

Industrially Applicable Inventions (Draft)
(Provisional Translation)

Examination Guidelines for Patent and Utility Model

Part II: REQUIREMENTS FOR PATENTABILITY

Chapter 1 Industrially Applicable Inventions

(omitted)

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2.1 List of Industrially Inapplicable Inventions

(1)Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body

Methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body have been termed "medical activity" and are normally practiced by physicians (or those who are directed by physicians).

Any devices used in such methods or products such as pharmaceutical substances are not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body." On the other hand, an operating method on the human body by means of such a device (e.g. scalpel) or a method for treatment of the human body with a pharmaceutical substance is considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

A method for controlling the operation of medical device is not considered as "the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body" as long as the method represents in a manner of processes functions provided to the medical device per se. The method for controlling the operation of the medical device here may includes not only a method for controlling the internal operation of the medical device but also a functional and/or systematic operation provided to the medical device per se such as moving, opening and/or closing operations of incising means in accordance with an operating signal, or emitting and/or receiving of a radioactive ray, an electromagnetic wave, a sound wave, or the like. A method including an action of an operator (for example, the action by a physician for operating the device in accordance with a symptom) and/or an influence on the human body by the device (for example, incision and/or excision of a specific part of a patient by the device) is not considered as the said method for controlling the operation of the medical device.

Methods for treating samples that have been extracted from the human body (e.g. blood, urine, skins, hairs, cells or tissues), or methods of gathering data by analyzing the samples, are not considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body." However, if methods for treating these samples are performed on the presumption that the samples are supposed to be returned to the same body (e.g. a method of dialyzing blood), then, such methods are considered as "methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body."

A method for manufacturing a medicinal product (for example, blood preparation, vaccine, genetically modified preparation) or a medical material (for example, an artificial substitute or alternative for each part of human body, such as an artificial bone, a cultured skin sheet, or the like) by use of a collection from the human being as a raw material does not come under "the method for performing operation on, medically treating, or diagnosing the human being", even if the method is a method for processing the collection from the human being based on a

presupposition that the collection from the human being is returned to the same human being for his medical treatment.

Methods of contraception or deliveries to the human body shall be considered as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

On the contrary, even if methods of treatment by surgery or therapy and diagnostic methods is practiced on animal bodies in general, unless it is clear that the human body is explicitly excluded for the methods of treatment to be practiced on, the methods of treatment are deemed as “methods for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

1) Methods for treatment of the human body by surgery practiced on the human body

Methods for surgical operations and gathering blood are included in “methods for treatment of the human body by surgery practiced on the human body.” Cosmetic methods having surgical operations whose purpose is not therapeutic or diagnostic are considered as “methods for treatment of the human body by surgery practiced on the human body.” Furthermore, preparatory treatment for surgery, such as anesthetic treatment, is also considered as methods for surgical operations because it is inevitably associated with methods for surgical operations.

2) Methods for treatment of the human body by therapy practiced on the human body

Those include the following:

- (i) methods of giving or injecting medicine, or giving physical treatment to a patient for curing or restraining a disease;
- (ii) methods of implanting substitute organs such as artificial internal organs or artificial limbs;
- (iii) methods of preventing a disease (e.g. methods of preventing tooth decay, or influenza).

Methods of treatment for maintenance of physical health (e.g. methods for massage, or *shiatsu* therapy) are also considered to fall within methods of preventing a disease.

- (iv) Preparatory methods of treatment by therapy (e.g. methods for skin disinfection before injections), supplemental methods for improving treatment results (e.g. rehabilitation methods), or methods for nursing associated with the treatment (e.g. methods to prevent bedsores).

3) Methods for treatment of the human body by diagnostic methods practiced on the human body

“Diagnostic methods practiced on the human body” contains methods of gathering various kinds of data by measuring structures or functions of each organ in the human body for medical purposes such as for detecting diseases or recognizing or judging the physical condition of the human body, and methods

of judging the condition of human diseases.

The following are applicable to the diagnostic methods for humans.

(i) Methods of measuring the shape or size of internal organs or the conditions of the interior or exterior of the human body for the medical purposes of detecting diseases or recognizing or judging the physical condition of the human body.

Example 1: A method for measuring the condition of internal organs of the human body by X-ray.

Example 2: A method for measuring the degree of skin inflammation.

(ii) Preparatory methods for diagnosis

Example: A method for arranging electrodes for taking an electro-cardiogram.

However, methods per se for measuring structures or functions of the human body whose purposes are other than medical ones such as detecting diseases or recognizing or determining the physical condition of the human body are not deemed as “methods for treatment of the human body by diagnostic methods.”

Example 1: A method for measuring human skin for cosmetic treatment (except for those by surgery)

Example 2: A method for measuring physical dimensions for tailoring clothes

Example 3: A method for measuring a finger for making a ring

(Note)

A method regarded as the method for controlling the operation of the medical device is not included in “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”.

4. Examples

(Examples 1 through 9 are omitted.)

Example 10 (A method regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Giving Electric Stimulus by Pacemaker

[Claim]

A method for giving electric stimulus by a pacemaker, comprising steps of: comparing the heart rate detected at a detecting unit with the threshold value stored in a memory by control means of the pacemaker, reading out the average heart rate at a steady state from the memory when the heart rate is lower than the threshold value, calculating the difference between the average heart rate and the detected heart rate, and setting a pulse generating interval value in accordance with the difference, wherein: respective said steps are performed, and a stimulus is given by the pulse generating unit to the ventricle of the heart with the pulse generating interval having been set and the heart rate is kept steady.

[Excerpt from the detailed description of the invention]

Since the pacemaker constantly analyzes an electric signal from the myocardium to give a stimulus to the ventricle of the heart with the signal of a pattern most fitted to the state, maintenance of the optimum heart rate is made possible without performing switching operation of the output signal.

[Explanation]

Since the matter reading “a stimulus is given to the ventricle of the heart and the heart rate is kept steady” includes an influence on the human body by the device, the claimed method is not regarded as the method for controlling the operation of the medical device.

Moreover, since means for reducing and suppressing the disease is applied to the human body, the method above comes under the method for treatment of the human body by therapy practiced on the human body. Accordingly, the claimed method includes the method for treatment of the human body by therapy practiced on the human body as a part of the steps of the invention, thus it is regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

[Remark]

It should be noted that, if the claim is amended as described in the Examples 11-13 on the basis of the description, it is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

Example 11 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Controlling Pacemaker

[Claim]

A method for controlling a pacemaker, comprising steps of:

comparing the heart rate detected at a detecting unit with the threshold value stored in a memory by control means of the pacemaker, reading out the average heart rate at a steady state from the memory when the heart rate is lower than the threshold value, calculating the difference between the average heart rate and the detected heart rate, and setting a pulse generating interval value in accordance with the difference, wherein: respective said steps are performed.

[Excerpt from the detailed description of the invention]

Since the pacemaker constantly analyzes an electric signal from the myocardium to set a generating interval of the pulse most fitted to the state, maintenance of an optimum heart rate is made possible.

[Explanation]

The method in this example relates to a method for controlling the internal operation of a pacemaker which represents in a manner of processes functions provided to the medical device per se.

And each step does not include an action of an operator or an influence on a human body by the devices.

Therefore, the method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it is the method for controlling the operation of the medical device.

Example 12 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Controlling Pacemaker

[Claim]

A method for controlling a pacemaker, comprising steps of: comparing the heart rate detected at a detecting unit with the threshold value stored in a memory by control means of the pacemaker, reading out the average heart rate at a steady state from the memory when the heart rate is lower than the threshold value, calculating the difference between the average heart rate and the detected heart rate, setting a pulse generating interval value in accordance with the difference, and generating a pulse for giving a stimulus to the ventricle of the heart with the pulse generating interval set by the pulse generating means, wherein: said respective steps are performed.

[Excerpt from the detailed description of the invention]

Since the pacemaker constantly analyzes electric signals from the myocardium to set the generating interval of the pulse most fitted to the state, maintenance of an optimum heart rate is made possible.

[Explanation]

The method in this example relates to a method representing in a manner of processes functions provided to the medical device per se and, in addition to the method for controlling the internal operation of the pacemaker as Example 11, includes a step of generating a pulse toward the outside of the pacemaker.

The step of “generating a pulse for giving a stimulus to the ventricle of the heart with the pulse generating interval set by the pulse generating means” means that “the pulse generating means” provided to the pacemaker per se generates a pulse, and stimulation of the ventricle of the heart by the generated pulse is beyond the inclusion, thus it is regarded that the method does not include the influence on the human body by the device.

It should be noted that a pulse “for giving stimulus to the ventricle of the heart” does not include the influence on the human body, since it specifies a technical meaning of the pulse and differs from the step of “a stimulus is given by the pulse generating unit to the ventricle of the heart with the pulse generating interval having been set and the heart rate is kept steady” described in the Example 10.

Therefore, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.

(Remark)

A pace maker is generally designed to be placed and operated in a human body by

nature. However, when a method representing in a manner of processes functions provided with the pacemaker is described in a claim, it is regarded as the method for controlling the operation of the pacemaker as long as it does not include an action of an operator and/or an influence on the human body by the device.

Example 13 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for controlling the operation of Pacemaker

[Claim]

A method for controlling the operation of a pacemaker, wherein: means for comparing the heart rate detected in a detecting unit with the threshold value stored in a memory is operated, means for reading out the average heart rate at a steady state from the memory is operated when the heart rate is lower than the threshold value, means for calculating the difference between the average heart rate and the detected heart rate is operated, means for setting the pulse generating interval value in accordance with the difference is operated, and pulse generating means for generating the pulse for giving a stimulus to the ventricle of the heart with a set pulse generating interval is operated.

[Excerpt from the detailed description of the invention]

Since the pacemaker constantly analyzes electric signals from the myocardium to set the pulse-generating interval as it most fits to the state, maintenance of the optimum heart rate is made possible.

[Explanation]

The method in this example represents in a manner of processes functions provided to the pacemaker per se

“A pulse generating means for generating the pulse for giving a stimulus to the ventricle of the heart is operated” means that “the pulse generating means” provided to the medical device per se is operated, but it does not mean so farther that the generated pulse gives the stimulus to the ventricle of the heart as the result of “the pulse generating means is generated” and is judged that the influence on the human body by the device is not included.

Therefore, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.

Example 14 (A method regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Giving Stimulus to Retina by Artificial Eye System

[Claim]

A method for giving stimulus to the retina by an artificial eye system comprising: an extracorporeal devices composed of a visor device provided with an image receiving element and a light emitting element and an extracorporeal image processing device, and an intraocular devices having a light receiving element, a signal processing circuit and an electrode, and performing steps of: making a picture signal by processing an outside picture image obtained from the image receiving element of the visor device, converting the picture signal into an optical signal for dispatching to the light receiving element of the intraocular devices from the light emitting element of the visor device, receiving the optical signal by the light receiving element of the intraocular devices installed inside the oculus, converting the received signal into a signal for use in electrical stimulation by the signal processing circuit of the intraocular devices, and dispatching the signal for use in the electrical stimulation to an electrode buried in the retina to transfer to the retina, wherein: stimulus of the picture information is given to the retina of a patient by the artificial eye system.

[Excerpt from the detailed description of the invention]

The artificial eye system according to the present invention can transfer the signal of the artificial picture information to the retina of the patient, by combining the image receiving element, the light emitting element, the light receiving element, and the signal processing circuit.

[Explanation]

Since “the step of dispatching the signal for use in electrical stimulation to an electrode buries in the retina to transfer to the retina” includes such influence on the human body by the device as transferring the signal for use in electrical stimulation to the retina.

In addition, the step of “stimulus of the picture information is given to the retina of a patient” includes such influence on the human body by the device as giving stimulus to the retina of a patient.

The claimed method, therefore, is not regarded as the method for controlling the operation of the medical device

Since reducing and suppressing means for the disease is applied to the human body, the method is regarded as the method for treatment of the human body by therapy. Accordingly, since the method includes the steps for medically treating the human being as a part of the steps of the invention, it is regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”

[Remark]

It should be noted that, if the claim is amended as described in the Example 15 on

the basis of the description, it is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

Example 15 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Controlling Artificial Eye System

[Claim]

A method for controlling an artificial eye system comprising: an extracorporeal devices composed of a visor device provided with an image receiving element and a light emitting element and an extracorporeal image processing device, and an devices for intraocular use having a light receiving element, a signal processing circuit and an electrode, and performing respective steps of: making a picture signal by processing an outside picture image by the image receiving element of the visor device, converting the picture signal into an optical signal for dispatching to the light receiving element of the devices for intraocular use from the light emitting element of the visor device, receiving the optical signal by the light receiving element of the devices for intraocular use, converting the received signal into a signal for use in the electrical stimulation for transferring to the retina by the signal processing circuit of the devices for intraocular use, and dispatching the signal for use in the electrical stimulation to the electrode buried in the retina.

[Excerpt from the detailed description of the invention]

The artificial eye system according to the present invention can transfer the signal of the artificial picture information to the retina of the patient suffering from a visual impairment, by combining the image receiving element, the light emitting element, the light receiving element, and the signal processing circuit.

[Explanation]

The method in this example represents in a manner of processes functions provided to the Artificial Eye System per se.

Since the matter reading “dispatching the signal for use in the electrical stimulation to the electrode buried in the retina” does not mean so farther as transferring the signal for use in the electrical stimulation to the retina, judgment is made that the influence on the human body by the device is not included. Accordingly, the claimed method comes under the method for controlling the operation of the medical device, and does not come under “the method for performing operation on, medically treating, or diagnosing the human being.”

It should be noted that the matter referring to “the electrode buried in the retina” specifies a technical meaning of the electrode in the Artificial Eye System and distinguished from burying the electrode in the retina, and judged that the influence on the human body by the device is not included therein.

Therefore, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.

Example 16 (A method regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Treating Affected Part by Micro Operation Robot

[Claim]

A method for treating an affected part by a capsule type micro operation robot having receiving means and treating means and extracorporeal device, comprising steps of: operating a manipulator of the extracorporeal device while viewing a monitor, receiving a signal from the pertinent manipulator by the receiving means, and incising the affected part of a patient by incising means based on the signal from the manipulator.

[Excerpt from the detailed description of the invention]

The capsule type micro operation robot according to the present invention can, owing to very delicate constitution thereof, perform treatment such as incision, excision, or the like of the infected part by remote control, without burdening an excessive load on the patient, in an organ such as a blood vessel or the like.

[Explanation]

In “the step of operating a manipulator of the extracorporeal device while viewing a monitor,” included is an action of the operator. Furthermore, “the step of incising the affected part of a patient by incising means” includes an influence on the human body by the device.

Accordingly, the claimed method is not regarded as the method for controlling the operation of the medical device.

And, “the step of incising the affected part of a patient by incising means” is nothing but the method for treatment of the human body by surgery. Accordingly, the claimed method includes the method for treatment of the human body by surgery as a part of the steps of the invention, thus the method is regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”

[Remark]

It should be noted that, if the claim is amended as described in the Example 17 on the basis of the description, it is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

Example 17 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for controlling the operation of Micro Operation Robot System

[Claim]

A method for controlling the operation of a micro operation robot system provided with a capsule type micro operation robot having receiving means and treating means and extracorporeal device, wherein the receiving means for receiving a signal from a manipulator of the extracorporeal device is operated and the treating means is operated based on the signal received, and the incising means is operated based on the signal received.

[Excerpt from the detailed description of the invention]

The micro operation robot according to the present invention can, owing to very delicate constitution thereof, perform treatment of the infected part by remote control, without burdening an excessive load on the patient, in an organ such as a blood vessel or the like.

[Explanation]

The method in this example represents in a manner of processes functions provided to the medical device per se.

The matter reading “the incising means is operated based on the signal received” means that “the incising means” provided to Micro Operation Robot System, and is distinguished from incising the human body with “the incising means”, thus it is judged that the influence on the human body by the device is not included.

Therefore, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.

[Remark]

(1) A Micro Operation Robot System is generally designed to be operated based on the manipulator signal operated by a physician by nature. However, when a method representing in a manner of processes functions provided to the Micro Operation Robot System is described in a claim, it is regarded as the method for controlling the internal operation of the pacemaker as long as it does not include an action of an operator and/or an influence on the human body by the device.

(2) Even if a method seems to be claimed in a manner of processes by describing functions provided to the medical device per se, it should be noted that the claim may not meet the requirement of description or embodiment if the device per se is not disclosed in the description as in the case where only a method carried out by a physician is disclosed.

Example 18 (A method regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Controlling X-ray CT Scanner

[Claim]

A method for controlling respective parts of an X-ray CT scanner by control means, provided with steps of: controlling X-ray generating means by the control means for irradiating X-rays onto a human body, controlling X-ray detecting means by the control means for detecting the X-rays permeated through the human body, and performing reconstruction processing of the data detected by the control means for converting into a picture data for displaying.

[Excerpt from the detailed description of the invention]

The present invention is an invention related to the method of controlling an X-ray CT scanner for picking up an image of a human body, and a picture image thereof can be accurately displayed on account of reconstruction processing performed.

[Explanation]

“The step of irradiating X-rays onto a human body” includes an influence on the human body by the device, thus it is not regarded as the method for controlling the operation of the medical device.

Since the collection of various kinds of materials from the human body is performed for the medical object such as discovery of a disease, recognition of the health condition, or the like, the claimed method includes the method for diagnosing the human body as a part of the steps of the invention, thus it is regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”

[Remark]

It should be noted that, if the claim is amended as described in the Example 19 on the basis of the description, it is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

Example 19 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Controlling X-ray CT Scanner

[Claim]

A method for controlling respective parts of an X-ray CT scanner by control means, comprising steps of: generating X-ray by controlling X-ray generating means, detecting X-rays permeated through a human body by controlling X-ray detecting means, and performing reconstruction processing of the data detected by the control means and converting into a picture data to display.

[Excerpt from the detailed description of the invention]

The present invention is an invention related to a method of controlling an X-ray CT scanner for picking up an image of a human body, and a picture image thereof can be accurately displayed on account of reconstruction processing performed.

[Explanation]

The method in this example represents in a manner of processes functions provided to the medical device per se.

The matter reading “the step of generating X-ray by controlling X-ray generating means” means that the “X-ray generating means” provided on the medical device per se generates X-ray, and it does not include so far as the human body is irradiated by the X-rays. And judgment is made that the influence on the human body by the device is not included.

Furthermore, “the step of detecting X-rays permeated through a human body by controlling X-ray detecting means” means the function that “X-ray detecting means” provided to the X-ray CT Scanner receives a signal (X-ray) permeated through a human body. And judgment is made that it does not include the influence on the human body by the device.

Therefore, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.

Example 20 (A method regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Magnetic Resonance Imaging

[Claim]

A method for magnetic resonance imaging by a magnetic resonance imaging device comprising the steps of: placing a territory doubtful of cancer in a uniform magnetic field space, irradiating 90° pulse to the territory while applying a gradient magnetic field in the slice direction, applying a predetermined quantity of the gradient magnetic field in the phase encode direction, irradiating 180° pulse while applying the gradient magnetic field in the slice direction, and detecting a magnetic resonance signal from the pertinent territory while applying the gradient magnetic field in the lead-out direction, repeating pulse sequences carried out by detecting the magnetic resonance signals from the territory while sequentially changing the intensity of the gradient magnetic field in the phase encode direction in the order from lower to higher.

[Excerpt from the detailed description of the invention]

The magnetic resonance imaging device according to the present invention acquires magnetic resonance signals in the order of phase encode from lower to higher order when a human body is imaged by the spin-echo method.

[Explanation]

Since the matter reading “placing a territory doubtful of cancer in a uniform magnetic space” includes an action of an operator that a territory doubtful of cancer is placed to the device.

Furthermore, the matters reading “irradiating 90° pulse while applying a gradient magnetic field” and “Irradiating 180° pulse while applying the gradient magnetic field” also include the influence on the human body by the device.

This method, therefore, is not regarded as the method for controlling the operation of the medical device.

And, since various kinds of materials are collected from the human body for medical object such as discovery of a disease, recognition of the health condition, or the like, the method is regarded as a diagnostic method practiced on the human body. Accordingly, since the claimed method includes the method for diagnosing the human body as a part of the steps of the invention, this method is regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”

[Remark]

It should be noted that, if the claim is amended as described in the Example 21 on the basis of the description, it is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body.”

Example 21 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for controlling the operation of Magnetic Resonance Imaging Device

[Claim]

A method for controlling the operation of a magnetic resonance imaging device in which a method for controlling the magnetic resonance imaging device controls dispatching and receiving circuit, a high frequency coil, and a gradient magnetic field coil, wherein pulse sequence, in which: the high frequency coil dispatches 90° pulse while a gradient magnetic field is generating the gradient magnetic field in the slice direction toward a uniform magnetic field space, the gradient magnetic field coil generates a predetermined quantity of the gradient magnetic field in the phase encode direction, the high frequency coil dispatches 180° pulse while the gradient magnetic field coil is generating the gradient magnetic field in the slice direction, and the high frequency coil receives a magnetic resonance signal from a human body while the gradient magnetic field coil is generating the gradient magnetic field in the lead-out direction, repeating pulse sequences carried out by detecting the magnetic resonance signals from the territory while sequentially changing the intensity of the gradient magnetic field in the phase encode direction in the order from lower to higher.

[Excerpt from the detailed description of the invention]

The magnetic resonance imaging device of the present invention acquires magnetic resonance signals in the order of the phase encode from lower to higher when a human body is imaged by a spin-echo method.

[Explanation]

The method in this example represents in a manner of processes functions provided to the medical device per se.

The matters reading “a high frequency coil dispatches 90° pulse while generating the gradient magnetic field” and “the high frequency coil dispatches 180° pulse while the gradient magnetic field coil is generating the gradient magnetic field” do not mean the irradiation of the pulse on the human body after the generation of the pulses. And it is judged that the influence on the human body by the device is not included.

Furthermore, the matter reading “the high frequency coil receives a magnetic resonance signal from a human body” means that “the high frequency coil receives signal (magnetic resonance signal) from the human body, thus it is judged that the influence on the human body by the device is not included.

Therefore, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.

Example 22 (A method regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for Sampling Body Fluid

[Claim]

A method for sampling body fluid by a body fluid sampling device provided with a hollow piercing element installed inside housing and a sample extracting tube communicating with the piercing element, wherein the piercing element is pierced, and the body fluid is absorbed from the piercing element arranged in the vein blood vessel into the sample extracting tube.

[Excerpt from the detailed description of the invention]

The present invention relates to a method for sampling body fluid such as blood or the like from a human body for analysis or processing. The housing of the body fluid sampling device is placed on a human body and a piercing element is pierced into the surface of the skin. When the device is operated, an absorbing power is added to the piercing element to absorb the body fluid into the tube.

[Explanation]

The matter of “the piercing element is pierced” is not an action by a means provided to this Fluid Sampling Device but an action carried out by an operator operating this device.

The matter of “the body fluid is absorbed from the piercing element arranged in the vein blood vessel into the sample extracting tube” is not the method for controlling the operation of the medical device since it includes the influence on the human body by the device as the sample (body fluid) is extracted from the human body unlike the Examples 19 and 21 wherein a signal is received from a human body..

The claimed method is a method for collecting samples from the human body for the medical object such as discovery of the disease, recognition of the health condition, or the like, and thus comes under the method for diagnosing the human being. Accordingly, the claimed method includes the method for diagnosing the human body as a part of the steps of the invention, and is therefore regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”

Example 23 (A method not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body”)

[Title of the Invention]

Method for controlling the operation of Body Fluid Sampling Device

[Claim]

A method for controlling the operation of a body fluid sampling device provided with a piercing element which is hollow and installed inside a housing, a sample extracting tube communicating with the piercing element, a sampling vessel connected with the end of the tube and having a pressure detecting unit inside, and a negative pressure generating unit giving a negative pressure on the sampling vessel, wherein a suppressing means controlling the operation of the negative pressure generating means is operated when the pressure detecting means detects a pressure lower than the predetermined value in the operation of the negative pressure generating unit.

[Excerpt from the detailed description of the invention]

The present invention relates to a method for sampling body fluid such as blood or the like from a human body for analysis or processing. The housing of the body fluid sampling device is placed on a human body and a piercing element is pierced from the surface of the skin. When the device is operated, an absorbing power is applied to the piercing element to absorb the body fluid into the tube. In this invention, the pressure detecting means and the suppressing means provided to the sampling vessel are operated to avoid a danger to a human body of giving a higher absorbing pressure than expected.

[Explanation]

The method in this example represents in a manner of processes functions provided to the medical device per se.

The matter reading “a suppressing means controlling the operation of the negative pressure generating means is operated when the pressure detecting means detects a pressure lower than the predetermined value in the operation of the negative pressure generating unit” means that the “suppressing means” provided to the body fluid sampling device is operated and it does not mean that the volume of the body fluid absorbed is changed by the operation of the suppressing means, and is judged not to include the influence on the human body by the device.

Accordingly, the claimed method is not regarded as “the method for treatment of the human body by surgery or therapy and diagnostic methods practiced on the human body” since it represents in a manner of processes functions provided to the medical device per se and not includes an action of an operator and/or an influence on the human body by the device.