

Format No. 64 (1) (Under Article 115)

Manufacturing and Marketing Authorization Applications for Designated Medical Devices

| | | | | |
|-------------------------------------|-----------------------------|--|--|--------------------------------|
| Type | | Equipment and Instruments 9 Medical X-ray device and X-ray tube for medical X-ray device | | |
| Name | General name | Whole body X-ray CT scanner (Code : 37618010) | | |
| | Sales name | X-ray CT scanner J I R A - C T | | |
| Usage purpose, efficacy or effect | | Computer processing of X-ray penetration signals from various directions in connection with patients, and presentation of reconstituted images for diagnostic purposes. | | |
| Shape, structure and principle | | As Attachment 1 | | |
| Raw materials and components | | As Attachment 2 | | |
| Product specification | | As Attachment 3 | | |
| Operation method or usage outline | | As Attachment 4 | | |
| Manufacturing process | | As Attachment 5 | | |
| Storage method and effective period | | | | |
| Manufacturing site of product | Name | Address | Approval or recognition classification | Approval or recognition number |
| | Hongo Plant, JIRA Co., Ltd. | Hongo, Bunkyo-ku, Tokyo | General | □□□□□□□□ |
| Manufacturing site of raw materials | Name | Address | Approval or recognition classification | Approval or recognition number |
| | | | | |
| Remarks | | Particular maintenace controlled medical apparatus Attached technical document (draft) : Attached License number of medical apparatus manufacture : ○○○○○○○○ Approval classification : Class II medical apparatus manufacturere Address of the primary business site : ○○○, Yusima 2-shome, Bunkyo-ku, Tokyo | | |

We, hereby, file an application of license for manufacturing and marketin the particular management medical apparatus as above.

Month/date/year

Address: ○○○, 2-Come, Bunkyo-ku, Tokyo

Name: JIRA Co., Ltd.

○○○, President Seal

(Third Party Certification Body)

Name of a person in charge:
 JIRA Pharmaceutical Affair Division
 Contact to: TEL 03-3816-○○○○
 FAX 03-3818-xxxx
 Manufacturer code ○○○○○○-○○

Shape, structure and principle

1. Shape and structure

1. 1 Configuration

The configuration of this device are as follows:

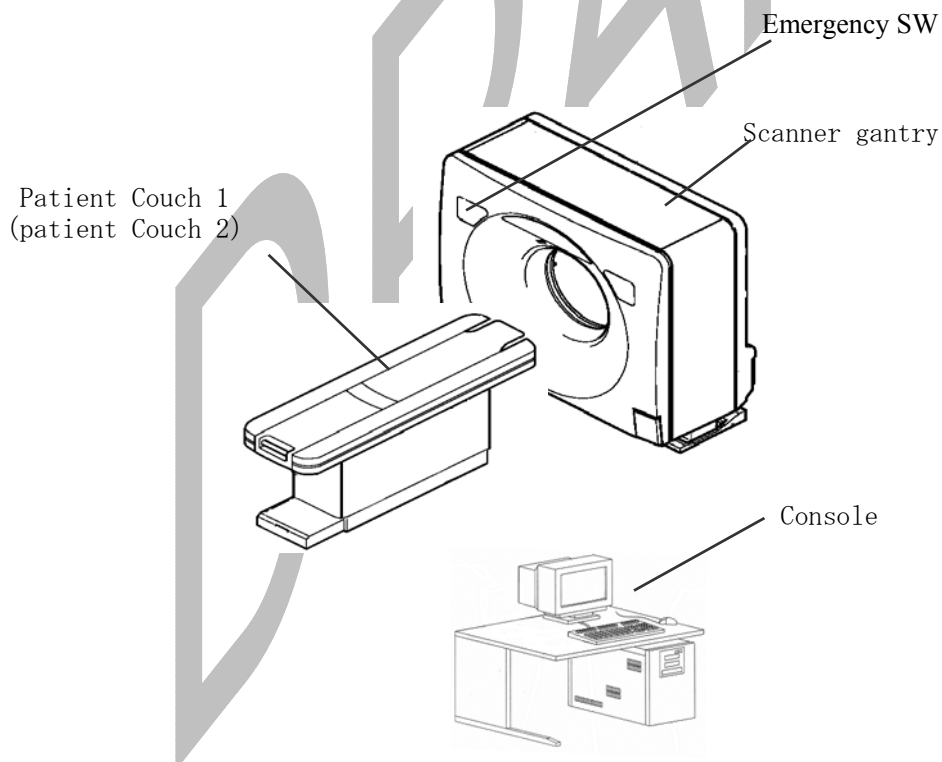
- (1) Scanner gantry
- (2) Patient couch 1
- (3) Console

The optional equipment and function are as follows:

- (1) X-ray tube assembly 2
- (2) Patient couch 2
- (3) Independent image display processing unit

1. 2 External appearance

The external appearance of this device is shown in the following figure.

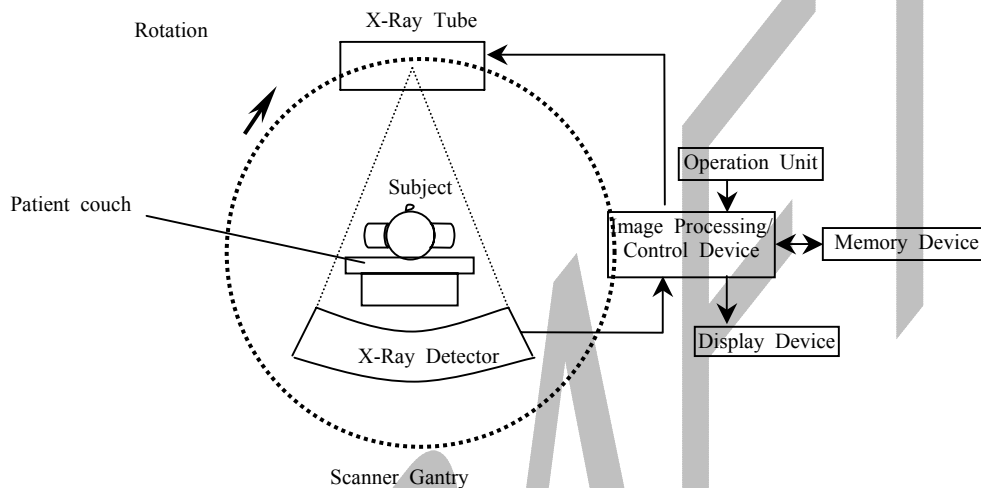


Examples other than components are omitted. Optional apparatus and function that are not embedded in the unit, the external appearance of which is shown, should be provided.

2. Operating Principles and Functions of Each Unit

2.1 Basic Operating Principles

This device is provided with an X-ray tube assembly that rotates around the tomographic plane center of a scanner gantry, and an X-ray detector. In order to obtain a tomographic image, it reconstructs an image using X-ray transmission data, the X-rays exposing from the X-ray tube assembly onto a human body, passing through the body, and being measured by the detector. The images are displayed on a monitor, and the image data is recorded in a recording device such as a magnetic disk. As required, based on the obtained images, it employs an image processing/control device for operations that include 3-D image processing.



By combining the movement of the scanner gantry and the patient couch, the following general scan methods are available: axial scan (alternately moving the scanning position via the patient support and irradiating with X-rays), dynamic scan (not moving the patient support, but irradiating the same location with X-rays to take intermittent and continuous photographs); helical scan (while moving the patient support, continuously irradiating with X-rays); and scout scan (fixing the X-ray tube assembly and continuously irradiating with X-rays while moving the patient support. These images are used to plan scan positions).

2.2 Main Functions of Each Unit

(1) Standard Configuration

i. Scanner Gantry

The scanner gantry has an aperture for inserting a subject into its center and has a tilt mechanism so that an operator can adjust the angle at which the subject is scanned. In the principle scanning operation, an X-ray tube assembly and an X-ray detector that are positioned opposite each other inside the cover rotate around the central axis of the aperture, while X-rays are irradiated from the X-ray unit, which is supplied with high voltage from a high voltage generator. The detector collects the amount of X-rays that pass through the subject, and this data is transmitted to an image-processing device in the console.

Two types of X-ray tube assemblies can be mounted:

| | Standard equipment | Optional equipment |
|--|-----------------------------|-----------------------------|
| Name of medical equipment manufacturer and seller. | Company X | Company X |
| Sales name | X-ray tube assembly XX-5000 | X-ray tube assembly XX-8000 |
| Certification number | xxxxxxxxxxxx | xyxyxyxyxyxyx |
| Anode heat capacity | 5 MHU | 8 MHU |

ii. Patient support 1

The subject is held on a patient support of the patient couch. It has a movement mechanism for moving up, down, forward and backward, whereby an operator can adjust the position of the subject. This operation can be carried out from a control board on the exterior of the gantry or from a console. While scanning, motion control is performed corresponding to the operation of the scanner gantry. Supplementary equipment for securing the subject to the Patient support is provided as Patient support accessories.

iii. Console

The main features of the console include interactive processing with the operator; scanning sequence setting and control; image reconstruction processing; image processing and measurement; and the display, recording, management, input and output of images, data, etc. It has the following image display, processing, and measurement functionality: image selecting; windows level/width setting; image reverse, rotation, enlargement, smoothing, and sharpening processes; Image addition/subtraction processing¹ processing; ROI processing; CT number display; and other general processes.

The main elements in the configuration include a monitor, microphone, speaker, keyboard, and control box. Among other items, a computer for performing image reconstruction, etc, and a magnetic disk for storing images and other data are built into the control box. Also included is an interface for the input and output of images and data.

(2) Optional Configuration

i. X-ray tube assembly (2)

This option places an anode heat capacity of 8 MHU in the scanner gantry. (Instead of the standard 5MHU, an 8MHU is built into the scanner gantry.)

ii Patient couch 2

This is the same as Patient support 1 except that the length is shorter for installation in small scanning rooms.

(This replaces Patient support 1.)

iii Independent image display processing unit

This feature performs image display and processing using equipment that is separate from the main unit. Functionality is the same as the main unit's console.

(3) Devices that can be combined

Use is possible in combination with the following devices (not included in the present application).

i Medical apparatus manufacture: Company CCC

Sales Name: Contrast medium injector □□□-300

Certification number: 00000BZY00000000

3 Supplementary Features

Names based on supplementary feature notifications should be indicated in brackets. Indications in brackets may be omitted in the case where these are the same as the names in the unit.

The content of the unit, etc., should be clearly indicated in the content of the list of supplementary features.

The device has the following supplementary features:

| No. | Feature Name | Configuration | Feature Definition |
|-----|---|---------------|--|
| 1 | Perfusion Image Analysis Software, Xe-Study (Blood flow information measurement/display) | * | This feature uses a series of contrast scanned CT images, and traces temporal changes in CT numbers (signals) at specified locations in the images to calculate information related to blood flow and the like. It can also create and display a functional map of image density information. |
| 2 | Brain-Atrophy Rate Measurement Software (Brain-atrophy information measurement) | * | This feature calculates information related to brain atrophy (cross section, cross section ratio etc.) by setting a CT number threshold for CT images of the head. |
| 3 | Stereotaxic Neurosurgery Support Software (Positional information measurement/display for supporting to Stereotaxic Neurosurgery) | * | For cranial CT images made using an attached special positioning jig, this feature calculates and displays positional information such as coordinates, angles and distances for a targeted area with respect to a reference axis that is previously set.. |
| 4 | Cardiac Function Analysis Software (Cardiac information measurement/display) | * | From a series of CT images, this feature displays any cross section of the heart region, or a 3-D image. From the image it calculates distances, surface area, capacity, vascular stenosis rates, etc, providing information related to heart functions. |
| 5 | Vasoconstriction Analysis Software (Vasoconstriction information measurement/display) | * | From a series of CT images, this feature displays vascular image. From the image it calculates distances, surface area, capacity, vascular stenosis rates, etc, providing information related to heart functions. |
| 6 | MPR/3-D Software (Arbitrary Cross Section and 3-D Image Processing) | * | This feature processes a series of CT images to display arbitrary cross sections, or 3-D images. The principle processes include surface and volumetric rendering, maximum value projection, minimum value projection, arbitrary cross section processing (MPR), etc. It is possible to combine such features as changing the viewpoint with respect to 3-D image data, developing a view of any cross section, and projected image display. Used in combination with functions such as changes in viewpoint with respect to three-dimensional image data, expanded display on arbitrary cross sections, and projected image display, etc. |
| 7 | CT Fluoroscopic System (CT fluorography) | * | In order to perform monitoring (observation) that is used for centesis surgery and the like, this feature displays images using continuous scan that employs low level radiation and high speed scanning. |
| 8 | ECG Synched Scanning | * | This feature collects patient's ECG signals and uses them as synch signals to obtain images with controlled scan timing. |
| 9 | Respiration Synched Scanning | * | This feature collects patient's respiration signals and uses them as synch signals to obtain images with controlled scan timing. |

| | | | |
|----|--|---|--|
| 10 | Prep Scanning | | Monitoring photography is performed prior to the main scan, and variations in the CT number in accordance with the density of the contrast medium inside the region of interest (ROI) is measured with the aim of controlling the photography timing so that an optimum graphic image can be obtained. |
| 11 | Injector Synched Scanning (Auto-Contrast Medium Injection and Continuous CT scanning | * | This feature coordinates the timing of the operation of the automatic contrast agent-injecting device and the timing of the CT scan in order to obtain the optimum image contrast. |
| 12 | Stand-alone image display processing | | This feature displays and images, manipulates and measures images, and calculates image constructions independently from console. However, this device has no feature other than the above feature. |
| 13 | Multi-slice CT photography (axial scan photography (photography)) | | This is a basic CT scanning method whereby the top does not move and X-ray irradiation occurs while the same surface is rotated. A single scan makes it possible to obtain either one slice or several slices (maximum of 64 slices, including several different slice thicknesses). |
| 14 | Helical scanning | | A method of photography whereby continuous X-ray irradiation occurs while the top is moved. |
| 15 | Dynamic scanning | | A scanning (photography) method in which the same area is repeatedly subjected to axial scanning and involving either intermittent or continuous scanning. |
| 16 | Scanogram (preview image scanning) | | A photography method in which the position of the X-ray tube device is held steady and continuous X-ray irradiation occurs while the top is moved. These images are used for planning the photography position. |
| 17 | Contrast radiography function | | A photography method that makes it possible to obtain high-contrast images as a consequence of a doctor injecting a contrast medium into the patient, absorption of Xe gas, etc. Differentiation can be made by attaching a CE mark to the photographed image. |
| 18 | Photography Condition Setting | | Scanning conditions include, among other things, tube current, tube voltage, slice thickness, scan time, and the amount of patient support movement. With this feature the user can set these. There is also a device that can set scanning protocol and automatic exposure control (Auto Exposure Control ²). |
| 19 | Function relating to determination of position | | A function for determining the position of photography by means of gantry sloping, raising and lowering the patient couch, mechanical operation of horizontal movement of the top, etc. Remote operation from the console is also possible. Functions for displayed the standard position using a floodlight (laser beam) are also included. |
| 20 | Recording, saving, delete | | These features are for recording, saving and deleting data on the memory device that constitutes the device. The memory device includes an additional external memory unit. Memory units for this device include HDD, FDD, DVD-RAM and MO. |
| 21 | Input | | This function is for inputting commands and data into the device. Input devices include keyboards, mouses and microphones. |
| 22 | External Data Exchange | * | This feature is capable of exchanging data and signals with external devices. The unit possesses online and offline input/output functions based on DVD-RAM and MO employing networks in line with DICOM standards. |
| 23 | Display | | A function that displays images, data, photography conditions, set values, warnings and instructions, etc., to the operator and the patient. In addition to visual indications, vocal displays are also used. |

| | | |
|----|--|--|
| 24 | Image Display and Processing (Software) | This feature displays and processes images and accompanying data, etc. This type of apparatus includes window level and width settings, image selecting and update, multi-frame display, screen saver, annotation and dynamic image display. It also includes vertical and horizontal image flipping, rotation, enlargement and reduction, black/white reverse, grayscale conversion, ROI detection (referred to in the case of this device as a “user filter” and denoting an image filter), image addition/subtraction processing, and picture point correction. Additionally, it is possible to combine each process. |
| 25 | Image Measurement (Software). | This feature calculates and chart value, from CT numbers and position information that are in image data. Among others, examples include the display (numerical, profile, histogram) of mean CT number and standard deviations, surface areas, volumes, distances, angles, and CT numbers ³ . Additionally it is possible to combine each process. |
| 26 | Image restructuring mathematical operation | An image generation function involving the performance of restructuring mathematical functions from live data recorded by means of photography. It includes cases where mathematical operations are performed in parallel with data collection (during scanning) and the method of calculation whereby previously stored live data is recalled (referred to as batch re-formation). |
| 27 | Patient support and assistance | This refers to accessories for use with the unit and auxiliary items connected with examinations conducted on patients. Includes mats, head rests, armrests, extended tops, root attachment devices, intravenous drop attachment devices, etc. |

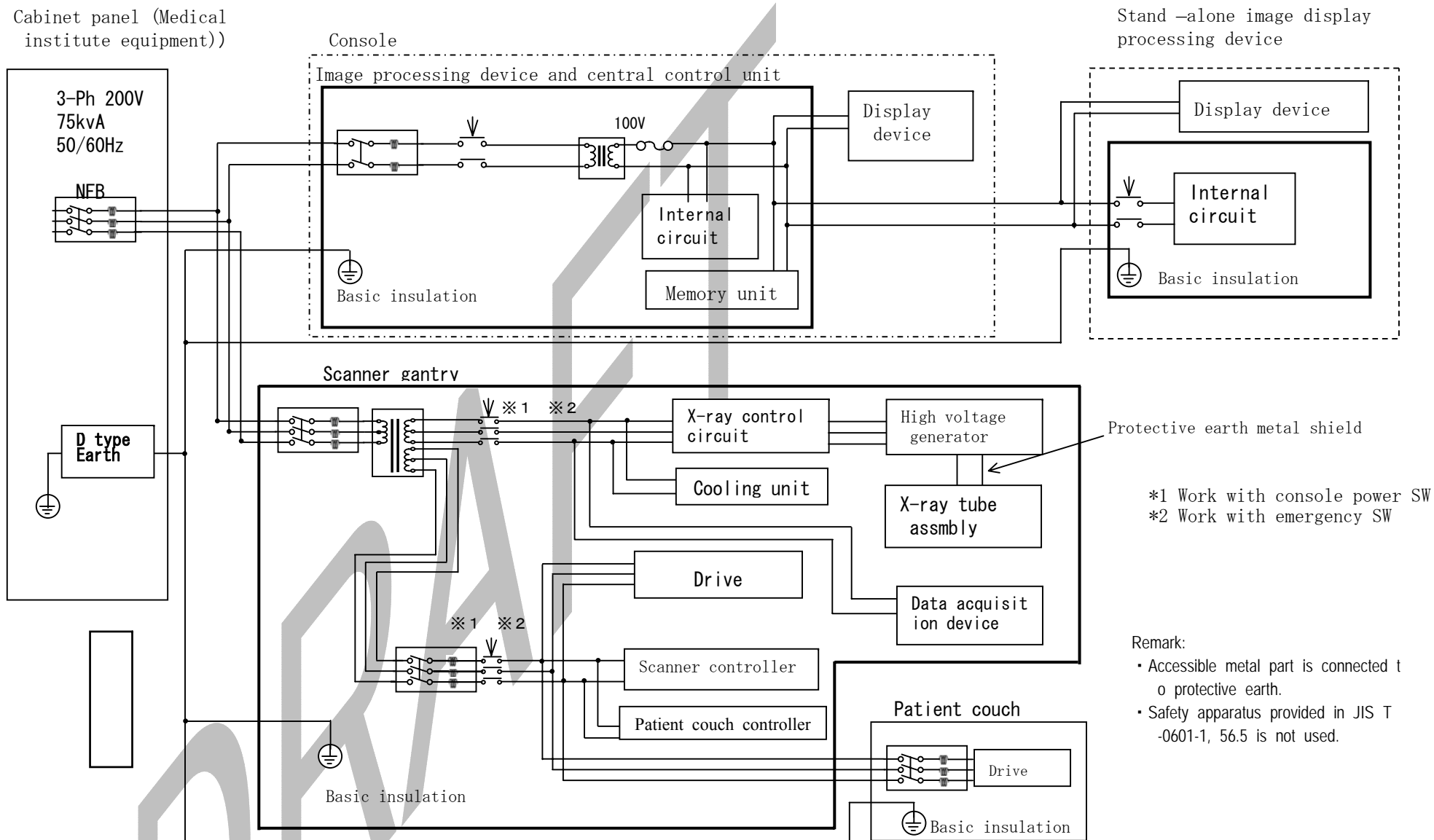
* Indicates an optional feature.

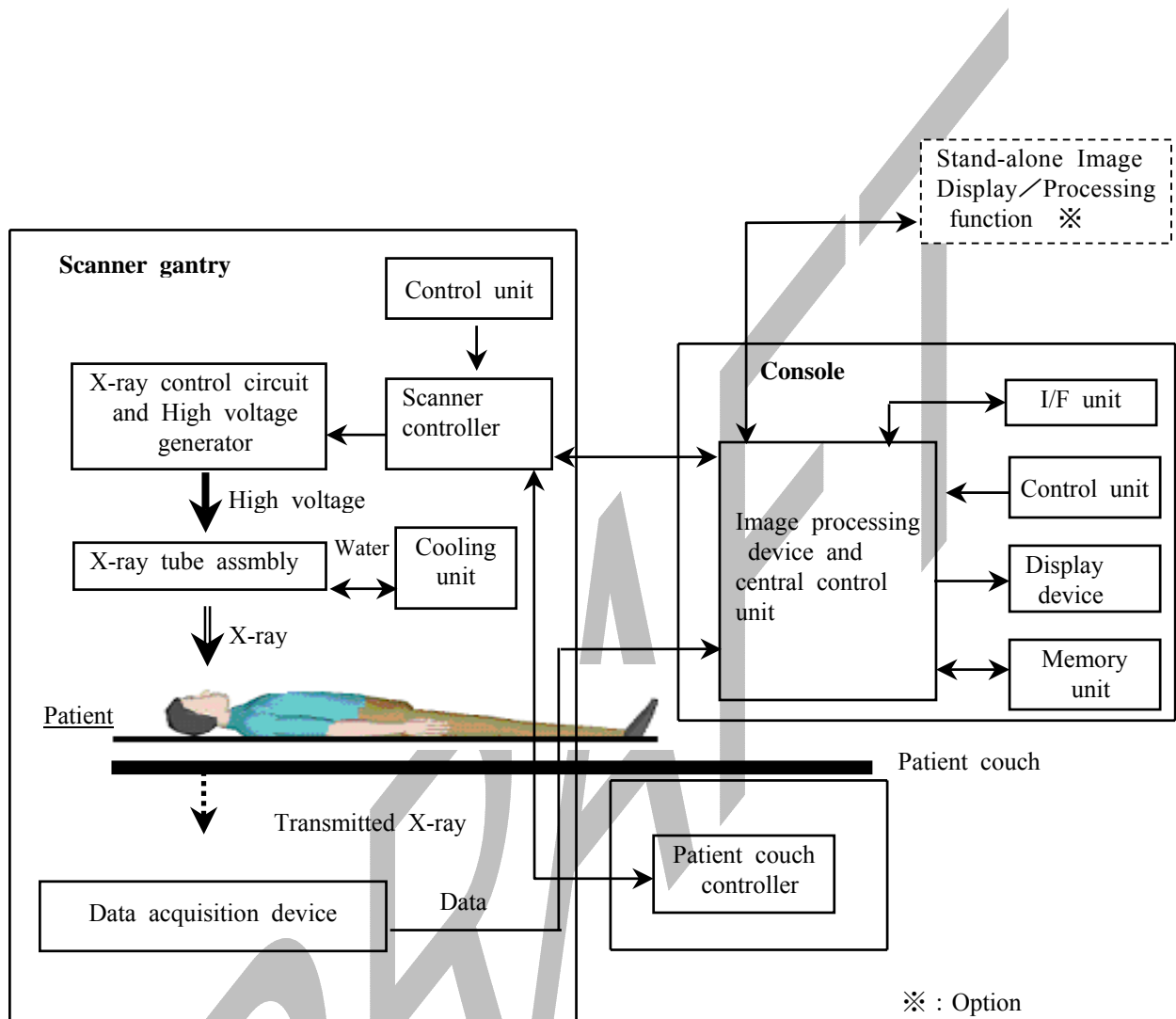
4. Electric Rating and Classification

- (1) Rated Power Voltage : AC, 3 phase, 200 V
- (2) Rated Power Frequency : 50/60 Hz
- (3) Power supply input : 75 kVA
- (4) According to the type of protection against electric shock : Class I equipment, Permanently installed equipment, Stationary equipment
- (5) According to the degree of protection against electric shock : Equipment with Type B attachment

The electric source diagram of this device is shown below.

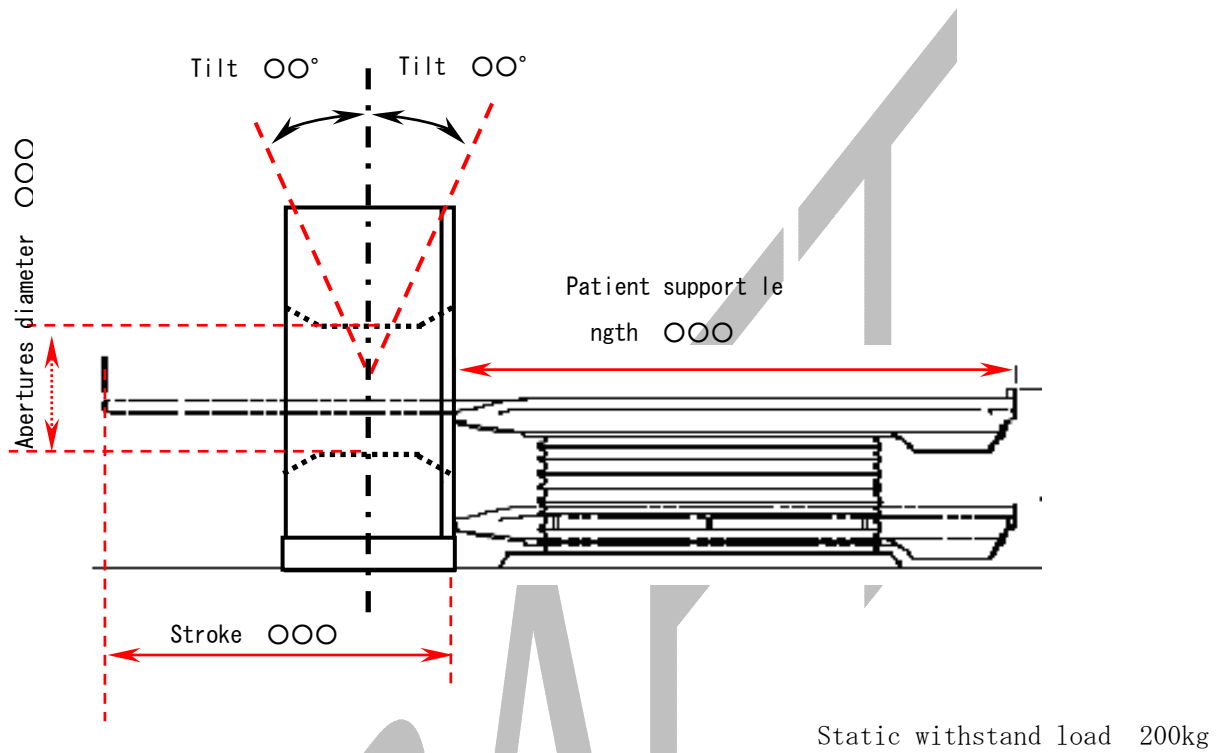
Electric Source Diagram





System Block Diagram

Optional equipment/function should be also provided to make clear if they are built in the present unit or another unit.



Static withstand load 200kg

Scanner Gantry/Patient couch Outline Drawing

As for the outline drawing concerning diagnosis or outside dimension, the operating section and the other sections relating to the product specification or should be provided. If there is not the said section, the length, width and/or height of

Outline drawing of patient support 2 is omitted in this Example. Outline drawing and outside dimension should be provided according to the characteristics of the product.

Raw Material or Component

Names of constituent units and raw materials are shown below.

| | Name | Parts | Raw materials |
|---|---|-----------------|--------------------------------|
| 1 | Scanner gantry | Cover | Steel sheet |
| 2 | Patient couch 1 | Cover | Bonderized steel sheet |
| | | Patient support | Fiber-glass reinforced plastic |
| 3 | Operation table | Cover | Plastic |
| | | Keyboard | General electrical component |
| 4 | Patient couch 2 | Cover | Bonderized steel sheet |
| | | Patient support | Fiber-glass reinforced plastic |
| 5 | Stand-alone Image Display/Processing function | Cover | Plastic |
| | | Keyboard | General electrical component |

If materials are not associated with performance, efficacy or effect and do not directly contact with blood circuit or body fluid, they may be briefly provided.

Product Specification

特性・性能又は機能

| Item | Specification | | Remarks |
|-------------------------|---|---|---|
| Section Slice thickness | <ul style="list-style-type: none"> • 10mm : 10mm±10% • 7mm : 7mm±10% • 5mm : 5mm ±10% • 2mm : 2mm ±10% • 1mm : 1mm±10% Scanning condition : 120kV, 1s, 200mA, FOV210mm, Reconstruction filter; head type, Axial Scan | | Test method is shown as IEC 61223-3-5, 5.3. |
| Dose | Head | 30 mGy±20% Scanning condition : 120kV, 10mm of section slice thickness, 1s, 200mA, FOV210mm, Reconstruction filter; head type, Axial Scan | Test method is shown as IEC61223-3-5, 5.4. |
| | Abdominal | 20 mGy±20% Scanning condition : 120kV, 10mm of section slice thickness,, 1s, 150mA, FOV350mm, Reconstruction filter; body type, Axial Scan | |
| Noise | Head | 0.2%±0.02% Scanning condition : 120kV, 10mm of setion slice thickness, 1s, 200mA, FOV210mm, Reconstruction filter; head type, Axial Scan | Test method is shown as IEC61223-3-5, 5.5. |
| | Abdominal | 1.0%±0.10% Scanning condition : 120kV, 10mm of section slice thickness, 1s, 150mA, FOV350mm, Reconstruction filter; body type, Axial Scan | |
| Uniformity | 4 HU(Hunsfield unit) and below (300mm diameter of water phantom) Scanning condition : 120kV, 10mm of section slice thickness, 1s, 150mA, FOV350mm, Reconstruction filter; body type, Axial Scan | | Test method is shown as IEC61223-3-5, 5.5. |
| Mean CT number | 4 HU(Hunsfield unit) and below (300mm diameter of water phantom) Scanning condition : 120kV, 10mm of section slice thickness, 1s, 150mA, FOV350mm, Reconstruction filter; body type, Axial Scan | | Test method is shown as IEC61223-3-5, 5.5. |
| Spatial resolution | Head | <ul style="list-style-type: none"> • 5 lp/cm±0.5 lp/cm@50%MTF • 10 lp/cm±1 lp/cm@10%MTF Scanning condition : 120kV, 10mm of section slice thickness, 2s, 150mA, FOV210mm, Reconstruction filter; head type, Axial Scan | Test method is shown as IEC61223-3-5, 5.6. |
| | Abdominal | <ul style="list-style-type: none"> • 4 lp/cm±0.5 lp/cm@50%MTF • 8 lp/cm±0.8 lp/cm@10%MTF Scanning condition : 120kV, 10mm of section slice thickness, 1s, 150mA, FOV350mm, Reconstruction filter; body type, Axial Scan | |

If more than two test methods are shown in the standard, the applied test method should be written in the Remarks.

| Item | Specification | Comments |
|---|-----------------|--|
| Scan Time | 0.5, 1, 2s | Tested according to company standards. |
| Tube Voltage | 100, 120, 140kV | |
| Density Resolution(Low Contrast Resolution) | 2mm@0.2% | Attachment C IEC 61223-3-5 |

The item only related to functions should be basically provided in the attachment 1

2. Safety related items

| Standard No. Year | Subject |
|--------------------------------|---|
| March 22, 2001 Notice No 75 | Medical X-ray device standard |
| JIS T 0601-1: 1999 | Medical electronic equipment – Part 1: General requirements for safety |
| JIS T 0601-1-3 : 2005 | Medical electronic equipment – Part 1-3: General requirements for safety – Collateral standard: General requirements for radiation protection in diagnostic X-ray apparatus |
| IEC60601-1-2: 2001 | Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| JIEC60601-2-44 Amd. 1: 2002 | Amendment 1 (Medical electrical equipment – Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography) (Medical X-ray CT device safety) |

Operation and Use

The following is an overview explaining how to use this device.

1. Before Using

- (1) Turn on power to the system.
- (2) Carry out daily startup inspection (around the device, control panel operation, etc.).
- (3) Carry out device warm-up (warm-up, calibration).

2. Prepare the Subject

- (1) Place the subject on the Patient support and secure the patient with the attachments.
- (2) Using a positioning light, position the subject by moving the Patient support vertically and horizontally.

3. Photography

- (1) Use the console to input information on the subject, etc.
- (2) Set scanning conditions according to the region to be scanned.
- (3) Press the scan start button to perform the scanning.
- (4) Data collection, image reconstruction and other processes will be performed, and images will be obtained.

4. Image display and image processing

- (1) After scanning, set window level and window width, and display an image that is appropriated to the examination.
- (2) Perform image processing as required.

5. Image Output

As required, process for output to film, or to external equipment.

6. After Using

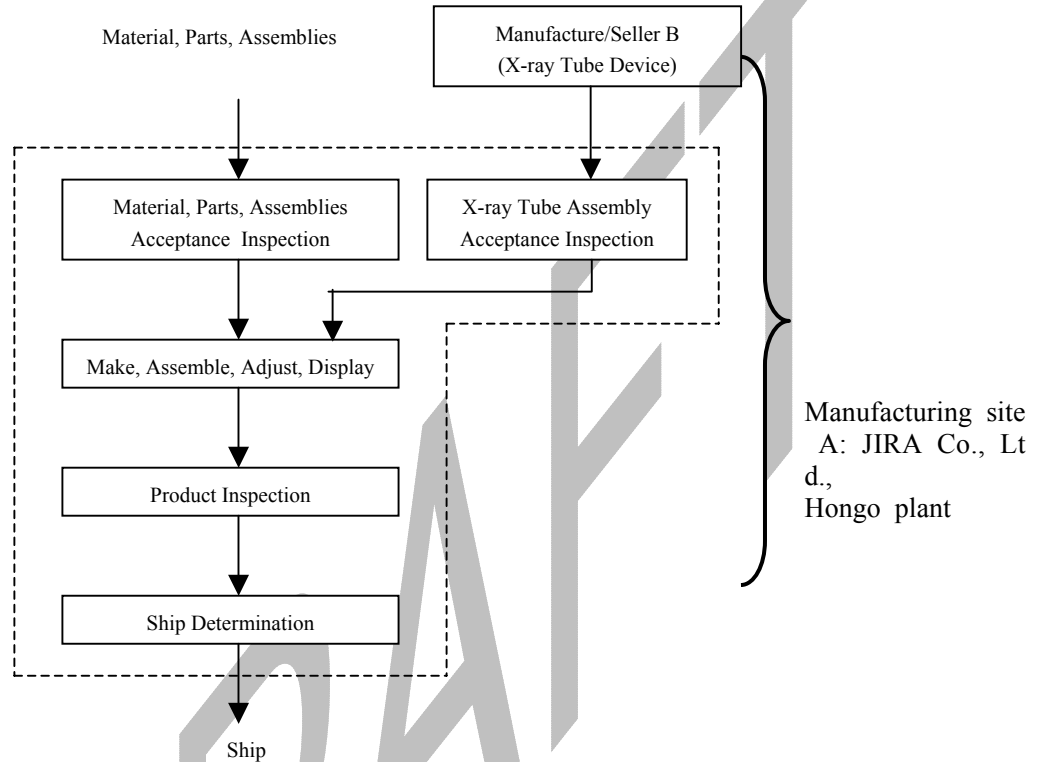
- (1) Carry out shutdown inspection (appearance, control panel, etc)
- (2) Turn off system power.

Overview of combined devices should be also provided. Emergency response (emergency shutdown time etc.) should be provided. The overview of the technical documents should be consistent with the operation methods.

Example 1: All inspections related to item specification are carried out during "Product Inspection".

Manufacturing Method

1. Manufactured with the following procedure at the following plant.



(X-ray tube assembly manufacturer/seller)

Name of manufacturer/seller: Company X

Name of main location of manufacturing/sales: XXX, Yokohama, Kanagawa

Manufacturer/seller permit number: Type, Number, Class II: XXXX

| Certification number | Sales name | Product name |
|----------------------|-----------------------------|--|
| YYYYYY | X-ray tube assembly XX-5000 | Standard equipment X-ray tube assembly |
| ZZZZZZ | X-ray tube assembly XX-8000 | Optional equipment X-ray tube assembly |

Name (,) ,

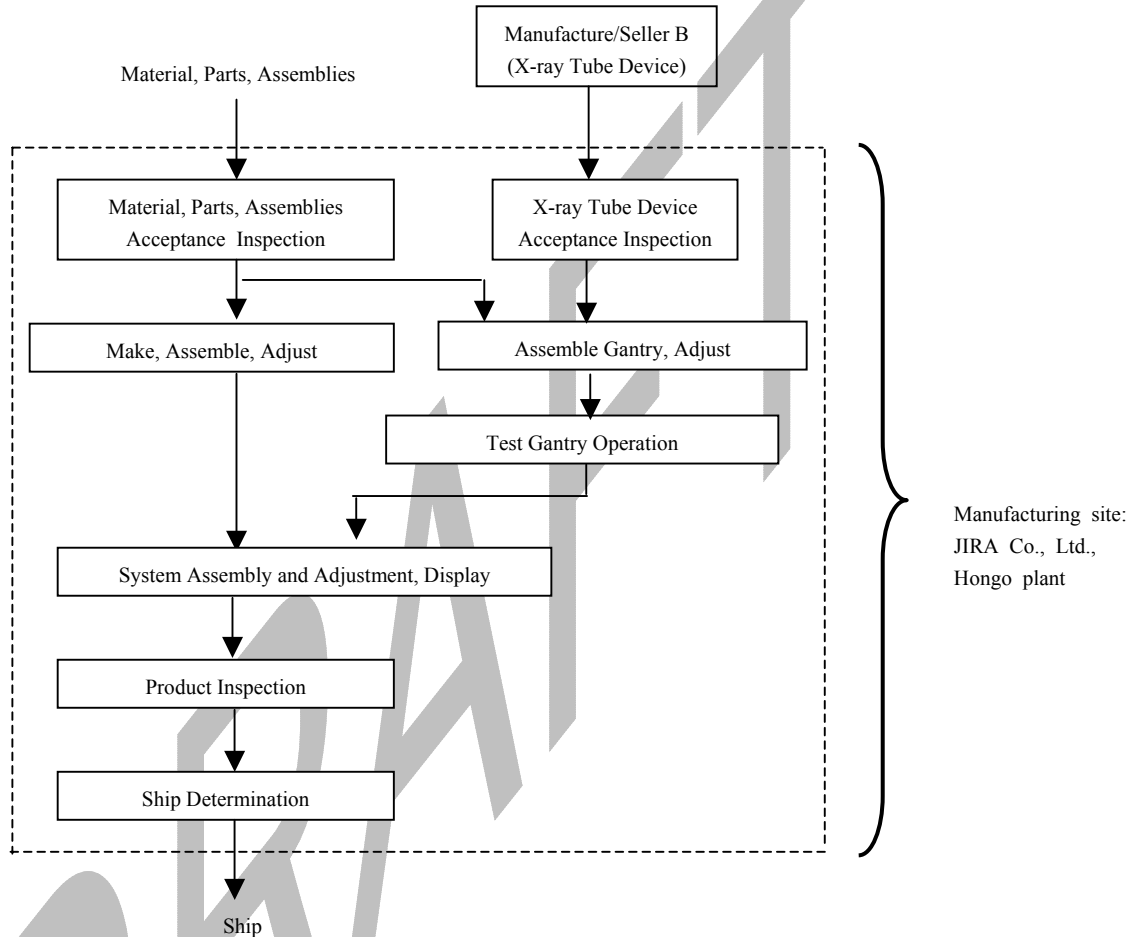
2. Name of main design controller and his or her office.

Company: JIRA Co., Ltd.

Example 2: Some inspections related to item specification are carried out during intermediate processing "Unit Assembly".

Manufacturing Method

1. Manufactured with the following procedure at the following plant.



(X-ray tube assembly manufacturer/seller)

Name of manufacturer/seller: Company X.

Name of main location of manufacturing/sales: XXX, Yokohama, Kanagawa

Manufacturer/seller permit number: XXXXX

| Certification number | Sales name | Componet name |
|----------------------|-----------------------------|--|
| YYYYYY | X-ray tube assembly XX-5000 | Standard equipment X-ray tube assembly |
| ZZZZZZ | X-ray tube assembly XX-8000 | Optional equipment X-ray tube assembly |

Name (Sales name,) ,

2. Name of main design controller and his or her office.

Company: JIRA Co., Ltd.