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(54) **Title:** CHARGED PARTICLE BEAM EXTRACTION METHOD AND APPARATUS USED IN CONJUNCTION WITH A CHARGED PARTICLE CANCER THERAPY SYSTEM

(57) **Abstract:** The invention comprises a charged particle beam extraction method and apparatus used in conjunction with charged particle beam radiation therapy of cancerous tumors. The system uses a radio-frequency cavity system to induce betatron oscillation of a charged particle stream. Sufficient amplitude modulation of the charged particle stream causes the charged particle stream to hit a material, such as a foil. The foil decreases the energy of the charged particle stream, which decreases a radius of curvature of the charged particle stream in the synchrotron sufficiently to allow a physical separation of the reduced energy charged particle stream from the original charged particle stream. The physically separated charged particle stream is then removed from the system by use of an applied field and deflector.

**CHARGED PARTICLE BEAM EXTRACTION METHOD AND
APPARATUS USED IN CONJUNCTION WITH A CHARGED
PARTICLE CANCER THERAPY SYSTEM**

CROSS REFERENCES TO RELATED APPLICATIONS

This application claims benefit of:

U.S. provisional patent application no. 61/055,395 filed May 22, 2008;

U.S. provisional patent application no. 61/137,574 filed August 1, 2008;

U.S. provisional patent application no. 61/192,245 filed September 17, 2008;

U.S. provisional patent application no. 61/055,409 filed May 22, 2008;

U.S. provisional patent application no. 61/203,308 filed December 22, 2008;

U.S. provisional patent application no. 61/188,407 filed August 11, 2008;

U.S. provisional patent application no. 61/???,??? filed March 2009
(attorney docket no. PROT0005PR);

U.S. provisional patent application no. 61/188,406 filed August 11, 2008;

U.S. provisional patent application no. 61/189,815 filed August 25, 2008;

U.S. provisional patent application no. 61/208,182 filed February 23, 2009
(attorney docket no. PROT0009PR);

U.S. provisional patent application no. 61/201,731 filed December 15, 2008
(attorney docket no PROT0010PR);

U.S. provisional patent application no. 61/???,??? filed March, 2009
(attorney docket no. PROT001 1PR);

U.S. provisional patent application no. 61/205,362 filed January 12, 2009;

U.S. provisional patent application no. 61/134,717 filed July 14, 2008;

U.S. provisional patent application no. 61/134,707 filed July 14, 2008;

U.S. provisional patent application no. 61/201,732 filed December 15, 2008;

U.S. provisional patent application no. 61/198,509 filed November 7, 2008;

U.S. provisional patent application no. 61/134,718 filed July 14, 2008;

U.S. provisional patent application no. 61/190,613 filed September 2, 2008;

U.S. provisional patent application no. 61/191,043 filed September 8, 2008;

U.S. provisional patent application no. 61/192,237 filed September 17, 2008,

U.S. provisional patent application no. 61/201,728 filed December 15, 2008;

U.S. provisional patent application no. 61/190,546 filed September 2, 2008;

U.S. provisional patent application no. 61/189,017 filed August 15, 2008;

U.S. provisional patent application no. 61/198,248 filed November 5, 2008;

U.S. provisional patent application no. 61/198,508 filed November 7, 2008;

U.S. provisional patent application no. 61/197,971 filed November 3, 2008;

U.S. provisional patent application no. 61/199,405 filed November 17, 2008;

U.S. provisional patent application no. 61/199,403 filed November 17, 2008; and

U.S. provisional patent application no. 61/199,404 filed November 17, 2008; and

claims priority to PCT patent application no. PCT/RU2009/00015, "Multi-Field Charged Particle Cancer Therapy Method and Apparatus", filed March 4, 2009 (attorney docket no. ZPRO0001 P);

all of which are incorporated herein in their entirety by this reference thereto.

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

This invention relates generally to treatment of solid cancers. More particularly, the invention relates to a charged particle beam extraction method and apparatus used in conjunction with radiation treatment of cancerous tumors.

DISCUSSION OF THE PRIOR ART

Cancer

A tumor is an abnormal mass of tissue. Tumors are either benign or malignant. A benign tumor grows locally, but does not spread to other parts of the body. Benign tumors cause problems, because of their spread, as they press and displace normal tissues. Benign tumors are dangerous in confined places, such as the skull. A malignant tumor is capable of invading other regions of the body. Metastasis is cancer spreading by invading normal tissue and spreading to distant tissues.

Cancer Treatment

Several forms of radiation therapy exist for cancer treatment, including: brachytherapy, traditional electromagnetic X-ray therapy, and proton therapy.

Proton therapy systems typically include: a beam generator, an accelerator, and a beam transport system to move the resulting accelerated protons to a plurality of treatment rooms where the protons are delivered to a tumor in a patient's body. Proton therapy works by aiming energetic ionizing particles, such as protons accelerated with a particle accelerator, into a target tumor. These particles damage the DNA of cells, ultimately causing their death. Cancerous cells, because of their high rate of division and their reduced ability to repair damaged DNA, are particularly vulnerable to attacks on their DNA.

Due to their relatively enormous size, protons scatter less easily than X-rays in tissue and there is very little lateral dispersion. Hence, the proton beam stays focused on the tumor shape without much lateral damage to surrounding tissue. All protons of a given energy have a certain range, defined by the Bragg peak, and the dosage delivery to tissue ratio is at a maximum over just the last few millimeters of the particle's range. The penetration depth depends on the energy of the particles, which is directly related to the speed to which the particles were accelerated by the proton accelerator. The speed of the proton is adjustable to the maximum rating of the accelerator. It is therefore possible to focus the cell damage due to the proton beam at the very depth in the tissues where the tumor is situated. Tissues situated before the Bragg peak receive some reduced dose of radiation and tissues situated after the peak receive no radiation.

Synchrotrons

K. Hiramoto, *et. al.* "Accelerator System", U.S. patent no. 4,870,287 (September 26, 1989) describes an accelerator system having a selector electromagnet for introducing an ion beam accelerated by pre-accelerators into either a radioisotope producing unit or a synchrotron.

K. Hiramoto, *et. al.* "Circular Accelerator, Method of Injection of Charged Particle Thereof, and Apparatus for Injection of Charged Particle Thereof, U.S. patent no. 5,789,875 (August 4, 1998) and K. Hiramoto, *et. al.* "Circular Accelerator, Method of Injection of Charged Particle Thereof, and Apparatus for Injection of Charged Particle Thereof, U.S. patent no. 5,600,213 (February 4, 1997) both describe a method and apparatus for injecting a large number of charged particles into a vacuum duct where the beam of injection has a height and width relative to a geometrical center of the duct.

Accelerator / Synchrotron

H. Tanaka, *et. al.* "Charged Particle Accelerator", U.S. patent no. 7,259,529 (August 21, 2007) describe a charged particle accelerator having a two period acceleration process with a fixed magnetic field applied in the first period and a timed second acceleration period to provide compact and high power acceleration of the charged particles.

T. Haberer, *et. al.* "Ion Beam Therapy System and a Method for Operating the System", U.S. patent no. 6,683,318 (January 27, 2004) describe an ion beam therapy system and method for operating the system. The ion beam system uses a gantry that has vertical deflection system and a horizontal deflection system positioned before a last bending magnet that result in a parallel scanning mode resulting from an edge focusing effect.

V. Kulish, *et. al.* "Inductional Undulative EH-Accelerator", U.S. patent no. 6,433,494 (August 13, 2002) describe an inductive undulative EH-accelerator for acceleration of beams of charged particles. The device consists of an electromagnet undulation system, whose driving system for electromagnets is made in the form of a radio-frequency (RF) oscillator operating in the frequency range from about 100 KHz to 10 GHz.

K. Saito, *et. al.* "Radio-Frequency Accelerating System and Ring Type Accelerator Provided with the Same", U.S. patent no. 5,917,293 (June 29, 1999) describe a radio-frequency accelerating system having a loop antenna coupled to a magnetic core group and impedance adjusting means connected to the loop antenna. A relatively low voltage is applied to the impedance adjusting means allowing small construction of the adjusting means.

J. Hirota, *et. al.* "Ion Beam Accelerating Device Having Separately Excited Magnetic Cores", U.S. patent no. 5,661,366 (August 26, 1997) describe an ion beam accelerating device having a plurality of high frequency magnetic field inducing units and magnetic cores.

J. Hirota, *et. al.* "Acceleration Device for Charged Particles", U.S. patent no. 5,168,241 (December 1, 1992) describe an acceleration cavity having a high frequency power source and a looped conductor operating under a control that combine to control a coupling constant and/or de-tuning allowing transmission of power more efficiently to the particles.

Magnet Shape

M. Tadokoro, *et. al.* "Electromagnetic and Magnetic Field Generating Apparatus", U.S. patent no. 6,365,894 (April 2, 2002) and M. Tadokoro, *et. al.* "Electromagnetic and Magnetic Field Generating Apparatus", U.S. patent no. 6,236,043 (May 22, 2001) each describe a pair of magnetic poles, a return yoke, and exciting coils. The interior of the magnetic poles each have a plurality of air gap spacers to increase magnetic field strength.

Extraction

T. Nakanishi, *et. al.* "Charged-Particle Beam Accelerator, Particle Beam Radiation Therapy System Using the Charged-Particle Beam Accelerator, and Method of Operating the Particle Beam Radiation Therapy System", U.S. patent no. 7,122,978 (October 17, 2006) describe a charged particle beam accelerator having an RF-KO unit for increasing amplitude of betatron oscillation of a charged particle beam within a stable region of resonance and an extraction quadrupole electromagnet unit for varying a stable region of resonance. The RF-KO unit is operated within a frequency range in which the circulating beam does not go beyond a boundary of stable region of resonance and the extraction quadrupole electromagnet is operated with timing required for beam extraction.

T. Haberer, *et. al.* "Method and Device for Controlling a Beam Extraction Raster Scan Irradiation Device for Heavy Ions or Protons", U.S. patent no. 7,091,478 (August 15, 2006) describe a method for controlling beam extraction irradiation in terms of beam energy, beam focusing, and beam intensity for every accelerator cycle.

K. Hiramoto, *et. al.* "Accelerator and Medical System and Operating Method of the Same", U.S. patent no. 6,472,834 (October 29, 2002) describe a cyclic type accelerator having a deflection electromagnet and four-pole electromagnets for making a charged particle beam circulate, a multi-pole electromagnet for generating a stability limit of resonance of betatron oscillation, and a high frequency source for applying a high frequency electromagnetic field to the beam to move the beam to the outside of the stability limit. The high frequency source generates a sum signal of a plurality of alternating current (AC) signals of which the instantaneous frequencies change with respect to time, and of which the average values of the instantaneous frequencies with respect to time are different. The system applies the sum signal via electrodes to the beam.

K. Hiramoto, *et. al.* "Synchrotron Type Accelerator and Medical Treatment System Employing the Same", U.S. patent no. 6,087,670 (July 11, 2000) and K. Hiramoto, *et. al.* "Synchrotron Type Accelerator and Medical Treatment System Employing the Same", U.S. patent no. 6,008,499 (December 28, 1999) describe a synchrotron accelerator having a high frequency applying unit arranged on a circulating orbit for applying a high frequency electromagnetic field to a charged particle beam circulating and for increasing amplitude of betatron oscillation of the particle beam to a level above a stability limit of resonance. Additionally, for beam ejection, four-pole divergence electromagnets are arranged: (1) downstream with respect to a first deflector; (2) upstream with respect to a deflecting electromagnet; (3) downstream with respect to the deflecting electromagnet; and (4) and upstream with respect to a second deflector.

K. Hiramoto, *et. al.* "Circular Accelerator and Method and Apparatus for Extracting Charged-Particle Beam in Circular Accelerator", U.S. patent no. 5,363,008 (November 8, 1994) describe a circular accelerator for extracting a charged-particle beam that is arranged to: (1) increase displacement of a beam by the effect of betatron oscillation resonance; (2) to increase the betatron oscillation amplitude of the particles, which have an initial betatron oscillation within a stability limit for resonance; and (3) to exceed the resonance stability limit thereby extracting the particles exceeding the stability limit of the resonance.

K. Hiramoto, *et. al.* "Method of Extracting Charged Particles from Accelerator, and Accelerator Capable Carrying Out the Method, by Shifting Particle Orbit", U.S. patent no. 5,285,166 (February 8, 1994) describe a method of extracting a charged particle beam. An equilibrium orbit of charged particles maintained by a bending magnet and magnets having multipole components greater than sextuple components is shifted by a constituent element of the accelerator other than these magnets to change the tune of the charged particles.

Beam Energy / Intensity

M. Yanagisawa, *et. al.* "Charged Particle Therapy System, Range Modulation Wheel Device, and Method of Installing Range Modulation Wheel Device", U.S. patent no. 7,355,189 (April 8, 2008) and Yanagisawa, *et. al.* "Charged Particle Therapy System, Range Modulation Wheel Device, and Method of Installing Range Modulation Wheel Device", U.S. patent no. 7,053,389 (May 30, 2008) both describe a particle therapy system having a range modulation wheel. The ion beam passes through the range modulation wheel resulting in a plurality of energy levels corresponding to a plurality of stepped thicknesses of the range modulation wheel.

M. Yanagisawa, *et. al.* "Particle Beam Irradiation System and Method of Adjusting Irradiation Apparatus", U.S. patent no. 7,297,967 (November 20, 2007); M. Yanagisawa, *et. al.* "Particle Beam Irradiation System and Method of Adjusting Irradiation Apparatus", U.S. patent no. 7,071,479 (July 4, 2006); M. Yanagisawa, *et. al.* "Particle Beam Irradiation System and Method of Adjusting Irradiation Apparatus", U.S. patent no. 7,026,636 (April 11, 2006); and M. Yanagisawa, *et. al.* "Particle Beam Irradiation System and Method of Adjusting Irradiation Apparatus", U.S. patent no. 6,777,700 (August 17, 2004) all describe a scattering device, a range adjustment device, and a peak spreading device. The scattering device and range adjustment device are combined together and are moved along a beam axis. The spreading device is independently moved along the axis to adjust the degree of ion beam scattering. Combined, the device increases the degree of uniformity of radiation dose distribution to a diseased tissue.

A. Sliski, *et. al.* "Programmable Particle Scatterer for Radiation Therapy Beam Formation", U.S. patent no. 7,208,748 (April 24, 2007) describe a programmable pathlength of a fluid disposed into a particle beam to modulate scattering angle and beam range in a predetermined manner. The charged particle beam

scatterer/range modulator comprises a fluid reservoir having opposing walls in a particle beam path and a drive to adjust the distance between the walls of the fluid reservoir under control of a programmable controller to create a predetermined spread out Bragg peak at a predetermined depth in a tissue. The beam scattering and modulation is continuously and dynamically adjusted during treatment of a tumor to deposit a dose in a targeted predetermined three dimensional volume.

M. Tadokoro, *et. al.* "Particle Therapy System", U.S. patent no. 7,247,869 (July 24, 2007) and U.S. patent no. 7,154,108 (December 26, 2006) each describe a particle therapy system capable of measuring energy of a charged particle beam during irradiation during use. The system includes a beam passage between a pair of collimators, an energy detector mounted, and a signal processing unit.

G. Kraft, *et. al.* "Ion Beam Scanner System and Operating Method", U.S. patent no. 6,891,177 (May 10, 2005) describe an ion beam scanning system having a mechanical alignment system for the target volume to be scanned and allowing for depth modulation of the ion beam by means of a linear motor and transverse displacement of energy absorption means resulting in depth-staggered scanning of volume elements of a target volume.

G. Hartmann, *et. al.* "Method for Operating an Ion Beam Therapy System by Monitoring the Distribution of the Radiation Dose", U.S. patent no. 6,736,831 (May 18, 2004) describe a method for operation of an ion beam therapy system having a grid scanner and irradiates and scans an area surrounding an isocentre. Both the depth dose distribution and the transverse dose distribution of the grid scanner device at various positions in the region of the isocentre are measured and evaluated.

Y. Jongen "Method for Treating a Target Volume with a Particle Beam and Device Implementing Same", U.S. patent no. 6,717,162 (April 6, 2004) describes a method of producing from a particle beam a narrow spot directed towards a target volume, characterized in that the spot sweeping speed and particle beam intensity are simultaneously varied.

G. Kraft, *et. al.* "Device for Irradiating a Tumor Tissue", U.S. patent no. 6,710,362 (March 23, 2004) describe a method and apparatus of irradiating a tumor tissue, where the apparatus has an electromagnetically driven ion-braking device in the proton beam path for depth-wise adaptation of the proton beam that adjusts both the ion beam direction and ion beam range.

K. Matsuda, *et. al.* "Charged Particle Beam Irradiation Apparatus", U.S. patent no. 6,617,598 (September 9, 2003) describe a charged particle beam irradiation apparatus that increased the width in a depth direction of a Bragg peak by passing the Bragg peak through an enlarging device containing three ion beam components having different energies produced according to the difference between passed positions of each of the filter elements.

H. Stelzer, *et. al.* "Ionization Chamber for Ion Beams and Method for Monitoring the Intensity of an Ion Beam", U.S. patent no. 6,437,513 (August 20, 2002) describe an ionization chamber for ion beams and a method of monitoring the intensity of an ion therapy beam. The ionization chamber includes a chamber housing, a beam inlet window, a beam outlet window, a beam outlet window, and a chamber volume filled with counting gas.

H. Akiyama, *et. al.* "Charged-Particle Beam Irradiation Method and System", U.S. patent no. 6,433,349 (August 13, 2002) and H. Akiyama, *et. al.* "Charged-Particle Beam Irradiation Method and System", U.S. patent no. 6,265,837 (July 24, 2001)

both describe a charged particle beam irradiation system that includes a changer for changing energy of the particle and an intensity controller for controlling an intensity of the charged-particle beam.

Y. Pu "Charged Particle Beam Irradiation Apparatus and Method of Irradiation with Charged Particle Beam", U.S. patent no. 6,034,377 (March 7, 2000) describes a charged particle beam irradiation apparatus having an energy degrader comprising: (1) a cylindrical member having a length; and (2) a distribution of wall thickness in a circumferential direction around an axis of rotation, where thickness of the wall determines energy degradation of the irradiation beam.

Dosage

K. Matsuda, *et. al.* "Particle Beam Irradiation System", U.S. patent no. 7,372,053 (November 27, 2007) describe a particle beam irradiation system ensuring a more uniform dose distribution at an irradiation object through use of a stop signal, which stops the output of the ion beam from the irradiation device.

H. Sakamoto, *et. al.* "Radiation Treatment Plan Making System and Method", U.S. patent no. 7,054,801 (May 30, 2006) describe a radiation exposure system that divides an exposure region into a plurality of exposure regions and uses a radiation simulation to plan radiation treatment conditions to obtain flat radiation exposure to the desired region.

G. Hartmann, *et. al.* "Method For Verifying the Calculated Radiation Dose of an Ion Beam Therapy System", U.S. patent no. 6,799,068 (September 28, 2004) describe a method for the verification of the calculated dose of an ion beam therapy system that comprises a phantom and a discrepancy between the calculated radiation dose and the phantom.

H. Brand, *et. al.* "Method for Monitoring the Irradiation Control of an Ion Beam Therapy System", U.S. patent no. 6,614,038 (September 2, 2003) describe a method of checking a calculated irradiation control unit of an ion beam therapy system, where scan data sets, control computer parameters, measuring sensor parameters, and desired current values of scanner magnets are permanently stored.

T. Kan, *et. al.* "Water Phantom Type Dose Distribution Determining Apparatus", U.S. patent no. 6,207,952 (March 27, 2001) describe a water phantom type dose distribution apparatus that includes a closed water tank, filled with water to the brim, having an inserted sensor that is used to determine an actual dose distribution of radiation prior to radiation therapy.

Respiration

K. Matsuda "Radioactive Beam Irradiation Method and Apparatus Taking Movement of the Irradiation Area Into Consideration", U.S. patent no. 5,538,494 (July 23, 1996) describes a method and apparatus that enables irradiation even in the case of a diseased part changing position due to physical activity, such as breathing and heart beat. Initially, a position change of a diseased body part and physical activity of the patient are measured concurrently and a relationship therebetween is defined as a function. Radiation therapy is performed in accordance to the function.

Problem

There exists in the art of particle beam treatment of cancerous tumors in the body a need for efficient extraction of charged particles from a synchrotron of a charged particle therapy system. Further, there exists a need for extraction of charged particles at a specified energy, time, and/or intensity to yield a charged

particle beam for efficient, precise, and accurate *in-vivo* treatment of a solid cancerous tumor with minimization of damage to surrounding healthy tissue in a patient.

SUMMARY OF THE INVENTION

The invention comprises a charged particle beam extraction method and apparatus used in conjunction with charged particle beam radiation therapy of cancerous tumors.

DESCRIPTION OF THE FIGURES

Figure 1 illustrates sub-system connections of a particle beam therapy system;

Figure 2 illustrates a synchrotron;

Figure 3 illustrates a turning magnet within the synchrotron;

Figure 4 illustrates a particle beam extraction system;

Figure 5 illustrates a particle beam intensity control system;

Figure 6 demonstrates beam acceleration;

Figure 7 demonstrates beam intensity;

Figure 8A illustrates charged particle treatment of a tumor in a patient and Figure 8B illustrates 3-dimensional scanning of the charged particle beam;

Figure 9 illustrates tumor irradiation timed to respiration; and

Figure 10 illustrates charged particle delivery synchronized to variable respiration rates.

DETAILED DESCRIPTION OF THE INVENTION

The invention comprises a charged particle beam extraction method and apparatus used in conjunction with charged particle beam radiation therapy of cancerous tumors.

Accurate and precise delivery of protons to a tumor in body tissue is critical in charged particle beam therapy. Herein, extraction of a charged particle beam from a synchrotron is described as part of a charged particle cancer tumor therapy system. The system uses a radio-frequency (RF) cavity system to induce betatron oscillation of a charged particle stream. Sufficient amplitude modulation of the charged particle stream causes the charged particle stream to hit a material, such as a foil. The foil decreases the energy of the charged particle stream, which decreases a radius of curvature of the charged particle stream in the synchrotron sufficiently to allow a physical separation of the reduced energy charged particle stream from the original charged particle stream. The physically separated charged particle stream is then removed from the system by use of an applied field and deflector. The extraction system is further described, *infra*.

CHARGED PARTICLE BEAM THERAPY

Throughout this document, a charged particle beam therapy system, such as a proton beam, hydrogen ion beam, or carbon ion beam, is described. Herein, the charged particle beam therapy system is described using a proton beam. However, the aspects taught and described in terms of a proton beam are not intended to be limiting to that of a proton beam and are illustrative of a charged particle beam system. The techniques described herein are equally applicable to any charged particle beam system.

Referring now to Figure 1, a charged particle beam system 100 is illustrated. A charged particle beam, preferably comprises a number of subsystems including any of: a main controller 110; an injection system 120; a synchrotron 130 that typically includes: (1) an accelerator system 132 and (2) an extraction system 134; a targeting / delivery system 140; a patient interface module 150; a display system 160; and/or an imaging system 170.

In one embodiment, one or more of the subsystems are stored on a client. The client is a computing platform configured to act as a client device, e.g. a personal computer, a digital media player, a personal digital assistant, *etc.* The client comprises a processor that is coupled to a number of external or internal inputting devices, e.g. a mouse, a keyboard, a display device, *etc.* The processor is also coupled to an output device, e.g. a computer monitor to display information. In one embodiment, the main controller 110 is the processor. In another embodiment, the main controller 110 is a set of instructions stored in memory that is carried out by the processor.

The client includes a computer-readable storage medium, *i.e.* memory. The memory includes, but is not limited to, an electronic, optical, magnetic, or another storage or transmission device capable of coupling to a processor, e.g. such as a processor in communication with a touch-sensitive input device, with computer-readable instructions. Other examples of suitable media include, for example,

flash drive, CD-ROM, read only memory (ROM), random access memory (RAM), application-specific integrated circuit (ASIC), DVD, magnetic disk, memory chip, etc. The processor executes a set of computer-executable program code instructions stored in the memory. The instructions may comprise code from any computer-programming language, including, for example, C, C++, C#, Visual Basic, Java, and JavaScript.

An exemplary method of use of the charged particle beam system 100 is provided. The main controller 110 controls one or more of the subsystems to accurately and precisely deliver protons to a tumor of a patient. For example, the main controller 110 obtains an image, such as a portion of a body and/or of a tumor, from the imaging system 170. The main controller 110 also obtains position and/or timing information from the patient interface module 150. The main controller 110 then optionally controls the injection system 120 to inject a proton into a synchrotron 130. The synchrotron typically contains at least an accelerator system 132 and an extraction system 134. The main controller preferably controls the proton beam within the accelerator system, such as by controlling speed, trajectory, and timing of the proton beam. The main controller then controls extraction of a proton beam from the accelerator through the extraction system 134. For example, the controller controls timing, energy, and/or intensity of the extracted beam. The controller 110 also preferably controls targeting of the proton beam through the targeting / delivery system 140 to the patient interface module 150. One or more components of the patient interface module 150 are preferably controlled by the main controller 110. Further, display elements of the display system 160 are preferably controlled via the main controller 110. Displays, such as display screens, are typically provided to one or more operators and/or to one or more patients. In one embodiment, the main controller 110 times the delivery of the proton beam from all systems, such that protons are delivered in an optimal therapeutic manner to the patient.

Herein, the main controller 110 refers to a single system controlling the charged particle beam system 100, to a single controller controlling a plurality of subsystems controlling the charged particle beam system 100, or to a plurality of individual controllers controlling one or more sub-systems of the charged particle beam system 100.

Synchrotron

Herein, the term synchrotron is used to refer to a system maintaining the charged particle beam in a circulating path; however, cyclotrons are alternatively used, albeit with their inherent limitations of energy, intensity, and extraction control. Further, the charged particle beam is referred to herein as circulating along a circulating path about a central point of the synchrotron. The circulating path is alternatively referred to as an orbiting path; however, the orbiting path does not refer a perfect circle or ellipse, rather it refers to cycling of the protons around a central point or region.

Referring now to Figure 2, an illustrative exemplary embodiment of one version of the charged particle beam system 100 is provided. The number, position, and described type of components is illustrative and non-limiting in nature. In the illustrated embodiment, the injection system 120 or ion source or charged particle beam source generates protons. The protons are delivered into a vacuum tube that runs into, through, and out of the synchrotron. The generated protons are delivered along an initial path 262. Focusing magnets 230, such as quadrupole magnets or injection quadrupole magnets, are used to focus the proton beam path. A quadrupole magnet is a focusing magnet. An injector bending magnet 232 bends the proton beam toward the plane of the synchrotron 130. The focused protons having an initial energy are introduced into an injector magnet 240, which is preferably an injection Lamberson magnet. Typically, the initial beam path 262 is along an axis off of, such as above, a circulating plane of the synchrotron 130. The injector bending magnet 232 and injector magnet 240

combine to move the protons into the synchrotron 130. Main bending magnets, dipole magnets, or circulating magnets 250 are used to turn the protons along a circulating beam path 264. A dipole magnet is a bending magnet. The main bending magnets 250 bend the initial beam path 262 into a circulating beam path 264. In this example, the main bending magnets 250 or circulating magnets are represented as four sets of four magnets to maintain the circulating beam path 264 into a stable circulating beam path. However, any number of magnets or sets of magnets are optionally used to move the protons around a single orbit in the circulation process. The protons pass through an accelerator 270. The accelerator accelerates the protons in the circulating beam path 264. As the protons are accelerated, the fields applied by the magnets are increased. Particularly, the speed of the protons achieved by the accelerator 270 are synchronized with magnetic fields of the main bending magnets 250 or circulating magnets to maintain stable circulation of the protons about a central point or region 280 of the synchrotron. At separate points in time the accelerator 270 / main bending magnet 250 combination is used to accelerate and/or decelerate the circulating protons while maintaining the protons in the circulating path or orbit. An extraction element of the inflector/deflector system 290 is used in combination with a Lamberson extraction magnet 292 to remove protons from their circulating beam path 264 within the synchrotron 130. One example of a deflector component is a Lamberson magnet. Typically the deflector moves the protons from the circulating plane to an axis off of the circulating plane, such as above the circulating plane. Extracted protons are preferably directed and/or focused using an extraction bending magnet 237 and extraction focusing magnets 235, such as quadrupole magnets along a transport path 268 into the scanning / targeting / delivery system 140. Two components of a scanning system 140 or targeting system typically include a first axis control 142, such as a vertical control, and a second axis control 144, such as a horizontal control. In one embodiment, the first axis control 142 allows for about 100 mm of vertical or y-axis scanning of the proton beam 268 and the second axis control 144 allows for about 700 mm of horizontal or x-axis scanning of the proton beam 268. A

nozzle system is used for imaging the proton beam and/or as a vacuum barrier between the low pressure beam path of the synchrotron and the atmosphere. Protons are delivered with control to the patient interface module 150 and to a tumor of a patient. All of the above listed elements are optional and may be used in various permutations and combinations. The above listed elements are further described, *infra*.

ION BEAM GENERATION SYSTEM

An ion beam generation system generates a negative ion beam, such as a hydrogen anion or H^- beam; preferably focuses the negative ion beam; converts the negative ion beam to a positive ion beam, such as a proton or H^+ beam; and injects the positive ion beam 262 into the synchrotron 130. Portions of the ion beam path are preferably under partial vacuum.

SYNCHROTRON

Herein, the term synchrotron is used to refer to a system maintaining the charged particle beam in a circulating path. Further, the charged particle beam is referred to herein as circulating along a circulating path about a central point of the synchrotron. The circulating path is alternatively referred to as an orbiting path; however, the orbiting path does not refer a perfect circle or ellipse, rather it refers to cycling of the protons around a central point or region 280.

Circulating System

The synchrotron 130 preferably comprises a combination of straight sections and ion beam turning sections. Hence, the circulating path of the protons is not circular in a synchrotron, but is rather a polygon with rounded corners.

In one illustrative embodiment, the synchrotron 130, which is also referred to as an accelerator system, has four straight elements and four turning sections. Examples of straight sections include the: inflector 240, accelerator 270, extraction system 290, and deflector 292. Along with the four straight sections are four ion beam turning sections, which are also referred to as magnet sections or turning sections. For example, a turning section is a set of about 2, 4, 6, or 8 turning magnets 250. Turning sections are further described, *infra*.

Referring still to Figure 2, an exemplary synchrotron is illustrated. In this example, protons delivered along the initial proton beam path 262 are inflected into the circulating beam path with the inflector 240 and after acceleration are extracted via a deflector 292 to the beam transport path 268. In this example, the synchrotron 130 comprises four straight sections and four bending or turning sections where each of the four turning sections use one or more magnets to turn the proton beam about ninety degrees. As is further described, *infra*, the ability to closely space the turning sections and efficiently turn the proton beam results in shorter straight sections. Shorter straight sections allows for a synchrotron design without the use of focusing quadrupoles in the circulating beam path of the synchrotron. The removal of the focusing quadrupoles from the circulating proton beam path results in a more compact design. In this example, the illustrated synchrotron has about a five meter diameter versus eight meter and larger cross-sectional diameters for systems using a quadrupole focusing magnet in the circulating proton beam path.

Additional description of the first bending or turning section between injector magnet 240 and inflector/deflector system 290 is provided. Additional turning sections are (1) from the inflector/deflector system 290 to the Lamberson extraction magnet 292; (2) from the Lamberson extraction magnet 292 to the accelerator 270; and (3) from the accelerator 270 to the injector magnet 240. Each of the turning sections preferably comprise multiple magnets, such as

about 2, 4, 6, 8, 10, or 12 magnets. In this example, four turning magnets or circulating magnets 250 in the first turning section 920 are used to illustrate key principles, which are the same regardless of the number of magnets in a turning section.

Turning Magnet Focusing Geometry

Referring now to Figure 3, a cross section of a single turning magnet 250 is provided. The turning section includes a gap 310 through which protons circulate. The magnet assembly has a first magnet 320 and a second magnet 330. A magnetic field induced by coils runs between the first magnet 320 to the second magnet 330 across the gap 310. Return magnetic fields run through a first yoke 322 and second yoke 332. The magnetic field is created using a first winding coil 350 and a second winding coil 360. Isolating or concentrating gaps 340, such as air gaps, isolate the iron based yokes from the gap 310. The gap 310 is approximately flat to yield a uniform magnetic field across the gap 310. As illustrated, the first magnet 320 preferably contains an initial cross sectional distance 370 of the iron based core. The contours of the magnetic field are shaped by the magnets 320, 330 and the yokes 322, 332 from a first cross sectional distance or area 374 to a second cross sectional distance or area 376. For example, the first cross-sectional distance is about 15 cm and the second cross-section distance is about 10 cm. In a second example, the second cross section distance is less than seventy percent of the first cross-section distance. In these examples, the core tapers to a second cross sectional distance 372 with an angle theta, θ . As described, *supra*, the magnetic field in the magnet preferentially stays in the iron based core as opposed to the isolating gaps 340. As the cross-sectional distance decreases from the initial cross sectional distance 370 to the final cross-sectional distance 372, the magnetic field concentrates. The angle theta results in an amplification of the magnetic field in going from the longer distance 370 to the smaller distance 372. The concentration of the magnetic field is illustrated by representing an initial density

of magnetic field vectors in the initial cross section 370 to a concentrated density of magnetic field vectors in the final cross section 372. The concentration of the magnetic field due to the geometry of the turning magnets results in fewer winding coils 350, 360 being required and also a smaller power supply to the winding coils 350, 360 being required.

Turning Magnet Correction Coils

Still referring to Figure 3, optional correction coils 380, 390 are illustrated that are used to correct the strength of one or more turning magnets. The correction coils 380, 390 supplement the winding coils 350, 360. The correction coil power supplies typically operate at a fraction of the power required compared to the winding coil power supplies, such as about 1, 2, 3, 5, 7, or 10 percent of the power and more preferably about 1 or 2 percent of the power used with the winding coils 350, 360. The smaller operating power applied to the correction coils 380, 390 allows for more accurate and/or precise control of the correction coils. The correction coils 380, 390 are used to adjust for imperfection in the turning magnets 250. Optionally, separate correction coils are used for each turning magnet allowing individual tuning of the magnetic field for each turning magnet, which eases quality requirements in the manufacture of each turning magnet.

The winding coils preferably cover 1, 2, or 4 turning magnets 250. One or more high precision magnetic field sensors are placed into the synchrotron and are used to measure the magnetic field at or near the proton beam path. For example, the magnetic sensors are optionally placed between turning magnets and/or within a turning magnet, such as at or near the gap 310 or at or near the magnet core or yoke. The sensors are part of a feedback system to the correction coils, which is optionally run by the main controller. Thus, the system preferably stabilizes the magnetic field in the synchrotron elements rather than stabilizing the current applied to the magnets. Stabilization of the magnetic field

allows the synchrotron to come to a new energy level quickly. This allows the system to be controlled to an operator or algorithm selected energy level with each pulse of the synchrotron and/or with each breath of the patient.

Turning Magnets Beveled Edges

The ends of a single bending or turning magnet are preferably beveled. Beveling the edge of the turning magnet 250 focuses the proton beam. Multiple turning magnets provide multiple magnet edges that each have edge focusing effects in the synchrotron 130. For example, if four magnets are used in a turning section of the synchrotron, then for a single turning section there are eight possible edge focusing effect surfaces, two edges per magnet. The eight focusing surfaces yield a smaller cross-sectional beam size, which allows the use of a smaller gap. For a synchrotron 130 having four turning sections, where each turning sections has four turning magnets and each turning magnet has two focusing edges, a total of thirty-two focusing edges exist for each orbit of the protons in the circulating path of the synchrotron 130. Similarly, if 2, 6, or 8 magnets are used in a given turning section, or if 2, 3, 5, or 6 turning sections are used, then the number of edge focusing surfaces expands or contracts according to equation 1.

$$TFE = NTS * \frac{M}{NTS} * \frac{FE}{M} \quad (\text{eq. 1})$$

where TFE is the number of total focusing edges, NTS is the number of turning sections, M is the number of magnets, and FE is the number of focusing edges. Naturally, not all magnets are necessarily beveled and some magnets are optionally beveled on only one edge.

In various embodiments of the system described herein, the synchrotron has any combination of:

- at least 4 and preferably 6, 8, 10, or more edge focusing edges per 90 degrees of turn of the charged particle beam in a synchrotron having four turning sections;
- at least about 16 and preferably about 24, 32, or more edge focusing edges per orbit of the charged particle beam in the synchrotron;
- only 4 turning sections where each of the turning sections includes at least 4 and preferably 8 edge focusing edges;
- an equal number of straight sections and turning sections;
- exactly 4 turning sections;
- at least 4 focusing edges per turning section;
- no quadrupoles in the circulating path of the synchrotron;
- a rounded corner rectangular polygon configuration;
- a circumference of less than 60 meters;
- a circumference of less than 60 meters and 32 edge focusing surfaces; and/or;
- any of about 8, 16, 24, or 32 non-quadrupole magnets per circulating path of the synchrotron, where the non-quadrupole magnets include edge focusing edges.

Proton Beam Extraction

Referring now to Figure 4, an exemplary proton extraction process from the synchrotron 130 is illustrated. For clarity, Figure 4 removes elements represented in Figure 2, such as the turning magnets, which allows for greater clarity of presentation of the proton beam path as a function of time. Generally, protons are extracted from the synchrotron 130 by slowing the protons. As described, *supra*, the protons were initially accelerated in a circulating path 264, which is maintained with a plurality of turning magnets 250. The circulating path

is referred to herein as an original central beamline 264. The protons repeatedly cycle around a central point in the synchrotron 280. The proton path traverses through an RF cavity system 410. To initiate extraction, an RF field is applied across a first blade 412 and a second blade 414, in the RF cavity system 410. The first blade 412 and second blade 414 are referred to herein as a first pair of blades.

In the proton extraction process, an RF voltage is applied across the first pair of blades, where the first blade 412 of the first pair of blades is on one side of the circulating proton beam path 264 and the second blade 414 of the first pair of blades is on an opposite side of the circulating proton beam path 264. The applied RF field applies energy to the circulating charged-particle beam. The applied RF field alters the orbiting or circulating beam path slightly of the protons from the original central beamline 264 to an altered circulating beam path 265. Upon a second pass of the protons through the RF cavity system, the RF field further moves the protons off of the original proton beamline 264. For example, if the original beamline is considered as a circular path, then the altered beamline is slightly elliptical. The applied RF field is timed to apply outward or inward movement to a given band of protons circulating in the synchrotron accelerator. Each orbit of the protons is slightly more off axis compared to the original circulating beam path 264. Successive passes of the protons through the RF cavity system are forced further and further from the original central beamline 264 by altering the direction and/or intensity of the RF field with each successive pass of the proton beam through the RF field.

The RF voltage is frequency modulated at a frequency about equal to the period of one proton cycling around the synchrotron for one revolution or at a frequency than is an integral multiplier of the period of one proton cycling about the synchrotron. The applied RF frequency modulated voltage excites a betatron oscillation. For example, the oscillation is a sine wave motion of the protons.

The process of timing the RF field to a given proton beam within the RF cavity system is repeated thousands of times with successive passes of the protons being moved approximately one micrometer further off of the original central beamline 264. For clarity, the approximately 1000 changing beam paths with each successive path of a given band of protons through the RF field are illustrated as the altered beam path 265.

With a sufficient sine wave betatron amplitude, the altered circulating beam path 265 touches a material 430, such as a foil or a sheet of foil. The foil is preferably a lightweight material, such as beryllium, a lithium hydride, a carbon sheet, or a material of low nuclear charge. A material of low nuclear charge is a material composed of atoms consisting essentially of atoms having six or fewer protons. The foil is preferably about 10 to 150 microns thick, is more preferably 30 to 100 microns thick, and is still more preferably 40-60 microns thick. In one example, the foil is beryllium with a thickness of about 50 microns. When the protons traverse through the foil, energy of the protons is lost and the speed of the protons is reduced. Typically, a current is also generated, described *infra*. Protons moving at a slower speed travel in the synchrotron with a reduced radius of curvature 266 compared to either the original central beamline 264 or the altered circulating path 265. The reduced radius of curvature 266 path is also referred to herein as a path having a smaller diameter of trajectory or a path having protons with reduced energy. The reduced radius of curvature 266 is typically about two millimeters less than a radius of curvature of the last pass of the protons along the altered proton beam path 265.

The thickness of the material 430 is optionally adjusted to create a change in the radius of curvature, such as about v_z , 1, 2, 3, or 4 mm less than the last pass of the protons 265 or original radius of curvature 264. Protons moving with the smaller radius of curvature travel between a second pair of blades 414, 416. The second pair of blades 414, 416 is also referred to as a pair of extraction blades.

In one case, the second pair of blades is physically distinct and/or are separated from the first pair of blades. In a second case, one of the first pair of blades is also a member of the second pair of blades. For example, the second pair of blades is the second blade 414 and a third blade 416 in the RF cavity system 410. A high voltage DC signal, such as about 0.5, 1, 2, 3, 4, or 5 kV, is then applied across the second pair of blades, which directs the protons out of the synchrotron through a deflector 292, such as a Lamberson magnet, into a transport path 268.

Example I

In a first example, protons are extracted from a synchrotron by slowing the protons with a foil. Initially, an RF signal is applied across a proton path, such as through two metal elements where one metallic element is on a first side of a cyclic proton path in the synchrotron and a second metallic element is on an opposite side of the proton path. An RF voltage is applied across the two metal elements. The applied voltage is modulated or frequency modulated to induce an oscillation in the path of the protons. The oscillation forces a portion of the proton beam through a foil. In this case, the foil is a beryllium material of about fifty microns in thickness. The electrons on the foil slow the protons resulting in a beam path having a smaller average diameter compared to protons repeatedly cycling in the synchrotron. The protons having the smaller average diameter beam path traverse a high DC voltage field, which directs the protons out of the synchrotron or into a Lamberson magnet directing the protons out of the synchrotron.

Example II

Still referring to Figure 4, an exemplary synchrotron 130 is illustrated. A set of magnets control protons in the synchrotron in a repeated cyclic path 264 having a first radius of curvature. Protons in the first path traverse between a first pair of

metal plates 412, 414 having an AC frequency voltage applied across the two metal plates. The AC voltage induces an oscillation on some of the protons causing them to pass through a foil material 430 that reduces the speed of the protons. The protons moving at a slower speed have a reduced radius of curvature path 266. The protons having the reduced radius of curvature then pass through a DC field, such as a high voltage field between a second pair of metal plates 414, 416, which directs the protons along a new path. The new path 266 optionally traverses another magnetic field, such as that of a Lamberson magnet, that directs the protons away from the synchrotron.

Generally, the extraction process takes a proton circulating in a synchrotron and slows the proton by passing the proton through a foil. The circulating proton has a first radius of curvature associated with the energy of the circulating proton and the applied magnetic fields of the turning magnets. The protons passing through the foil have less energy resulting in a second radius of curvature that is less than the first radius of curvature. Hence, the protons are extracted toward the center of the synchrotron relative to the circulating proton beam path. The smaller radius of curvature slowed protons, after passing through the foil, are kicked out of the synchrotron by application of a field between the second and third plates and via use of a deflector, such as a Lamberson deflector.

Intensity Control

Referring now to Figure 5, typically when protons in the proton beam hit the material 430 electrons are given off. The resulting current is optionally measured and sent to the main controller 110 or to an intensity controller subsystem 540. The current is used as a measure of the circulating beam path intensity and is optionally used to control the RF cavity system. In one instance, when a current is measured beyond a threshold, the RF field modulation in the RF cavity system is terminated or reinitiated to establish a subsequent cycle of proton beam extraction. This process is repeated to yield many cycles of proton beam

extraction from the synchrotron accelerator. In another instance, the current is used as a feedback control to control the intensity of the extracted particle beam.

Referring still to Figure 5, a feedback loop is added to the extraction system described *supra*. When protons in the proton beam hit the material 430 electrons are given off resulting in a current. The resulting current is converted to a voltage and is used as part of a ion beam intensity monitoring system or as part of an ion beam feedback loop for controlling beam intensity. The voltage is optionally measured and sent to the main controller 110 or to the controller subsystem 410. More particularly, when protons in the charged particle beam path pass through the material 430, some of the protons lose a small fraction of their energy, such as about one-tenth of a percent, which results in a secondary electron. That is, protons in the charged particle beam push some electrons when passing through material 430 giving the electrons enough energy to cause secondary emission. The resulting electron flow results in a current or signal that is proportional to the number of protons going through the target material 430. The resulting current is preferably converted to voltage and amplified. The resulting signal is referred to as a measured intensity signal.

The amplified signal or measured intensity signal resulting from the protons passing through the material 430 is preferably used in controlling the intensity of the extracted protons. For example, the measured intensity signal is compared to a goal signal, which is predetermined in an irradiation of the tumor plan 560. The difference between the measured intensity signal and the planned for goal signal is calculated. The difference is used as a control to the RF generator. Hence, the measured flow of current resulting from the protons passing through the material 430 is used as a control in the RF generator to increase or decrease the number of protons undergoing betatron oscillation and striking the material 430. Hence, the voltage determined off of the material 430 is used as a measure of the orbital path and is used as a feedback control to control the RF cavity

system. Alternatively, the measured intensity signal is not used in the feedback control and is just used as a monitor of the intensity of the extracted protons.

As described, *supra*, the photons striking the material 430 is a step in the extraction of the protons from the synchrotron 130. Hence, the measured intensity signal is used to change the number of protons per unit time being extracted, which is referred to as intensity of the proton beam. The intensity of the proton beam is thus under algorithm control. Further, the intensity of the proton beam is controlled separately from the velocity of the protons in the synchrotron 130. Hence, intensity of the protons extracted and the energy of the protons extracted are independently variable.

For example, protons initially move at an equilibrium trajectory in the synchrotron 130. An RF field is used to excite the protons into a betatron oscillation. In one case, the frequency of the protons orbit is about 10 MHz. In one example, in about one millisecond or after about 10,000 orbits, the first protons hit an outer edge of the target material 430. The specific frequency is dependent upon the period of the orbit. Upon hitting the material 430, the protons push electrons through the foil to produce a current. The current is converted to voltage and amplified to yield a measured intensity signal. The measured intensity signal is used as a feedback input to control the applied RF magnitude, RF frequency, or RF field. Preferably, the measured intensity signal is compared to a target signal and a measure of the difference between the measured intensity signal and target signal is used to adjust the applied RF field in the RF cavity system 510 in the extraction system to control the intensity of the protons in the extraction step. Stated again, the signal resulting from the protons striking and/or passing through the material 430 is used as an input in RF field modulation. An increase in the magnitude of the RF modulation results in protons hitting the foil or material 430 sooner. By increasing the RF, more protons are pushed into the

foil, which results in an increased intensity, or more protons per unit time, of protons extracted from the synchrotron 130.

In another example, a detector 550 external to the synchrotron 130 is used to determine the flux of protons extracted from the synchrotron and a signal from the external detector is used to alter the RF field or RF modulation in the RF cavity system 510. Here the external detector generates an external signal, which is used in a manner similar to the measured intensity signal, described in the preceding paragraphs. Particularly, the measured intensity signal is compared to a desired signal from the irradiation plan 560 in a feedback intensity controller 540, which adjusts the RF field between the first plate 412 and the second plate 414 in the extraction process, described supra.

In yet another example, when a current from material 430 resulting from protons passing through or hitting material is measured beyond a threshold, the RF field modulation in the RF cavity system is terminated or reinitiated to establish a subsequent cycle of proton beam extraction. This process is repeated to yield many cycles of proton beam extraction from the synchrotron accelerator.

In still yet another embodiment, intensity modulation of the extracted proton beam is controlled by the main controller 110. The main controller 110 optionally and/or additionally controls timing of extraction of the charged particle beam and energy of the extracted proton beam.

The benefits of the system include a multi-dimensional scanning system. Particularly, the system allows independence in: (1) energy of the protons extracted and (2) intensity of the protons extracted. That is, energy of the protons extracted is controlled by an energy control system and an intensity control system controls the intensity of the extracted protons. The energy control

system and intensity control system are optionally independently controlled. Preferably, the main controller 110 controls the energy control system and the main controller 110 simultaneously controls the intensity control system to yield an extracted proton beam with controlled energy and controlled intensity where the controlled energy and controlled intensity are independently variable. Thus, the radiation spot hitting the tumor is under independent control of:

- time;
- energy;
- intensity;
- x-axis position, where the x-axis represents horizontal movement of the proton beam relative to the patient; and/or
- y-axis position, where the y-axis represents vertical movement of the proton beam relative to the patient.

In addition, the patient is optionally independently translated and/or rotated relative to a translational axis of the proton beam at the same time.

Timing

In yet another embodiment of the invention, the main controller 110 controls timing of extraction. For example, extraction is in synchronization with patient respiration or breathing. For instance, extraction is performed when the patient is at the bottom of a breath so that the proton beam is generated when the internal organs, bones, and structures of the patient are in reproducible positions or are in reproducible relative positions. Accurate and precise delivery of protons to a tumor in body tissue is critical in charged particle beam therapy. Complicating accurate and precise delivery is natural movement of the body. Movement of the body occurs on multiple levels, including: (1) general patient movement, such as walking; (2) standing, sitting, or lying position variation; and (3) relative movement of internal body parts, such as organs. All of these movements

change with time. Hence, the method of timing extraction of the proton beam results in enhanced targeting, precision, and/or accuracy of the delivered proton beam to the tumor of the patient.

Proton Energy and Intensity Control

Referring now to Figures 6 and 7, proton energy and intensity capabilities of the proton delivery system are demonstrated. Referring now to Figure 6, beam acceleration up to a maximum energy of 330 MeV is demonstrated. Further illustrated is a flexible repeated acceleration and retardation of the proton beam in one cycle. Particularly, in the first cycle from the first to fourth seconds, the beam is accelerated to 100 MeV, retarded to 50 MeV and accelerated once more to 150 MeV. In the next cycle starting at the fifth second, the proton energy is increased rapidly to 330 MeV where it is maintained for one second, which is needed for carrying out tomography. Referring now to Figure 7, the corresponding beam intensity is provided for the two serial cycles of the synchrotron accelerator's work. From approximately the VA to 31A second marks, the beam is directed to a certain irradiating point. Upon achieving the necessary dose value, the extraction is interrupted, the beam is moved to the next point and the extraction process is resumed from the 514 to VA second marks. Combined, Figures 6 and 7 demonstrate independent control of energy and intensity. Figures 6 and 7 are demonstrative in nature. In real time operation, each of the above described processes optionally are generated at ten times the demonstrated rate.

Proton Beam Position Control

Referring now to Figure 8, a beam delivery and tissue volume scanning system is illustrated. Presently, the worldwide radiotherapy community uses a method of dose field forming using a pencil beam scanning system. In stark contrast, Figure 8 illustrates a spot scanning system or tissue volume scanning system. In

the tissue volume scanning system, the proton beam 268 is controlled, in terms of transportation and distribution, using an inexpensive and precise scanning system. The scanning system is an active system, where the beam is focused into a spot focal point of about one-half, one, two, or three millimeters in diameter in the tumor 820. The focal point is translated to a momentary position 269 along two axes while simultaneously altering the applied energy of the proton beam, which effectively changes the third dimension of the focal point. For example, in the illustrated system in Figure 8A, the spot is moved horizontally, is translated down a vertical axis, and then is moved again horizontally. In this example, current is used to control a vertical scanning system having at least one magnet. The applied current alters the magnetic field of the vertical scanning system to control the vertical deflection of the proton beam. Similarly, a horizontal scanning magnet system controls the horizontal deflection of the proton beam. The degree of transport along each axes is controlled to conform to the tumor cross-section at the given depth. The depth is controlled by changing the energy of the proton beam. For example, the proton beam energy is decreased, so as to define a new penetration depth, and the scanning process is repeated along the horizontal and vertical axes covering a new cross-sectional area of the tumor.

The system has five axes of control: x-axis, y-axis, energy, intensity, and time. The intensity control provided by the feedback current and the sub-controller 540 provides the fifth axis of intensity control. Combined, the five axes of control allow scanning or movement of the proton beam focal point over the entire volume of the cancerous tumor. The time at each spot and the direction into the body for each spot is controlled to yield the desired radiation dose at each sub-volume of the cancerous volume while distributing energy hitting outside of the tumor.

The focused beam spot volume dimension is preferably tightly controlled to a diameter of about 0.5, 1, or 2 millimeters, but is alternatively several centimeters

in diameter. Preferred design controls allow scanning in two directions with: (1) a vertical amplitude of about 100 mm amplitude and frequency up to 200 Hz; and (2) a horizontal amplitude of about 700 mm amplitude and frequency up to 1 Hz. More or less amplitude in each axis is possible by altering the scanning magnet systems.

In Figure 8B, the proton beam goes along a z-axis controlled by the beam energy, the horizontal movement is an x-axis, and the vertical direction is a y-axis. The distance the protons move along the z-axis into the tissue, in this example, is controlled by the kinetic energy of the proton. This coordinate system is arbitrary and exemplary. The actual control of the proton beam is controlled in 3-dimensional space using two scanning magnet systems and by controlling the kinetic energy of the proton beam.

Respiration Control

Accurate and precise delivery of protons to a tumor in body tissue is critical in charged particle beam therapy of tumors. Complicating accurate and precise delivery is natural movement of the body. One form of movement of the body is related to respiration of the patient, which results in movements throughout the body and especially in the chest cavity of the patient. The movement results in relative movement of internal body parts, such as organs, as a function of time. Hence, a method of determining position of elements of the body at and/or in close proximity in time to the charged particle therapy is needed. Herein, patient respiration monitoring and/or control methods and apparatus used in conjunction with charged particle therapy are described. Particularly, a patient respiration monitoring and/or control method and apparatus used in conjunction with multi-axis charged particle or proton beam radiation therapy of cancerous tumors is described. For example, the respiration monitoring system uses thermal and/or force sensors to determine where a patient is in a respiration cycle, optionally in combination with a feedback signal control delivered to the patient to inform the

patient when breath control is required. The resulting breath control is timed with charged particle delivery to the tumor to enhance accuracy, precision, and efficiency of tumor treatment.

Referring now to Figure 9, timing of proton delivery to the tumor based on the patient's respiration 900 is described. In one example, a patient is positioned 910 and once the rhythmic pattern of the subject's breathing or respiration cycle is determined 920, a signal is optionally delivered to the patient, such as via the display monitor, to more precisely control the breathing frequency 930. For example, the display screen is placed in front of the patient and a message or signal is transmitted to the display screen directing the subject when to hold their breath and when to breathe. Typically, a respiration control module uses input from one or more of the breathing sensors, described *infra*. For example, the input is used to determine when the next breath exhale is to complete. At the bottom of the breath, the control module displays a hold breath signal to the subject, such as on a monitor, via an oral signal, digitized and automatically generated voice command, or via a visual control signal. Preferably, a display monitor is positioned in front of the subject and the display monitor displays breathing commands to the subject. Typically, the subject is directed to hold their breath for a short period of time, such as about $\frac{1}{2}$, 1, 2, 3, 5, or 10 seconds. The period of time the breath is held is preferably synchronized to the delivery time of the proton beam to the tumor, which is about $\frac{1}{2}$, 1, 2, or 3 seconds. While delivery of the protons at the bottom of the breath is preferred, protons are optionally delivered at any point in the respiration cycle, such as upon full inhalation. Delivery at the top of the breath or when the patient is directed to inhale deeply and hold their breath by the breathing control module is optionally performed as at the top of the breath the chest cavity is largest and for some tumors the distance between the tumor and surrounding tissue is maximized or the surrounding tissue is rarefied as a result of the increased volume. Hence, protons hitting surrounding tissue is minimized. Optionally, the display screen tells the patient when they are about to be asked to hold their breath, such as

with a 3, 2, 1, second countdown so that the patient is aware of the task they are about to be asked to perform.

Respiration Sensors

A first example of a respiration monitoring system is provided. In a thermal respiration monitoring system, a sensor is placed by the nose and/or mouth of the patient. To avoid steric interference of the thermal sensor system components with proton therapy, the thermal breath monitoring system is preferably used when treating a tumor not located in the head or neck, such as when treating a tumor in the torso or limbs. In the thermal monitoring system, a first thermal resistor is used to monitor the patient's respiration cycle and/or location in the patient's respiration cycle. Preferably, the first thermal resistor is placed by the patient's nose, such that the patient exhaling through their nose onto the first thermal resistor warms the first thermal resistor indicating an exhale. Preferably, a second thermal resistor operates as an environmental temperature sensor. The second thermal resistor is preferably placed out of the exhalation path of the patient but in the same local room environment as the first thermal resistor. Generated signal, such as current from the thermal resistors, is preferably converted to voltage and communicated with the main controller 110 or a sub-controller of the main controller. Preferably, the second thermal resistor is used to adjust for the environmental temperature fluctuation that is part of a signal of the first thermal resistor, such as by calculating a difference between the values of the thermal resistors, to yield a more accurate reading of the patient's breathing cycle.

A second example of a monitoring system is provided. In an example of a force breath monitoring system, a sensor is placed by the torso. To avoid steric interference of the force sensor system components with proton therapy, the force breath monitoring system is preferably used when treating a tumor located

in the head, neck, or limbs. In the force monitoring system, a belt or strap is placed around an area of the patient's torso that expands and contracts with each breath cycle of the patient. The belt is preferably tight about the patient's chest and is flexible. A force meter is attached to the belt and senses the patient's respiration pattern. The forces applied to the force meter correlate with periods of the breathing cycle. The signals from the force meter are preferably communicated with the main controller 110 or a sub-controller of the main controller.

Proton Beam Therapy Synchronization with Respiration

In one embodiment, charged particle therapy and preferably multi-field proton therapy is coordinated and synchronized with patient respiration via use of the respiration feedback sensors, described *supra*, used to monitor and/or control patient respiration. Preferably, the charged particle therapy is performed on a patient in a partially immobilized and repositionable position and the proton delivery to the tumor is timed to patient respiration via control of charged particle beam injection, acceleration, extraction, and/or targeting methods and apparatus. The synchronization enhances proton delivery accuracy by removing position ambiguity due to the relative movement of body constituents during a patient respiration cycle.

In a second embodiment, an X-ray system is used to provide X-ray images of a patient in the same orientation as viewed by a proton therapy beam and both the X-ray system and the proton therapy beam are synchronized with patient respiration. Preferably, the synchronized system is used in conjunction with the negative ion beam source, synchrotron, and / or targeting method and apparatus to provide an X-ray timed with patient breathing where the X-ray is collected immediately prior to and/or concurrently with particle beam therapy irradiation to ensure targeted and controlled delivery of energy relative to a patient position resulting in efficient, precise, and/or accurate treatment of a solid cancerous

tumor with minimization of damage to surrounding healthy tissue in a patient using the proton beam position verification system.

Referring again to Figure 9, a proton delivery control algorithm is used to synchronize delivery of the protons to the tumor within a given period of each breath, such as at the top of a breath, at the bottom of a breath, and/or when the subject is holding their breath. The proton delivery control algorithm is preferably integrated with the respiration control module. Thus, the proton delivery control algorithm knows when the subject is breathing, where in the respiration cycle the subject is, and/or when the subject is holding their breath. Based on monitoring the patient's respiration 920 or controlling the patient's respiration 930, the proton delivery control algorithm or main controller 110 controls timing of proton delivery. For example, the main controller 110 controls when protons are injected 940 and/or inflected into the synchrotron, how the protons are accelerated 950, when a radio frequency signal is applied to induce an oscillation, as described *supra*, and when a direct current voltage is applied to extract protons 960 from the synchrotron, as described *supra*. Hence, the tumor is irradiated 970 at a known or controlled point in the patient's respiration cycle, thereby enhancing precision and accuracy of proton delivery to the tumor. Typically, the proton delivery control algorithm initiates proton inflection and subsequent radio frequency induced oscillation before the subject is directed to hold their breath or before the identified period of the breathing cycle selected for a proton delivery time. In this manner, the proton delivery control algorithm delivers protons at a selected period of the respiration cycle by simultaneously or nearly simultaneously delivering the high direct current voltage to the second pair of plates, described *supra*, which results in extraction of the protons from the synchrotron and subsequent delivery to the subject at the selected time point. Since the period of acceleration of protons in the synchrotron is constant or known for a desired energy level of the proton beam, the proton delivery control algorithm is used to set an alternating current RF signal that matches the breathing cycle or directed breathing cycle of the subject.

Referring now to Figure 10, an example is used to clarify the magnetic field control using a feedback loop to change delivery times and/or periods of proton pulse delivery. In one case, a respiration sensor senses the respiration cycle of the patient. Optionally, the respiration sensor sends the patient's breathing pattern or information to an algorithm in the magnetic field controller, typically via the patient interface module 150 and/or via the main controller 110 or a subcomponent thereof. The algorithm predicts and/or measures when the patient is at a particular point in the breathing cycle, such as at the top or bottom of a breath. One or more magnetic field sensors are used as inputs to the magnetic field controller, which controls a magnet power supply for a given magnetic, such as within a first turning magnet 240 of a synchrotron 130. The control feedback loop is thus used to dial the synchrotron to a selected energy level and to deliver protons with the desired energy at a selected point in time, such as at a particular point in the respiration cycle. The selected point in the respiration cycle is optionally anywhere in the respiration cycle and/or for any duration during the respiration cycle. As illustrated in Figure 10, the selected time period is at the top of a breath for a period of about 0.1, 0.5, or 1 second. More particularly, the main controller 110 controls injection of hydrogen into the injection system, formation of the negative ion 1020, controls extraction of negative ions from a negative ion source, controls injection 940 of protons into the synchrotron 130, and/or controls acceleration 950 of the protons in a manner that combined with extraction 960 delivers 970 the protons 268 to the tumor at a selected point in the respiration cycle. Intensity of the proton beam is also selectable and controllable by the main controller 110 at this stage, as described *supra*. The feedback control from the magnetic field controller is optionally to a power or power supplies for one or both of the main bending magnet 250 or to the correction coils 380, 390 within the main bending magnet 250. Having smaller applied currents, the correction coils 380, 390 are rapidly adjustable to a newly selected acceleration frequency or corresponding charged particle energy

level. Particularly, the magnetic field controller alters the applied fields to the main bending magnets or correction coils that are tied to the patient's respiration cycle. This system is in stark contrast to a system where the current is stabilized and the synchrotron delivers pulses with a fixed period. Preferably, the feedback of the magnetic field design coupled with the correction coils allows for the extraction cycle to match the varying respiratory rate of the patient, such as where a first respiration period P_1 , does not equal a second respiration period P_2 .

Although the invention has been described herein with reference to certain preferred embodiments, one skilled in the art will readily appreciate that other applications may be substituted for those set forth herein without departing from the spirit and scope of the present invention. Accordingly, the invention should only be limited by the Claims included below.

CLAIMS

1. An apparatus for extracting a circulating charged particle beam from *i* synchrotron, said synchrotron having a center, said apparatus comprising:

an extraction material;

at least a one kilovolt direct current field applied across a pair of extractor blades; and

a deflector,

wherein the circulating charged particle beam passes through said extraction material resulting in a reduced energy charged particle beam,

wherein the reduced energy charged particle beam passes between said pair of extraction blades, and

wherein the direct current field redirects the reduced energy charged particle beam through said deflector,

wherein said deflector yields an extracted charged particle beam.

2. The apparatus of Claim 1, wherein said extraction material consists essentially of atoms having six or fewer protons.

3. The apparatus of Claim 2, wherein said deflector comprises a Lamberson magnet.

4. The apparatus of Claim 1, wherein said extraction material comprises any of:

beryllium;

lithium hydride; and

carbon.

5. The apparatus of Claim 4, wherein said extraction material comprises a foil of about thirty to one hundred micrometers thickness.

6. The apparatus of Claim 1, further comprising a pair of betatron oscillation inducing blades, wherein the circulating charged particle beam traverses said pair of betatron oscillation inducing blades during acceleration.

7. The apparatus of Claim 1, wherein said extraction material comprises a foil less than about one hundred fifty micrometers thick.

8. The apparatus of Claim 7, wherein a radio frequency voltage applied across a pair of betatron oscillation inducing blades induces a betatron oscillation on the circulating charged particle beam.

9. The apparatus of Claim 8, wherein a first distance between said center of said synchrotron and said pair of extraction blades is less than a second distance between said center of said synchrotron and said pair of betatron oscillation inducing blades,

wherein the circulating charged particle beam comprises a radius of curvature passing through said betatron oscillation blades,

wherein the reduced energy charged particle beam, resulting from transmission through said extraction material, comprises a radius of curvature passing through said extraction blades.

10. The apparatus of Claim 9, further comprising a patient respiration monitor generating a respiration signal, wherein timing of the extracted charged particle beam is synchronized to said respiration signal.

11. The apparatus of Claim 10, further comprising a main controller, said main controller timing all of:

- (1) particle beam injection,
- (2) particle beam acceleration, and
- (3) timing of said radio frequency voltage

to synchronize with said respiration signal.

12. The apparatus of Claim 9, wherein an inner blade of said pair of betatron oscillation blades is in common with an outer blade of said pair of extraction blades.

13. The apparatus of Claim 9, further comprising an intensity controller controlling intensity of the extracted charged particle beam via a feedback control.

14. The apparatus of Claim 13, wherein an induced current results from the circulating charged particle beam passing through said extraction material, wherein the induced current comprises a feedback input to said intensity controller.

15. The apparatus of Claim 9, further comprising a respiration monitor providing a respiration signal, wherein the extracted charged particle beam is synchronized in time to patient respiration using said respiration signal.

16. The apparatus of Claim 1, further comprising an intensity controller controlling intensity of the extracted charged particle beam via a feedback control.

17. The apparatus of Claim 16, wherein an induced current results from the circulating charged particle beam passing through said extraction material, wherein the induced current comprises a feedback input to said intensity controller.

18. The apparatus of Claim 16, wherein said intensity controller alters an applied radio frequency inducing betatron oscillation on the circulating charged particle beam.

19. The apparatus of Claim 1, further comprising at least one turning magnet.

20. The apparatus of Claim 19, wherein said turning magnet comprises a magnetic field concentrating first magnet, wherein said first magnet comprises:

a gap through which the circulating charged particle beam circulates;

a first cross-section diameter not in contact with said gap; and

a second cross-sectional diameter proximate said gap, wherein said second cross-section diameter is less than seventy percent of said first cross-sectional diameter, wherein a magnetic field passing through said first cross-sectional diameter concentrates in said second cross-sectional diameter before crossing said gap.

21. A method for extracting a circulating charged particle beam from a synchrotron, comprising the steps of:

transmitting the circulating charged particle beam through an extraction material, said extraction material yielding a reduced energy charged particle beam;

applying at least five hundred volts across a first pair of blades; and

passing the reduced energy charged particle beam between said first pair of blades,

wherein said first pair of blades redirect the reduced energy charged particle beam to a deflector,

wherein said deflector yields an extracted charged particle beam.

22. The method of Claim 21, wherein said extraction material consists essentially of atoms having six or fewer protons.

23. The method of Claim 21, wherein said extraction material comprises any of:

beryllium;

lithium hydride; and

carbon.

24. The method of Claim 23, wherein said extraction material comprises a foil of about forty to sixty microns thickness.

25. The method of Claim 21, further comprising the step of:

inducing betatron oscillation using a second pair of blades, wherein the circulating charged particle beam passes between said second pair of blades prior to said step of transmitting.

26. The method of Claim 21, wherein said extraction material comprises a foil less than one hundred microns thick.

27. The method of Claim 26, further comprising the step of:

applying a radio frequency voltage across a second pair of blades to alter the circulating path of the circulating charged particle beam.

28. The method of Claim 26, wherein a first distance between said center of said synchrotron and said first pair of blades is less than a second distance between said center of said synchrotron and said second pair of blades,

wherein the circulating charged particle beam comprises a second radius of curvature passing through said second pair of blades,

wherein the reduced energy charged particle beam, resulting from transmission through said extraction material, comprises a first radius of curvature passing through said first pair of blades

wherein said reduced energy charged particle beam exits said synchrotron within an inner diameter of said circulating charged particle beam.

29. The method of Claim 28, further comprising the step of:

controlling intensity of the extracted charged particle beam with an intensity controller using a feedback control.

30. The method of Claim 29, wherein an induced current results from the circulating charged particle beam passing through said extraction material, wherein the induced current comprises a feedback input to said step of controlling intensity.

31. The method of Claim 21, further comprising the step of:

controlling intensity of the extracted charged particle beam with an intensity controller using a feedback control.

32. The method of Claim 31, wherein an induced current results from the circulating charged particle beam passing through said extraction material, wherein the induced current comprises a feedback input to said step of controlling intensity.

33. The method of Claim 32, wherein said intensity controller alters duration of an applied radio frequency inducing altered trajectory of the circulating charged particle beam.

34. A method for extracting a circulating charged particle beam from a synchrotron, comprising the steps of:

transmitting the circulating charged particle beam through an extraction material, said extraction material yielding a reduced energy charged particle beam;

applying a field of at least five hundred volts across a pair of extraction blades;

passing the reduced energy charged particle beam between said pair of extraction blades,

wherein said field redirects the reduced energy charged particle as an extracted charged particle beam.

35. The method of Claim 34, further comprising the step of:

synchronizing said step of transmitting with a patient respiration signal.

36. The method of Claim 34, further comprising the step of:

prior to said step of transmitting, inducing betatron oscillation on the circulating charged particle beam,

wherein said step of inducing occurs at a selected energy level of the circulating charged particle beam,

wherein the betatron oscillation increases average radius of curvature of the circulating charged particle beam until said step of transmitting yields the reduced energy charged particle beam,

wherein said step of inducing at said selected energy level yields an energy controlled extracted charged particle beam.

37. The method of Claim 36, further comprising the step of:

controlling intensity of the energy controlled extracted charged beam with an intensity controller.

38. The method of Claim 37, wherein said step of controlling comprises the steps of:

inputting a feedback signal to said intensity controller, said step of transmitting yielding emitted electrons in the process of the circulating charged particle beam striking said extraction material, wherein the emitted electrons are converted to said feedback signal;

comparing said feedback signal to an irradiation plan intensity;

adjusting betatron oscillation with said intensity controller until said feedback signal proximately equals said irradiation plan intensity,

wherein said energy controlled extracted charged particle beam comprises an independent intensity control.

39. The method of Claim 34, further comprising the steps of:

inducing a change in radial movement of the circulating charged particle beam: (1) after acceleration of the charged particle beam to a selected energy and (2) prior to said step of transmitting the circulating charged particle beam through said extraction material; and

controlling intensity of said extracted charged particle beam using an electron flow resultant from the charged particle beam transmitting through said extraction material.

40. The method of Claim 39, wherein energy control of said extracted charged particle beam is independent of intensity control of said extracted charged particle beam.

1/10

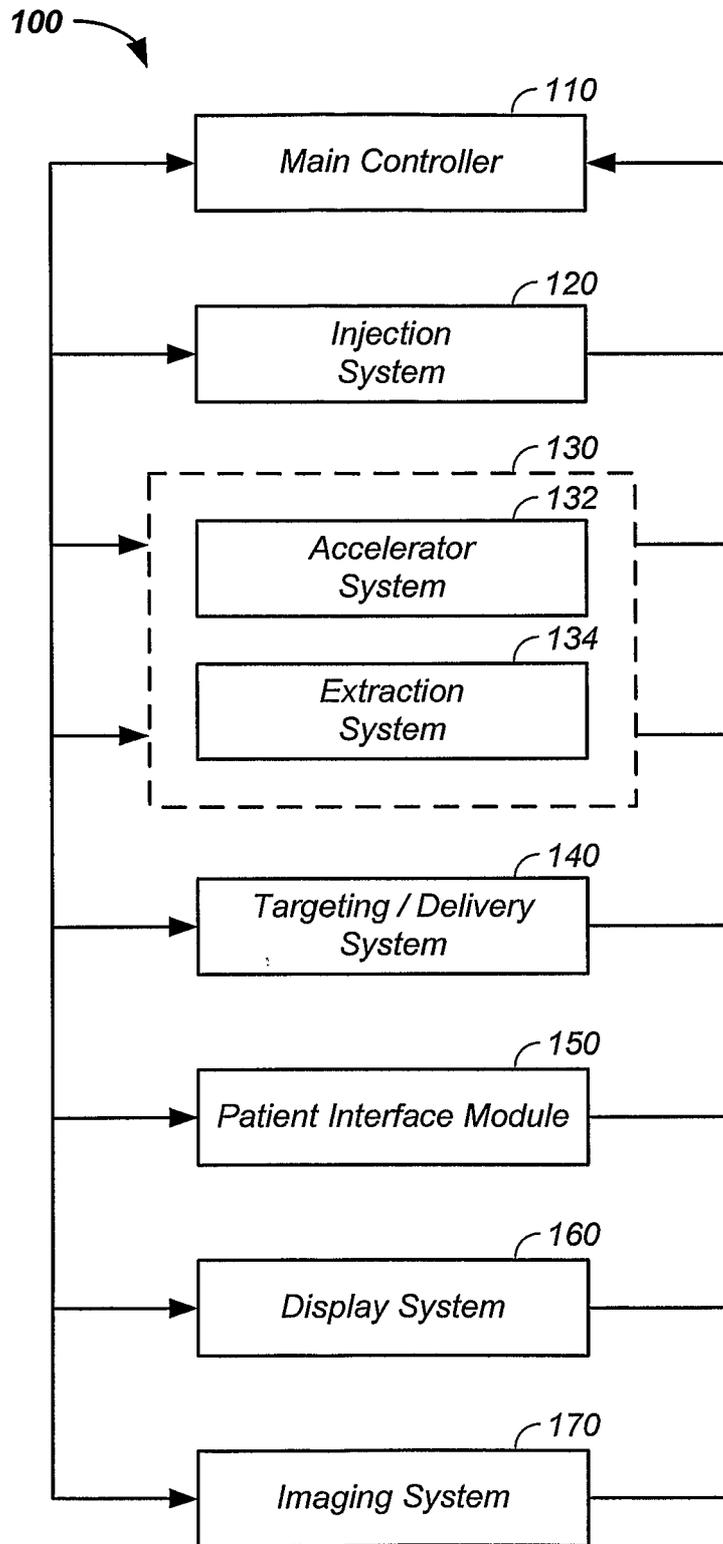


FIG. 1

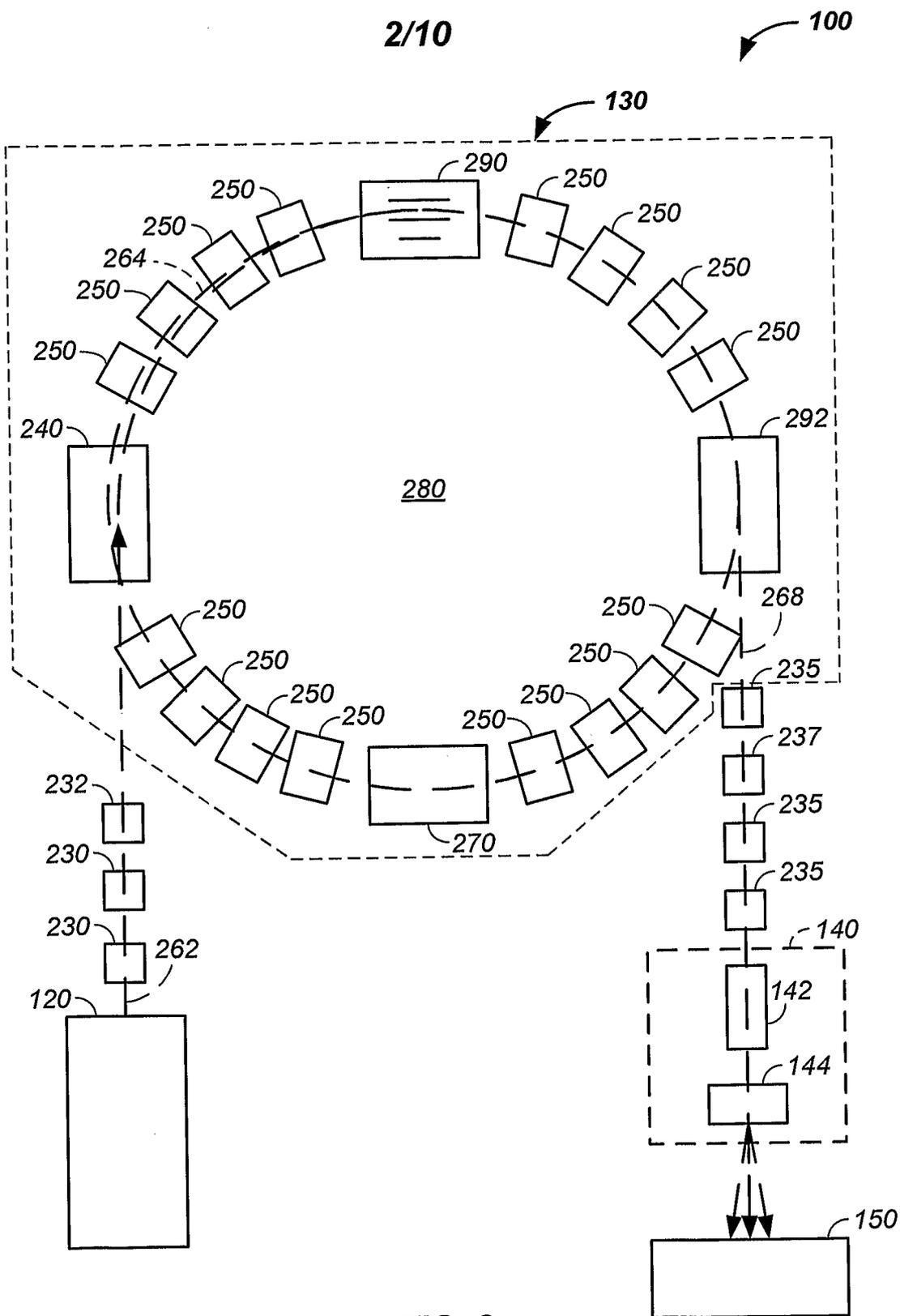


FIG. 2

3/10

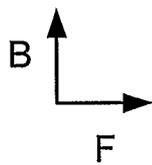
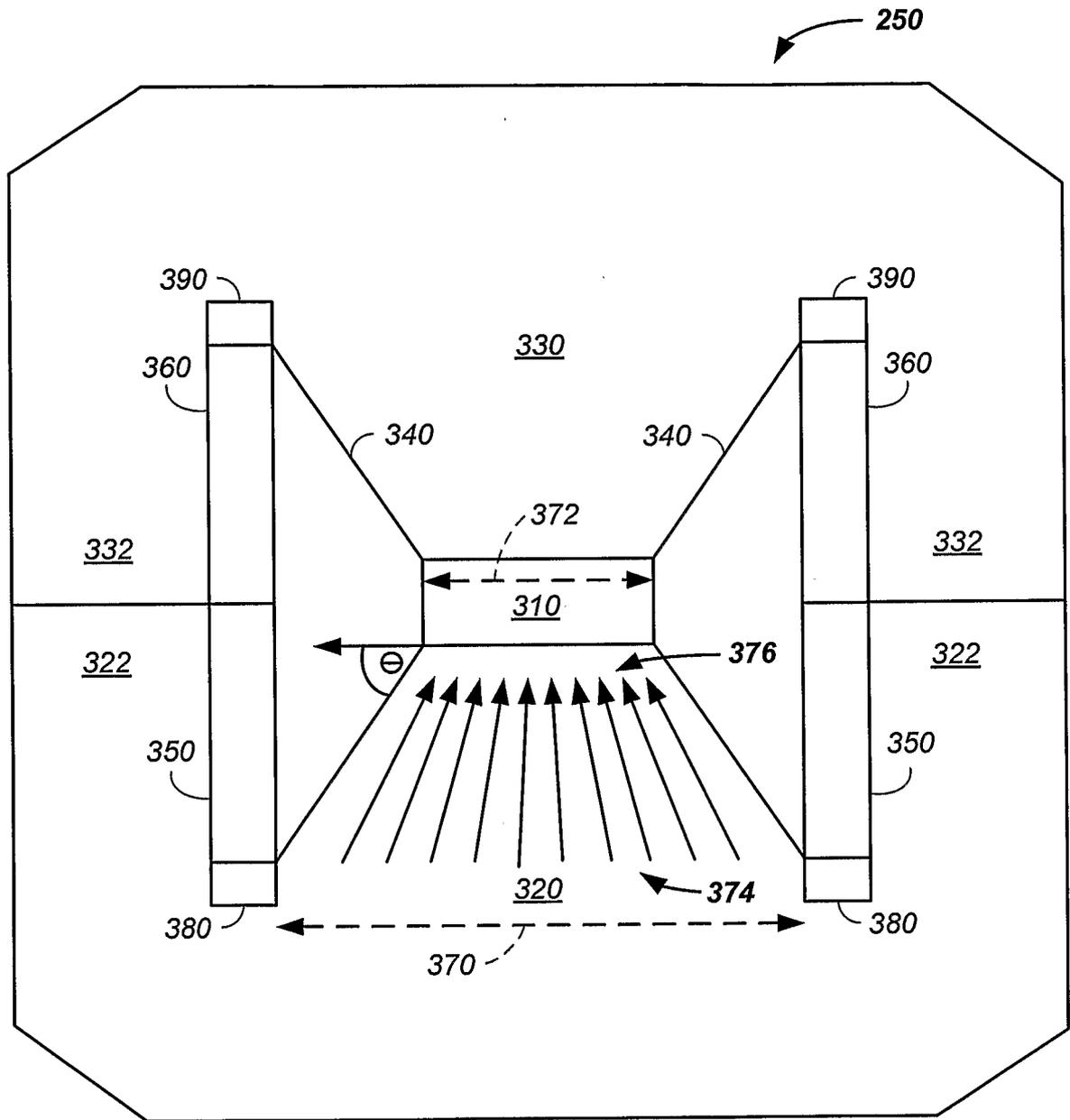


FIG. 3

4/10

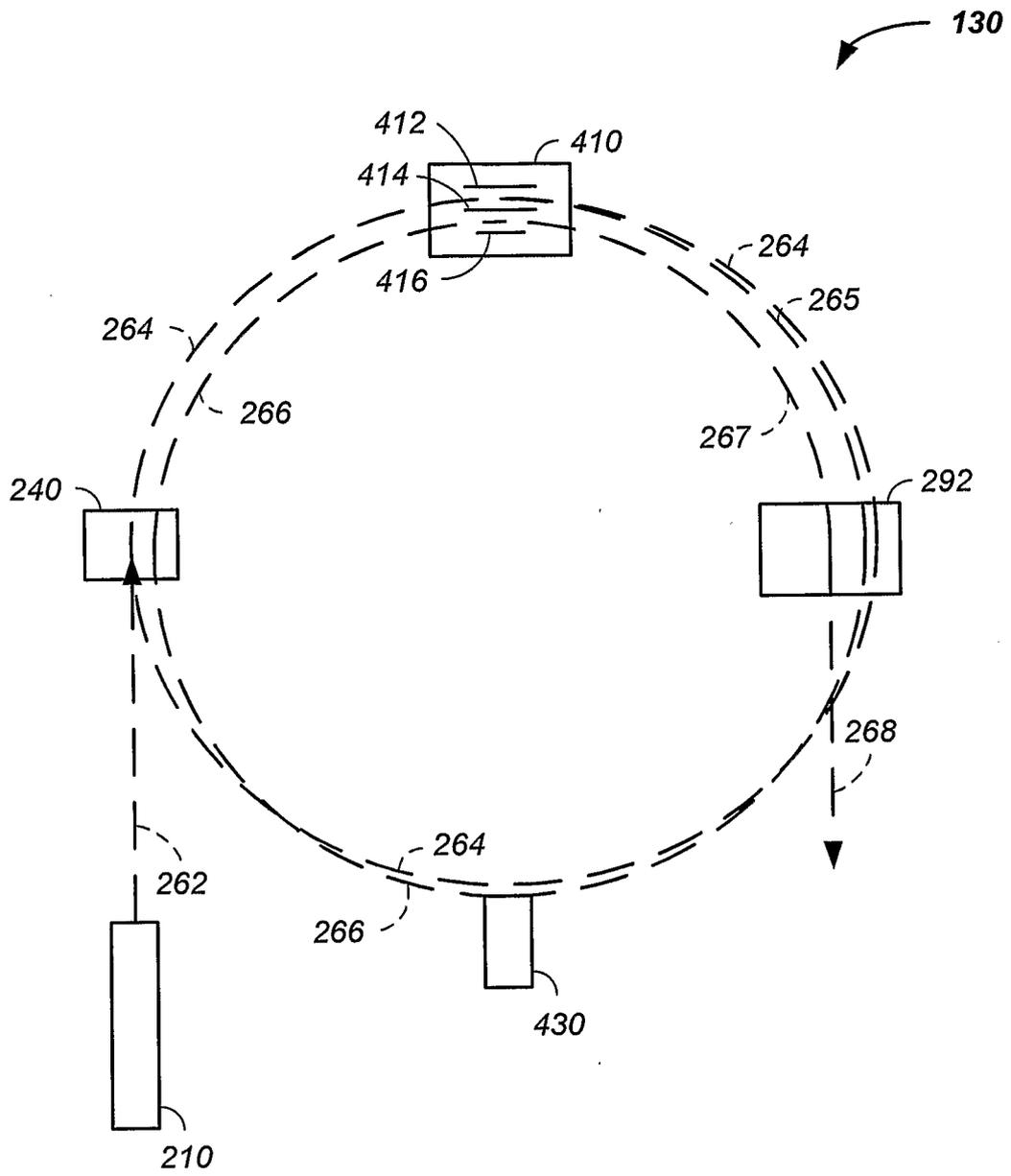


FIG. 4

5/10

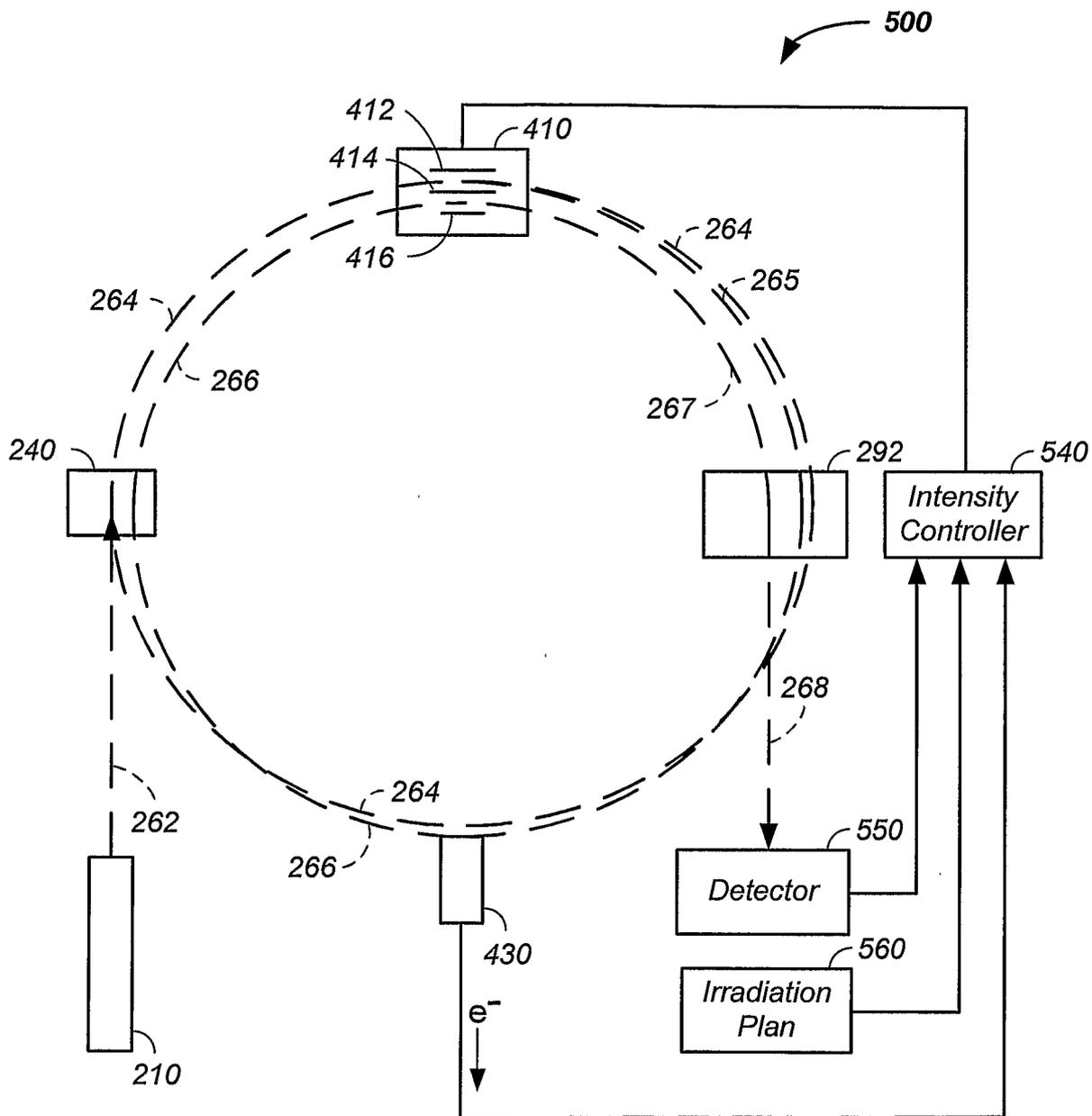


FIG. 5

6/10

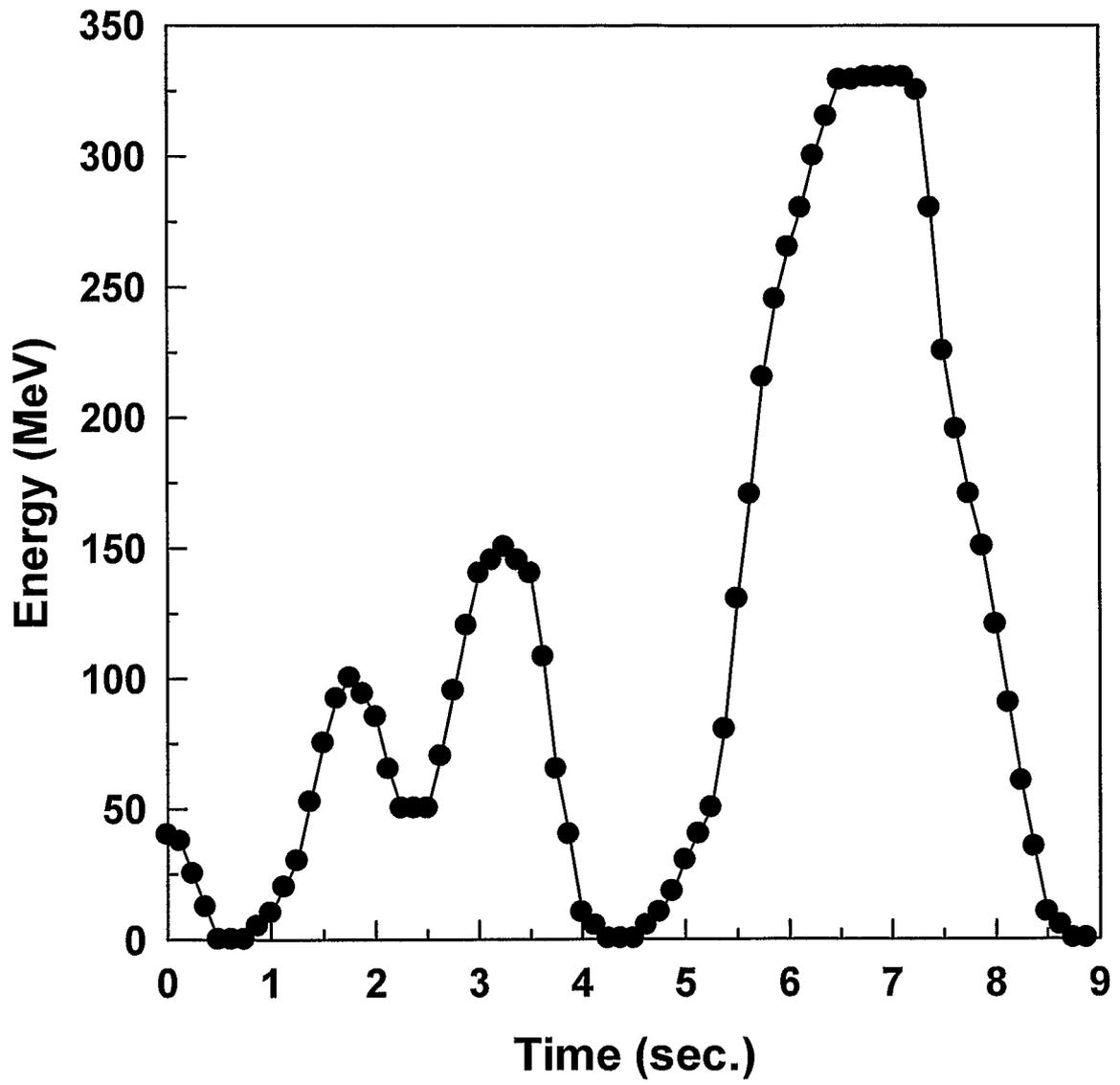


FIG. 6

7/10

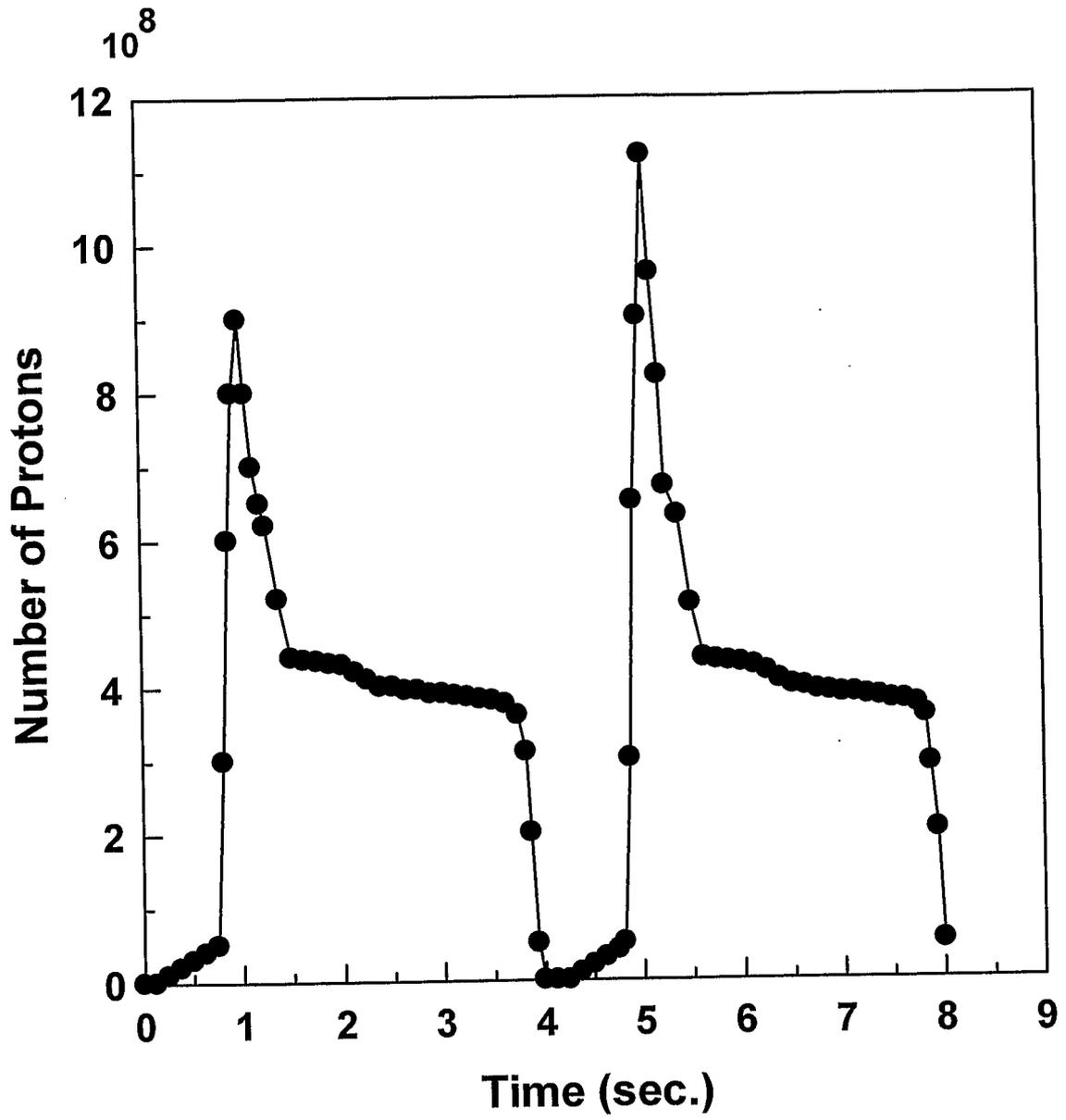
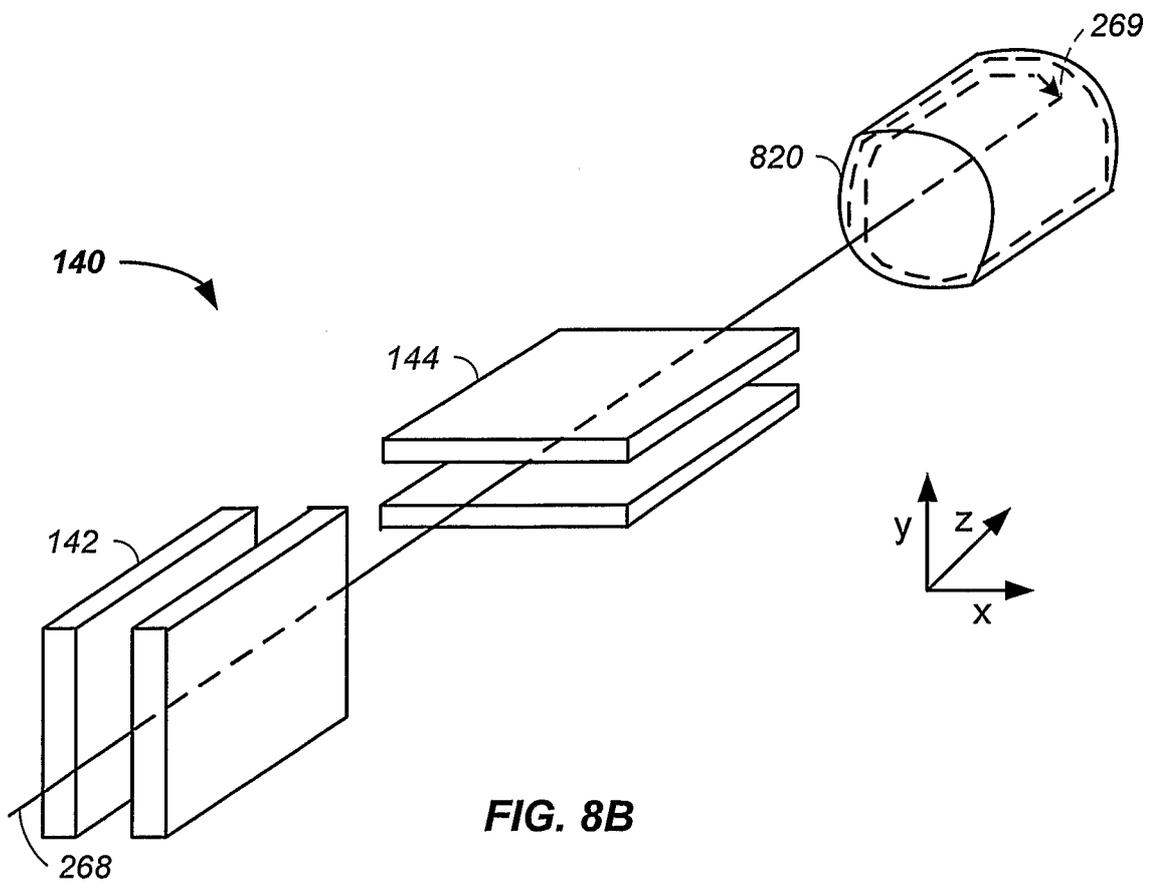
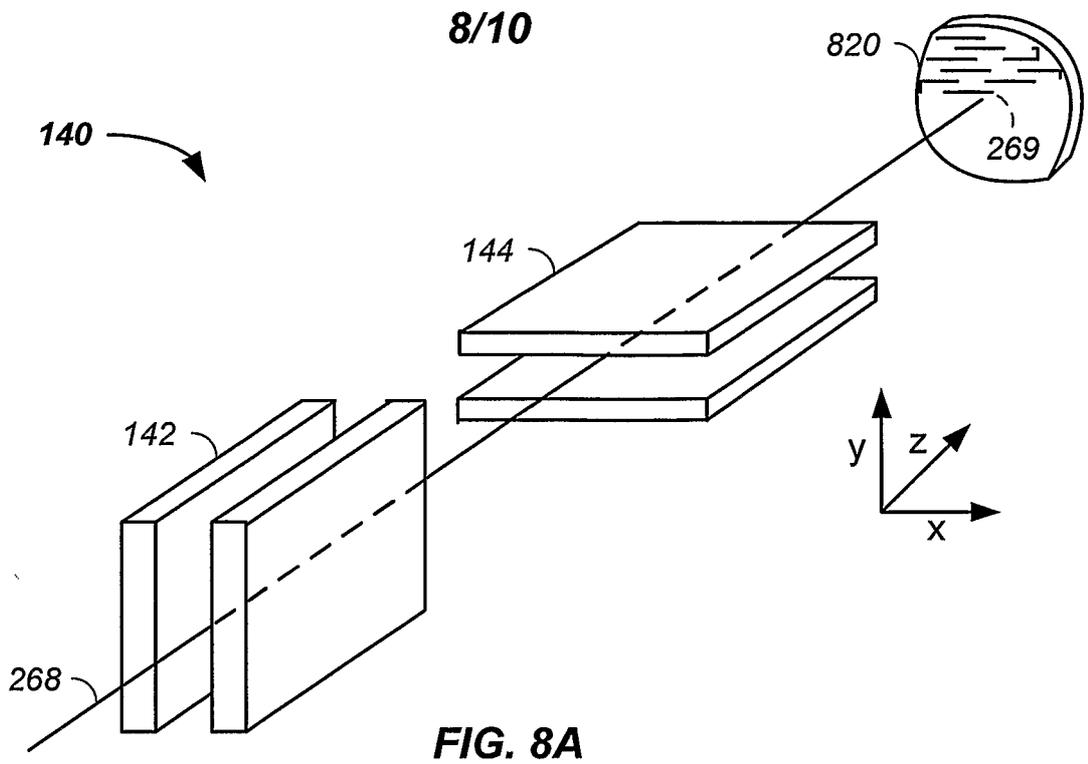


FIG. 7



9/10

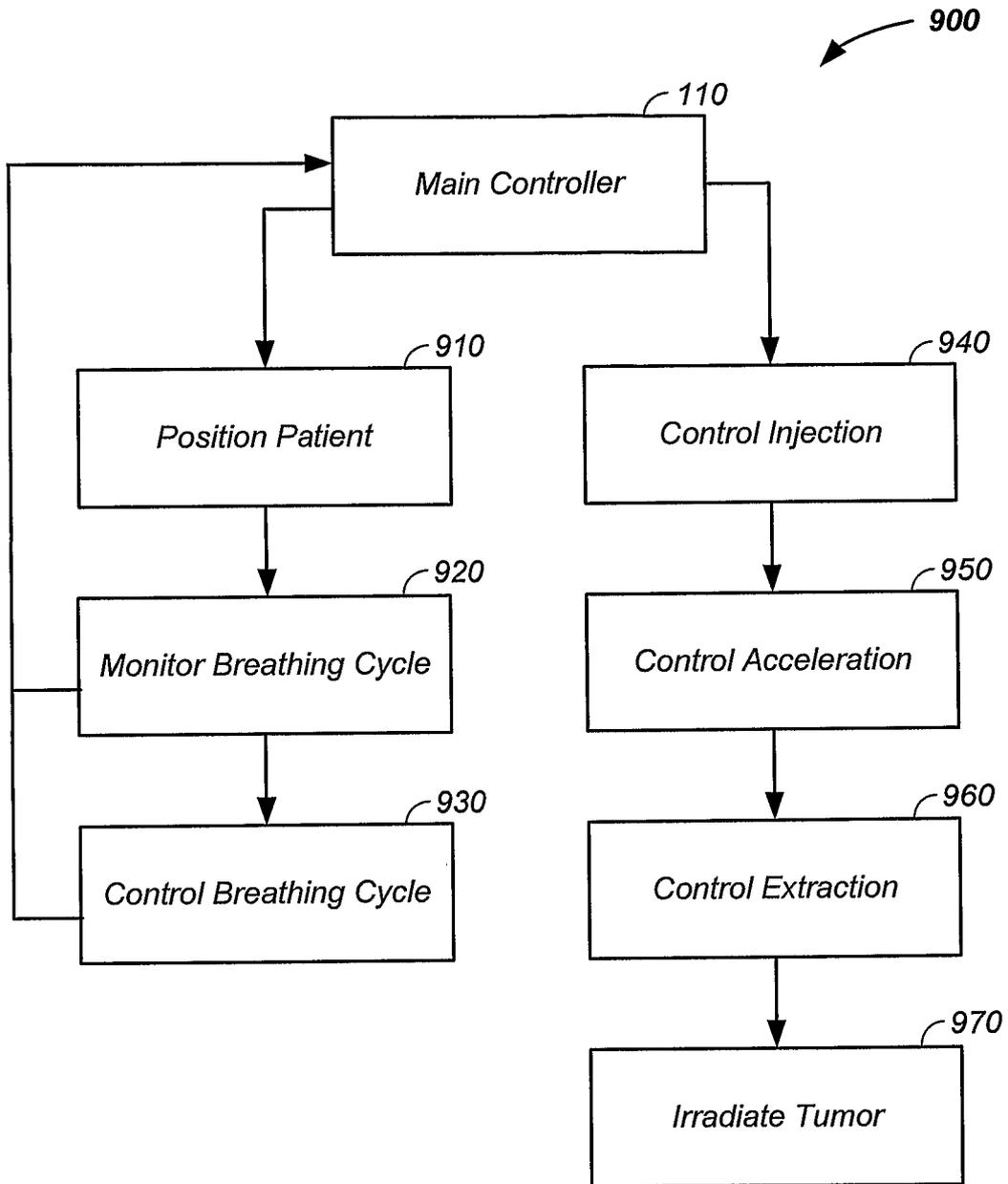


FIG. 9

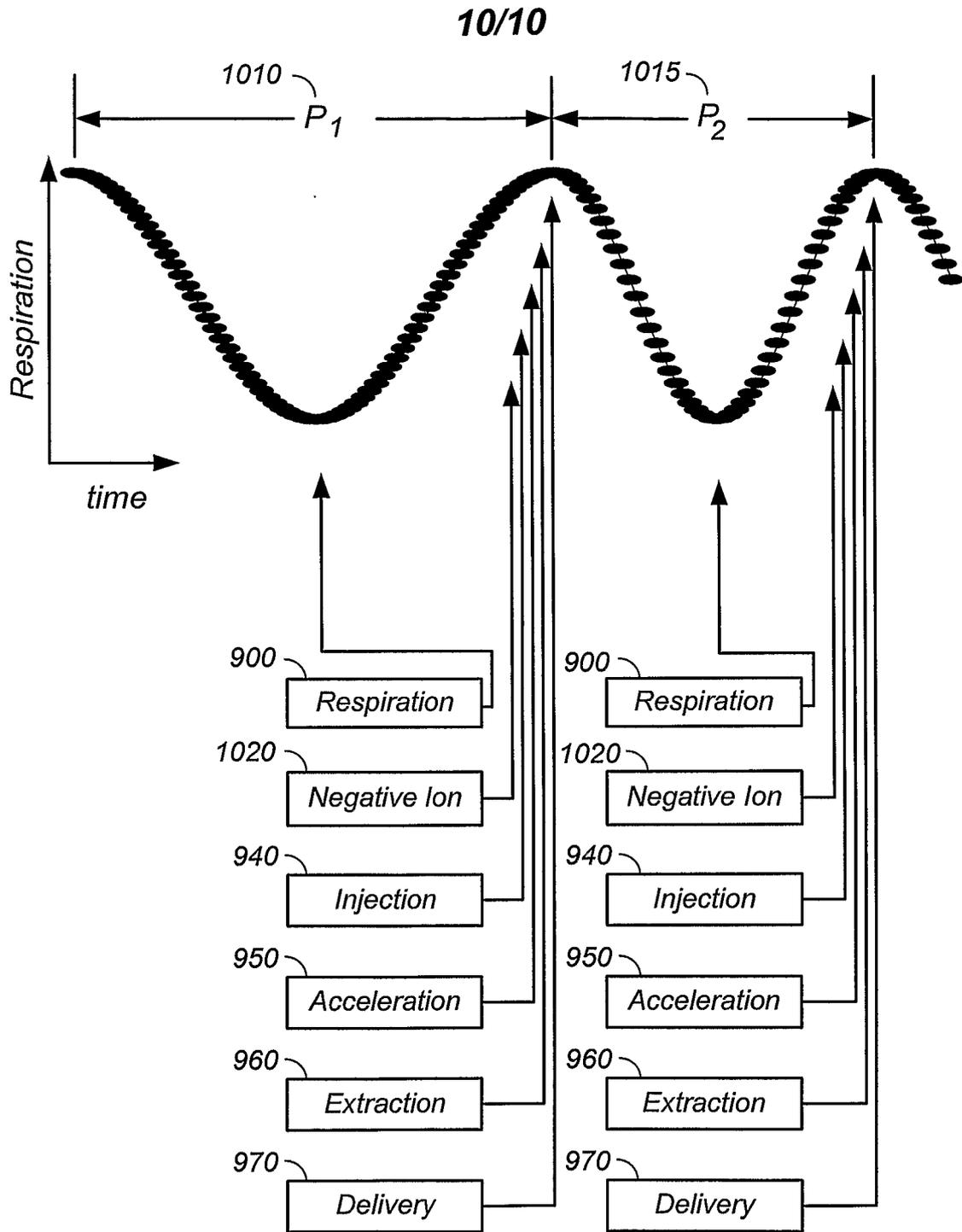


FIG. 10