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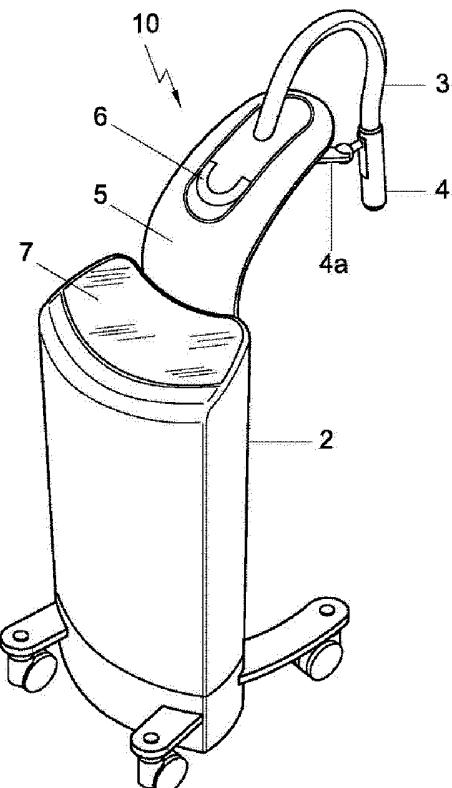
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(54) **A mobile X-ray unit.**

(57) The invention relates to a mobile X-ray unit (10) comprising a base (2) for accommodating a control unit, a power supply and a cooler and further comprising an articulated displaceable arm (4a) supporting an X-ray applicator (4) provided with an X-ray tube, said X-ray applicator being connected to the base, the X-ray tube comprising a target for generating an X-ray beam and a collimator for shaping the generated X-ray beam, a distance between the target and the collimator being in the range between 4 and 10 cm.



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Dit octrooi is verleend ongeacht het bijgevoegde resultaat van het onderzoek naar de stand van de techniek en schriftelijke opinie. Het octrooischrift komt overeen met de oorspronkelijk ingediende stukken.

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Title: A mobile X-ray unit

FIELD OF THE INVENTION

The invention relates to a mobile X-ray unit comprising a base for accommodating a control unit, a power supply and a cooler and further comprising an articulated displaceable arm supporting an X-ray applicator 5 comprising an X-ray tube, said X-ray applicator being connected to the base, the X-ray tube comprising a target for generating an X-ray beam and a collimator for shaping the generated X-ray beam.

The invention further relates to a method of manufacturing the X-ray unit and a method of delivering an X-ray beam.

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BACKGROUND OF THE INVENTION

Skin cancer, having increased incidence rate in the last decade of the 20th century, requires substantial effort from medical professionals in terms of early diagnosis, logistics and availability of suitable treatment. However, it is 15 appreciated that over 1.3 million new skin cancers are diagnosed annually and are increasing at a rate of about 5 % per year. Increased exposure to the sun without skin protection and a decreased ozone layer are regarded as the main causes of this increase – a problem estimated to be costing over 1 billion Euros in annual medical treatment expenses. Over 80% of skin cancers occur in the 20 head and neck regions with 50% occurring in patients over 60 years of age. It is expected that a portion of the senior population will double in year 2025 compared to the present demographics.

Non proliferated cancers being substantially superficial lesions may be treated in different ways. First, surgery may be envisaged. However, such 25 technique may be disadvantageous in terms of long waiting lists and complications related to post-treatment care. In addition, due to invasive character of surgery contamination of the wound by infections may present an additional risk. Secondly, irradiation using electrons or soft X-rays may be

envisaged. Such techniques have an advantage of being non invasive, wherein a treatment session may be as short as 2 to 4 minutes. It will be appreciated that usually the integral treatment using radiotherapeutic techniques may comprise a number of sessions.

5 Accordingly, the growing incidence of skin cancer and increasing of a share of the senior population in overall demographics pose substantial challenge on the cancer treatment logistics.

Recently, the use of a portable X-ray unit has been suggested, which may be used inside a hospital radiotherapy department. An embodiment of
10 such portable unit is described in US 2007/0076851. The known unit comprises an X-ray source provided with a filtering device having a plurality of filters rotatably arranged with respect to a focal point of the X-ray tube for changing filtering characteristics on demand. The plurality of filters is arranged in a filtering device, which is transversely arranged with respect to a longitudinal
15 axis of the X-ray tube.

It is a disadvantage of the known X-ray tube that beam characteristics due to internal geometry of the known X-ray tube may be detrimentally affected, for example leading to a broadened penumbra of the X-ray beam.
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SUMMARY OF THE INVENTION

It is an object of the invention to provide a mobile X-ray unit having improved operational characteristics. In particular, it is an object of the invention to provide a mobile X-ray unit having improved penumbra of the X-ray beam and/or a reduced skin dose, when dose delivery is specified at 5 mm depth.
25

To this end in the mobile X-ray unit according to the invention a distance between the target and the collimator is in the range between 4 and 10 cm.

It is found that by setting a distance between the X-ray target and the collimator in the range of 4...10 cm, preferably to a distance of about 5 to 6 cm improved beam characteristics are achieved. For example, it is found that improved beam flatness as well as sharpened penumbra are achievable for the 5 target-collimator distance of 4...10 cm, particularly for the target-collimator distance of about 5 to 6 cm due to a relatively small focal size. For example, for the target-collimator distance of about 5 cm penumbra of 1.5 – 1.8 mm is achievable (specified for 20/80% lines).

It is appreciated that such sharpened penumbra is important 10 particularly for treating of small lesions, like skin cancers, as dose to healthy tissue, being a critical item in dose delivery planning, is minimized.

In an embodiment of an X-ray unit according to the invention, the target and the collimator are accommodated in a substantially cylindrically shaped X-ray tube having a longitudinal axis, a direction of propagation of the 15 X-ray beam being substantially parallel to said longitudinal axis.

It is found to be advantageous to arrange the anode-collimator geometry in such a way that the axis of the X-ray tube substantially coincides with a direction of propagation of the generated X-ray beam. Thus, the X-ray tube and the X-ray applicator may have the same longitudinal axis. Such 20 configuration is advantageous from mechanical perspective as balancing of the applicator on the articulated arm is simplified for a coaxial geometry. It will be appreciated that the X-ray tube, accommodated in the X-ray applicator represents a relatively slim (outer diameter of less than 10 cm) elongated cylinder (length of about 30 cm), which is preferably displaced in a vertical 25 direction for delivering the X-ray beam to the patient. Once the internal geometry of the X-ray tube is coaxial, the weight of the X-ray tube may be suitably balanced enabling easy and reproducible displacement of the articulated arm supporting the X-ray applicator.

In a further embodiment of the X-ray unit according to the 30 invention, the collimator is provided with automatic identification means

arranged to generate a signal in the control unit representative of collimator characteristics.

- It is found to be advantageous to enable a fully automatic identification of the collimator inserted in the X-ray tube, as human errors
- 5 with respect to defining the field geometry may be minimized or even eliminated. For example, in case when the collimator is conceived to be provided in a receptacle, such receptacle may be provided with a resistive path whose resistivity may be changed. The collimator may then be arranged with projections adapted to cooperate with the resistive path of the receptacle for
- 10 changing the resulting resistivity and thus for generating a signal representative of the collimator being inserted. Preferably, the signal is made available to the control unit of the mobile X-ray unit for independent verification. Preferably, the X-ray unit comprises a set of collimators provided with respective identification means.
- 15 In a still further embodiment of the X-ray unit according to the invention, it is provided with a signaling means indicating generation of the X-ray beam.

- It is found advantageous to provide means of signaling that the X-ray beam is on. For example, such signaling may be implemented as a suitable
- 20 light on the X-ray applicator. One or more light emitting diodes may be used for this purpose. It may be possible to provide a plurality of signaling means in dependence of the energy of the generated X-ray beam.

- For example, for the X-ray beam of a lower portion of the spectrum (about 50 kV) a first indicator may be used, for example a first light color. For
- 25 an intermediate portion of the spectrum (about 60 – 65 kV) a second indicator may be used, for example a second light color. Finally, for the higher portion of the spectrum (66 – 75 kV, preferably 66 – 70 kV) a third indicator may be used, for example a third light color. It will be appreciated that a plurality of possibilities exist for indicating different spectra, including but not limited to a
- 30 progressive illumination of a plurality of indicators upon hardening of the

delivered X-ray beam. It will be further appreciated that such indication of the kV range may be allowed in the device, in a user interface or in a supplementary unit. It will be further appreciated that the named kV ranges may be scaled, for example with the factors 1,1; 1,2; 1,3; 1,4; 1,5.

- 5 Preferably, the signaling means comprises a light indicator arranged on the outer housing. Such arrangement of the signaling means is advantageous as the patient is made aware about the starting point and the termination of irradiation so that the patient may retain a static position during the course of treatment.

10 In a further embodiment of an X-ray unit according the invention, the cooler is arranged with piping to provide a cooling medium in a vicinity of the X-ray tube, the piping running in a space between the X-ray tube and a shielding wall associated with the X-ray tube.

It is found to be advantageous to provide a spacing between the
15 outer surface of the X-ray tube and the inner surface of the outer housing of the X-ray applicator, said spacing being at least partially filled with a coolant. It is found to be advantageous to provide circulated water as a cooling agent due to high specific heat capacity, offering improved heat transfer of water with respect to a gas. However, pressurized gas may also be used as a suitable
20 coolant. Preferably, a temperature sensor is arranged on the outer housing of the X-ray applicator for measuring actual temperature of the outer housing. The temperature sensor may be connected to the control unit for controlling the cooler and/or for controlling the high voltage supply. Should temperature rise above a pre-determined shut-off value, the control unit may be arranged to
25 disable the high voltage supply and/or to intensify the cooling mode, for example by increasing a pumping capacity of the coolant.

In a still further embodiment of the X-ray unit according to the invention a radiation detector is provided inside the outer housing for detecting the X-ray beam.

It is found to be advantageous to provide independent means for detecting presence of the generated X-ray beam. Preferably, the X-ray unit according to the invention comprises a primary timer which sets a time for the high voltage supply for delivering a predetermined radiation dose. The 5 radiation sensor accommodated inside the outer housing of the X-ray applicator may be part of a secondary timer circuit adapted to shut down the high voltage supply upon the event the predetermined radiation dose is delivered. In this way radiation safety control may be improved.

In a still further embodiment of the X-ray unit according to the 10 invention, the X-ray applicator comprises an exit surface conceived to be directed towards a patient, said surface being covered by an applicator cap. It is found advantageous to provide such applicator cap, which may have many functions in use. First, the applicator cap may be used for protecting the exit surface of the X-ray applicator from intra-patient contamination. Secondly, 15 thickness of the cap in a direction of the beam propagation may be selected to be sufficient for substantially eliminating electron contamination from the X-ray beam. It will be appreciated that those skilled in the art will readily appreciate the relation between the energy of the secondary electrons emanating from the X-ray tube and a required thickness of a given material, 20 for example plastic, glass, ceramics sufficient for fully intercepting these electrons. Preferably, the applicator cap is disposable.

Thirdly, the applicator cap may function as a heat absorber for mitigating the elevated temperature of the X-ray applicator in use. As a result the patient will feel the applicator contacting the skin as a slightly warm 25 object.

In a still further embodiment of the X-ray unit according to the invention, the X-ray applicator is connected to the base using a displaceable panel, the flexible cabling running substantially in the displaceable panel.

It is found to be advantageous to provide an intermediate 30 mechanical unit connecting the base of the mobile X-ray unit and the X-ray

applicator for housing the flexible cables thereby preventing their entanglement. The displaceable panel may be arranged with a pre-defined travel distance with respect to a lowest achievable stand and a highest achievable stand. Such predefined travel distance may be advantageous for

5 increasing durability of the cables tubes and wiring of the X-ray unit, especially of the tubes accommodating the coolant.

In a still further embodiment of the X-ray unit according to the invention, the displaceable panel comprises a user interface for controlling the X-ray unit. Preferably, the user interface comprises a display. For example, the

10 display may be implemented as a touch screen arranged for enabling data input. Alternatively, display may be arranged for echoing data, whereas dedicated buttons or other suitable means may be provided for entering input data into the X-ray unit.

According to another embodiment of the invention there is provided

15 a method for manufacturing a mobile X-ray unit comprising a base for accommodating a control unit, a power supply and a cooler and further comprising an articulated displaceable X-ray arm supporting an X-ray applicator comprising an X-ray tube, according to the invention comprises the steps of:

20 - connecting said arm to the base using a flexible cable;
- arranging the X-ray tube with a target for generating an X-ray beam and a collimator for shaping the generated X-ray beam;
- setting a distance between the target and the collimator in the range between 4 and 10 cm.

25 Preferably, in the X-ray unit according to the invention, the target and the collimator are accommodated in a substantially cylindrically shaped X-ray applicator having a longitudinal axis, a direction of propagation of the X-ray beam being substantially parallel to said longitudinal axis. Further advantageous embodiments of the method according to the invention will be

30 discussed with reference to Figure 3.

In a method of delivering an X-ray beam for irradiating a superficial lesion, wherein an X-ray unit comprises a base for accommodating a control unit, a power supply and a cooler and further comprising an articulated displaceable X-ray arm accommodating an X-ray tube, said arm being

5 connected to the base using a flexible cable, the X-ray tube comprises a target for generating an X-ray beam and a collimator for shaping the generated X-ray beam, a distance between the target and the collimator being in the range between 4 and 10 cm.

The invention still further relates to an applicator cap for an X-ray unit comprising an X-ray tube accommodated in an X-ray applicator, said X-ray applicator comprising an exit surface conceived to be directed towards a patient, the applicator cap being arranged for covering at least said surface. Preferably, the applicator cap is disposable. More preferably, thickness of the cap in a direction of the beam propagation is sufficient for substantially

10 eliminating electron contamination from the X-ray beam. An applicator cap may be advantageously manufactured from a substantially transparent material for enabling visualization of delineation between the exit surface of the X-ray applicator and a lesion conceived to be treated.

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These and other aspects of the invention will be discussed with reference to drawings wherein like reference numerals or signs relate to like elements. It will be appreciated that the drawings are presented for illustration purposes only and may not be used for limiting the scope of the appended claims.

25 **BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1a presents in a schematic way an embodiment of a mobile X-ray unit according to the invention.

Figure 1b presents in a schematic way an embodiment of a displaceable panel of the mobile X-ray unit.

Figure 1c presents in a schematic way an embodiment of displacement functionality of the applicator of the X-ray unit according to the invention.

Figure 2 presents in a schematic way an embodiment of architecture 5 of the mobile X-ray unit according to the invention.

Figure 3 presents in a schematic way an embodiment of a cross section of an X-ray applicator of the mobile X-ray unit according to the invention.

Figure 4 presents in a schematic way an embodiment of the X-ray 10 applicator of Figure 3 provided with an applicator cap.

Figure 5 presents in a schematic way an embodiment of a collimator provided with identification means.

Figure 6 presents in a schematic view an embodiment of a collimator identification system.

15 Figure 7 presents in a schematic view a further embodiment of the X-ray tube according to a further aspect of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Figure 1a presents in a schematic way an embodiment of a mobile X-ray unit according to the invention. The mobile X-ray unit 10 comprises a base 2 comprising at least a power supply unit, a cooling system and a control unit for controlling an operation of the X-ray applicator 4 comprising an X-ray tube accommodated in an outer housing. The X-ray applicator 4 is connected with the base using flexible cables 3, which may be at least partially received in a 25 displaceable panel 5. The applicator 4 is supported by an articulated displaceable arm 4a, which may comprise a pivot for altering angulation of the applicator 4 in space. The articulated arm 4a may also be mechanically connected with the displaceable panel 5 for enabling alteration of a vertical position of the applicator 4. Preferably, the displaceable panel 5 is provided 30 with a handle 6 enabling easy manipulation thereof. The displaceable panel 5

may be guided along suitable rails for enabling a substantially smooth and shock-free displacement thereof.

The displaceable panel 5 may be also referred to as a displaceable mast. It is found to be advantageous to allow the mast to be displaceable along a substantially upright axis with respect to the base 2. It will be appreciated that the substantially upright axis extends in a substantially vertical direction, which is generally upright. However, it will be further appreciated that the terms 'generally upright' or 'substantially vertical' may relate to a direction substantially perpendicular (+- 20 degrees) to a plane of the surface 10 on which the mobile X-ray unit is sitting.

Preferably, the base 2 is provided with a display 7 for feeding-back suitable user information. The display 7 may be arranged as a touch-sensitive screen for enabling suitable data input into the system.

Figure 1b presents in a schematic way an embodiment of a displaceable panel of the mobile X-ray unit. In this enlarged view 10a specific elements of the displaceable panel 5 are depicted. Accordingly, a handle 6 may be implemented as a mechanical item for pulling or pushing the panel 5. Alternatively, the handle 6 may be arranged as an electrical actuator for triggering motors (not shown) for displacing the panel 5. For example, when the handle 6 is pulled the motors may be activated for causing the panel 5 to displace in direction A. Pushing of the handle 6 may cause lowering of the panel 5 in direction B. Preferably, the mobile X-ray unit comprises means for limiting the movement of the panel 5. This may be advantageous for ensuring mechanical stability of the system on one hand (limitation of the upper level) and, on the other hand, may be beneficial for preventing cable damage (limitation of the lower level). Preferably, the panel 5 is movable using built-in rails whose length may be chosen for limiting the displacement range of the panel 5 in a desirable way.

The base 2 preferably further comprises a display 7, which may function as a suitable user interface 7a. For example, the patient data, such as a photo of the patient and/or a photo of a lesion may be provided in window 7b, whereby relevant patient information, such as the date of birth, gender, dose 5 prescription and dose delivery protocol and so on may be displayed in window 7c. Buttons 7d may be provided as touch functionality for enabling entering data. Alternatively or additionally, suitable hardware switches or buttons may be provided as well.

Figure 1c present in a schematic way an embodiment of
 10 displacement functionality of the applicator of the X-ray unit according to the invention. In accordance with an aspect of the invention mechanics of the mobile X-ray unit is developed and realized to support a broad range of translational and rotational movements for the X-ray applicator 4.

In view 11 a schematic embodiment is presented wherein the X-ray applicator is in its parked position. It will be appreciated that cabling is not depicted for clarity reasons. Such position may be suitable for transport of the mobile X-ray unit towards a booth and/or for maneuvering the X-ray unit around the patient. In order to retract the X-ray applicator as close as possible to the base 2, the articulated arm 4 may be bent under the outer portion 5a of
 20 the displaceable panel 5. For ensuring stability of the mobile X-ray unit during maneuvering thereof, a load block 2a close to a floor is provided for lowering an absolute position of the point of gravity of the overall construction.

View 12 presents in a schematic way a further possibility, wherein the X-ray application 4 is in one of its working positions having an X-ray exit 25 surface 8 being oriented towards a patient P. In order to suitably position the X-ray applicator with respect to the patient P, the displaceable panel may be moved to a certain dwell position located between the lowest position and the highest position of the panel 5. The articulated arm 4a may be used for suitably rotating the X-ray applicator about a rotation axis. Preferably, a

rotation axis is selected to coincide with a direction of emanation of the X-ray beam from the exit surface for a vertically oriented X-ray applicator.

View 13 presents in a schematic way a still further possibility, wherein the X-ray applicator 4 is to be used at a lowered position. For this 5 purpose the displaceable panel 5 may resume its lowest stand and the arm 4a may be used for orienting the X-ray applicator in a desirable way.

Figure 2 presents in a schematic way an embodiment of architecture of the mobile X-ray unit according to the invention. The mobile X-ray unit according to the invention comprises a high voltage supply, preferably adapted 10 to generate 50 – 75 kV X-rays in a suitable X-ray tube, a cooling system for cooling the X-ray tube during use and a control system for controlling electronic and electric parameters of sub-units of the X-ray unit during use. View 20 schematically depicts main units of the control system 21 and of the X-ray applicator 22.

15 The control system 21 preferably comprises a hard wired user interface 21a for enabling switching on and switching off of the high voltage supply 21b. Preferably, the high voltage supply 21b comprises a high voltage generator 21c with improved ramp-up and ramp-down characteristics. The high voltage supply is preferably operable for delivering power of about 200 W 20 in use. Preferably, the ramp-up time is of the order of 100 ms. The hard wired interface 21a, may also be arranged to automatically switch on the cooling system 21d when the high voltage generator is switched on. In addition, the control system 21 may comprise a primary controller 21e arranged for controlling the dose delivery from the X-ray applicator in use. Such primary 25 controller 21e may be provided with a primary counter adapted to register time lapsed after the X-ray radiation is initiated. The primary counter may then automatically switch off the high voltage supply to the X-ray tube in the event a pre-determined dose is reached. It will be appreciated that the pre-determined dose is at least dependent on the energy of generated X-rays and 30 the dose rate, wherein such dependence may be calibrated in advance.

Provided corresponding calibrated data is made available to the primary controller adequate primary dose delivery control may be achieved. Preferably, a secondary controller 21f is provided for enabling an independent loop of dose delivery control. The secondary controller may be connected to a dose meter

5 accommodated inside the X-ray applicator in the X-ray field before the collimator. Accordingly, the dose meter may provide real-time data on actual dose delivery taking into account dose variation during ramp up and ramp down of the high voltage source. Still preferably, the control system may further comprise a safety controller 21g adapted to compare readings from the

10 primary controller 21e and the secondary controller 21g for triggering switching off of the high voltage generator 21c wherein a desired dose is delivered. In addition or alternatively, the safety controller 21g may be wired to guard emergency stop, door interlock and a generator interlock.

The X-ray applicator 22 may preferably comprise the following

15 features: an X-ray tube 22a, conceived to be housed in an outer housing (shielding) 22k. In accordance with the invention the X-ray tube is provided having a target-collimator distance of about 4 – 10 cm, preferably about 5 to 6 cm. The X-ray applicator may further comprise a beam hardening filter 22b selected to intercept low-energy radiation and a beam flattening filter 22c,

20 designed to intercept portions of X-ray radiation for generating a substantially flat beam profile near the exit surface of the X-ray applicator. Further, the X-ray applicator 22 may comprise one or more collimators arranged to define treatment beam geometry. Preferably a set of collimators is used, for example, having diameters of 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5 cm. It will be appreciated that

25 although circular collimators are discussed, collimators of any shape, such as square, elliptic or custom made collimators are possible. It is found to be advantageous to provide the X-ray applicator 22 with automatic collimator detection means 22f adapted to automatically signal which collimator is being used. Preferably, resistive sensing is used, wherein each collimator is provided

30 with at least a couple of projections for bridging a resistive path provided in a

collimator receptacle. The resulting electrical resistance of the receptacle constitutes a signal representative of a collimator being used. The X-ray applicator 22 still further preferably comprises a built-in temperature sensor adapted to signal temperature of the X-ray tube and/or its shielding. The 5 signal from the temperature sensor is received by the control system which carried out analysis thereof. Should the measured temperature be elevated beyond an allowable level, an alarm signal may be generated. Optionally, a shut-off signal to the high voltage generator may be provided. The X-ray applicator 22 further comprises a radiation sensor 22h arranged inside the 10 outer housing 22k for detecting X-ray radiation which is actually being delivered by the X-ray tube. Preferably, for safety reasons the X-ray applicator 22 further comprises a non-volatile data storage 22i arranged for recording operational parameters at least of the X-ray tube. Further, to enhance radiation safety, the X-ray applicator 22 may be provided with a 15 radiation indicator 22j arranged for providing a visual and/or an audio output to the user and/or the patient regarding ON/OFF condition of the X-ray tube. It will be appreciated that the radiation indicator 22j may comprise a plurality of distributed signaling means. Preferably, at least one signaling means, for example a light emitting diode (LED) is associated with the X-ray 20 applicator 22. More preferably, the signaling means is provided on the X-ray applicator 22.

Figure 3 presents in a schematic way an embodiment of a cross section of an X-ray applicator of the mobile X-ray unit according to the invention. The X-ray applicator 30 comprises an outer housing 36 25 accommodating the X-ray tube assembly 35 provided with external shielding 35a. The X-ray applicator 30 further comprises a target 45 arranged to emit a beam of X-rays having a longitudinal propagation axis 45a. In accordance to the invention the distance between the target (anode) and the collimator 41 is 30 in the range of 4 ... 10 cm, preferably about 5 to 6 cm. Such relatively short target-collimator distance is surprisingly suitable for generating an X-ray

beam having a substantially narrow penumbra (1.5 – 1.8 mm for 20/80% lines) and good beam flatness.

The X-ray applicator 30 further comprises a filter 39 for hardening the X-ray beam emanating from the target 45, a beam flattening filter 40 for flattening out a beam profile and collimator 33 insertable in a collimator receptacle 41.

In order to prevent overheating of the X-ray tube in use a cooling system 34 is provided, which may advantageously be arranged in spacing between the X-ray tube 35 and the shielding 35a in contact with the surface of the X-ray tube 35. A suitable coolant may be provided using a pipe 31. Preferably, the coolant is circulating and may be water, a pressurized gas or even a special oil.

The X-ray assembly 30 may further comprise a suitable radiation detector 38, connected to a radiation indicator 43. Preferably, data collected by the radiation detector 38 is stored in a data storage unit 44.

In order to protect an X-ray exit surface of the X-ray applicator 30 from intra-patient contamination, an applicator cap 42 may be provided to cover at least the exit surface of the X-ray applicator 30. Preferably, the applicator cap is thick enough to fully intercept secondary electrons emanating from the X-ray applicator.

Figure 4 presents in a schematic way an embodiment of the X-ray applicator of Figure 3 provided with an applicator cap. The applicator cap 42 may be manufactured from transparent glass, transparent plastic or from ceramics. It is also possible, although not preferable to manufacture the applicator cap from a metal. In the latter case the applicator cap may be sterilized, however, it is preferably to use a disposable applicator cap. In view 50 of Figure 4 it is seen that the outer dimension of the X-ray applicator 51 may be larger than the outer dimension of the exit portion covered by the applicator cap 42. Although such embodiment is preferable for minimizing

total weight of the X-ray applicator, it is possible that the exit portion has the same dimension as the body of the X-ray applicator 51.

Figure 5 presents in a schematic way an embodiment of a collimator provided with identification means. The collimator 63 is provided with a central opening 64 for defining a shape and dimension of the resulting X-ray beam emanating from the X-ray applicator 30 as is discussed with reference to Figure 3. The collimator 63 is adapted to be received in a collimator receptacle 61, which may be shaped as a suitable chamber wherein the collimator 63 is to be firmly fitted. In order to enable automatic collimator identification, the collimator is provided with two projections 65a, 65b adapted to interact with a resistive path 62 provided in the collimator receptacle 61. When the projections 65a, 65b come into contact with the path 62 a net resistance of the collimator receptacle will be changed. The change in the resistance of the collimator receptacle is used as an automatic identifier of the collimator being inserted in the collimator receptacle. It will be appreciated that for a set of collimators, each collimator has to be provided with a unique pair of projections leading to a distinguishable change in the net resistivity of the collimator receptacle. Those skilled in the art will readily appreciate that a plurality of pairs 65a, 65b having different respective positions on a surface of the collimator may be envisaged. Alternatively, it is possible to provide each collimator with electronic identification means, for example, a chip cooperating with a plug. When the plug is plugged-in the collimator receptacle (provided with a cooperating socket) the collimator identification may be communicated to the control unit of the mobile X-ray unit.

Figure 6 presents in a schematic way an alternative embodiment of a collimator provided with identification means. Different embodiments of a collimator 33, shown in Figure 3, will be discussed here in more detail. The collimator 33 may be provided with an aperture 71, which may have any shape. The identification means 72a, 72b may be used for automatically detecting whether a correct (i.e. intended) collimator is being inserted in the X-

ray applicator. For example, the identification means 72a, 72b may refer to suitable spring loaded pins arranged for interacting with a resistive body (shown in the view 33a) for causing a change in a net resistance of the resistive body. By detecting a signal representative of the absolute or relative resistance 5 of the resistive body an automatic identification of the inserted collimator may be carried out.

- In view 33a a schematic embodiment of the resistive body is depicted, wherein each dot of the series 74a, 74b, 74c, 74d, 74e, 74f is attributed to a separate resistive contact circle (only few are shown for clarity).
- 10 The net resistive change of the resistive path 33a depends upon where the pin 72a or 72b contacts a resistive circle of the resistive circuit 33a and will change according to the contact positions. The individual collimators of the type 33, may be coded by differently positioning the contact pins 72a, 72b on the outer surface 70.
- 15 In alternative embodiments 33', 33'', the contact pins 72a, 72b may be supplemented by a contact bar 76, used for locking and/or enabling an appropriate insertion of the collimator into a collimator receptacle. This feature is particularly advantageous for collimators not having rotational symmetry.
- 20 In a still further embodiment, the collimators and/or the pins may be color coded.

Figure 7 describes in a schematic way a further embodiment of the X-ray tube according to a further aspect of the invention. The X-ray tube 100, has a body 102 enclosing at one end an end window 104 through which the X-rays pass. The end window is made from a thin sheet of Beryllium metal. Covering the end window 104 to provide protection against the damage of the window and protection against the toxic effects of the metal is an applicator cap 106. Applicator cap 106 is preferably made from a plastics material. In the tube body 102 a target 108 is located at between 4 - 10 cm from an exit 25 surface 124, and preferably at 4-6cm from the exit surface. The target is made 30

from Tungsten metal to provide the desired X-ray spectrum. The tungsten tip of the target is mounted on a large anode assembly 110 which also serves to conduct away the heat created from the generation of the X-rays in the target.

5 Most of the anode assembly is made from copper. The cathode 112 is located slightly off-axis near the end window. Electrons emitted from the cathode are accelerated across the gap by the potential difference between the cathode and anode, in this case set at about 70kV, to the target which they impact and cause the generation of X-rays in a known manner. X-rays emitted from the target 108 pass through a beam hardening filter 122 before passing through a

10 collimator 130 and an exit surface 124 on an applicator cap 106. The collimator 130 may be housed in a suitable collimator receptacle 128.

The anode assembly 110 is mounted in the body 102 and electrically insulated from it. One of a number of known techniques and materials can be used to provide the desired level of insulation between the anode and the body 102.

15 As is also well known in the art, the production of X-rays generates large amounts of waste heat, with the result that it is necessary to cool the tube in order to maintain it at a safe temperature. Various cooling mechanisms are known and used in the art. In this embodiment, the X-ray tube is cooled by means of cooled water forced around the anode region.

20 Cooled water enters the back of the tube by means of conduits 116 and leaves by means of a second conduit 118. The water cooling circuit is a closed loop circuit, with the water leaving the tube assembly to be cooled by a remote cooler (not shown) before returning to the tube. Alternatively oil or another liquid could be used as the cooling medium. It is also known that a

25 pressurized gas is used as an effective coolant in some applications.

As is known in the art, X-rays are generated and emitted in all directions, but the shielding by the body of the tube 102 and other internal components will tend to reduce the amount of radiation emitted from the body of the tube to a minimum, with most of the radiation emitted from the end window. The thickness of the shielding provided by the body is designed such

that it provides at least the minimum level of shielding required for safe use by the operator.

A high voltage cable assembly 120 is connected to the anode assembly 110. The high voltage cable assembly is connected to flexible cable 5 means (not shown) which in turn is connected to a high voltage power supply.

A radiation detector 114 is placed outside the path of the X-ray beam emitted from the target 108 and passing through the end window 104. This detector can be any known form of radiation detector. In this embodiment it is a known form of suitably radiation hardened semi-conductor connected to an 10 amplifier. The radiation detector 114 detects when the tube 102 is working and emitting X-ray energy. Output from the detector is connected to a control unit, the output signals from which may be used to provide an optical indication to a user of whether the tube is operating or not. By this means an X-ray detector is provided which can be used to detect whether the tube is on or off.

15 In order to enable the tube 102 to be placed accurately over a tumour, a tumour illumination means is used. The tumour illumination means comprises a plurality of lights 126 placed around the circumference of the tube near the end window. When in use, the lights shine onto the skin of the patient. Since the lights 126 are positioned around the circumference of the 20 tube body 102, at a short distance from the end of the tube they create a circle of light with a sharp cut off of the inner part of the circle. In this way, the position of the lights on the tube body 102 creates a shadow. This shadow circle is used to indicate the region which will be subject to irradiation when the X-ray tube is turned on. It should be appreciated the area within the circle 25 will not be completely dark; the ambient light will be able to enter the shadow region.

Preferably the lights 126 are white LEDs which can be bright enough to clearly illuminate the target region but do not generate amounts of heat and have very long lives. The lack of heat generation is important because the 30 lights will be in close proximity to the skin of the patient, and so it is

important to minimise the risk of burning or other damage to the skin. Other colours of LEDs could be used. Alternatively, other light sources could be used, such as known filament lamps or even a remote light source connected to the ring by fibre optic cables.

- 5 With further calibration of the radiation detector 114, it is possible to determine and calculate the X-ray dose administered to the patient during the treatment. By this means it is possible to have a real time dosimetry measurement system, in which the precise amount of radiation dose administered can be determined. Once the dose rate is known, a treatment
- 10 plan can be modified during treatment. This is advantageous because it enables a very accurate and carefully controlled dose of X-rays to be administered.

- While specific embodiments have been described above, it will be appreciated that the invention may be practiced otherwise than as described.
- 15 The descriptions above are intended to be illustrative, not limiting. Thus, it will be apparent to one skilled in the art that modifications may be made to the invention as described in the foregoing without departing from the scope of the claims set out below.

Conclusies

1. Mobiele röntgeneenheid, omvattende een basis voor het huisvesten van een regeleenheid, een voeding en een koeler en voorts omvattende een gelede verplaatsbare arm die een röntgentoedieneenheid ondersteunt die is voorzien van een röntgenbuis, waarbij de röntgentoedieneenheid verbonden is met de basis, waarbij de röntgenbuis een trefplaat voor het genereren van een röntgenstralenbundel en een collimator voor het omvormen van de gegenereerde röntgenstralenbundel omvat, waarbij een afstand tussen de trefplaat en de collimator in het bereik ligt van 4 tot 10 cm.
- 10 2. Mobiele röntgeneenheid volgens conclusie 1, waarbij de trefplaat en de collimator zijn gehuisvest in een hoofdzaak cilindrisch gevormde röntgenbuis met een lengteas, waarbij een richting van voortplanting van de röntgenstralenbundel in hoofdzaak parallel is aan de lengteas.
- 15 3. Mobiele röntgeneenheid volgens conclusie 1 of 2, waarbij de collimator is voorzien van automatische identificatiemiddelen die zijn ingericht voor het genereren van een signaal in de regeleenheid dat representatief is voor collimatorkenmerken.
- 20 4. Mobiele röntgeneenheid volgens conclusie 3, waarbij de collimator is ingericht om te worden voorzien in een opneemeenheid met een weerstand biedende baan, waarbij de collimator is voorzien van uitsteeksels die zijn ingericht om samen te werken met de weerstand biedende baan van de opneemeenheid voor generatie van het signaal.

5. Mobiele röntgeneenheid volgens conclusie 4, waarbij de collimator uitwisselbaar is, waarbij de röntgeneenheid een set collimatoren omvat die zijn voorzien van respectievelijke identificatiemiddelen.
6. Mobiele röntgeneenheid volgens één der voorgaande conclusies, voorzien van signaleringsmiddelen die generatie van de röntgenstralenbundel indiceren.
7. Mobiele röntgeneenheid volgens conclusie 6, waarbij de signaleringsmiddelen een lichtindicator omvatten die is geplaatst op de röntgentoedieneenheid.
- 10 8. Mobiele röntgeneenheid volgens één der voorgaande conclusies, waarbij de koeler is voorzien van een pijpleiding voor het verschaffen van een koelmedium in een nabijheid van de röntgenbuis, waarbij de pijpleiding in een ruimte tussen de röntgenbuis en een afschermwand loopt.
- 15 9. Mobiele röntgeneenheid volgens één der voorgaande conclusies, waarbij een stralingsdetector is voorzien in de röntgentoedieneenheid voor detectie van de röntgenstralenbundel.
10. Mobiele röntgeneenheid volgens conclusie 9, waarbij de stralingsdetector is ingericht voor het genereren van een volgend regelsignaal bij generatie van de röntgenstralenbundel.
- 20 11. Mobiele röntgeneenheid volgens één der voorgaande conclusies, voorts omvattende een temperatuursensor voor het meten van een eigenlijke temperatuur van een buitenoppervlak van de röntgentoedieneenheid.
- 25 12. Mobiele röntgeneenheid volgens één der voorgaande conclusies, waarbij de röntgentoedieneenheid een uitgangsoppervlak omvat dat is ingericht om naar een patiënt te worden gericht, waarbij de röntgentoedieneenheid voorts een toedieneenhedenkop omvat voor het afdekken van ten minste het genoemde oppervlak.

13. Mobiele röntgeneenheid volgens conclusie 12, waarbij de toedieneenhedendop wegwerpbaar is.
14. Mobiele röntgeneenheid volgens conclusie 12 of 13, waarbij dikte van de dop in een richting van de voortplanting van de stralenbundel voldoende is voor het in hoofdzaak elimineren van elektronenvervuiling van de röntgenstralenbundel.
- 5 15. Mobiele röntgeneenheid volgens één der voorgaande conclusies, waarbij de voeding bruikbaar is in het bereik van 60 - 75 kV voor het genereren van de röntgenstralenbundel.
- 10 16. Mobiele röntgeneenheid volgens conclusie 15, waarbij de voeding bruikbaar is voor het leveren van gebruiksvormen van ongeveer 200 W.
17. Mobiele röntgenteedieneenheid volgens één der voorgaande conclusies, waarbij de röntgentoedieneenheid is verbonden met de basis door middel van een verplaatsbaar paneel, waarbij de flexibele bekabeling in
- 15 hoofdzaak in het verplaatsbare paneel loopt.
18. Mobiele röntgeneenheid volgens conclusie 17, waarbij het verplaatsbare paneel een gebruikersinterface omvat voor het regelen van de röntgeneenheid.
19. Mobiele röntgeneenheid volgens conclusie 18, waarbij de
- 20 gebruikersinterface een display omvat, bij voorkeur een touchscreen dat is ingericht om invoer van data mogelijk te maken.
20. Werkwijze voor het vervaardigen van een mobiele röntgeneenheid die een basis voor het huisvesten van een regeleenheid, een voeding en een koeler omvat en die voorts een gelede verplaatsbare arm omvat die een röntgentoedieneenheid ondersteunt die is voorzien van een röntgenbuis, waarbij de werkwijze de stappen omvat van:
 - het verbinden van de arm met de basis door middel van een flexibele kabel;

- het inrichten van de röntgenbuis met een trefplaat voor het genereren van een röntgenstralenbundel en een collimator voor het omvormen van de gegenereerde röntgenstralenbundel;
 - het instellen van een afstand tussen de trefplaat en de collimator in het bereik van 4 tot 10 cm.

21. Werkwijze voor het verschaffen van een röntgenstralenbundel voor het bestralen van een zich aan de oppervlakte bevindende laesie, waarbij een röntgeneenheid die een basis voor het huisvesten van een regeleenheid, een voeding en een koeler omvat, en een gelede

10 verplaatsbare arm die een röntgentoediening ondersteunt die is voorzien van een röntgenbuis worden verschafft, waarbij de arm met de basis is verbonden door middel van een flexibele kabel, waarbij de röntgenbuis een trefplaat omvat voor het genereren van een röntgenstralenbundel, en een collimator omvat voor het omvormen van de 15 gegenereerde röntgenstralenbundel en waarbij een afstand tussen de trefplaat en de collimator in het bereik ligt van 4 tot 10 cm.

22. Toedieneenhedendop voor een röntgeneenheid omvattende een röntgenbuis die is gehuisvest in een röntgentoedieneenhed die een uitgangsoppervlak omvat dat is ingericht om naar een patiënt te worden gericht, waarbij de toedieneenhedendop is ingericht voor het afdekken van ten minste het oppervlak.

23. Toedieneenhedendop volgens conclusie 22, waarbij de toedieneenhedendop wegwerpbaar is.

24. Toedieneenhedendop volgens conclusie 22 of 23, waarbij dikte van
25 de dop in een richting van de voortplanting van de stralenbundel
voldoende is voor het in hoofdzaak elimineren van elektronenvervuiling
van de röntgenstralenbundel.

25. Toedien een hedendop volgens één der conclusie 22 - 24, waarbij de dop is vervaardigd van een in hoofdzaak transparant materiaal.

Fig. 1b

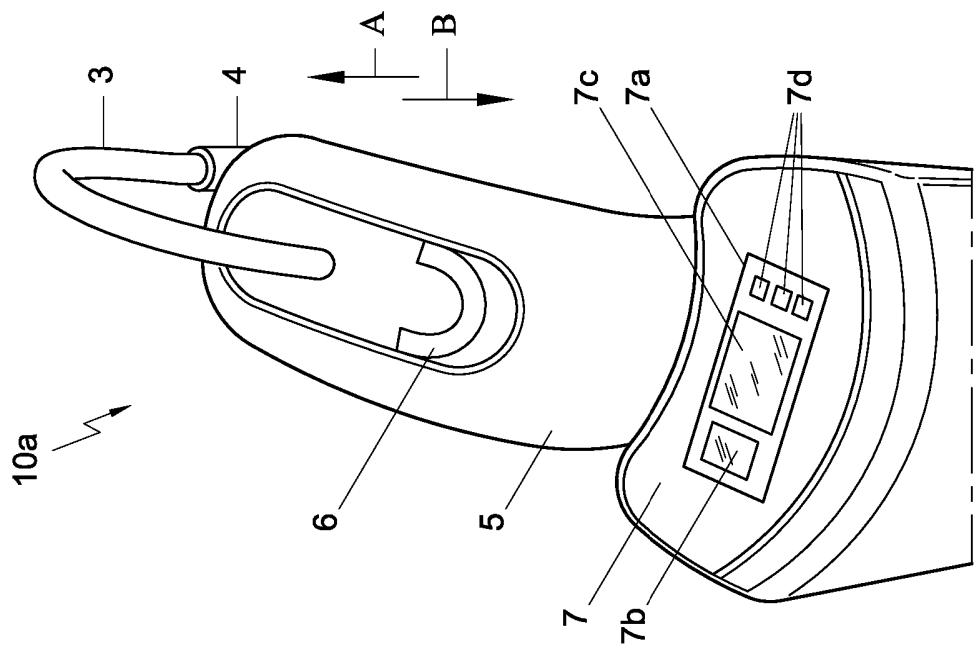
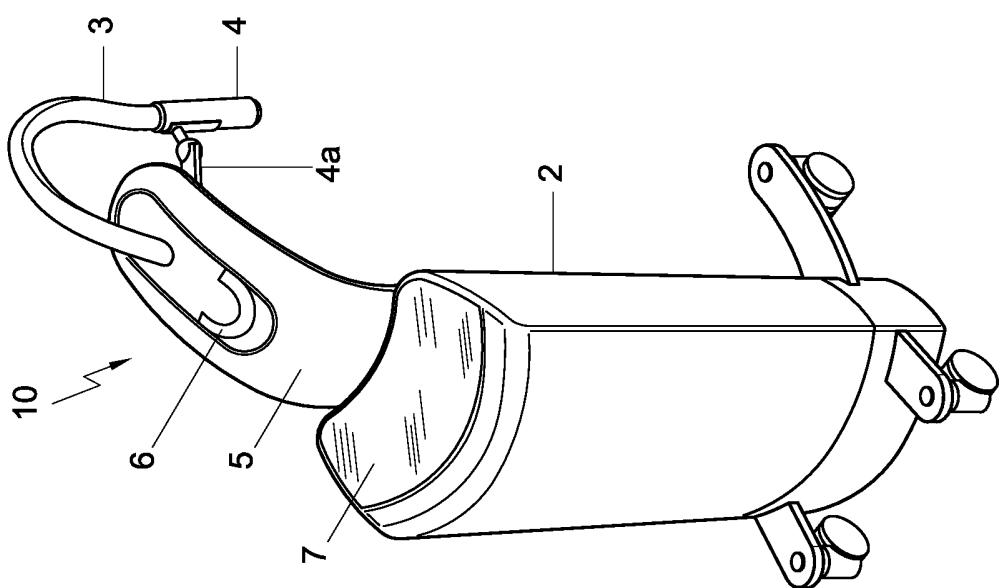


Fig. 1a



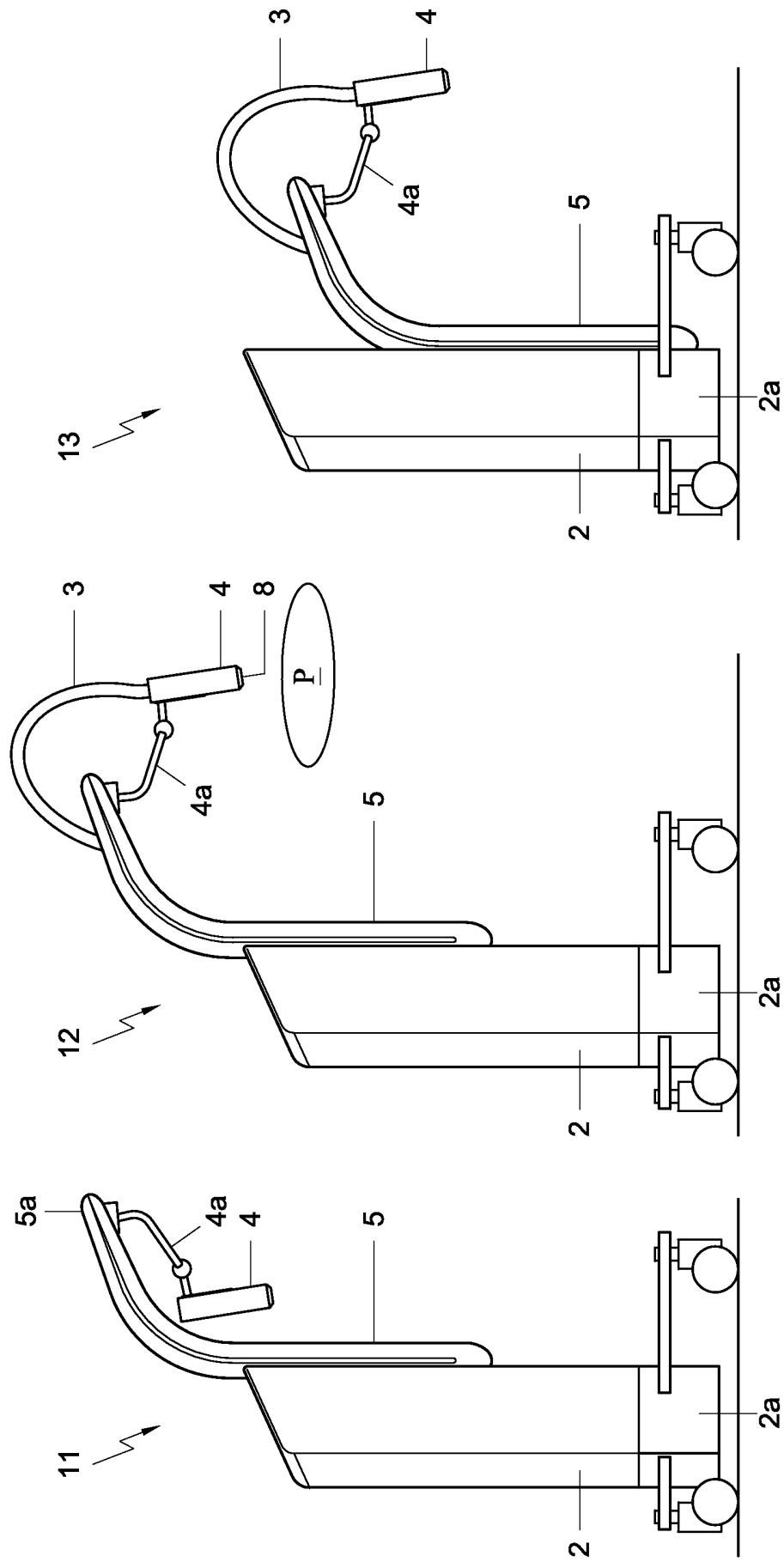


Fig. 1c

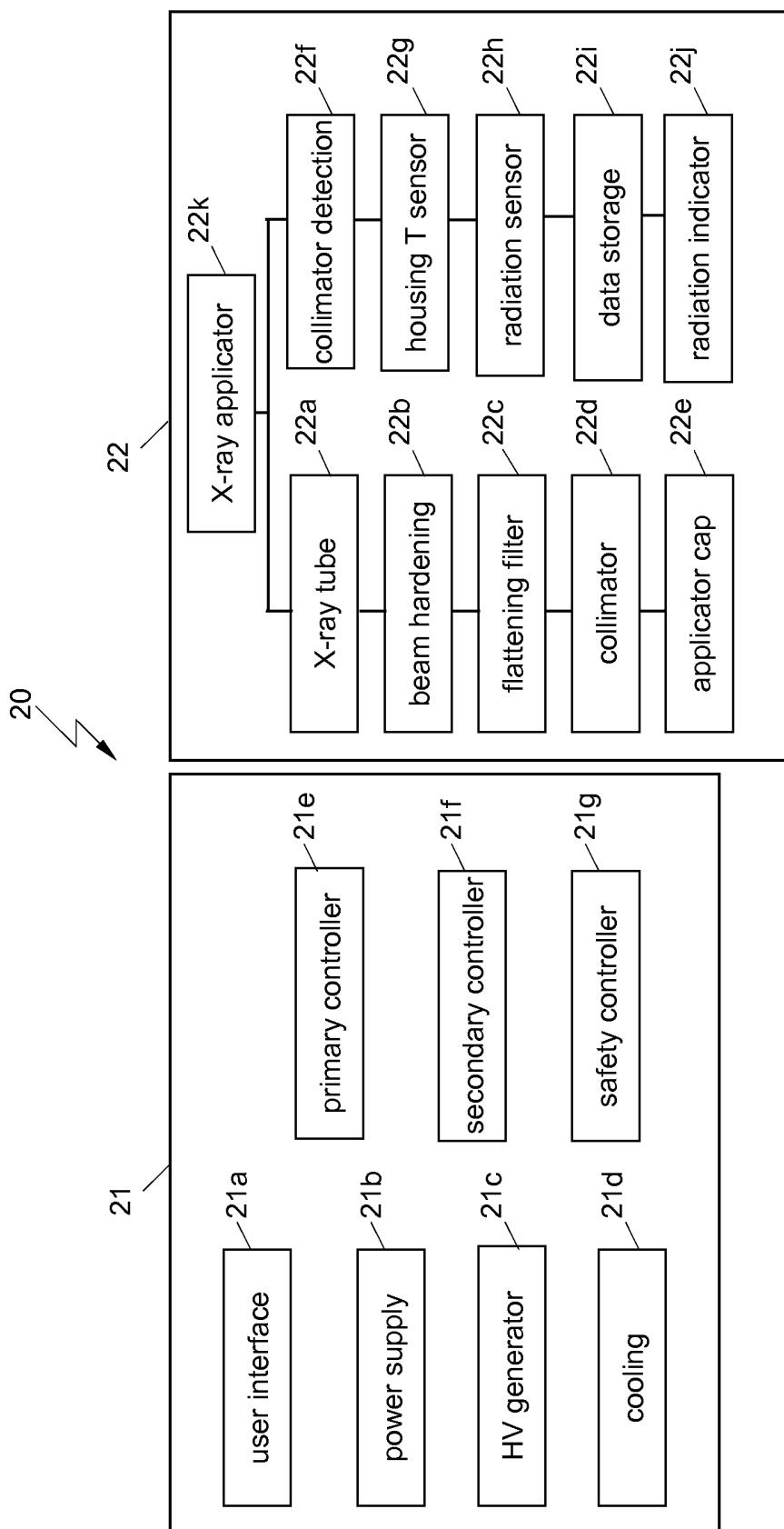


Fig. 2

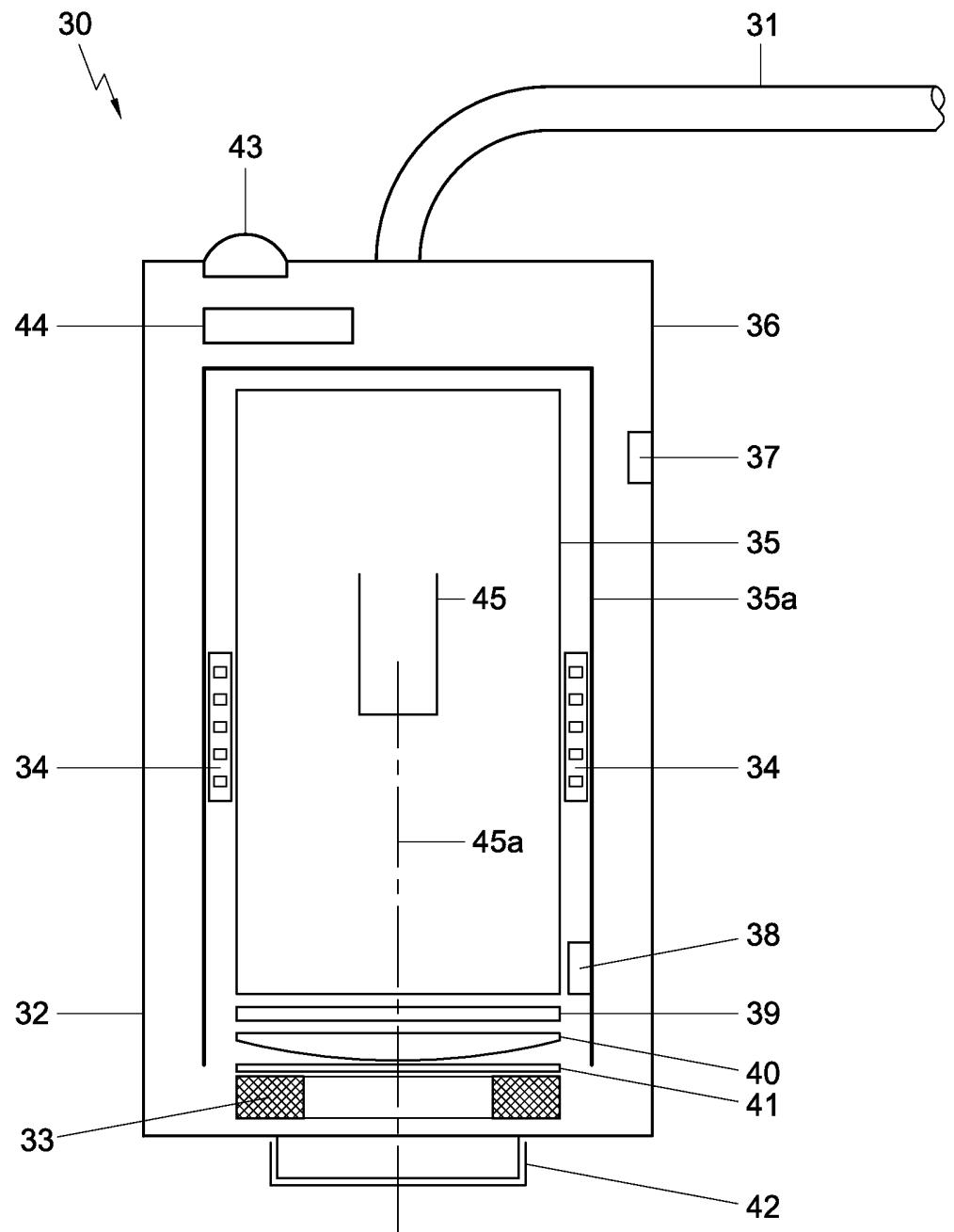


Fig. 3

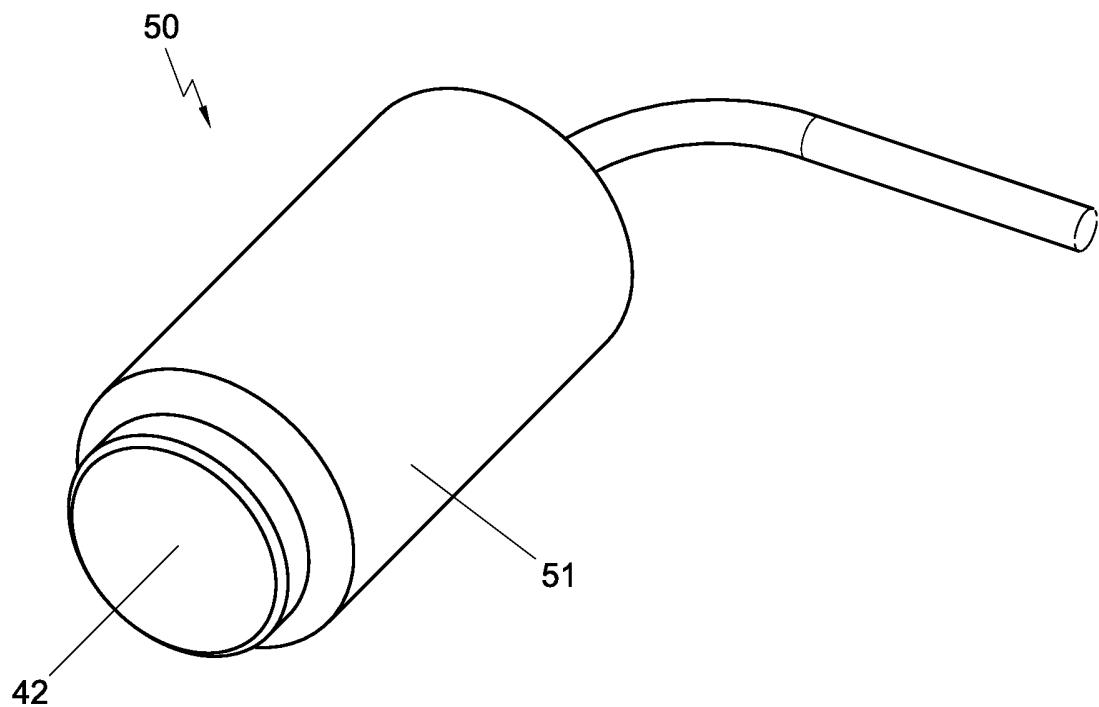


Fig. 4

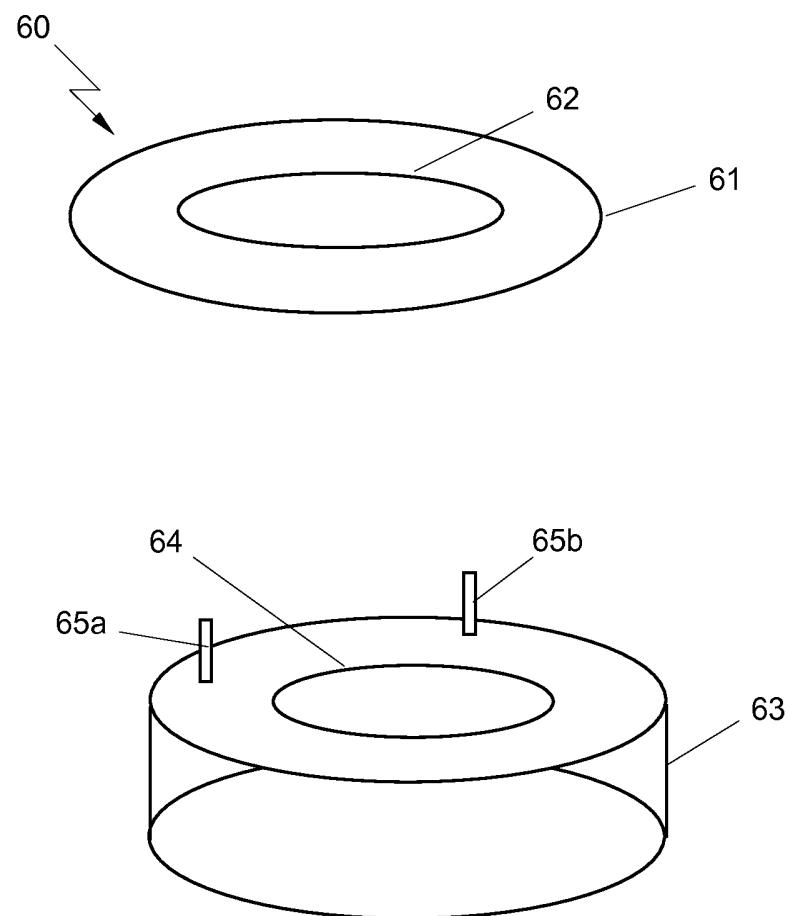


Fig. 5

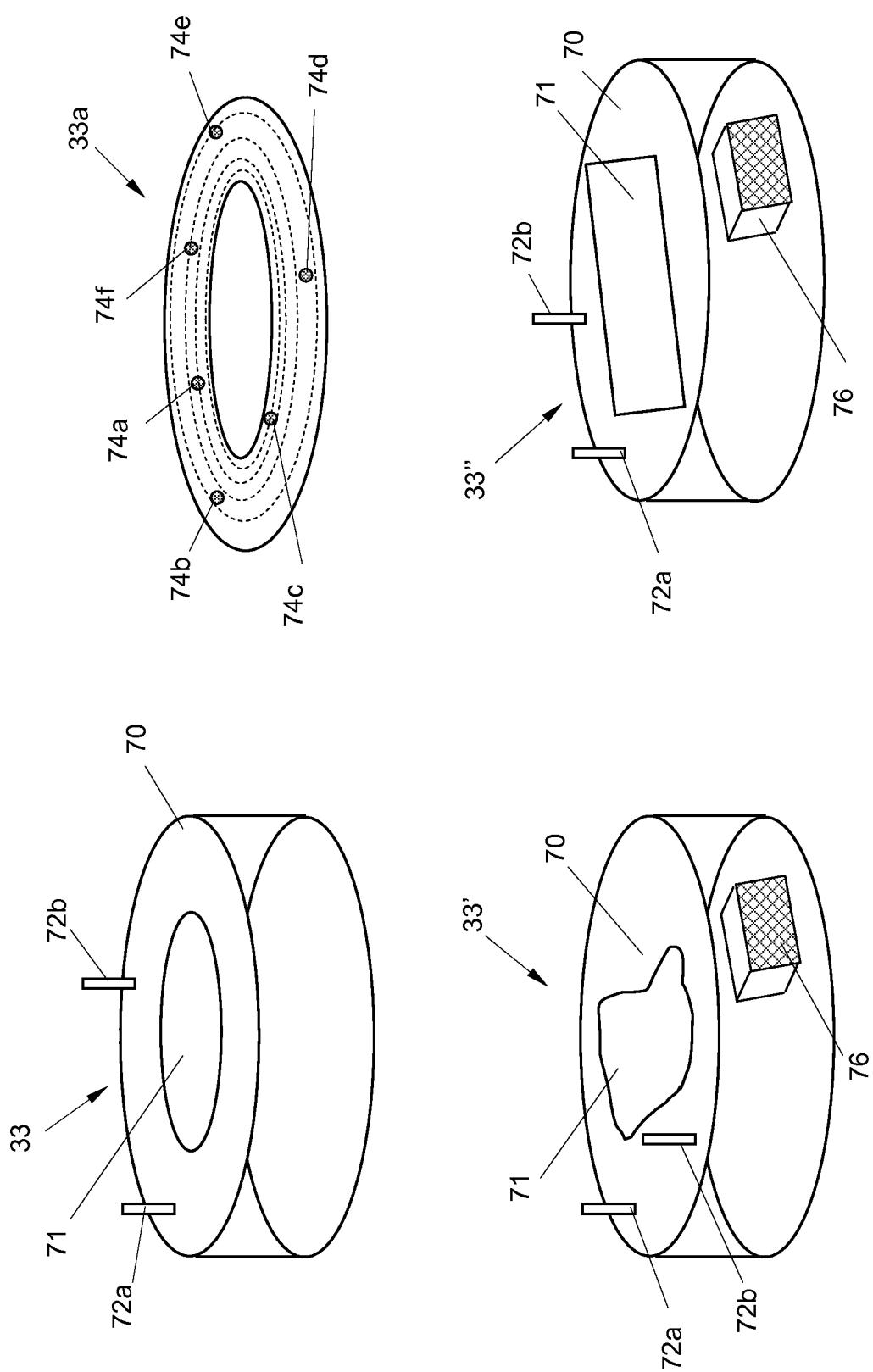


Fig. 6

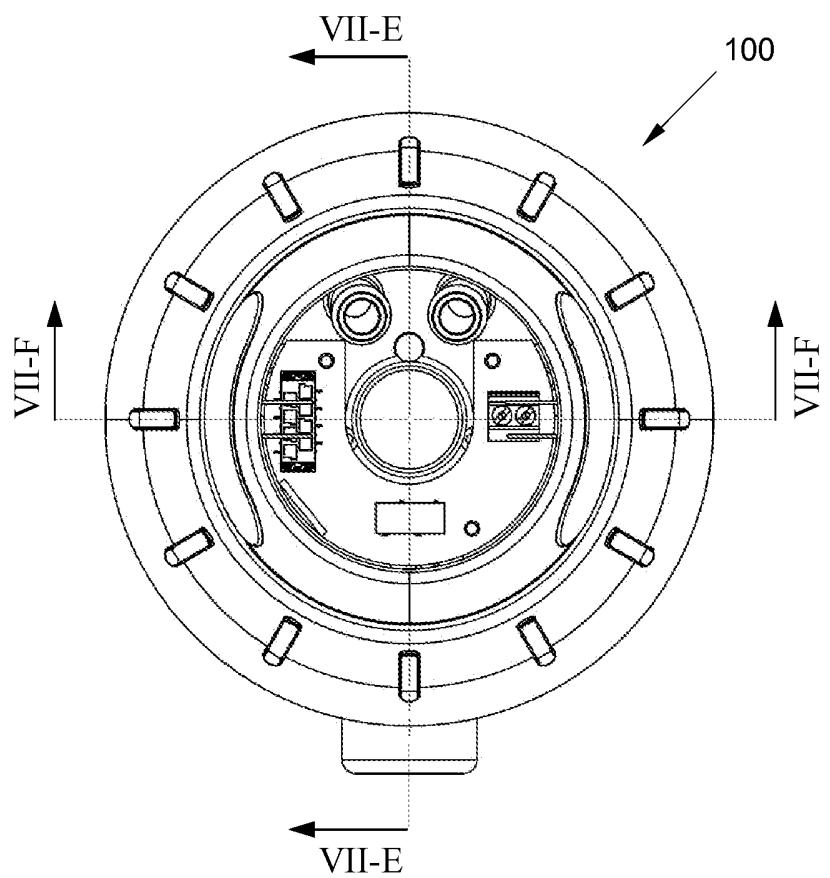


Fig. 7

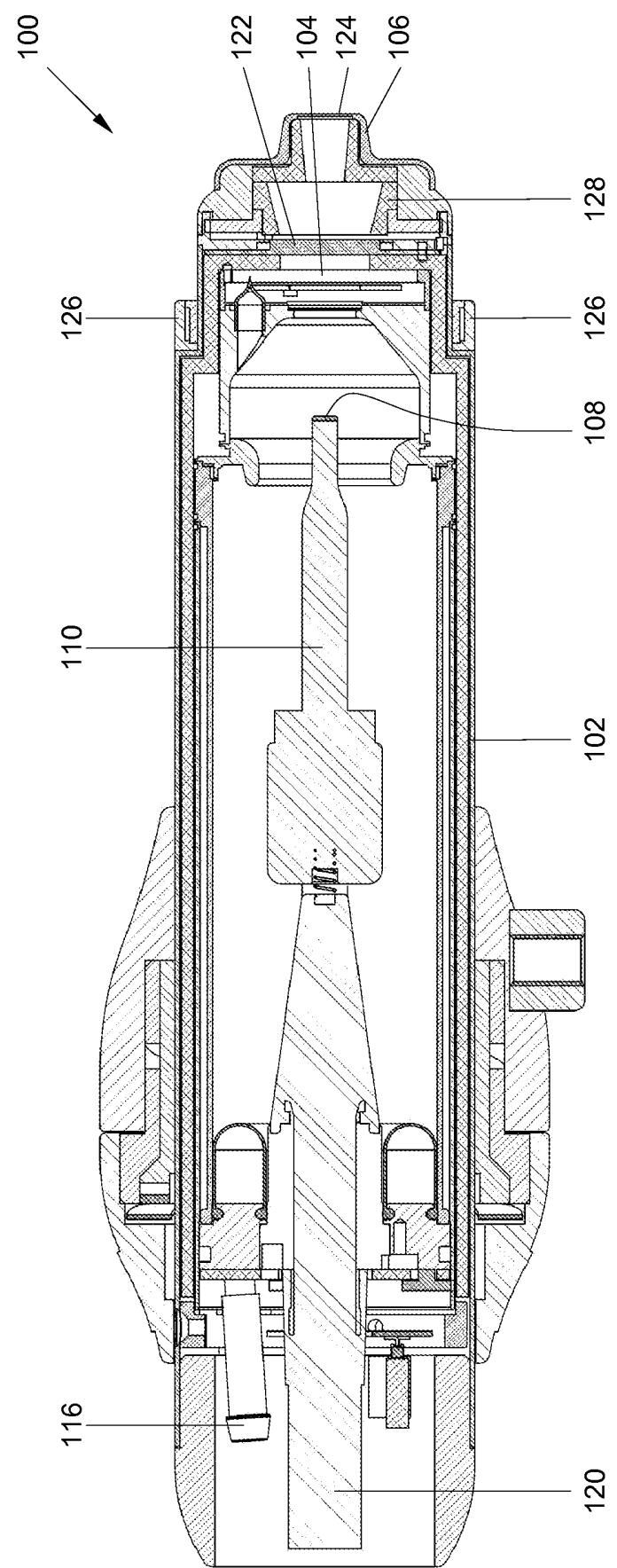


Fig. 7, E-E

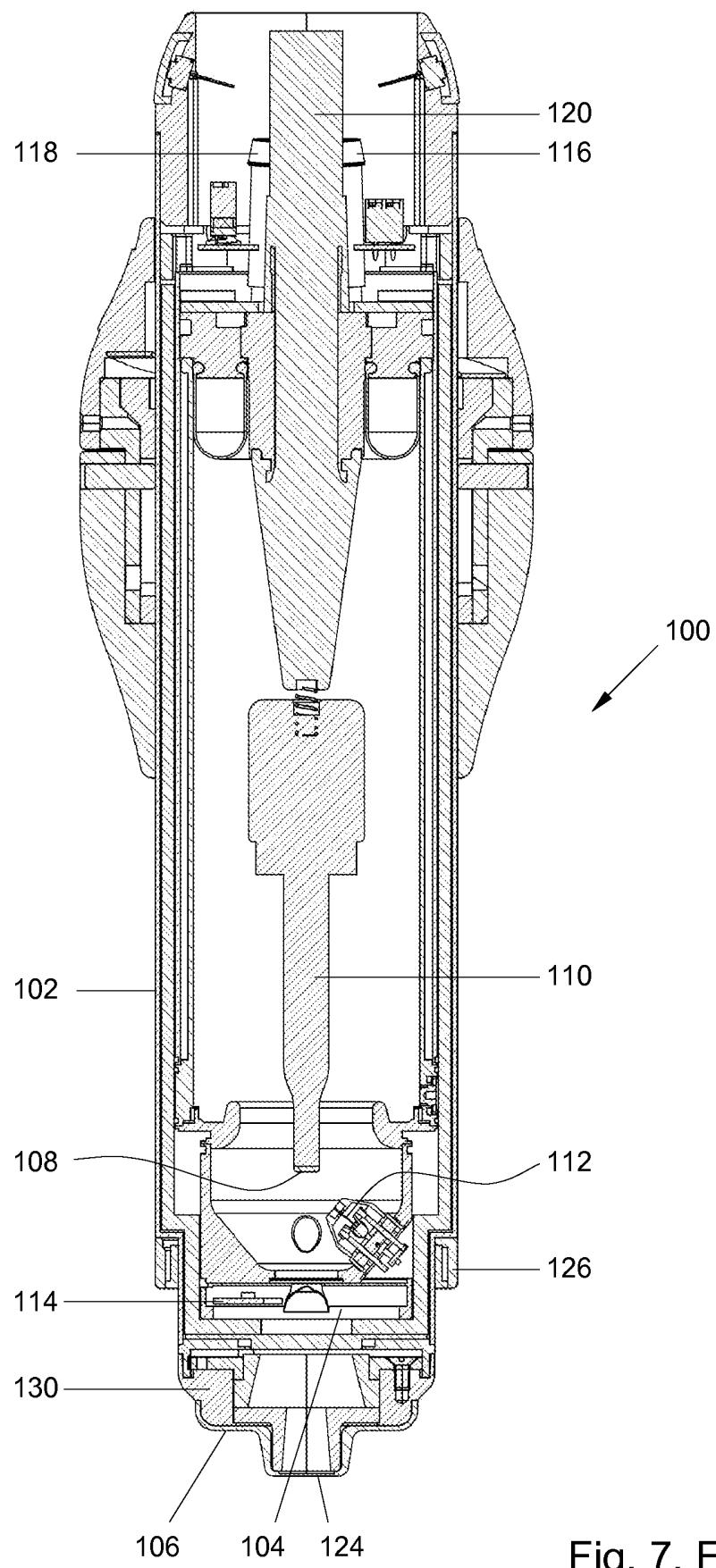


Fig. 7, F-F

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE		KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
		P91878NL00
Nederlands aanvraag nr. 2005906	Indieningsdatum 22-12-2010	
	Ingeroepen voorrangsdatum	
Aanvrager (Naam) Nucletron B.V.		
Datum van het verzoek voor een onderzoek van internationaal type 28-05-2011	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. SN 56200	
I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven) Volgens de internationale classificatie (IPC) A61N5/10		
II. ONDERZOCHE GEBIEDEN VAN DE TECHNIEK		
Onderzochte minimumdocumentatie		
Classificatiesysteem IPC8	Classificatiesymbolen A61N	
Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen		
III. <input type="checkbox"/>	GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES (opmerkingen op aanvullingsblad)	
IV. <input checked="" type="checkbox"/>	GEBREK AAN EENHEID VAN UITVINDING (opmerkingen op aanvullingsblad)	

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar
de stand van de techniek
NL 2005906

A. CLASSIFICATIE VAN HET ONDERWERP

INV. A61N5/10

ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimum documentatie (classificatie gevolgd door classificatiesymbolen)

A61N

Onderzochte andere documentatie dan de minimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)

EPO-Internal

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	EENHEID VAN UITVINDING ONTBREEKT zie aanvullingsblad B ----- US 2003/048875 A1 (MIHARA KAZUMASA [JP] ET AL) 13 maart 2003 (2003-03-13) * figuren 1,2 * * alineaas [0010], [0026], [0027], [0029] * ----- WO 2008/118198 A2 (ORAYA THERAPEUTICS INC [US]; GERTNER MICHAEL [US]) 2 oktober 2008 (2008-10-02) * alineaas [00126], [00148], [00150], [00151], [00154], [00168] – [00171]; figuren 1H,2A * * alineaas [00143], [00217], [00222], [00224], [00277] * ----- -/-	1,2,8, 11,17-21
X		1-7,9-21

Verdere documenten worden vermeld in het vervolg van vak C.

Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

* Speciale categorieën van aangehaalde documenten

T na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvraag, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

A niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

X de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

D in de octrooiaanvraag vermeld

Y de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

E eerdere octrooiaanvraag), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

L om andere redenen vermelde literatuur

O niet-schriftelijke stand van de techniek

P tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur *&* lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid

Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type

2 september 2011

Naam en adres van de instantie

De bevoegde ambtenaar

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Schwenke, Stephanie

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar de stand van de techniek NL 2005906

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie *	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	<p>Topex, Inc: "SRT 100 Superficial Radiotherapy System for the treatment of Skin Cancer", , 31 december 2007 (2007-12-31), XP000002656846, Gevonden op het Internet: URL:http://www.harpe11.ca/wp-content/uploads/2009/11/topexbrochure_v10.pdf [gevonden op 2011-08-25] * bladzijde 4, alinea 6 * -----</p>	3-5
A	<p>Topex, Inc: "Regulatory Information", , 31 december 2007 (2007-12-31), XP000002656847, Gevonden op het Internet: URL:http://www.topexmedical.com/product2.htm [gevonden op 2011-08-25] * het gehele document * -----</p>	3-5

GEBREK AAN EENHEID VAN UITVINDING
AANVULLINGSBLAD B

Ostroolaanvraag Nr.:

SN 56200
NL 2005906

De Instantie belast met het uitvoeren van het onderzoek naar de stand van de techniek heeft vastgesteld dat deze aanvraag meerdere uitvindingen bevat, te weten:

1. conclusies: 1-21

x-ray unit

2. conclusies: 22-25

applicator cap

Het vooronderzoek werd tot het eerste onderwerp beperkt.

It is considered that there are 2 inventions covered by the claims indicated as follows:

claims 1-21: x-ray unit

claims 22-25: applicator cap

The reasons for which the inventions are not so linked as to form a single general inventive concept, are as follows: independent apparatus claims 1 and 22 do not have any common technical features, nor do they solve the same problem.

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

**Nummer van het verzoek om een onderzoek naar
de stand van de techniek**

NL 2005906

Informatie over leden van dezezelfde octrooifamilie					
In het rapport genoemd octrocijgeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)			Datum van publicatie
US 2003048875	A1	13-03-2003	CA 2407809 A1		30-10-2002
			EP 1384493 A1		28-01-2004
			WO 02070067 A1		12-09-2002
			JP 2002253687 A		10-09-2002
<hr/>					
WO 2008118198	A2	02-10-2008	AU 2007349806 A1		02-10-2008
			CA 2666366 A1		02-10-2008
			EP 2077901 A2		15-07-2009
			JP 2010506689 A		04-03-2010
			KR 20090080976 A		27-07-2009
			US 2008187099 A1		07-08-2008
			US 2008187100 A1		07-08-2008
			US 2008181362 A1		31-07-2008
			US 2008187101 A1		07-08-2008
			US 2008192893 A1		14-08-2008
			US 2008187102 A1		07-08-2008
			US 2010172473 A1		08-07-2010
			US 2010195794 A1		05-08-2010
			US 2010254513 A1		07-10-2010
			US 2010260320 A1		14-10-2010
			US 2008144771 A1		19-06-2008
			US 2008187098 A1		07-08-2008
			US 2008089480 A1		17-04-2008
			US 2008089481 A1		17-04-2008
			US 2011038456 A1		17-02-2011
			US 2011170665 A1		14-07-2011



OCTROOICENTRUM NEDERLAND

WRITTEN OPINION

File No. SN56200	Filing date (day/month/year) 22.12.2010	Priority date (day/month/year)	Application No. NL2005906
International Patent Classification (IPC) INV. A61N5/10			
Applicant Nucletron B.V.			

This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the application
- Box No. VIII Certain observations on the application

	Examiner
--	----------

WRITTEN OPINION**Box No. I Basis of this opinion**

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - on paper
 - in electronic form
 - c. time of filing/furnishing:
 - contained in the application as filed.
 - filed together with the application in electronic form.
 - furnished subsequently for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of

- the entire application
- claims Nos. 22-25

because:

- the said application, or the said claims Nos. relate to the following subject matter which does not require a search (*specify*):
- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- no search report has been established for the whole application or for said claims Nos. 22-25
- a meaningful opinion could not be formed as the sequence listing was either not available, or was not furnished in the international format (WIPO ST25).
- a meaningful opinion could not be formed without the tables related to the sequence listings; or such tables were not available in electronic form.
- See Supplemental Box for further details.

Box No. IV Lack of unity of invention

1. The requirement of unity of invention is not complied with for the following reasons:

see separate sheet

2. This report has been established in respect of the following parts of the application:

- all parts.
- the parts relating to claims Nos. (see Search Report)

WRITTEN OPINION

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes: Claims	1-21
	No: Claims	
Inventive step	Yes: Claims	
	No: Claims	1-21
Industrial applicability	Yes: Claims	1-21
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV

- 1 It is considered that there are 2 inventions covered by the claims indicated as follows:

claims 1-21: x-ray unit

claims 22-25: applicator cap

The reasons for which the inventions are not so linked as to form a single general inventive concept, are as follows: independent apparatus claims 1 and 22 do not have any common technical features, nor do they solve the same problem.

Re Item V

- 2 Reference is made to the following documents:

D1 US 2003/048875 A1 (MIHARA KAZUMASA [JP] ET AL) 13 maart 2003 (2003-03-13)

D2 WO 2008/118198 A2 (ORAYA THERAPEUTICS INC [US]; GERTNER MICHAEL [US]) 2 oktober 2008 (2008-10-02)

- 3 The present application does not meet the criteria of patentability, because the subject-matter of claims 1-21 does not involve an inventive step.

- 3.1 Regarding independent apparatus claim 1: Document D1 describes:

A mobile X-ray unit comprising a base (see: carrier 3, par.[0026], Fig.1 and control unit S, Fig.1) for accommodating a control unit (see: control unit S, par. [0029], Fig.1), a power supply (see: main power supply, par.[0026]) and a cooler (implicit: water-cooling pipe, par.[0010]) and further comprising an articulated displaceable arm (see: Fig.1, movable connection portions joints, par. [0019]) supporting an X-ray applicator provided with an X-ray tube (see: x-ray generator 8, par.[0027], Fig.2, said X-ray applicator being connected to the base (Fig.1), the X-ray tube comprising a target for generating an X-ray beam (see: target 10, par.[0027], Fig.2) and a collimator for shaping the generated X-ray beam (see: collimator 14, par.[0027], Fig.2), a distance between the target and the collimator being in the range between 4 and 10 cm (implicit, see Fig.1 and 2).

Even if the control unit S, the power supply and the cooler are seen to be part of one single "base" in the broader meaning of the word. All three features being part of one single "base box" is however also known in the art, see e.g. D2, cooling: par.[00148], control module 120 [...] power supply 150, par. [00144]. D2 does also describe most of the subject-matter of claim 1, see Fig. 1H; anode [...] placed from about 5 cm to about 20 cm from the retina [...] collimator is typically within about 1 cm to about 12 cm from the beam entry point on the sclera, par.[00277]; par.[00126]. The only difference being that the X-ray tube is located in the base unit and lead through the arm, instead being generated by an X-ray tube that is supported by the arm. However, this is well known in the art (see e.g. D1, Fig.1) and considered to be merely a design option.

- 3.2 Regarding independent method claims 20 and 21: the same argumentation as above does also apply to the subject-matter of this claim.
- 3.3 Regarding the dependent claims: the additional subject-matter of these claims is also present in at least one of the documents D1 and D2:
 - claim 2, direction: D1, Fig.2; D2, Fig.2A
 - claims 3-5, collimator set: collimators, D2, par.[00150], [00151]
 - claims 6, 7: indicator: laser pointer, D2, par.[00154], [00224]
 - claim 8, cooling pipe: water-cooling pipe, D1, par.[0010]
 - claims 9-10, dosimetry: pointer can serve as a visual verification that the x-ray source is powered on, D2, par.[00155]
 - claims 12-14, cap: D2, par.[00169]-[00171]
 - claims 15, 16, power: 80kVp [...] 60kVp, D2, par.[00216]; 800 W, D2, par. [00217]
 - claims 17-19, interface: inputted, D1, par.[0029]; D2, par.[00143]
 - claim 11: As both devices of D1 and D2 include cooling, temperature measurements would be - if not implicit - a normal option to the man skilled in the art.