. The machine adapts to the patient using real-time kV imaging and dynamic multi-leaf collimator tracking[13-15]. We replace a fixed couch with the PRS presented in this Technical Note and the rotating MV and kV gantry system with a fixed kV and MV scheme. The kV imaging system acquires 2D fluoroscopic projections as the patient rotates about 360 degrees. Volumetric information on the patient anatomy is generated for any rotational angle and used to deform the treatment plan created from a CT volume acquired in the supine position (0 degrees). The kV system continues to acquire projections during treatment to monitor the displacement and deformation of a patient's soft-tissue in real-time. This information is used to update the multi-leaf

collimator to follow a moving, deforming target during treatment. Patient motion will be minimised in the PRS with a semi-automated restraint/airbag immobilisation scheme. Real-time image guidance and treatment adaptation will then maintain treatment quality. Further validation of patient tolerance to horizontal rotation will be measured in a proposed 100-patient clinical trial measuring human factors including ease of use and comfort.

Conclusions

We have designed, built and tested a horizontal patient rotation system (PRS) for the purposes of fixed-beam radiotherapy for cancer treatment. The system meets all design and safety requirements and complies with all appropriate standards pertaining to medical devices and linear accelerator equipment. The PRS control system architecture is a real-time computer to handle/manage all critical communication and several non real-time computers non-critical tasks. We have demonstrated the utility of the PRS from a human factor perspective with 10 healthy volunteers. The PRS will shortly be installed in a clinical bunker and integrated with a linear accelerator.

Conflicts of Interest

Authors Feain and Keall are founders of Nano-X Pty Ltd and inventors on several granted and pending patents related to fixed beam radiotherapy treatment systems.

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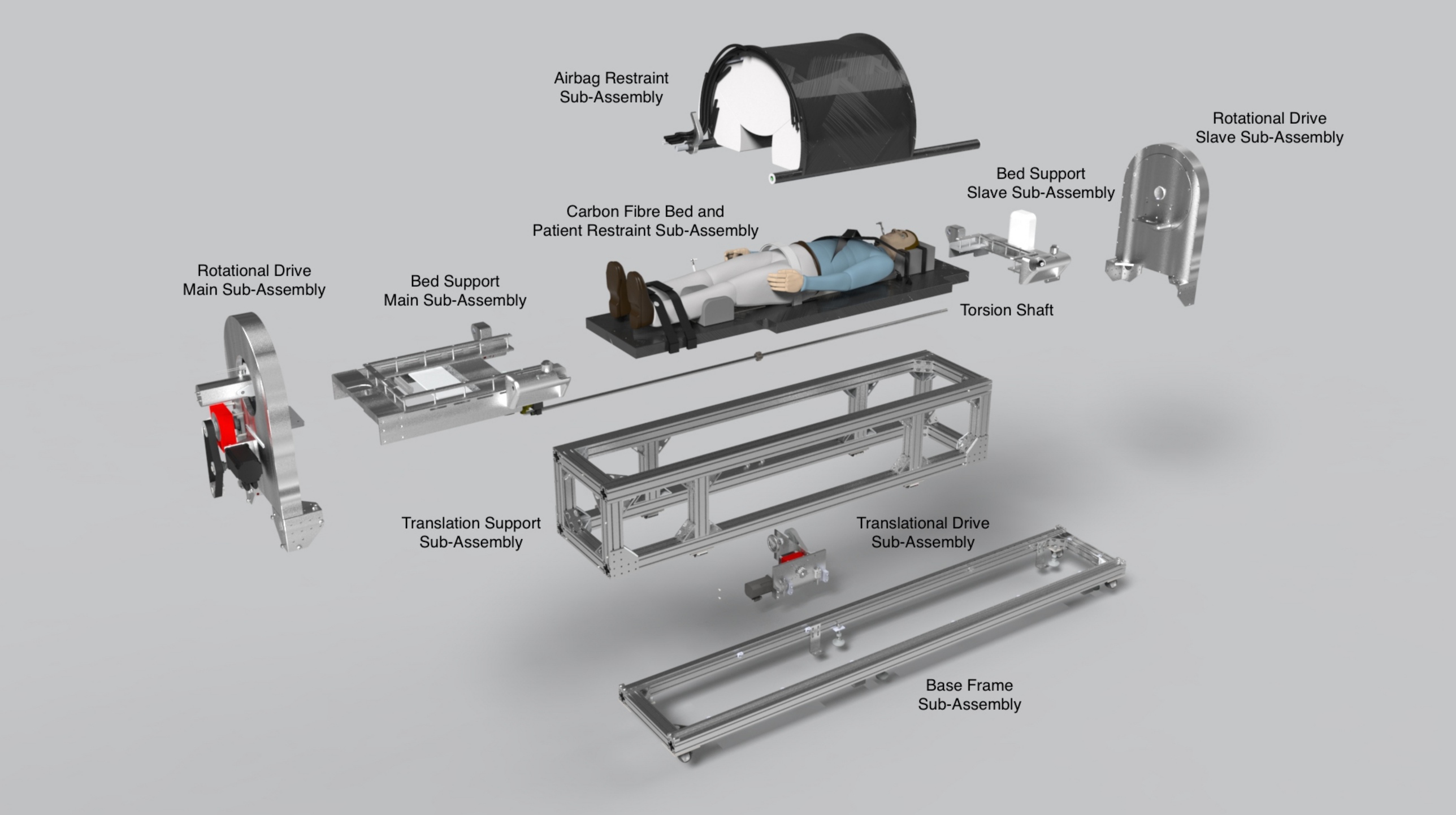
Airbag Restraint
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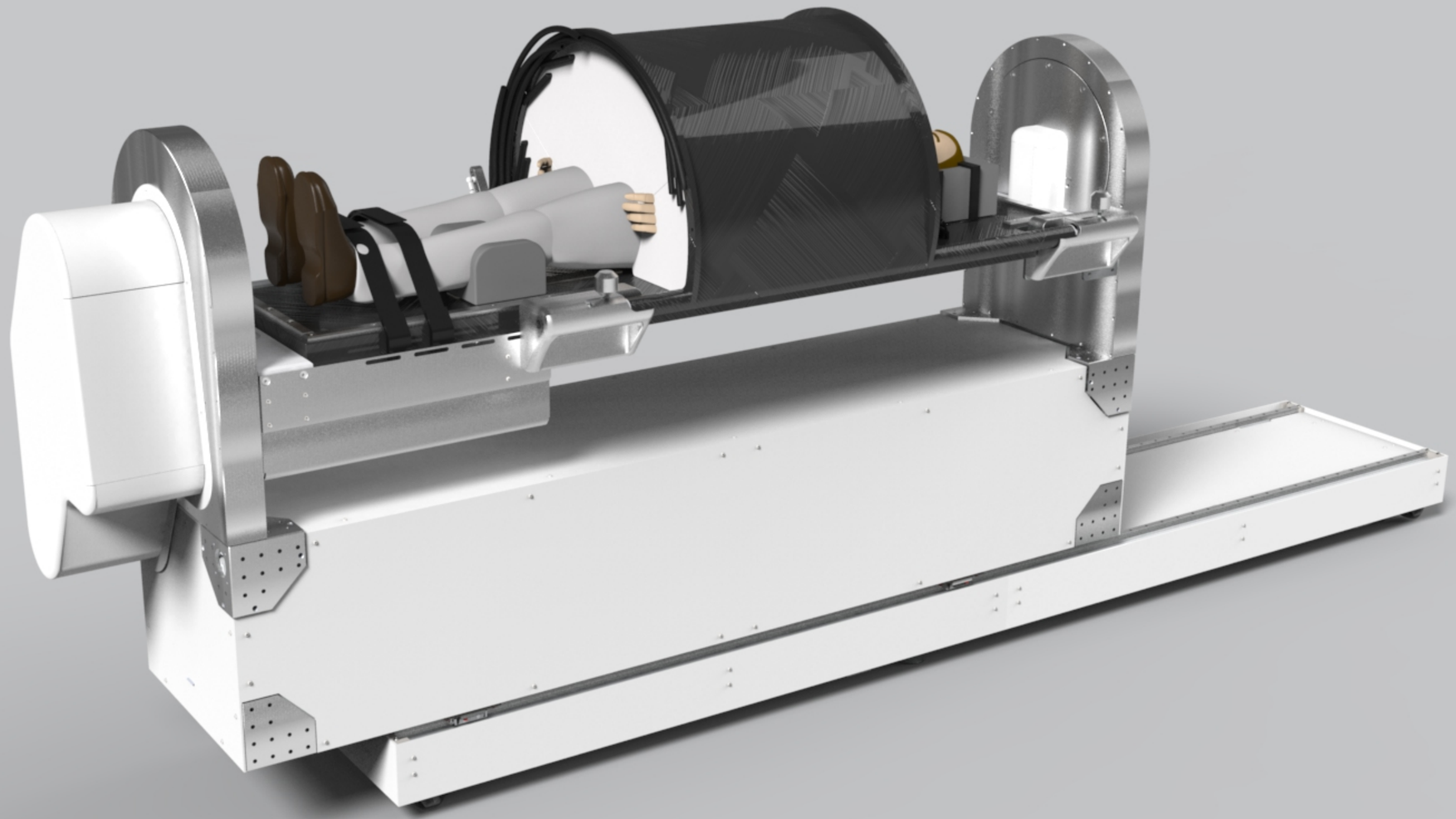
Rotational Drive
Slave Sub-Assembly
Bed Support
Slave Sub-Assembly
Carbon Fibre Bed and
Patient Restraint Sub-Assembly
Rotational Drive
Main Sub-Assembly
Bed Support
Main Sub-Assembly
Torsion Shaft
Translation Support
Sub-Assembly
Translational Drive
Sub-Assembly
Base Frame
Sub-Assembly

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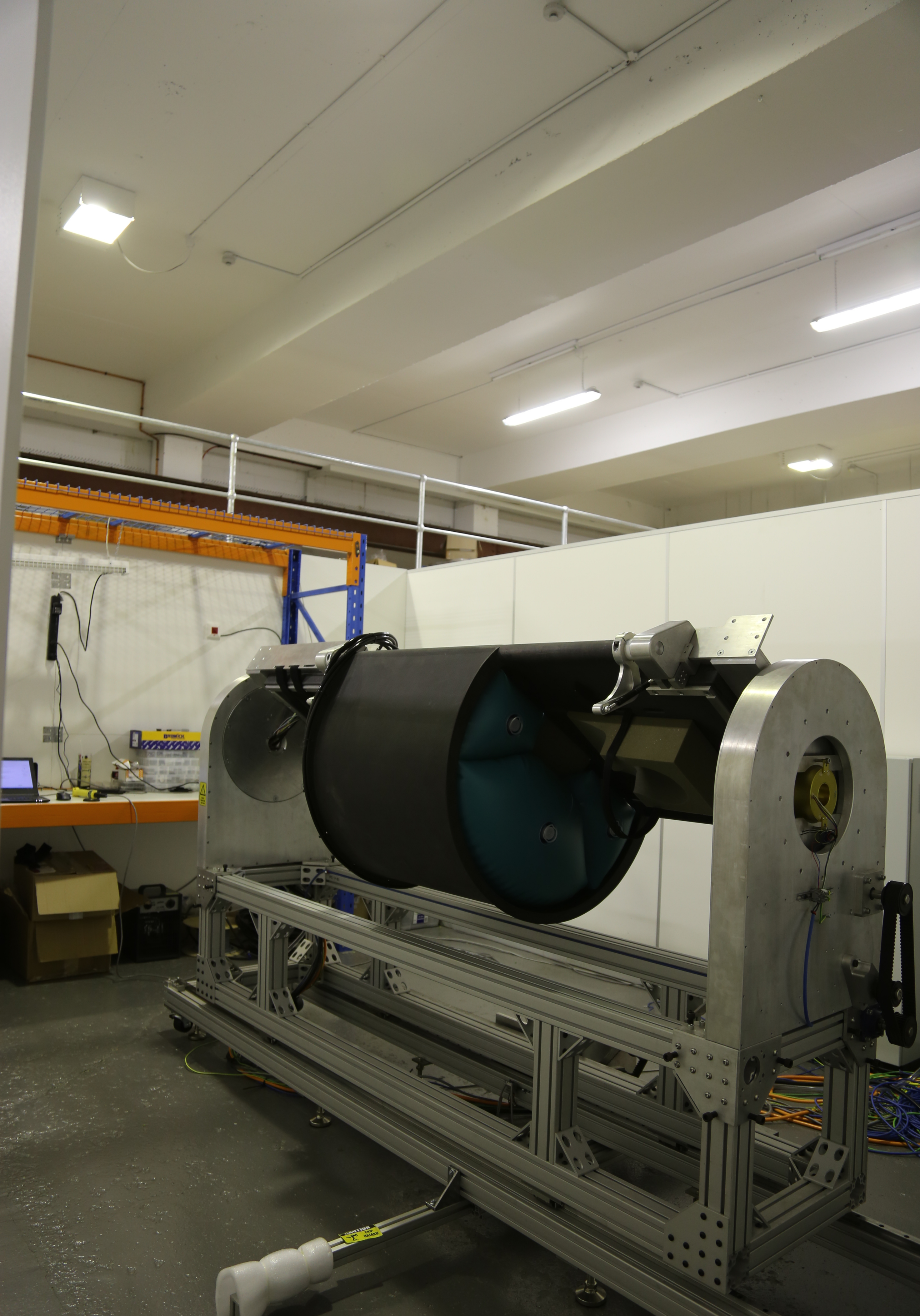
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