

SITE PLANNING MANUAL

FOR

TOSHIBA SCANNER



MODEL TSX-031A

(2A201-528EN*A)

TOSHIBA MEDICAL SYSTEMS CORPORATION

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Safety Precautions

1. Meaning of Signal Words

In this manual, the signal words **DANGER**, **WARNING**, and **CAUTION** are used to indicate safety and other important instructions. The signal words and their meanings are defined as follows. Please understand their meanings clearly before reading this manual.

Signal word	Meaning
 DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
 WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
 CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in property damage.

In addition to the above, the signal word **NOTE** is used to indicate other important information.

NOTE	Indicates reference information that enables more efficient use of the equipment.
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- ⚠ CAUTION:**
1. If the system transformer is installed beside the console, adequate distance must be kept between them. Otherwise, the displayed images may be adversely affected.
 2. The field engineers should examine and check the general works and share of responsibilities.
 3. Power supply system:

Install the special transformer (cubical output transformer) for this system in the hospital power supply.
 4. Air conditioning:

The scanning room must be provided with an independent air conditioning system.
Even if the room is maintained within the permissible temperature range, gradual temperature shifts (for example, a slow increase in room temperature from morning to evening) may adversely affect system performance. Therefore, the room temperature must be under constant control.
 5. Floor leveling work:

Although two different hardeners are available for the epoxy resin (winter-use hardener and summer-use hardener), the winter-use hardener (B-065) must be used.
The summer-use hardener is not suitable for work in hospitals or clinics because it requires a long hardening time and, in some cases, the application of heat may be necessary to achieve hardening.
 6. Floor leveling work:

The anchor must be well caulked to prevent the epoxy resin from being intruded into the anchor hole.
The paper wound on the anchor must be higher than the epoxy resin depth.
 7. Applying resin:
 - This job must be performed with a plastic floor-covering sheet laid on the floor.
 - Before mixing the liquid agents, they must be accurately weighed using an oil replenishment container.
 - The oil replenishment container that has been used for weighing must not be used to apply the resin.
 - Gloves, eye protection, etc. must be worn when handling the resin.
 - During handling of the resin, good ventilation must be provided since it is a volatile chemical.

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1. SCOPE

This document applies to the Toshiba X-ray CT scanner Activion16 (model TSX-031A).

2. APPLICATION

This document describes the site planning requirements for optimal performance. It also describes the necessary site facilities and outlines the range of responsibilities during installation work. This document applies to the following system and model.

System name	Model name	X-ray output	Type of system
Activion16	TSX-031A series	36 kW	Multislice system

3. SYSTEM COMPOSITION

3.1 Standard Composition

(1) Scanner

This refers to the CT main unit incorporating the X-ray tube, the high-voltage generator, the detector unit, etc. Note that the scanner is also referred to as the gantry in this document. This unit must be fixed with anchor bolts.

(2) Patient couch

The unit on which the patient to be scanned is placed is referred to as the patient couch. It is provided with a vertical movement mechanism which allows patients to get on and off the couch easily and facilitates scan center positioning. The patient couch is also provided with a couch-top slide mechanism for scan slice positioning. This unit must also be fixed with anchor bolts.

(3) Console

This unit is used to perform CT control, image reconstruction, image processing, etc. It consists of the following sub-units.

- Navibox..... This is the console main unit incorporating the computer system. It is placed on the floor.
- Keyboard
- Monitor..... Images and operation screens are displayed on the monitor. The console of the TSX-031A includes a 19-inch LCD monitor.
- Mouse

A desk on which the monitor, the keyboard, and the mouse are placed and a chair are required. They are not provided for the system.

(4) Accessories

Calibration phantom, couch accessories, speakers, operation manual, etc.

3.2 Optional Units

(1) System transformer

This is used to convert the voltage of 400-V power-supply facilities to 200 V.

(2) Patient monitoring system

A camera and video display monitor set is used to observe the patient being scanned from the scan control room.

3.3 Miscellaneous

The desk on which the console is to be placed and the chair for use with the console are not included with the system.

Note: The desk and the chair selected should meet the requirements below.

- Desk

- (1) Height : 800 mm (When the Navibox is installed under the desk, a height of more than 700 mm is required under the desk.)
- (2) Width : 1400 mm
- (3) Depth : 700 mm

- Chair

- (1) Seat height : The range from 500 to 550 mm should be covered.
- (2) High stability (5 legs)
- (3) With footrest or foot bar

4. MAIN SPECIFICATIONS FOR SITE PLANNING

4.1 Classification

- (1) According to the type of protection against electric shock:
CLASS I EQUIPMENT.
- (2) According to the degree of protection against electric shock:
TYPE B APPLIED PART.
- (3) According to the degree of protection against ingress of water:
Ordinary EQUIPMENT(IPX0).
- (4) According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:
EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.
- (5) According to the mode of operation:
CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

4.2 X-ray Specifications

- (1) X-ray type : Continuous fan-shaped beam
- (2) Maximum X-ray tube voltage : 135 kV
- (3) Maximum X-ray tube current : 300 mA
- (4) Scan time : Half scan : 0.48 s
Full scan : 0.75, 1.0, 1.5, 2.0, or 3.0 s

4.3 X-ray Tube Leakage Dose

- (1) X-ray tube leakage dose : 1.0 mGy or less in 1 hour
- (2) Effective beam shielding : At least 2.4 mmPb
- (3) X-ray tube inherent filtration : At least 1.1 mmAl eq.

4.4 Power Supply Requirements (For the standard system)

See subsection 8.1.

4.5 Grounding

Grounding must be provided in accordance with all applicable legal requirements for medically used electrical equipment.

4.6 Wiring Work

Wiring work for the power supply must be provided as detailed in subsections 8.1 and 8.2.

4.7 Site Environment

- (1) Ambient temperature, humidity, and calorific value

See appended table 1 "Heat generation by units and environmental conditions".

- (2) Vibration

0.98 m/s² (0.1 G) or less

- (3) Explosion-proof structure

The unit has no explosion-proof structure. Never use in the presence of explosive gas.

- (4) Other

Check for evidence of excessive dust or dirt.

4.8 External Dimensions and Mass

See appended tables 2-1 and 2-2 "External dimensions and mass".

4.9 Classification

- (1) According to the type of protection against electric shock:

CLASS I EQUIPMENT.

- (2) According to the degree of protection against electric shock:

TYPE B APPLIED PART.

- (3) According to the degree of protection against ingress of water:

Ordinary EQUIPMENT(IPX0).

- (4) According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE:

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE.

- (5) According to the mode of operation:

CONTINUOUS OPERATION WITH INTERMITTENT LOADING.

4.10 Maximum Cable Length

See appended tables 3-1 to 3-3 "List of inter-unit cables".

4.11 Installation Altitude

The installation altitude should be no more than 1000 m above sea level. Prior consultation is required for installations higher than 1000 m.

4.12 Transport and Storage Conditions

Observe the following conditions during transport and storage after shipment.

- (1) Ambient temperature : -10°C to 50°C
- (2) Relative humidity : 40% to 80% (No condensation)
- (3) Atmospheric pressure : 700 hPa to 1060 hPa
- (4) Vibration : 9.8 m/s^2 (1G) or less <during storage>
 19.6 m/s^2 (2G) or less <during transportation>

4.13 Installation Location Requirements

Group 1 (according to 64/1043/CD/(IEC60364-7-710 (draft))

Note 1: The title of IEC60364-7-710 is "Electrical installations of buildings/Particular requirements for special installations or locations/Medical locations and associated areas."

- 2: Group 1 is "Location where medical electrical equipment is intended to be used, but not for intracardiac procedure."

5. SPACE REQUIREMENT

The floor space for unit installation should be 21 m² or more, divided into two rooms.

For patient couch CBTB-018A

Required space : 22 m² or more

For patient couch CBTB-018B

Required space : 21 m² or more

Patient couch model	Scanner room	Operation room	Minimum required space
CBTB-018A	5.53 m × 3.02 m	1.50 m × 3.02 m	22 m ²
CBTB-018B	4.93 m × 3.02 m		21 m ²

See appended figures 2-1 and 2-2 for the sample layouts.

Installation conditions

Installation location : Group 1 according to IEC60364-7-710

NOTE:

1. Group 1 requirement is described in IEC60364-7-710.
2. The title of IEC60364-7-710 is "Electrical installations of buildings - Part 7-710: Requirements for special installations or locations - Medical locations".
3. The definition of Group 1 is "Medical location where applied parts are intended to be used as follows:
 - externally;
 - invasively to any part of the body, except where Group 2 applies".

The definition of Group 2 is "Medical location where applied parts are intended to be used in applications such as intracardiac procedures, operating theatres and vital treatment where discontinuity (failure) of the supply can cause danger to life".

5.1 Scanning Room

The gantry and patient couch are installed in the scanning room.

(1) Installation of the gantry

The space shown in appended figures 2-1 and 2-2 is required for installation and maintenance of the gantry and inward/outward movements of the couch top.

(2) X-ray shielding

Since the gantry releases X-rays, X-ray shielding of 1.5 mm or more in lead equivalence should be provided around the scanner room and the entrance.

(3) Ceiling height

As equipment such as contrast medium injection tools are installed on the ceiling, the ceiling height should be at least 2500 mm from the floor.

(4) Miscellaneous

The following should be provided where required:

- Washstand : For water phantom or contrast medium injector
- Storage rack : For first-aid kit or accessories
- Gases required for medical treatment : Oxygen and nitrogen dioxide
- Vacuum
- Ceiling traveling irrigator : For instillator

(5) Layout

See appended figures 2-1 to 3-2.

(6) Air conditioning

Since the gantry includes components such as detectors or electronic circuits which permit high-precision measurement, air conditioning is required to maintain high precision. A detailed description is given later.

(7) Illumination

Illumination should be adjustable, because it is easier to specify the desired scan slice position using the positioning projectors when illumination is decreased.

(8) Wiring pits and ducts

The wiring pits and ducts should be installed in accordance with the specifications described later.

5.2 Scan Control Room

⚠CAUTION: If the system transformer is installed beside the console, adequate distance must be kept between them. Otherwise, the displayed images may be adversely affected.

The operating console is installed in the scan control room.

(1) Window

The window for monitoring the scanning room should be in front of or on the side of the console. The lowest window frame should be 90 cm from the floor for easy patient monitoring. A curtain should be provided for the window facing the outside.

(2) Entry

Doors should be provided at both the corridor and scanning room. Take extreme care for X-ray leakage from the scanning room door.

(3) Illumination

For easy image reading, install freely adjustable or two-step-adjustable illumination.

(4) Receptacles

At least two standard outlets should be provided near the console for installation of the 3D workstation and InnerVision PC.

Installation of the outlet for connecting a communication line for InnerVision should also be taken into consideration.

In addition to the above, the wiring and power distribution ducting or pit should be installed in accordance with subsection 7.5 "Wiring Pits and Wall Ducts".

5.3 System Operating Environment and EMC

Recently, the EMC (electromagnetic compatibility) problem in hospitals has drawn attention. To prevent the problem from occurring and to ensure that the system operates in a stable manner, this system conforms to IEC60601-1-2, the international standards regarding EMC. The standards specify the requirements taking into account the following points:

- <1> Adverse effect on other systems due to noise generated by this system
- <2> Adverse effect on this system due to noise generated by other systems
- <3> Adverse effect on this system due to static electricity

In actual hospitals, not all systems meet the standards.

Systems such as laser surgical unit, microwave accelerator, microwave thermal therapy system, etc. emit high-level electromagnetic waves due to their characteristics. This system may adversely affect ultrasound systems which use faint signals.

With regard to static electricity, the level may easily exceed the level specified in the standards depending on the operating environment.

Therefore, take extreme care when determining the installation location.

For example, the system should be installed at a location as far from equipment emitting strong electromagnetic waves as possible.

There are methods for reducing mutual influence to prevent the EMC problem. Refer to APPENDIX 2 "HANDLING EMC".

6. CLASSIFICATION OF INSTALLATION-RELATED WORK

6.1 Scope of Work to Be Executed by the Customer

The work listed below should be executed by the customer as a general rule.

(1) Construction work	<ul style="list-style-type: none"> A. New construction, extension, and reconstruction works of the building B. X-ray shielding in the scanning room <ul style="list-style-type: none"> Wall shielding Door and frame shielding Window and frame shielding C. Reinforcement for floor load D. Wiring pit and ducting E. Interior finish work of the building
(2) Electrical work	<ul style="list-style-type: none"> A. Power supply system B. Power distribution board C. Grounding D. "X-ray on" indication lamp during X-ray exposure, piping, and wiring E. Interior illumination and dimmers F. Installation of a communication line for InnerVision
(3) Air conditioning and plumbing system	<ul style="list-style-type: none"> A. Air conditioning work (heater, cooler, and ventilation) B. Water supply and drainage work (e.g., for a washstand)

See section 7 or subsequent for details concerning the execution of the work.

6.2 Scope of Work to Be Executed by Toshiba Subsidiaries

- (1) Bringing-in, installation and adjustment of the entire system
- (2) Intersystem wiring and cable connections to the customer's facilities
- (3) Installation of the InnerVision service processor and connection to the public telephone line

⚠ CAUTION: The field engineers should examine and check the general works and share of responsibilities.

7. BUILDING CONSTRUCTION WORK

7.1 Entrance Used to Bring-in the Unit

To carry the units into the room without any difficulty, conditions such as sufficient door size, corridor width and ceiling height must be satisfied in advance.

(1) Bringing-in method

The system is normally shipped with the covers mounted.

If it is necessary to disassemble the system to reduce the external dimensions or mass for any reason, consult Toshiba in advance.

(2) External dimensions and mass

Appended figures 1-1 and 1-2 show the external dimensions and the mass of the gantry and the required size of the bringing-in entrance.

(3) Bringing-in jig

It is recommended that the bringing-in jig be used to facilitate installation of the main body of the scanner.

(4) Bringing-in with the patient couch tilted

The external dimensions and mass of the patient couch at the time of tilted bringing-in are shown in appended figures 1-3 and 1-4.

7.2 X-ray Shielding in the Scanning Room

The X-ray shielding of 1.5 mm or more in lead equivalent (approximately 13 cm in concrete thickness and $\rho=2.35 \text{ g/cm}^3$) must be provided for the scanning room wall, ceiling, floor, window glass for patient monitor from the scan control room, and the door in strict conformance with the Medical Treatment Regulations.

7.3 Support

The rooms in which the units are to be installed must be able to withstand the load of the units. For the mass of each unit, see appended tables 2-1 and 2-2 "External dimensions and mass".

7.4 Floor Structure of the Scanning Room

The structure of the floor must permit the driving of anchor bolts for securing the gantry and the patient couch. It is recommended that the thickness of the floor should be more than 150 mm. To ensure levelness of the installation floor for the base, perform floor leveling work using epoxy resin for the gantry and patient couch.

(Refer to appended figure 7 "Floor leveling work using epoxy resin" and APPENDIX 3 "FLOOR LEVELING WORK MANUAL".)

7.5 Wiring Pits and Wall Ducts

Wiring pits, wall ducts, and conduit pipes should be provided to facilitate wiring and interconnections between the units of the system.

7.5.1 Pit and duct sizes

The pit and duct sizes depend on the layout of the units, the number of cables, the sectional area of bundled cables, and required clearances. These factors must be checked by the field engineer.

The clearance required for a pit or a duct are as follows:

- For the system power400 percent of the total sectional area of the cables
- For the console
(for power and signal generation)..... 250 percent of the total sectional area of the cables

For cable interconnections between the units, the number of cables, and their sectional areas, see appended figure 5 "Cable connections" and tables 3-1 to 3-3 "List of inter-unit cables".

7.5.2 Partitions in the pit and duct

The wiring pit and duct should preferably be divided into three sections as a countermeasure against noise: one for the system power, one for signal lines between the gantry and the console, and one for the console power. At a minimum there must be at least two sections: one for power lines and one for signal lines.

7.5.3 Precautions

- (1) The pit and duct must be electrically shielded.
- (2) The pit and duct must be protected against flooding.
- (3) The cover should be divided into sections approximately 1 meter in length.

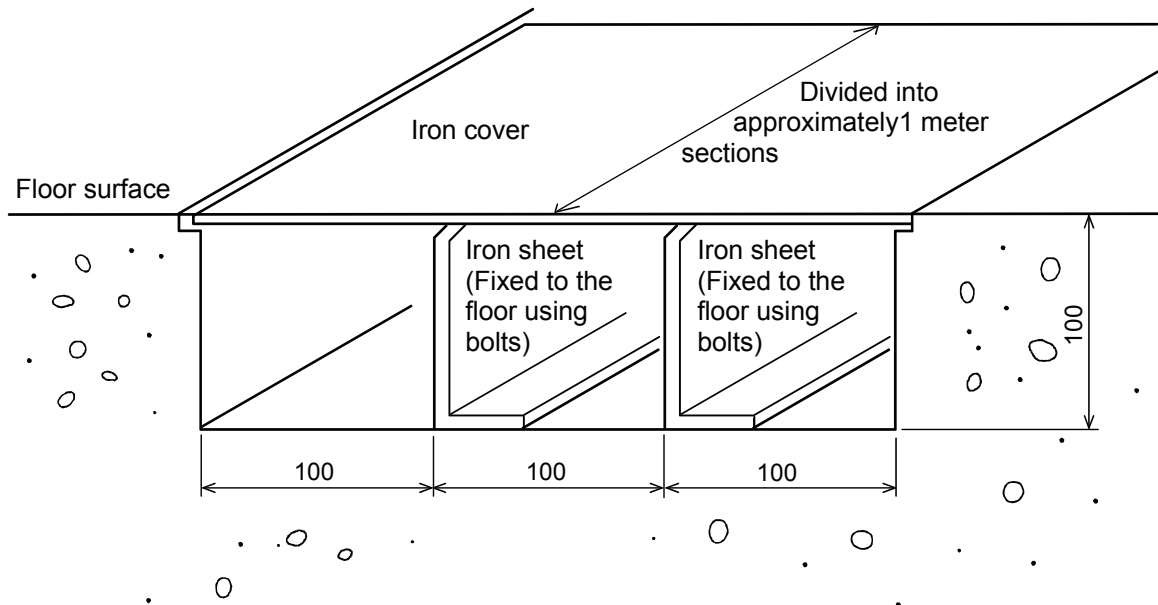


Figure 7-1 Sectional view of a sample wiring pit

8. ELECTRICAL WORK

8.1 Electrical Equipment

8.1.1 Electrical specification

Number of phases	Three phases
Line voltage	200 V
Frequency	50 Hz or 60 Hz
Power capacity (Notes 1, 3)	75 kVA
Rated capacity (Actual load capacity)	52 kVA
Power supply load	0.061 Ω or less
Voltage variation due to changing load	5% or less
Line voltage variation	10% or less (Note 2)

NOTE:

1. The cables between the power receiving transformer and the system power distribution board must exceed the minimum nominal sectional area, obtained from the cable length and the transformer capacity, as shown in appended figures 4-1 and 4-2.
2. This specification must be met even when a load is applied.
3. If the actual load capacity of the system is greater than the power supply unit capacity, confirm that there are no problems with the power supply unit when the system is operated.

8.1.2 Power transformer and power distribution cabling

- (1) Works for the power transformer and power distribution cabling must be performed to meet the electrical specification shown above.
- (2) Design and installation should be made considering the maximum input currents listed below if a power distribution cable is very long.

See appended figures 4-1 and 4-2 "Power supply system".

Output systems	Maximum input current
System current (3-phase at 200 V) (with a three-phase full-wave rectified circuit and reactor)	Approximately 160 A (36 kW)

* Power is calculated assuming a power factor of 1.0.

⚠ CAUTION: Install the special transformer (cubical output transformer) for this system in the hospital power supply.

8.1.3 Ground fault interrupter

If a ground fault interrupter is to be installed, note the following points:

- The sensitivity current should be 100 mA.
- The ground fault interrupter should be noise proof.

(For example, Toshiba NJV series or equivalent)

When the ground fault interrupter or the alarm functions, perform the countermeasures described below.

(1) Leakage current based on the IEC standards

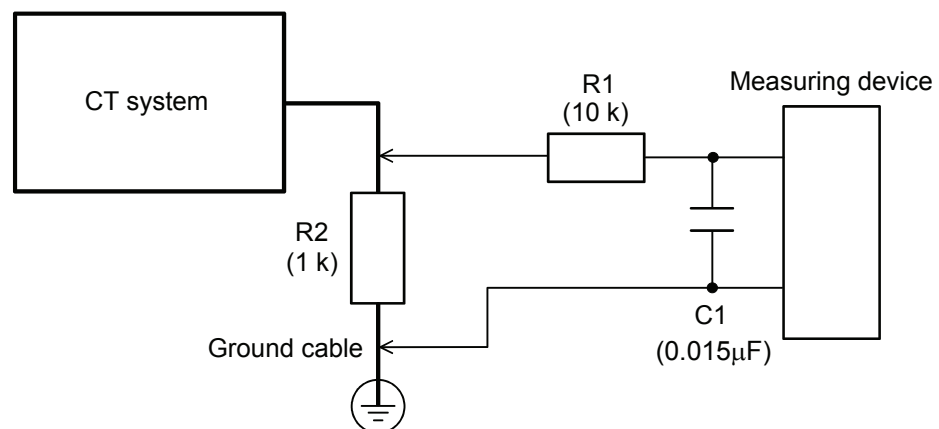
(The leakage current test was conducted according to the IEC standards and it was confirmed that the results completely satisfy the standards.)

International standards and test methods	IEC60601-1 Medical electrical equipment 19 Continuous leakage current and patient auxiliary currents
Allowable value	Earth leakage current (note 3) 5 mA
Conditions	After the humidity preconditioning treatment, the leakage current during scanning was measured at an input voltage of 200 V \pm 10%.

When the leakage current measurement test is performed, the circuit shown in the figure below is added to the grounding cable of the system.

This test is designed to simulate the worst conditions, i.e., the case where all the leakage currents flow through the body of a person touching the system with the ground cable disconnected. The circuit simulates the resistance of the human body and its insensitivity to high-frequency electromagnetic radiation. As the result, the high frequency of 10 kHz is reduced by approximately a factor of ten.

Therefore, the current may differ from that running through the ground cable in normal use.



(2) Leakage current in normal use

In addition to the standard test, the current of the ground cable was measured during normal use. It was seen that the current waveform included a noise waveform. However, frequency analysis showed that the level near the frequency of 50 Hz, which is of most relevance to safety considerations, was less than 10 mA; and the main frequency element was a high frequency element of more than 10 kHz.

CT systems include a large-capacity inverter and the operation frequency of the inverter is of the order of tens of kHz. Therefore, noise with a frequency of the same order occurs within the inverter. To prevent this noise element from coming out, a noise filter is installed. As this noise filter transfers the noise element to the ground cable, the high-frequency leakage current increases.

(3) Countermeasures

Replace the breaker with the Toshiba-recommended breaker.

Countermeasures against incorrect operation due to high-frequency elements have been taken in the leakage detector of the recommended breaker, therefore the effects of the high-frequency elements are eliminated.

The actual characteristics are shown in figure 8-1.

For the leakage alarm as well as for the breaker, investigate countermeasures to reduce high-frequency electromagnetic radiation.

Since the 50-Hz element is small, if the high-frequency element is reduced, it becomes possible to eliminate the problem without changing the sensitivity setting.

If the above actions cannot be performed, the following emergency measures can be performed.

- Change the sensitivity current.
- Set the time before operation of the alarm so that it is longer than the scan time.
(Example: 120 seconds)

If the constants of the noise filter, etc. of the CT system are changed, adverse effects such as EMI noise may result.

Therefore, countermeasures cannot be performed at the CT system.

In addition, use only noise filters, etc. manufactured by Toshiba. The noise filter of this system is designed taking into account extreme phenomena such as lightning. If a noise filter made by a manufacturer other than Toshiba is used, the system may not be protected adequately.

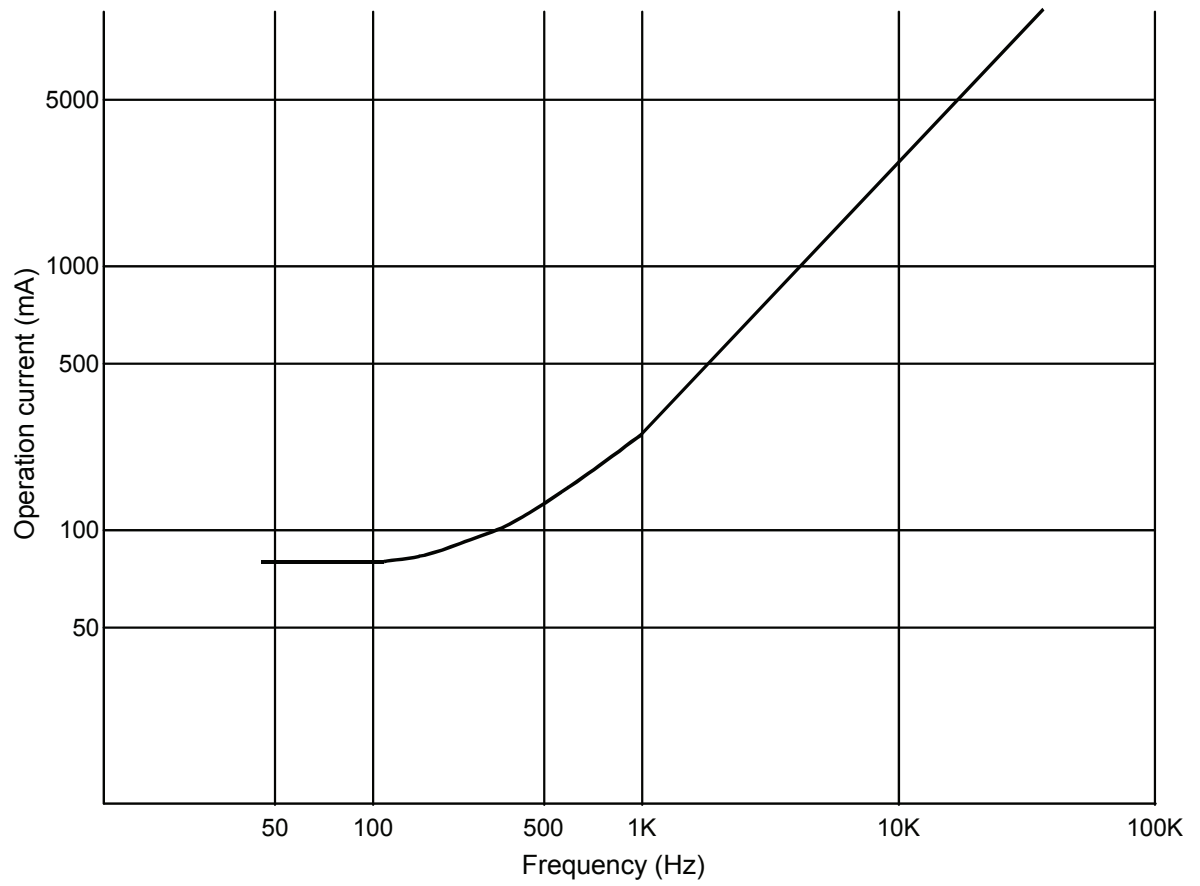


Figure 8-1 Frequency characteristics of the sensitivity of the recommended breaker
(Example for NJV225F) to electrical short circuits

8.1.4 Voltage regulation

- (1) All the units are designed to withstand power variation of $\pm 10\%$.
- (2) If variation exceeds $\pm 10\%$, the automatic voltage adjusting unit should be used (must be ordered separately).

8.1.5 Countermeasures against high-frequency electromagnetic radiation

(1) High-frequency electromagnetic radiation

The original alternating current is in the form of a sine wave, but the input current of an inverter, etc. is in the form of a wave with step-like distortions. General electric appliances such as TV sets, personal computers, air-conditioners, etc. generate high-frequency electromagnetic radiation. Elevators or other motor-driven device can also generate high-frequency radiation. Since CT systems include an inverter, they can be sources of high frequency radiation.

If the total level of the high frequency radiation becomes excessively high, some units may become abnormal because resonance occurs in a capacitor or a reactor due to the adverse effects of wave distortion.

(2) Measures for controlling high-frequency electromagnetic radiation

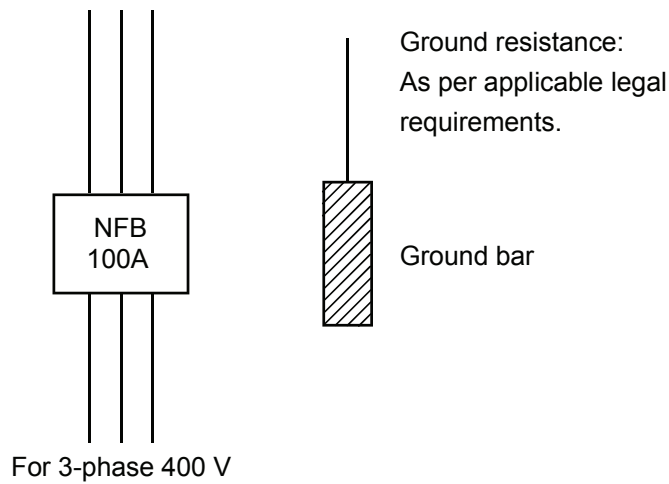
If excessive high-frequency electromagnetic radiation is generated, take the following countermeasures.

- Mount an alternating-current filter for the prevention of high-frequency electromagnetic radiation to the main power source to reduce high-frequency electromagnetic radiation.
- Insert alternating-current filters in the distribution panels of the major devices generating high-frequency electromagnetic radiation to partially reduce the radiation.

Since Toshiba does not handle these filters now, a specialist must be consulted to determine appropriate countermeasures based on the line capacity and the level of radiation.

8.2 Power Distribution Board

- (1) When 400 V is supplied



NOTE: The mounting orientation must be in accordance with IEC60447.

Figure 8-2 Cable connections to the power distribution board

8.3 Grounding

- (1) Grounding must be provided as described in subsection 4.5 of this document.
- (2) Route the grounding wires used exclusively for this system into the power distribution board and connect to the grounded busbar.
- (3) The grounded busbar must have grounding terminals for this system.

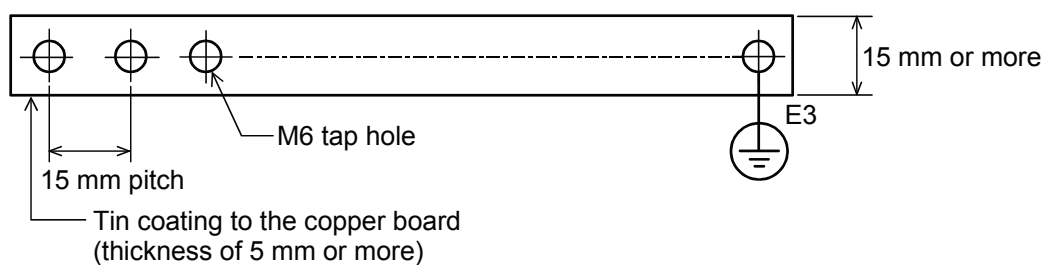


Figure 8-3 Grounded busbar

- (4) The grounding lines for wall ducts, the power distribution board case, and wiring pits must not be connected to the grounded busbar shown above. These lines must be grounded via another route.

8.4 Electrical Equipment

Electrical work should be executed according to the procedures below:

- (1) Mount an "X-ray ON" lamp (100 VAC or 200 VAC) indicating "X-ray exposure in progress" above the entrance to the scanning room and connect the power cable of the lamp to the corresponding power supply facility (100 VAC or 200 VAC) of the site. At this time, connect a 250-V/0.5-A fuse in series to the power input line. In addition, route the cable as described below to turn ON the lamp in synchronization with the desired CT system operation. Connection must be performed during system installation.

<1> To turn ON the lamp in synchronization
with the power ON operation : Route the cable near the console.

<2> To turn ON the lamp in synchronization
with the X-ray exposure start operation : Route the cable near the gantry
(use the X-ray system duct for cabling).

8.5 Illumination

Freely adjustable or two-step-adjustable illumination should be installed in the scanning room. Place illuminating fixtures so that light does not reflect on the display monitor of the console. Illumination should be adjustable in the range from 10 to 300 lux.

8.6 Cable Connections Between the Units

Cable connections should be made with reference to appended figure 5 "Cable connections", appended tables 3-1 to 3-4 "List of inter-unit cables", and appended figures 3-1 and 3-2 "Pit layout example".

8.7 Installing a Communication Line for InnerVision

The Toshiba medical equipment remote maintenance system InnerVision is intended to provide the following service functions:

- Diagnosis, inspection, etc. of the medical equipment
- Image check

By installing a service processor between the medical equipment and a communication line, externally transferred information is restricted (masking of personal ID information included in the image information such as patient name) to prevent transmission of personal information over a communication line, thus ensuring privacy and improving security.

Installation of the medical equipment, a service processor, and a single communication line for connection to the TAC (Technical Assistance Center) computer should be completed within the warranty period (including the period of installation of the equipment).

(1) Operating conditions

1. InnerVision remote support service expires when the warranty period of the equipment ends.

If a maintenance contract is signed after the warranty period ends, InnerVision remains available. Otherwise, the InnerVision service processor can no longer be used.

2. Since some facilities at the institution may be required for InnerVision, obtain prior permission from the user.

9. AIR CONDITIONING/WATER SUPPLY AND DRAINAGE WORKS

9.1 Air Conditioning

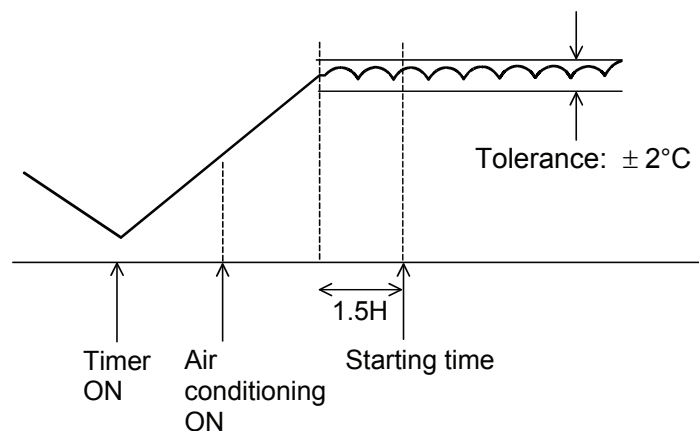
(1) Air conditioning system

Refer to calorific values and environmental requirements of each room given in appended table 1 and install an air conditioning system which satisfies the given environmental requirements. Insure appropriate air flow in the rooms so that temperature distribution is uniform.

Take extreme care with air conditioning in the scanning room. Temperature fluctuation in this room must be within the range given in the specification. The temperature setting need not be constant throughout year. It is important to have the same temperature when calibration data is acquired as when examinations are performed. It is recommended, however, that the temperature be maintained at approximately 26°C for patient comfort.

The temperature in the scanning room should be within the tolerance 1.5 hours before the first examination every morning. When the door is opened, for example, to bring the patient in or out, the temperature can be outside the tolerance for a short time (approximately 3 minutes). The appropriate temperature, however, should be restored until scanning of the next patient is started.

In addition, take care that the temperature near the floor does not get too low or high, because air near the floor is taken into the gantry. (Check for the presence of a boiler room downstairs or if air is cold near the floor because the scanning room is located in the basement.)



Temperature conditions in the scanning room

⚠ CAUTION: The scanning room must be provided with an independent air conditioning system. Even if the room is maintained within the permissible temperature range, gradual temperature shifts (for example, a slow increase in room temperature from morning to evening) may adversely affect system performance. Therefore, the room temperature must be under constant control as shown in the above figure.

(2) Dust

Since the inside of the console is easily affected by dust, take extreme care to keep dust from the console.

9.2 Water Supply and Drainage

A water supply and drainage facility is not required for this system, however, it is recommended that a washstand be provided.

10. APPENDED TABLES AND FIGURES

- | | | | |
|------|--------------------------------|---|---|
| (1) | Appended table 1 | : | Heat generation by units and environmental conditions |
| (2) | Appended tables 2-1 and 2-2 | : | External dimensions and mass |
| (3) | Appended tables 3-1 to 3-4 | : | List of inter-unit cables |
| (4) | Appended figures 1-1 to 1-4 | : | External dimensions and mass of the gantry and patient couch |
| (5) | Appended figures 2-1 and 2-2 | : | Room layout example |
| (6) | Appended figures 3-1 and 3-2 | : | Pit layout example |
| (7) | Appended figures 4-1 and 4-2 | : | Power supply system |
| (8) | Appended figure 5 | : | Cable connections |
| (9) | Appended figure 6 | : | Inter-unit distances |
| (10) | Appended figure 7 | : | Floor leveling work using epoxy resin |
| (11) | Appended figures 8-1 and 8-2 | : | Gantry and patient couch |
| (12) | Appended figures 9-1 and 9-2 | : | Grounding and anchoring positions of the gantry and the patient couch |
| (13) | Appended figures 10-1 and 10-2 | : | Layout of the gantry and patient couch |
| (14) | Appended figure 11 | : | Console |
| (15) | Appended figure 12 | : | Speaker |
| (16) | Appended figure 13 | : | System transformer (CETF004B) |

APPENDIX 1 APPENDED TABLES, FIGURES AND OUTLINE DRAWINGS

Appended table 1 Heat generation by units and environmental conditions

Names of rooms and units	Maximum heat generation ^{*1}		Normal heat generation ^{*1}		Environmental conditions	
	[kW]	[kJ/h] ^{*2}	[kW]	[kJ/h]	Temperature ^{*3} (°C)	Relative humidity (%)
1. Scanning room	(9.4)	(33870)	(3.0)	(10800)	20°C to 26°C Tolerance: ±2°C	40% to 80% (No condensation)
• Gantry	8.9	32070	2.7	9720		
• Patient couch	0.5	1800	0.3	1080		
2. Scan control room	(2.7)	(9720)	(2.7)	(9720)	16°C to 28°C	40% to 80% (No condensation)
• Console	2.7	9720	2.7	9720		

*1: Maximum heat generation is the heat that is generated when continuous scanning is performed at the maximum output rating of the unit.

Normal heat generation is the heat that is generated when scanning is not performed.

*2: 1 kW = 860 kcal/h, 1 cal = 4.19 J

*3: A temperature from 0°C to 40°C is permissible if the units are not operated.

Appended table 2-1 External dimensions and mass

Unit name	External dimensions			Mass (kg)
	Width (mm)	Depth (mm)	Height (mm)	
Gantry (with cover)	2070	900	1910	1280
Patient couch [CBTB-018A]	630	2690	450	450
Patient couch [CBTB-018B]	630	2390	450	420
Navibox CPU BOX	450	815	700	100
REC BOX	450	815	700	85
Keyboard	574	247	90	3
19-inch LCD monitor	414	203	500	8
Speaker	140	135	200	2

Appended table 2-2 External dimensions and mass (optional)

Unit name	External dimensions			Mass (kg)
	Width (mm)	Depth (mm)	Height (mm)	
Patient monitor	225	260	240	6
Camera (including lens and stand)	105	380	315	4
System transformer	800	770	980	550

Appended table 3-1 List of inter-unit cables (1/2)

Power cables

*: Values in parentheses are for multislice systems.

Cable No.	Wiring pit	Connected to: (1)	Connected to: (2)	Standard length (m)*	Effective length (m)*	Retract length (m)	Maximum length (m)	Number of cores × section area (mm ²)	Outer cable diameter (mm)	Connector diameter (mm)	Remarks
P01	P	Gantry	Console	14	12	1.5 while connecting to (1) 0.5 while connecting to (2)	19	3 cores × 5.5	17.5		Solderless contact while connecting to (1) Solderless contact while connecting to (2)
P03	P	System transformer	Gantry	11 (15)	8 (12)	1.5 while connecting to (1) 1.5 while connecting to (2)	15	3 cores × 35	35.2		Solderless contact while connecting to (1) Open wire while connecting to (2)
P04	P	Gantry	Console	14 (19)	12 (17)	1.5 while connecting to (1) 0.5 while connecting to (2)	19	6 cores × 0.75	11.5		Solderless contact while connecting to (1) Connector (28 × 21 × 28) plus solderless contact
P00	P	Power box	System transformer	5	3	1.5 while connecting to (1) 0.5 while connecting to (2)	5	3 cores × 35	35.3		Solderless contact while connecting to (2)

Appended table 3-1 List of inter-unit cables (2/2)

Power cables

*: Values in parentheses are for multislice systems.

Cable No.	Wiring pit	Connected to: (1)	Connected to: (2)	Standard length (m)*	Effective length (m)*	Retract length (m)	Maximum length (m)	Number of cores × section area (mm ²)	Outer cable diameter (mm)	Connector diameter (mm)	Remarks
E01	P	Power box	Gantry	11 (15)	8 (12)	1.5 while connecting to (1) 1.5 while connecting to (2)	15	1 core × 35	12.2	Solderless contact while connecting to (1) Solderless contact while connecting to (2)	
E00	P	Power box	System transformer	5	3	1.5 while connecting to (1) 0.5 while connecting to (2)	5	1 core × 35	11.94	Solderless contact while connecting to (2)	

Appended table 3-2 List of inter-unit cables (TSX-031A multislice system)

Signal cables

Cable No.	Wiring pit	Connected to: (1)	Connected to: (2)	Standard length (m)*	Effective length (m)*	Retract length (m)	Maximum length (m)	Number of cores × section area (mm ²)	Outer cable diameter (mm)	Connector diameter (mm)	Remarks
S01	S	Console	Gantry	14 (19)	12 (17)	0.5 while connecting to (1) 1.5 while connecting to (2)	19	1 pair Optical fiber	11	Connector (22 × 8 × 25)	
S02	S	Console	Gantry	14 (19)	12 (17)	0.5 while connecting to (1) 1.5 while connecting to (2)	19	36 cores × 0.08 shielding	11.3	Connector (62 × 20 × 52) while connecting to (1) Connector (62 × 20 × 52) while connecting to (2)	
S03	S	Console	(a) Gantry	14 (19)	12 (17)	0.5 while connecting to (1)	19	3 cores × 0.18 shielding	4.2	Connector (φ29 × 52) while connecting to (1)	
			(b) Speaker (Gantry)	14 (19)	12 (17)	1.5 while connecting to (2)-(a)	19	2 cores × 0.5 shielding	5.1	Connector (φ25 × 49) while connecting to (2)-(a)	
			(c) Speaker (C-room)	11	9	1.5 while connecting to (2)-(b) 1.5 while connecting to (2)-(c)	11	2 cores × 0.5 shielding	5.1		

Appended table 3-3 List of inter-unit cables

Cables attached to the gantry

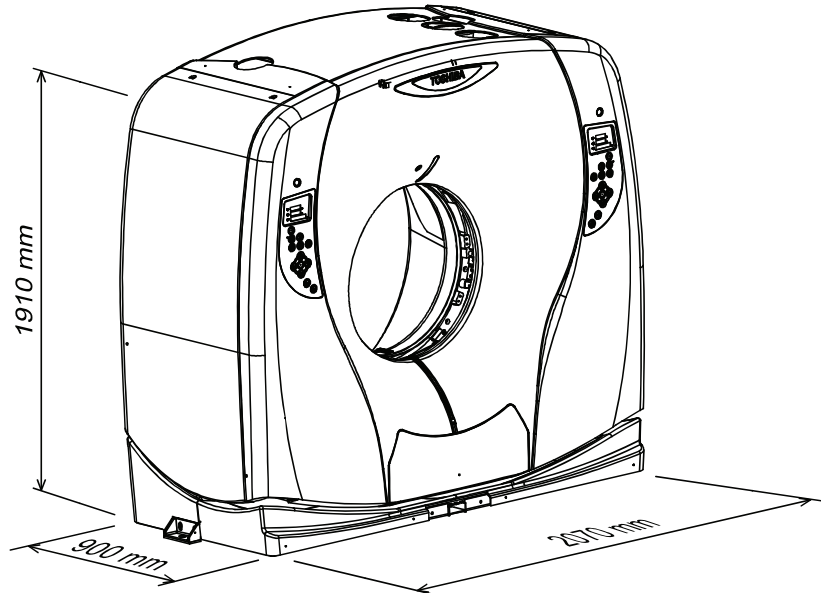
Cable No.	Wiring pit	Connected to: (1)	Connected to: (2)	Standard length (m)*	Effective length (m)*	Retract length (m)	Maximum length (m)	Number of cores × section area (mm ²)	Outer cable diameter (mm)	Connector diameter (mm)	Remarks
FCS12	S	Gantry	Patient couch	–	–	–	–	25TP × 0.08 shielding	8.3	Connector (77 × 20 × 52)	(1) connected inside gantry while connecting to (2)
FCP40	P	Gantry	Patient couch	–	–	–	–	8 cores × 0.75 3 cores × 0.5	9.1 6.4	Connector (28 × 33 × 28) Compound cable	(1) connected inside gantry Compound cable
FCP39	P	Gantry		–	–	–	–	4 cores × 0.5	6.5		
FCE01	E	Gantry	Patient couch	–	–	–	–	1 core × 8.9	7.8	Solderless contact while connecting to (2)	(1) connected inside gantry

Appended table 3-4 List of cables between the consoles (CPU BOX - REC BOX)

Cables for connection between the consoles are required.

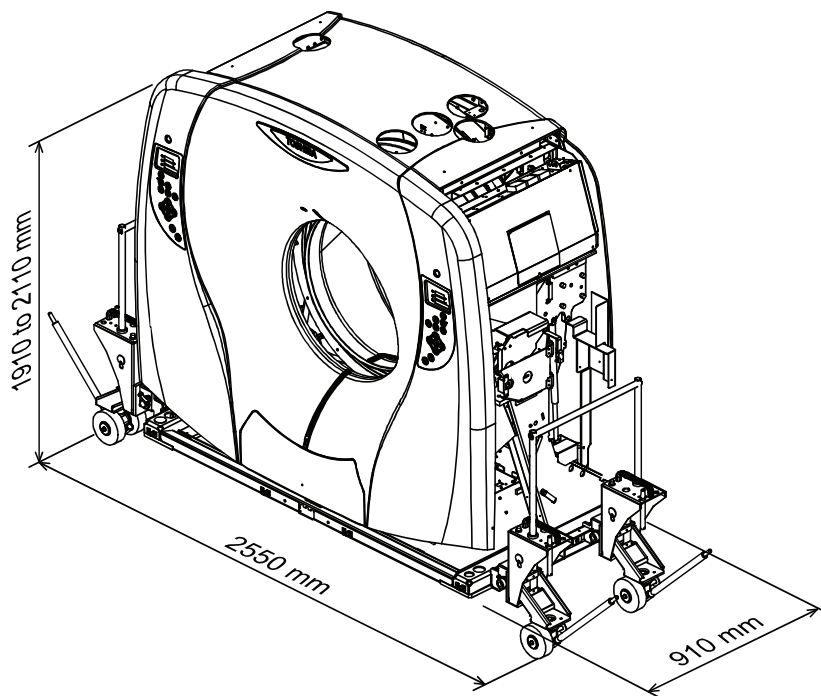
Cable No.	Wiring pit	Connected to: (1)	Connected to: (2)	Standard length (m)*	Effective length (m)*	Retract length (m)	Number of cores × section area (mm ²)	Outer cable diameter (mm)	Connector diameter (mm)	Remarks
CS01		CONSOLE CPU BOX	CONSOLE REC BOX	6	6	0.4	2 cores Optical fiber	11	Connector (22 × 8 × 25)	Minimum permissible bending radius: 110 mm
CS02		CONSOLE CPU BOX	CONSOLE REC BOX	6	6	0.4	25 pairs × 0.38 shielding	12.3	Connector (52.4 × 39 × 12.7)	
CS03		CONSOLE CPU BOX	CONSOLE REC BOX	6	6	0.4	25 pairs × 0.38 shielding	12.3	Connector (72.9 × 49 × 19)	
CP01		CONSOLE CPU BOX	CONSOLE REC BOX	6	6	0.4	3 cores × 1.93	14.2	Crimp terminal	

Recommended values for bringing-in route	
Door height	2070 mm or more
Door width	980 mm or more



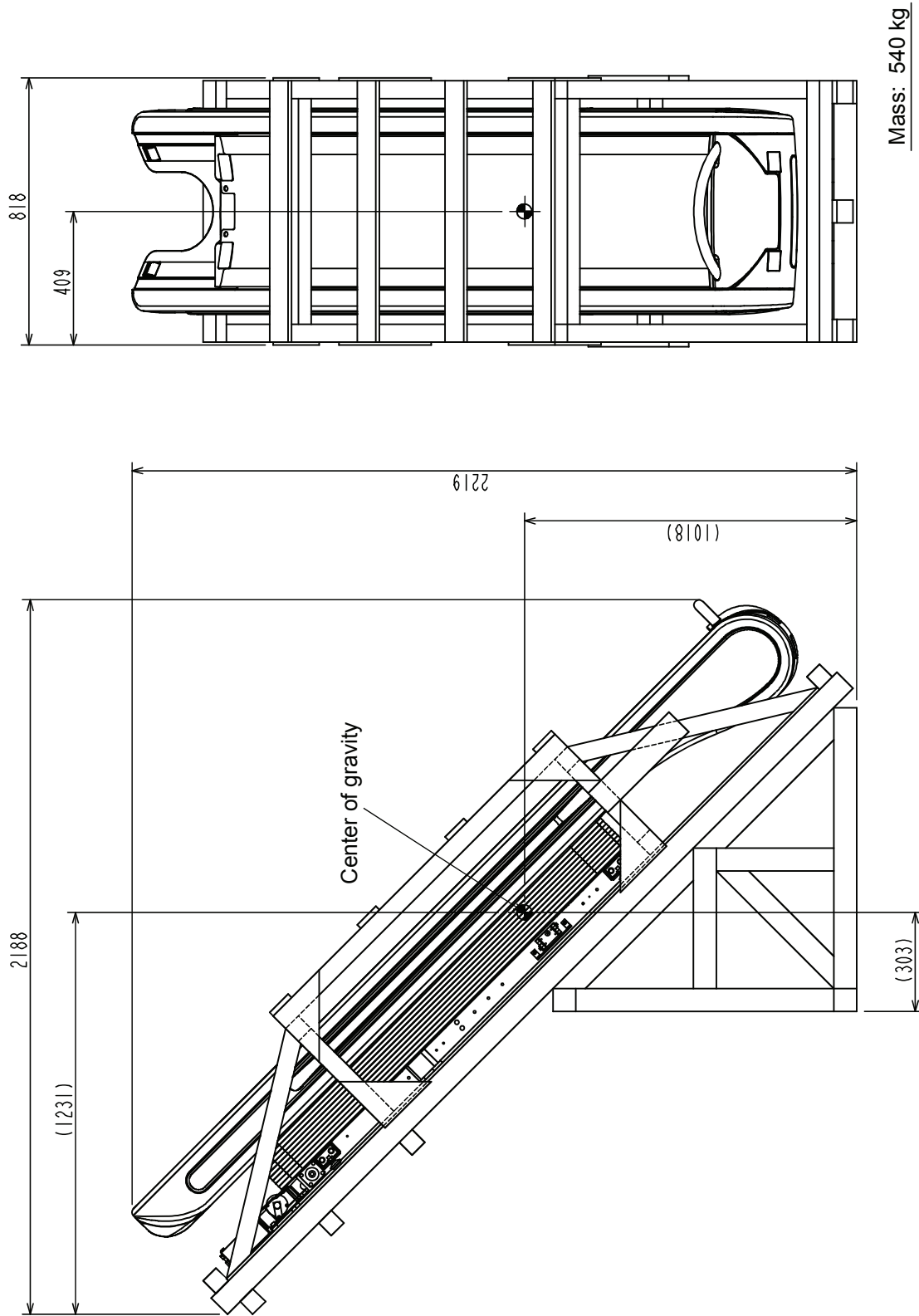
Mass: 1280 kg

Appended figure 1-1 External dimensions and mass of the gantry and required size of the bringing-in entrance

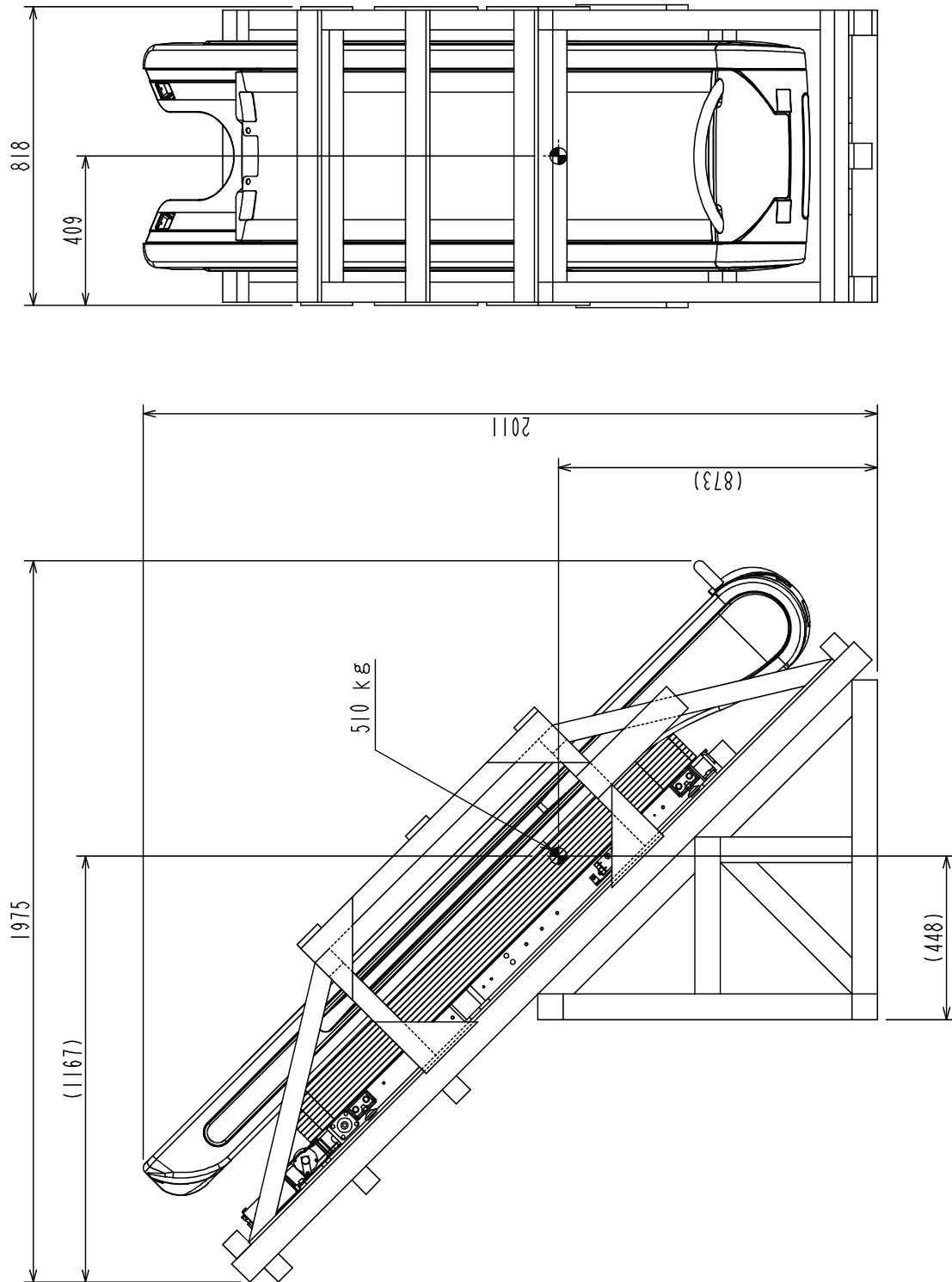


Mass: 1420 kg (including the bringing-in jig)

Appended figure 1-2 External dimensions and mass of the gantry with the gantry bringing-in jig mounted



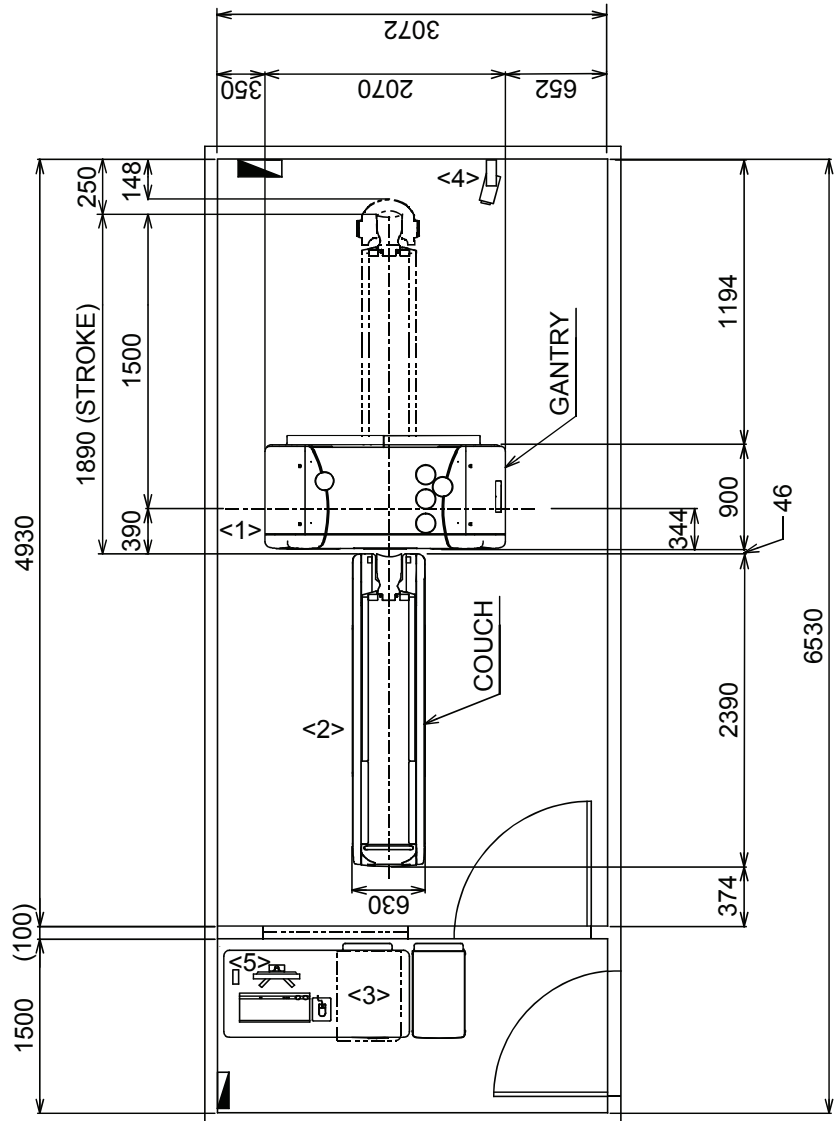
Appended figure 1-3 External dimensions and mass of the patient couch (CBTB-018A) when the tilted bringing-in method is used



Appended figure 1-4 External dimensions and mass of the patient couch (CBTB-018B) when the tilted bringing-in method is used

Patient couch: CBTB-018B

- <1> Gantry
- <2> Patient couch (CBTB-018B)
- <3> Console (CPU BOX, REC BOX, Liquid-crystal monitor, Keyboard, Mouse)
- <4> Patient observation system (This is not included in the system configuration. In this example layout, the patient observation monitor is provided by the hospital.)
- <5> PC for InnerVision



Unit: mm

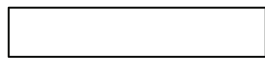
Appended figure 2-2 Room layout example

Patient couch: CBTB-018A

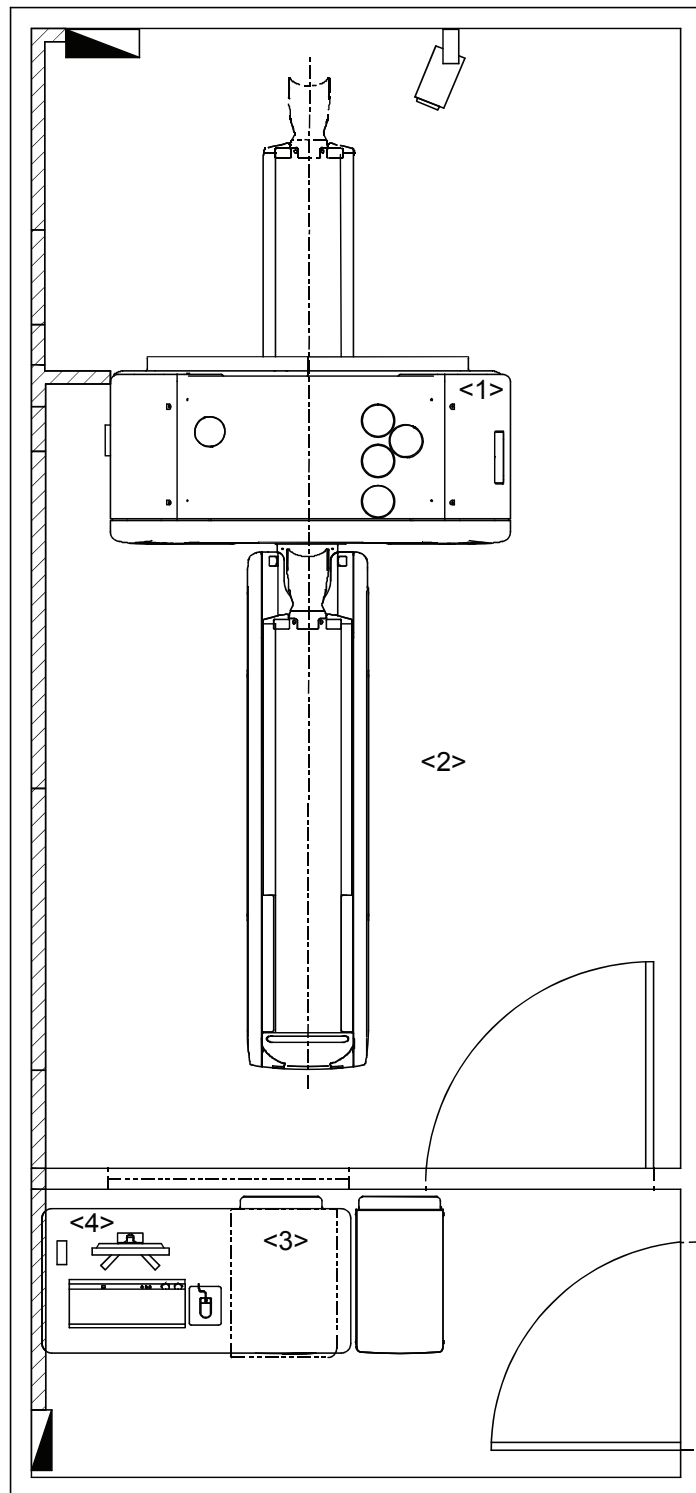
- <1> Gantry
- <2> Patient couch (CBTB-018A)
- <3> Console (CPU BOX, REC BOX, Liquid-crystal monitor, Keyboard, Mouse)
- <4> PC for InnerVision



Pit for power cable



Pit for signal cable



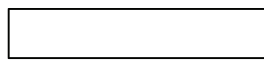
Appended figure 3-1 Pit layout example

Patient couch: CBTB-018B

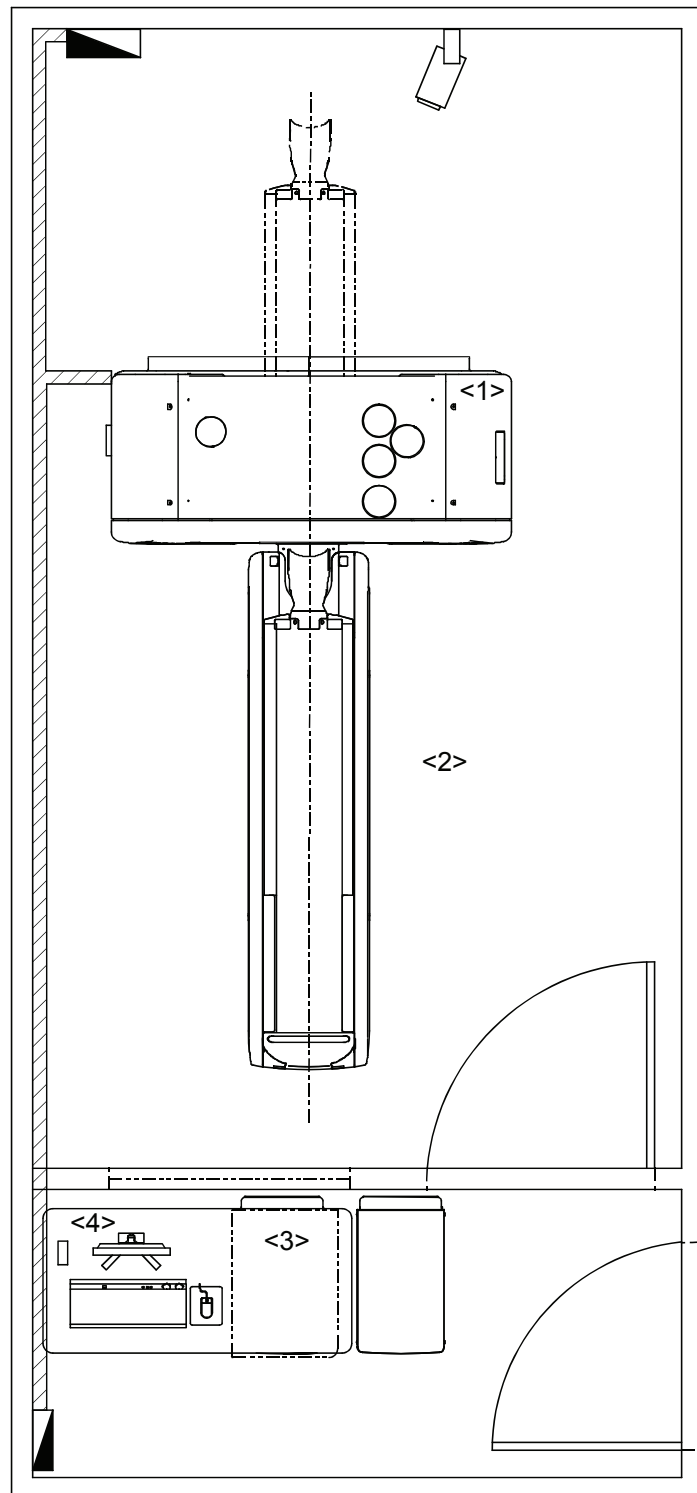
- <1> Gantry
- <2> Patient couch (CBTB-018B)
- <3> Console (CPU BOX, REC BOX, Liquid-crystal monitor, Keyboard, Mouse)
- <4> PC for InnerVision



Pit for power cable



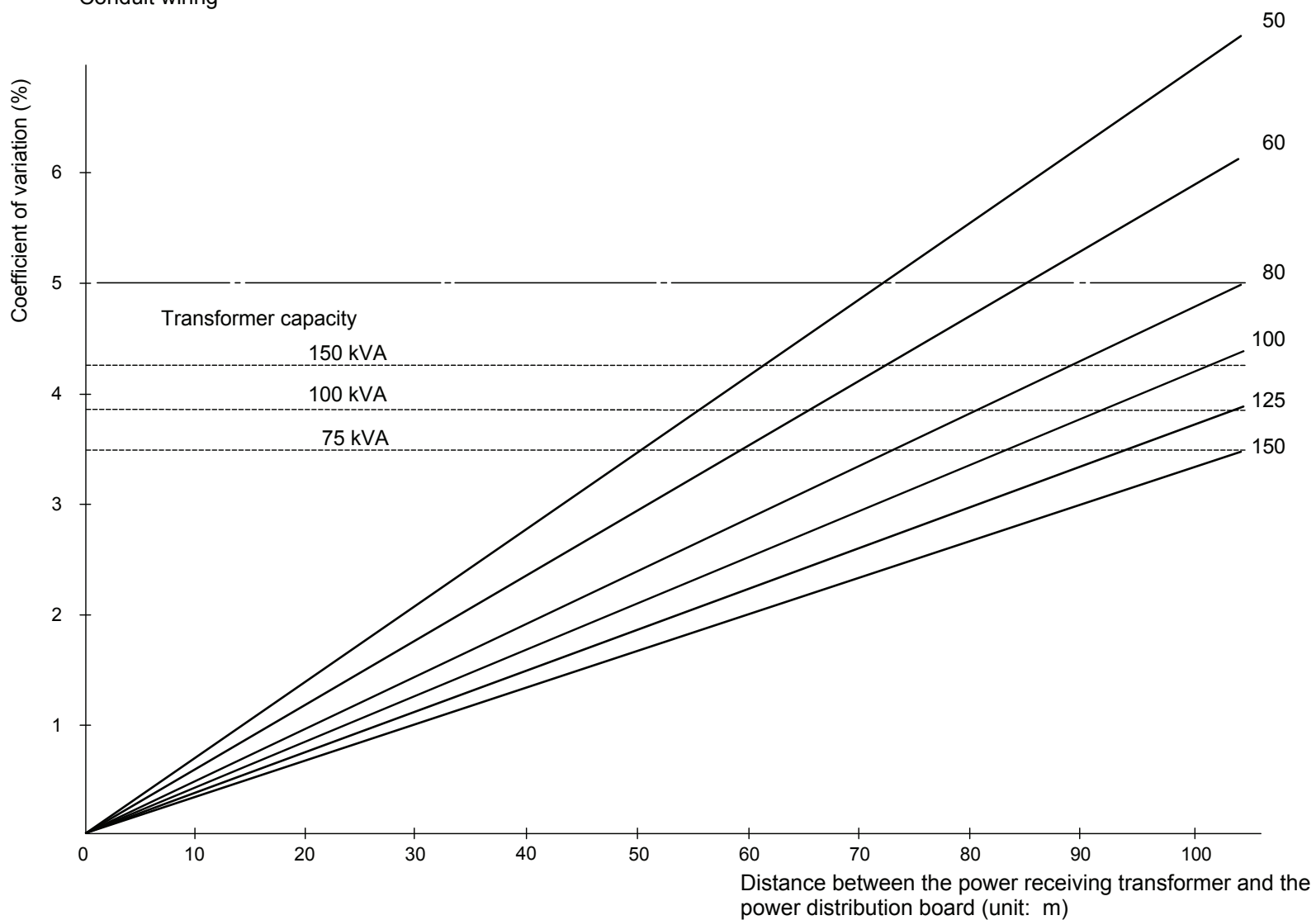
Pit for signal cable



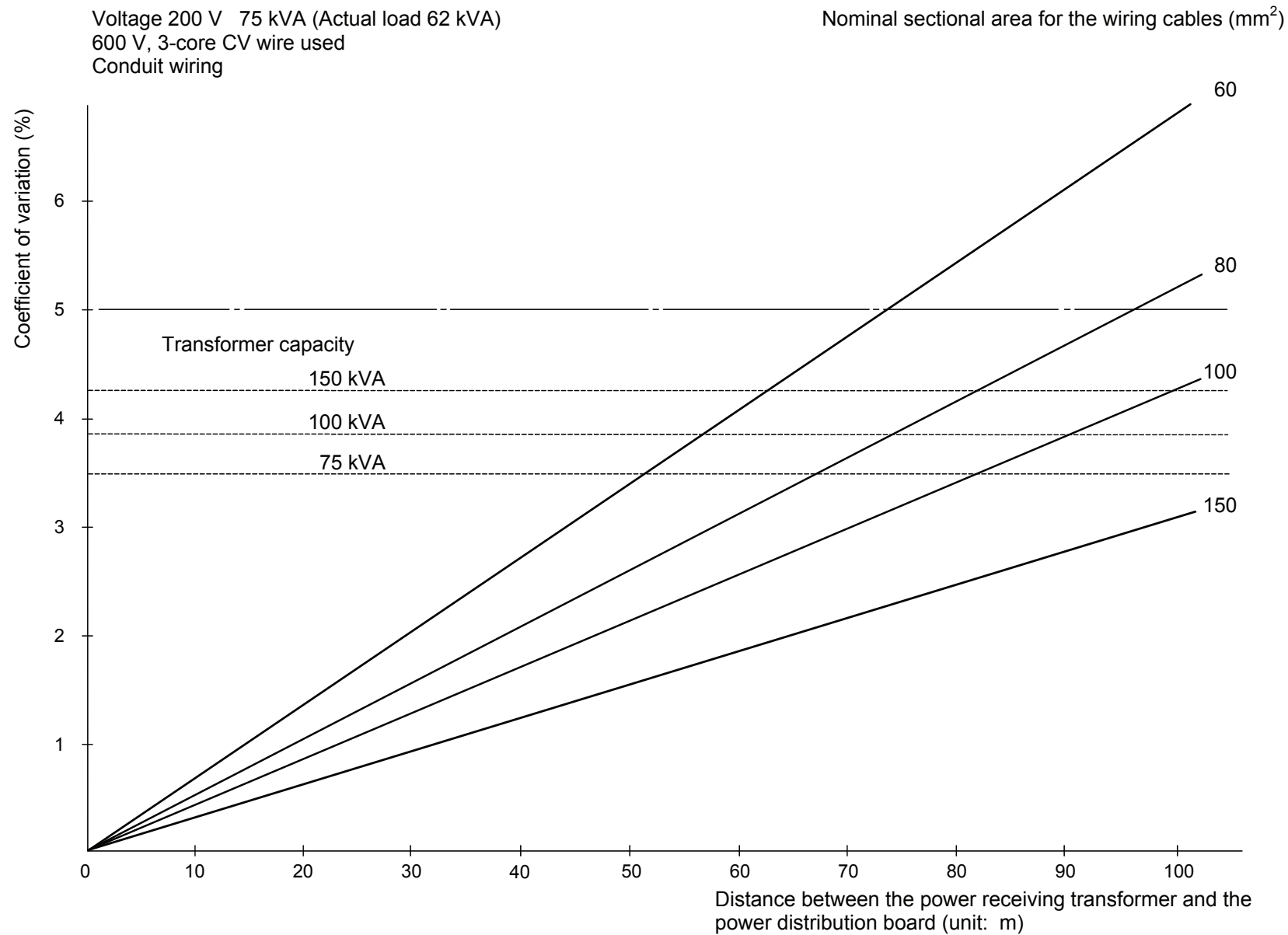
Appended figure 3-2 Pit layout example

Voltage 200 V 75 kVA (Actual load 57 kVA)
 600 V, IV wire used
 Conduit wiring

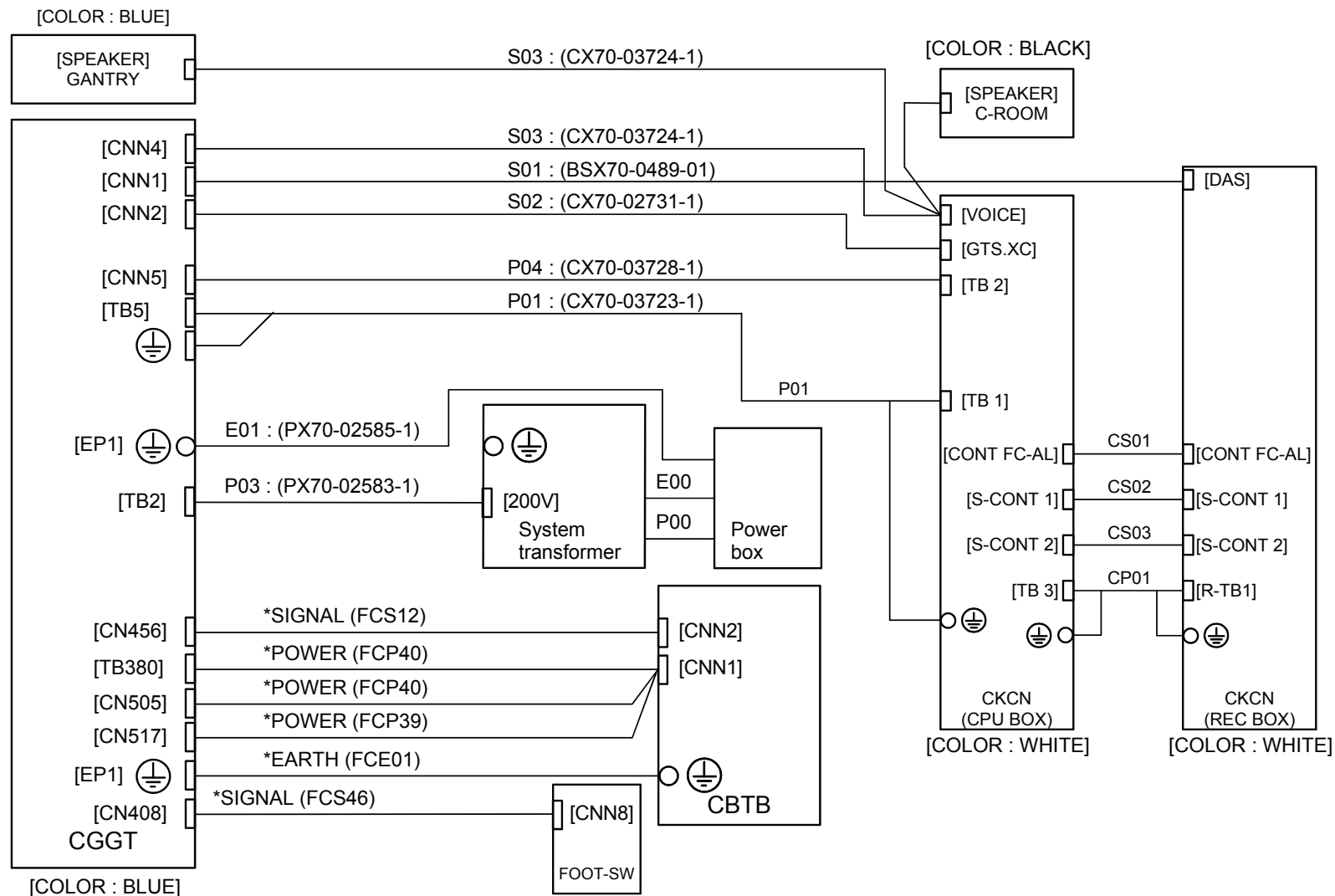
Nominal sectional area for the wiring cables (mm²)



Appended figure 4-1 Power supply system

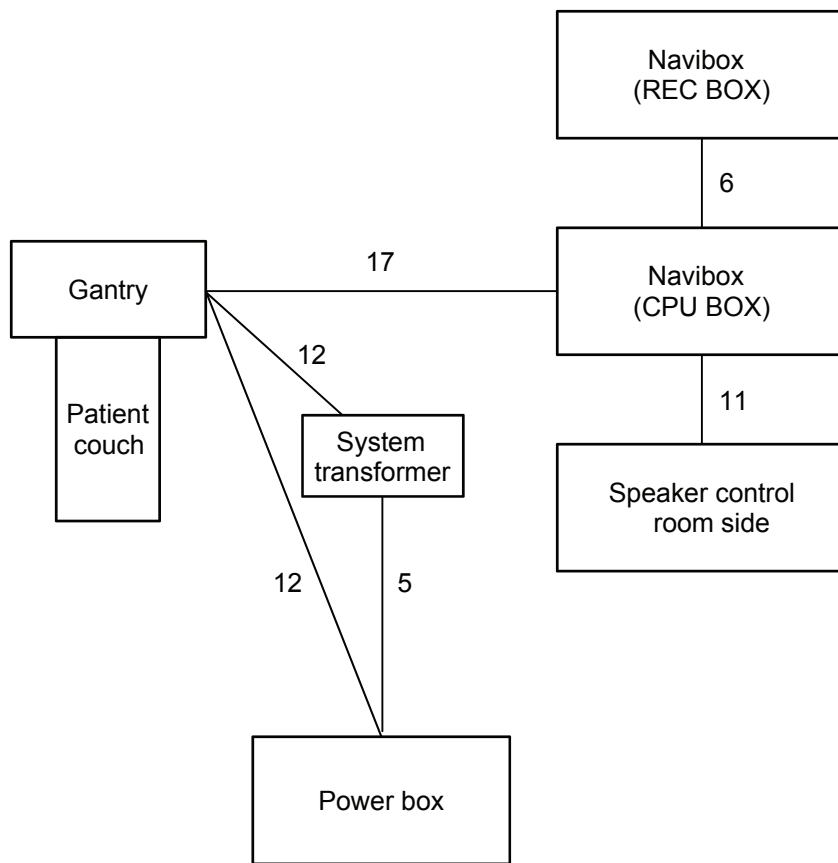


Appended figure 4-2 Power supply system



Note: The FCP40 and FCP39 cables are connected to CNN1 of CBTB.
 The CNN1 connector is mounted to FCP40 and the FCP39 cable is connected later.

Appended figure 5 Cable connections

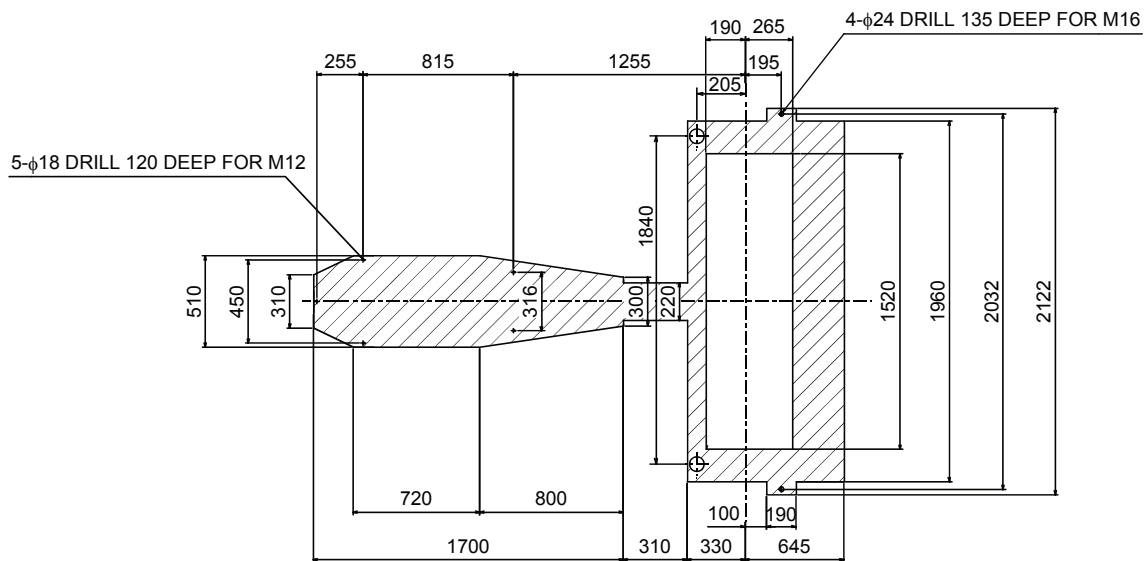


Unit: m

Distance between the units = Cable length - Retract length
 (Refer to appended tables 3-1 and 3-2.)

(Distance between the units when cables of standard lengths are used)

Appended figure 6 Inter-unit distances



Appended figure 7 Floor leveling work using epoxy resin

Note: During floor work, pour epoxy resin into the range shown in the figure above to make the installation surface.

(1) Epoxy resin

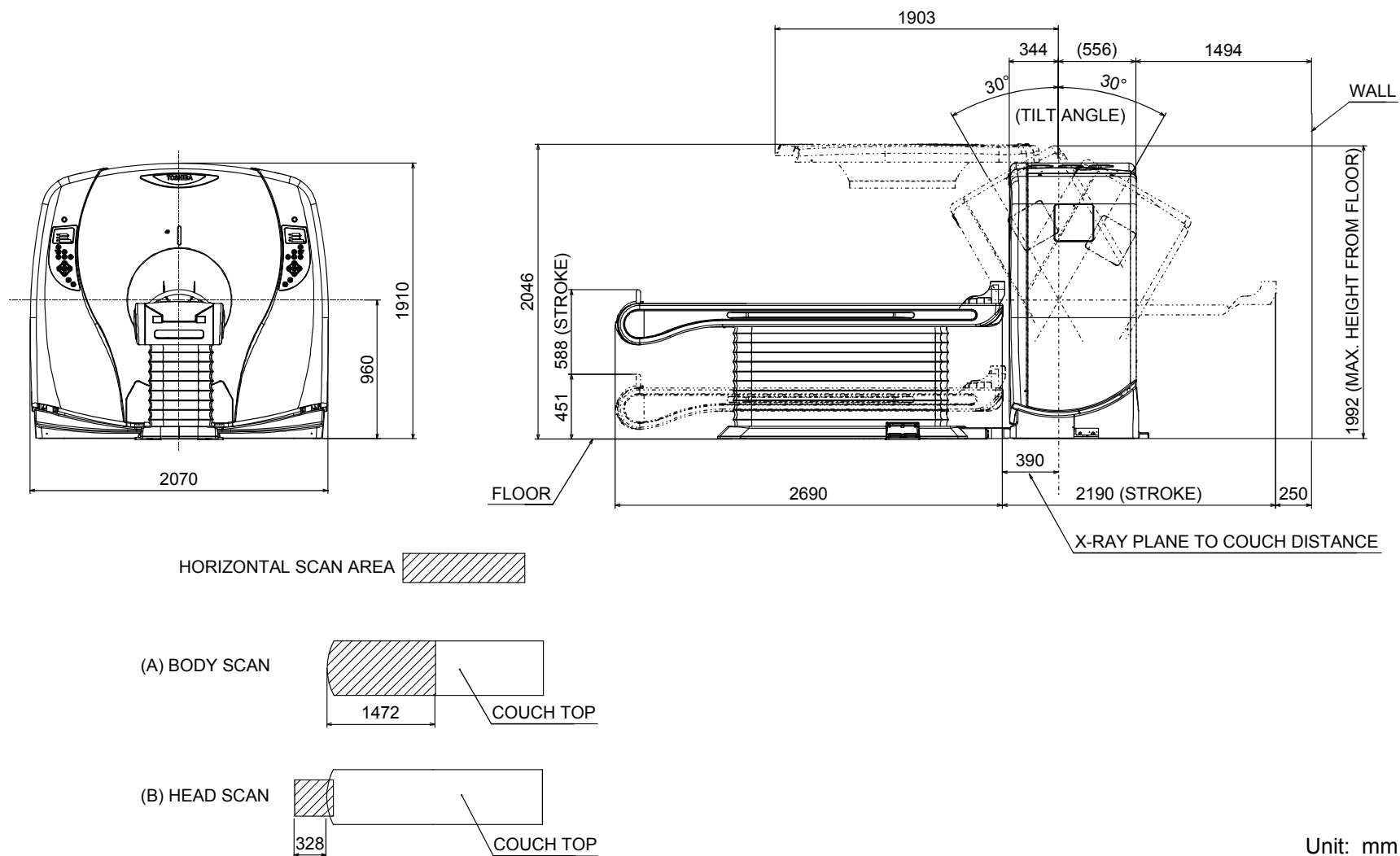
- Epoxy resin (Epichlon 857) specific gravity 1.2
- Hardener (Epichlon B-065) specific gravity 1.2

Mixture ratio : 857: B-065 = 3:1 (w/w)

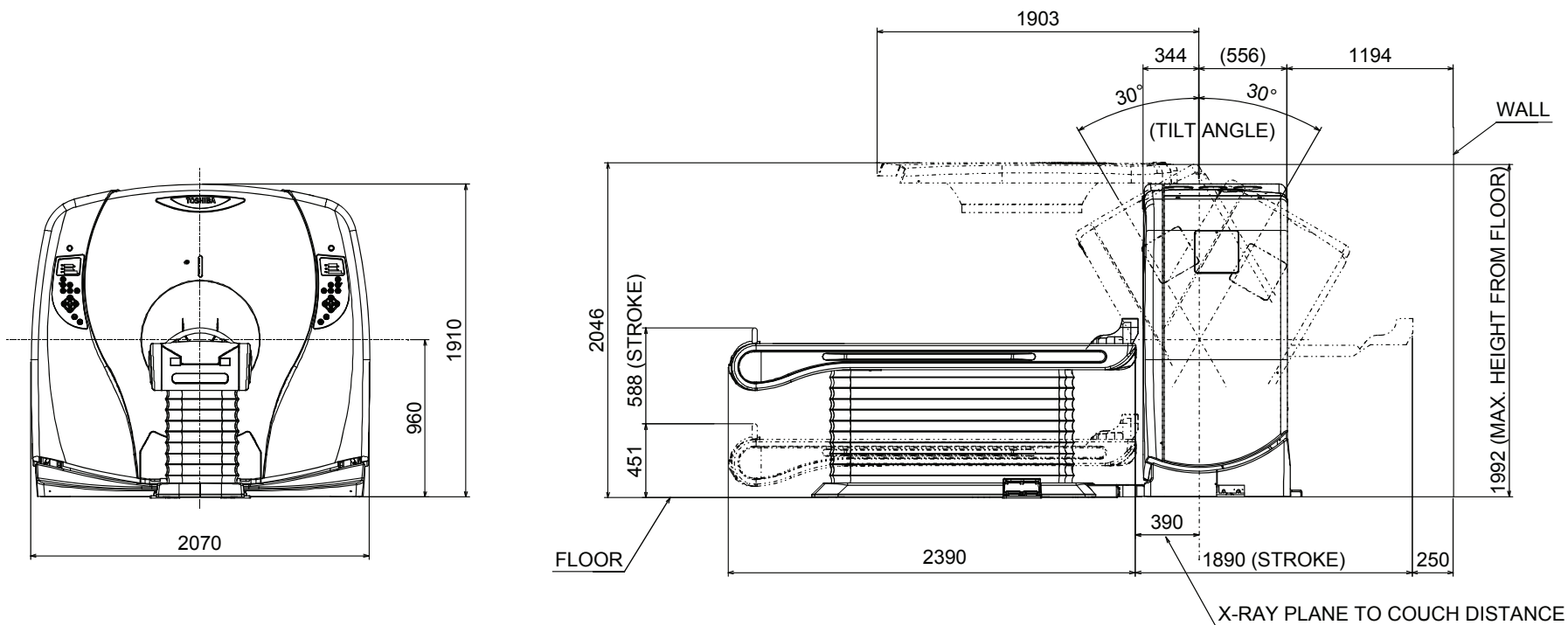
The proper mixture ratio should be confirmed with the manufacturer because the ratio differs depending on the particular formulation.

Time required for hardening : 48 hours at ordinary room temperature
(ambient temperature 25°C)

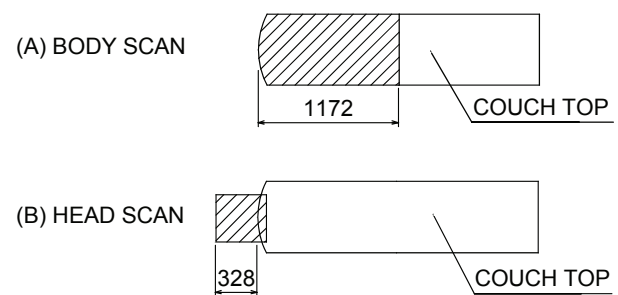
- (2) Complete this work before carrying in the system because a period of 2 to 5 days is required for the epoxy resin to harden (differs depending on the temperature).
- (3) For procedures for pouring epoxy resin, refer to APPENDIX 3 "FLOOR LEVELING WORK MANUAL" attached to this site planning manual.
- (4) The tolerance for the dimensions given in the figure above is within ± 1 mm, which can be measured using a tape measure.



Appended figure 8-1 Gantry and patient couch (for patient couch CBTB-018A)

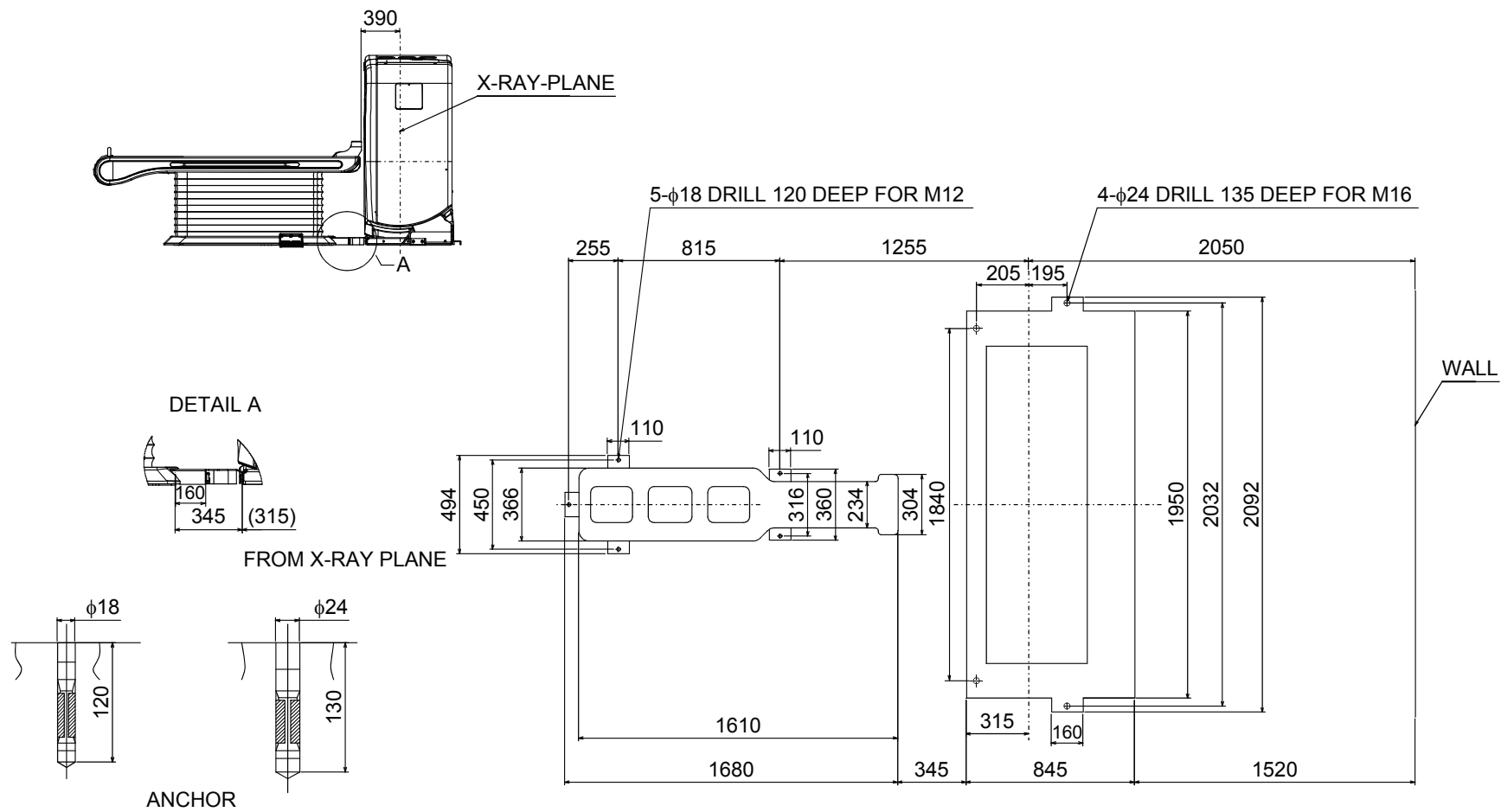


HORIZONTAL SCAN AREA



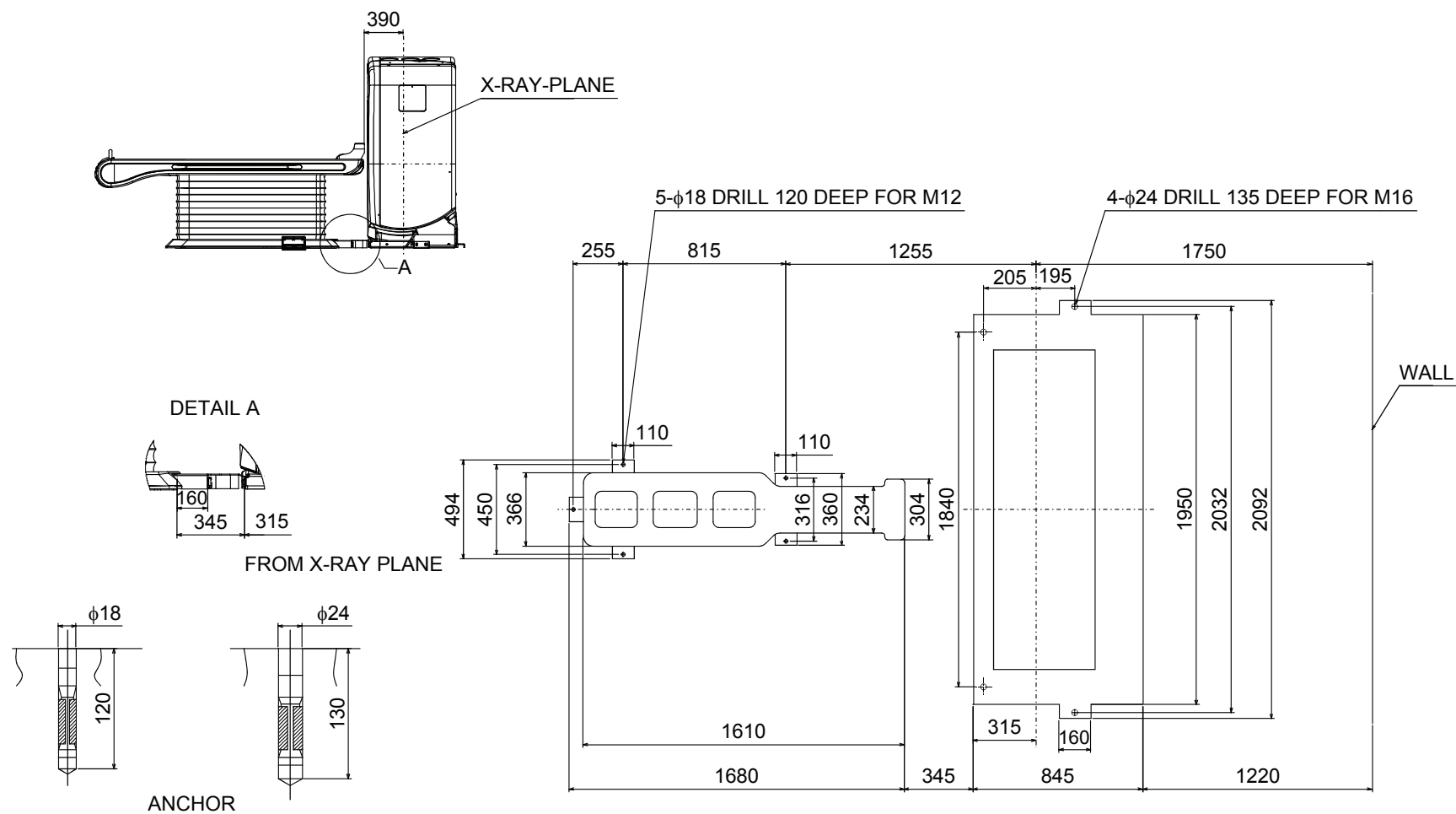
Unit: mm

Appended figure 8-2 Gantry and patient couch (for patient couch CBTB-018B)



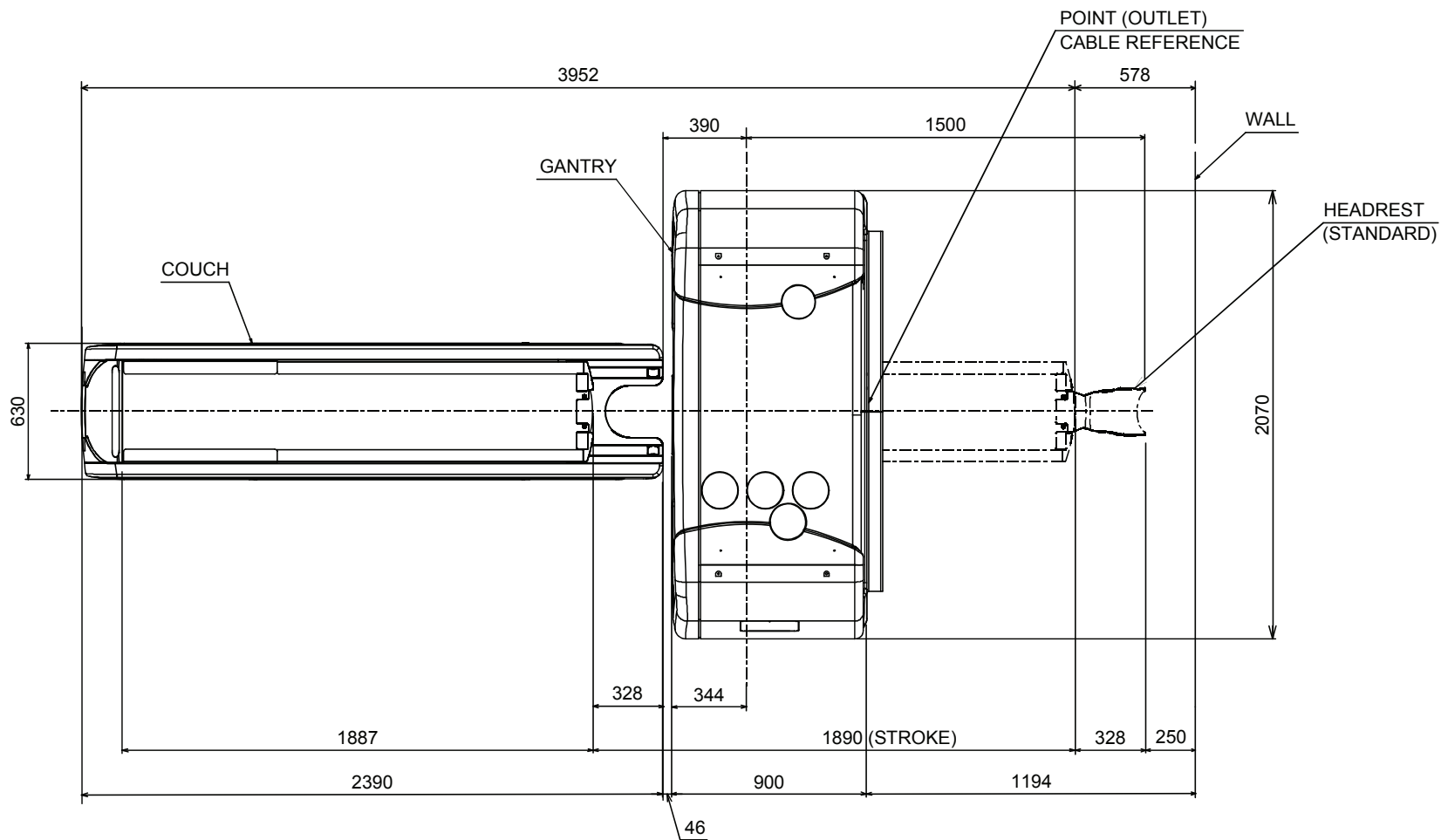
Unit: mm

Appended figure 9-1 Grounding and anchoring positions of the gantry and the patient couch (for patient couch CBTB-018A)



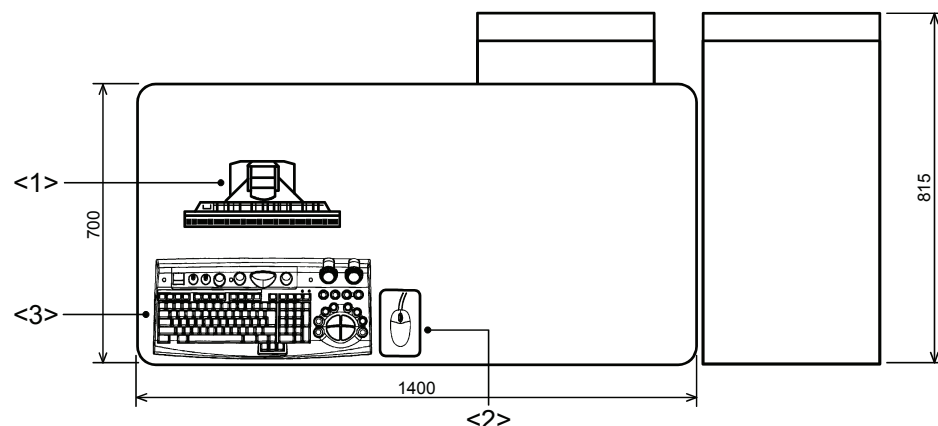
Unit: mm

Appended figure 9-2 Grounding and anchoring positions of the gantry and the patient couch (for patient couch CBTB-018B)



Unit: mm

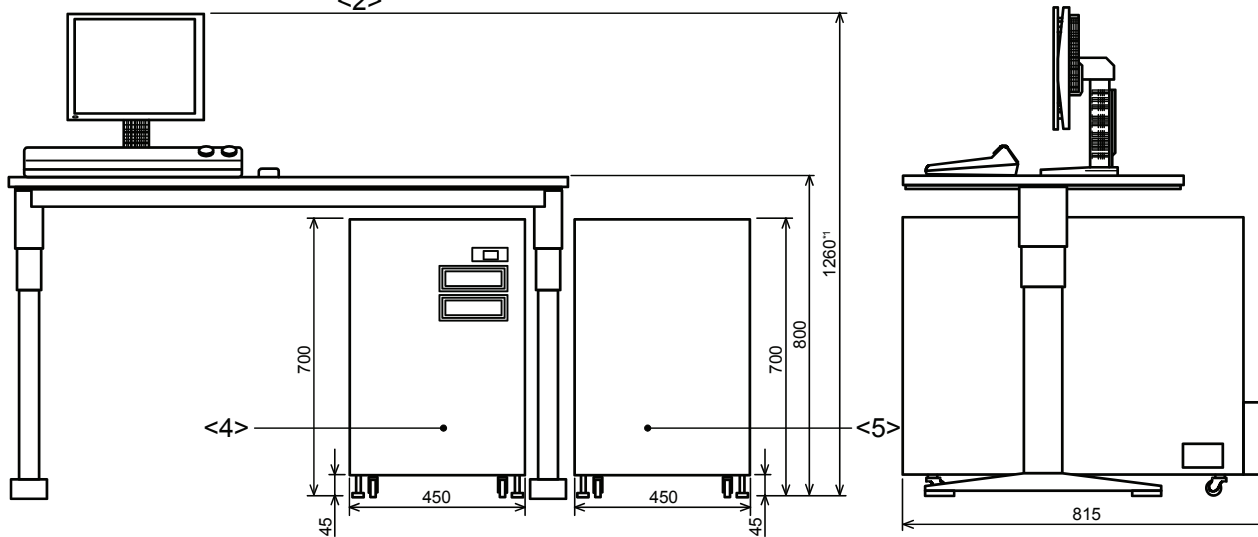
Appended figure 10-2 Layout drawing (top view) of the gantry and patient couch (patient couch: CBTB-018B)



- <1> Liquid-crystal monitor
- <2> Mouse
- <3> Keyboard
- <4> Navibox (CPU BOX)
- <5> Navibox (REX BOX)

Cable length

- Between the Navibox (CPU BOX) and the keyboard : 6 m
- Between the Navibox (CPU BOX) and the monitor : 6 m
- Between the keyboard and the mouse : 1.8 m

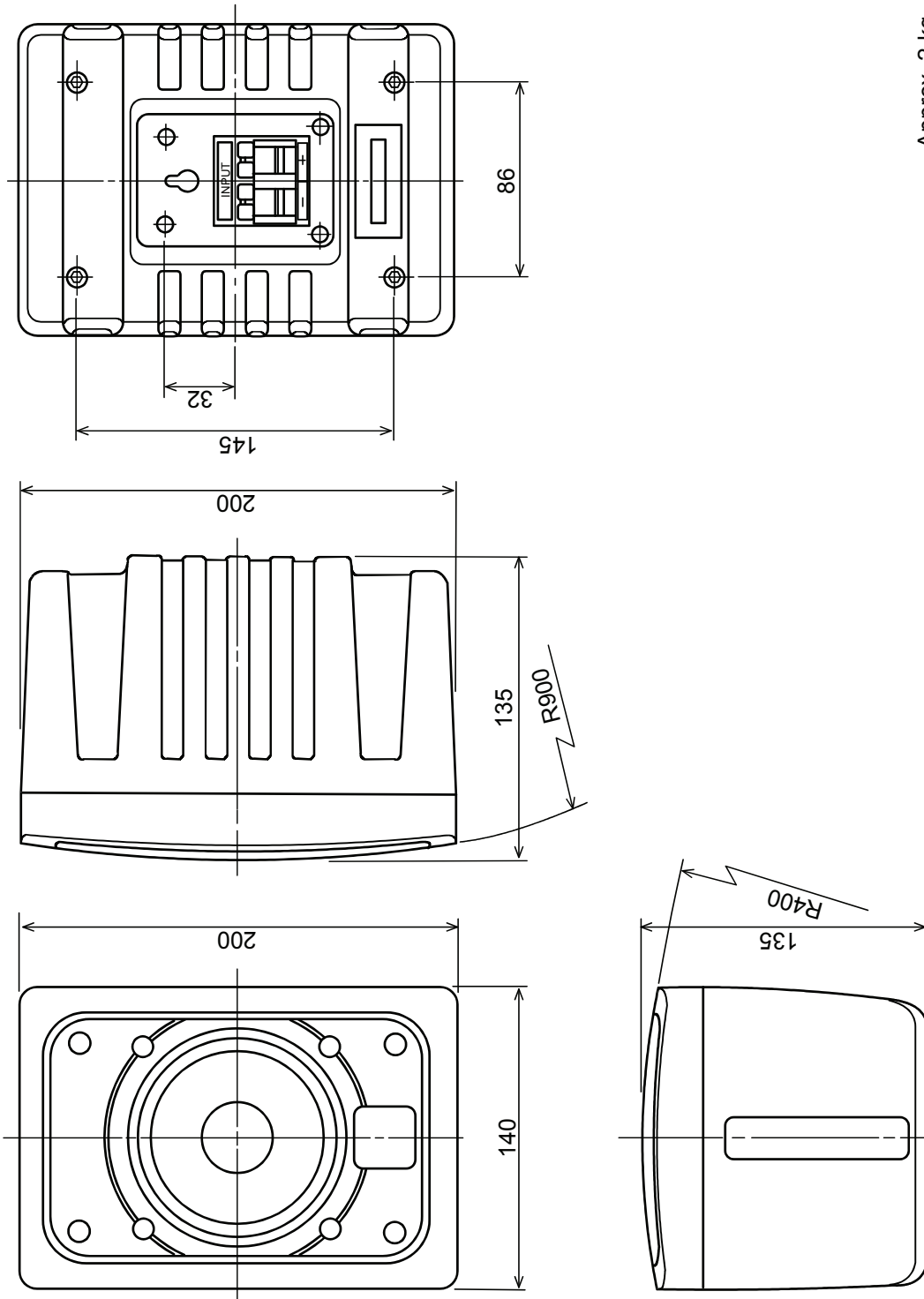


Unit: mm

Appended figure 11 Console

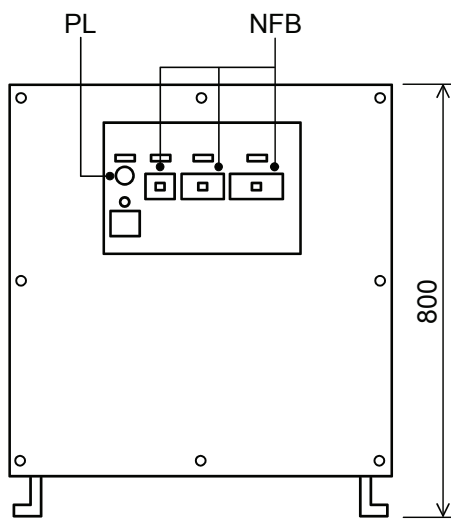
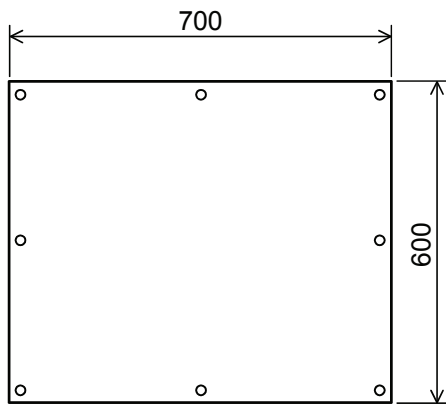
(Note: The desk used is a recommended one. The desk must be provided at the site.)

*1 The height of the monitor is adjustable (± 50 mm).

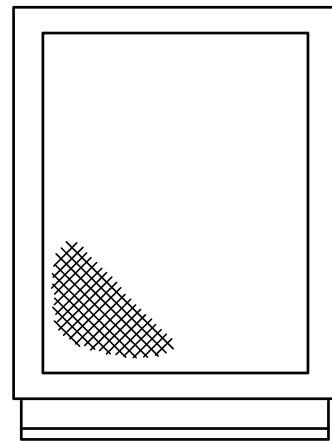


Approx. 2 kg

Appended figure 12 Speaker



Front side



Approx. 400 kg

Appended figure 13 System transformer (CETF004B)

APPENDIX 2 HANDLING EMC

1. Introduction

With regard to EMC, information regarding EMI noise and static electricity are described below.

2. Effects of EMI Noise and Countermeasures

(1) Symptoms

Some of the symptoms of EMI noise are listed below:

1. Noise occurs on the screen of an ultrasound system being used near the CT system.
2. Waveforms obtained by ECG equipment used near the CT system are irregular.
3. Noise which causes flickering on CRTs used near the CT system.
4. An abnormal image or a communication error may occur if an electric scalpel or a microwave unit is used.

(2) Causes

The X-ray unit of the CT system includes a large capacity inverter unit. When this inverter unit operates, EMI noise in the MHz range level conforms to the IEC 60601-102 standards, some system combinations may generate noise problems.

In particular, when an ultrasound system is used in the vicinity of a CT system, the former is easily affected by noise produced by the latter.

Possible routes of transmission of EMI noise are listed below.

1. EMI noise is radiated from the CT system, CT cables, etc. to the air in the form of the electric wave and enters the ultrasound system via the ultrasound system cable or some other unit connected with the ultrasound system which plays the role of an antenna. (This is called radiation noise.)
2. EMI noise transmits through a CT system cable, transfers to an ultrasound system cable, and enters the ultrasound system through this cable. (This is called conduction noise.)

The routes of noise entry described above may often exist simultaneously.

(3) Countermeasures

There are two main approaches to counter this problem; the prevention of noise generation in the system generating the noise, and the prevention of noise entry into the system affected by the noise. Both approaches must be investigated as countermeasures.

Actual countermeasures are described below for the example of an ultrasound system, electric scalpel, and a microwave unit used in combination with a CT system.

(1) Countermeasures for the CT system

Cause/route	Cause/route identification procedure	Countermeasures
<ul style="list-style-type: none"> System receives radiation noise. 	<ul style="list-style-type: none"> Turn OFF the power of the CT system and check whether there is any change in the noise characteristics of the ultrasound system. 	<ul style="list-style-type: none"> Change the orientation or position of the system receiving noise. If the problem still occurs after the above measures have been taken, the scanning room must be shielded using sintered-ferrite or a rubber material that absorbs the noise-causing signals.
<ul style="list-style-type: none"> System receives radiation noise. (When the CT system is affected) 	<ul style="list-style-type: none"> Remove the electric scalpel or microwave unit from the CT system. Alternatively, turn OFF the power of the electric scalpel or microwave unit. 	<ul style="list-style-type: none"> Orient the CT X-ray unit so that the noise is minimum. If the problem still occurs after the above measures have been taken, the scanning room must be shielded using sintered-ferrite or a rubber material that absorbs the noise-causing signals.
<ul style="list-style-type: none"> Conduction noise via the power-supply line 	<ul style="list-style-type: none"> Turn OFF the power of the CT system and check whether there is any change in the noise characteristics of the ultrasound system. 	<ul style="list-style-type: none"> Insert an EMI filter in the power-supply line. (For this system, the filter is already installed.)
<ul style="list-style-type: none"> Conduction noise via the ground cable. 	<ul style="list-style-type: none"> Turn OFF the power of the CT system and check whether there is any change in the noise characteristics of the ultrasound system. 	<ul style="list-style-type: none"> Make the connections independent. <p>For example, place a new ground cable for the CT system.</p> <p>(Difficulty: High)</p>
<ul style="list-style-type: none"> Radiation noise from CT cables <p>If the noise is reduced, the cause is radiation noise from CT cables.</p>	<ul style="list-style-type: none"> Perform simple shielding of the cables of the CT system using aluminum foil, ground the cables, and check the results. <p>(Difficulty: High)</p>	<ul style="list-style-type: none"> Shield the cables using mesh-type shielding material. <p>(Difficulty: High)</p> <p>(Since CT systems have several units and many cables, this procedure may be difficult.)</p>

(2) Countermeasures for the ultrasound system

Cause/route	Cause/route identification procedure	Countermeasures
Radiation noise	Move the ultrasound system to a location far from the CT system. Check whether or not the noise is reduced.	Ask the customer to use the ultrasound system at a location away from the CT system if possible.
Conduction noise via cables	Disconnect all the cables of optional units (printer, VCR, imager, etc.) connected to the ultrasound system. Insert a power-supply filter in the power-supply line of the ultrasound system.	<p>If the noise vanishes as a result of these actions, the route of entry of the noise lies in one of the cables.</p> <p>Connect the cables of the optional units one by one to identify which cables are the noise routes, and perform the following countermeasure. (Since several cables may be noise routes, check all the cables.)</p> <ul style="list-style-type: none"> • Use power-supply filters with the power supplies of the optional units from which the cables serving as the noise entry routes come. • Insert a core and filter between the ultrasound system and each of the cables serving as a noise entry route. (For the BNC cable of the imager, a filter for BNC connectors is provided.)
Radiation noise due to the transducer acting as an antenna	If the noise does not vanish, the transducer could also be the cause. Change the transducer of the ultrasound system to a transducer with reinforced shielding (for example, a double-shielded transducer).	Replace the transducer.
Conduction noise from the power-supply line or the ground	Remove the power-supply filter in the above status (status in which conduction noise via cables is checked) and check the result.	Insert the power-supply filter.
<p>Entry from cables exposed to radiation noise</p> <ul style="list-style-type: none"> • Radiation noise from the cables of the CT system transfers to the cables of the ultrasound system and enters the system via the cables. • Radiation noise from the cables of the ultrasound system transfers to the cables of the CT system and enters the system via the cables. 	<p>Check whether the cables of the ultrasound system and the optional units are close to the cables of the CT system. If they are close, change the cable routing to increase the distance between the sets of cables and check whether the noise is reduced.</p> <p>Perform simple shielding of the cables of the ultrasound system using aluminum foil and ground the cables and then check whether the noise is reduced.</p>	<p>Change the cable routing to increase the distance between the cables.</p> <p>Shield the cables using a mesh type of shielding material.</p>

3. Influence of Static Electricity and Required Countermeasures

3.1 What is static electricity?

The Static Electricity Handbook of the Static Electricity Institute (published by Ohm Inc.) defines static electricity as "electricity where the spatial movement of electric charges is small and the effects of the magnetic field due to the slight spatial movement of electric charges are negligible in comparison to the effects of the electric field." That is, static electricity is electricity which resides in the material and moves little.

To study actual phenomena related to static electricity, however, dynamic electricity phenomena (for example, static discharge) caused by static electricity phenomena must be included in the scope of study.

Thus, the study of static electricity phenomena includes the study of some dynamic electricity phenomena. It should be noted that the voltages involved in static electricity phenomena are generally higher in comparison to those involved dynamic electricity phenomena, but the total amount of electricity (electric charge) involved is generally much less for static electricity phenomena than for dynamic electricity phenomena.

3.2 Necessity of countermeasures against static electricity

CT systems contain various semiconductor devices which are very sensitive to static electricity.

The following table shows the static electricity levels at which each device is damaged.

Table A-3

Type of component	Voltage range resulting in component damage (V)
VMOS	30 to 1,800
MOS FET	100 to 200
GaAs FET	100 to 300
EPROM	100
JFET	140 to 7,000
SAW	150 to 500
OP-AMP	190 to 2,500
CMOS	250 to 3,000
Schottky diodes	300 to 2,500
Film resistors	300 to 3,000
Bipolar transistors	380 to 7,000
ECL	500 to 1,500
SCR	680 to 1,000
Schottky TTL	1,000 to 2,500

The level of static electricity that can cause damage differs depending on the type of device. Damage may be result from static electricity levels of less than 100 V as shown in the above table. This system conforms to EMC standards IEC60601-1-2 and therefore is not damaged due to supplied voltage of 3 kV (contact) or 8 kV (in the air).

If this system is to be used in an atmosphere where static electricity of more than 3 kV is present, countermeasures against static electricity must include the CT system as well as the environment in which the CT system is installed as targets.

3.3 Suppression and prevention of static electricity

Antistatic measures for nonconductors

(1) Increasing relative humidity

As shown in tables A-4 and A-5, the generation of static electricity can be prevented by increasing the relative humidity.

Table A-4 Dependence of generated static electricity voltage on relative humidity

Static electricity generated by	Static electricity voltage (V)	
	10% to 20% RH	65% to 90% RH
Walking on a carpet	35,000	1,500
Walking on a vinyl floor	12,000	250
Working at a work table	6,000	100
Storing/removing work instructions in/from a vinyl cover	7,000	600
Picking up an ordinary polyethylene bag from a work table	20,000	1,200
Sitting on a work chair with a polyurethane foam cushion	18,000	1,500

*: The voltage can be reduced to less than 1/10 by increasing the humidity.

Table A-5 Relationship between the humidity and the static electricity voltage for various fibers

Fiber	Static electricity voltage (kV)		
	50% RH	65% RH	80% RH
Wool	4.9	2.0	0.8
Cotton	0.1	0.0	0.0
Viscose rayon	4.7	1.6	0.5
Acetate rayon	6.0	3.5	3.3

However, increasing humidity too much causes humidity hazard.
(Refer to figure A-1.)

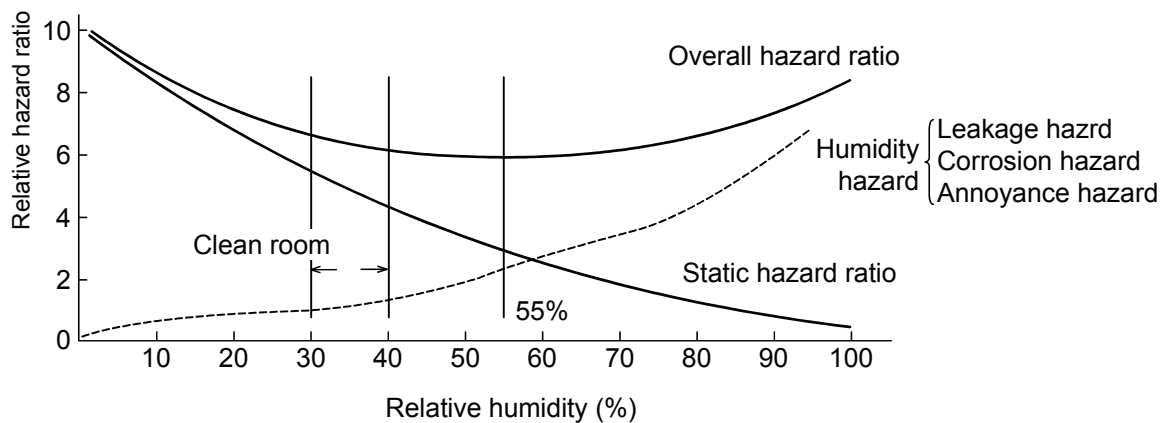


Figure A-1 The relation between relative humidity and relative hazard ratio

The above relationship indicates that the relative humidity for systems should be controlled in the 50% to 55% range as far as possible.

(2) Countermeasures using conductive materials

The above method (increasing relative humidity) is not always optimal because humidity hazard may be caused. Therefore, preventive measures using conductive materials are outlined below. (An example comparing conductive shoes with normal shoes is presented.)

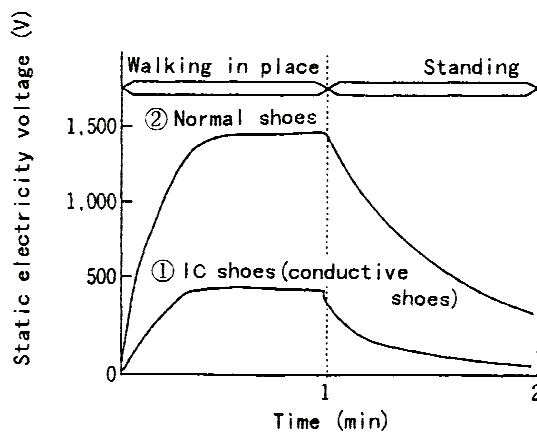


Figure A-2 Nonconductive flooring material

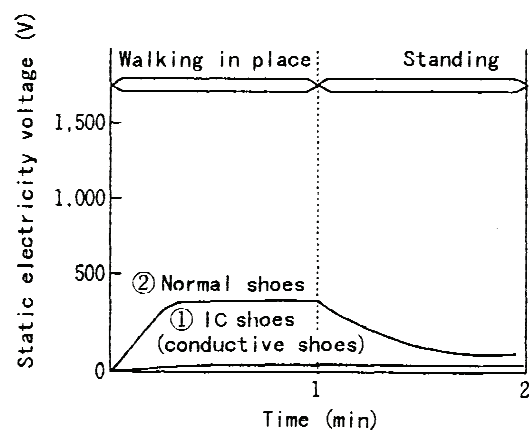


Figure A-3 Conductive flooring material

Figure A-2 illustrates an example of walking in place followed by standing on a nonconductive floor with normal shoes and conductive shoes. (The static electricity voltage may be higher depending on the material of the clothes, etc.) Wearing conductive shoes makes it possible to decrease the static electricity voltage level. However, the static electricity voltage even at this level could damage devices, as shown in table A-3.

Figure A-3 illustrates an example of walking in place followed by standing on a conductive floor with normal shoes and conductive shoes. Preventive measures against static electricity using a conductive floor and conductive shoes are extremely effective.

This method should therefore be used during site planning to prevent damage due to static electricity caused by users or service personnel.

Materials and manufacturers are listed below.

Reference manufacturer: Achilles Inc.

- Conductive floor ----- Conductive floor tiles SKY-11
- Conductive slippers ---- ICS-0100
- Conductive shoes ----- ICM0100 (for men)
ICM0230 (for women)

The installation area of the conductive floor is shown in the attachment. (Refer to figures A-4-1 and A-4-2 "Room layout example".)

It is recommended that special consultation with the flooring material manufacturer be held before building the floor.

Conductive floor space

<1> GTS service space

Connect the ground cable of the conductive floor to the gantry.

<2> Servo amplifier service space

Connect the ground cable of the conductive floor to the gantry.

<3>, <4>
Gantry front service space

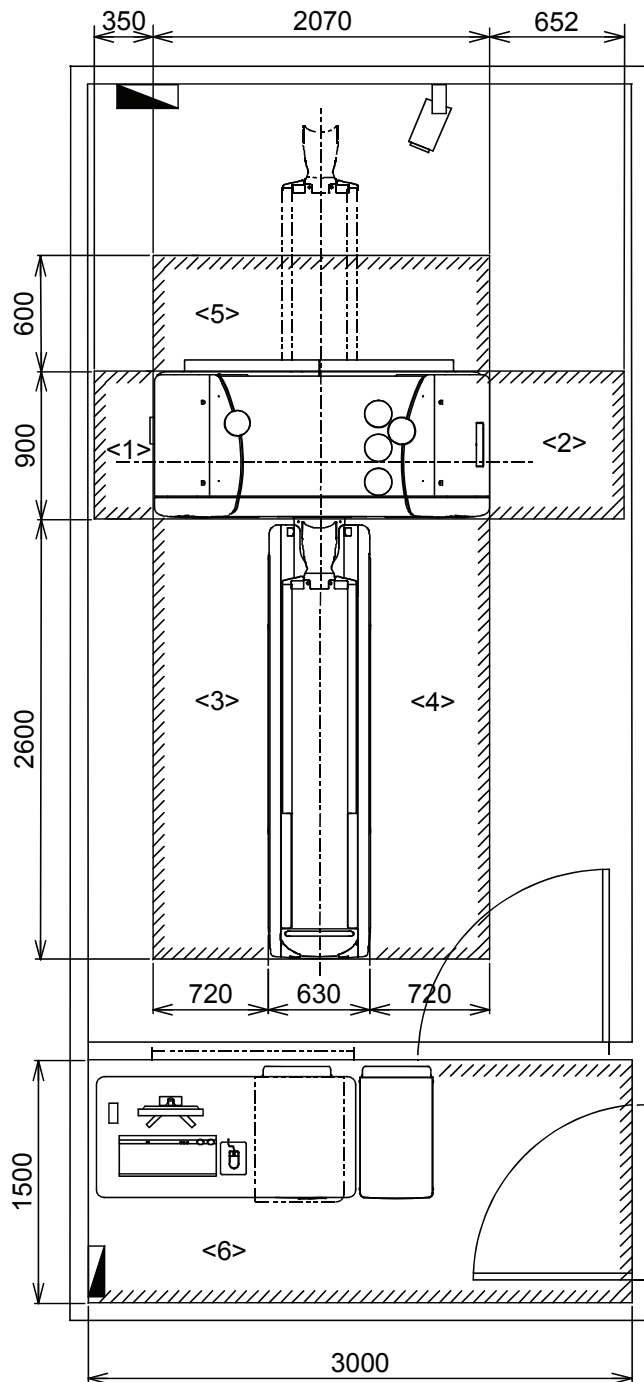
Connect the ground cable of the conductive floor to the patient couch.

<5> Gantry rear side and GCIF2 service space

Connect the ground cable of the conductive floor to the gantry.

<6> Console service space

Connect the ground cable of the conductive floor to the console ground.



Unit: mm

Figure A-4-1 Room layout example
(for patient couch CBTB-018A)

Conductive floor space

<1> GTS service space

Connect the ground cable of the conductive floor to the gantry.

<2> Servo amplifier service space

Connect the ground cable of the conductive floor to the gantry.

<3>, <4>
Gantry front service space

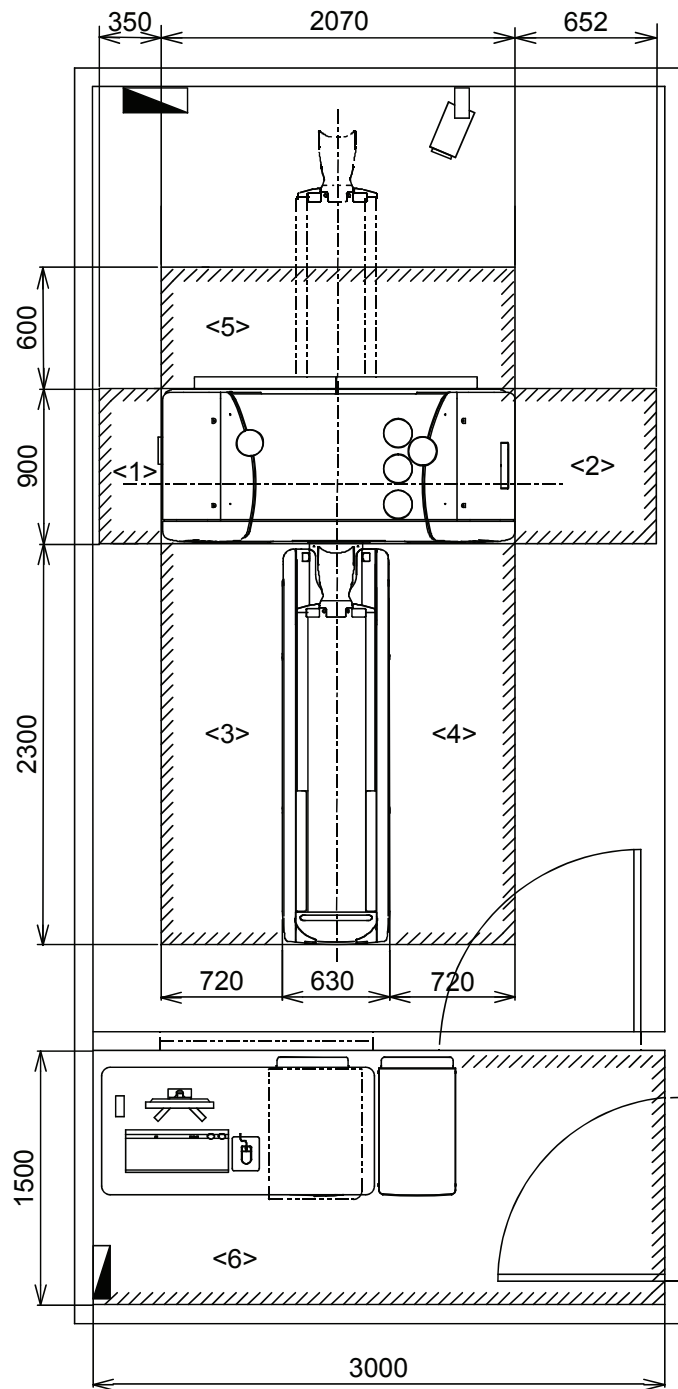
Connect the ground cable of the conductive floor to the patient couch.

<5> Gantry rear side and GCIF2 service space

Connect the ground cable of the conductive floor to the gantry.

<6> Console service space

Connect the ground cable of the conductive floor to the console ground.



Unit: mm

Figure A-4-2 Room layout example
(for patient couch CBTB-018B)

APPENDIX 3
FLOOR LEVELING WORK MANUAL
(TECHNIQUES FOR USING EPOXY RESIN)
FOR
Activion16

1. OUTLINE

This manual describes the procedures for performing floor work using epoxy resin to ensure levelness of the installation floor for the gantry and patient couch of the Activion16.

This manual, although written specifically for the Activion16, is also applicable to other models.

2. TOOLS AND MATERIALS REQUIRED

Tools or materials required	Quantity	Remarks
(1) Plastic L-angle plates (20 × 20 × 1830 mm)	12	Used for the frames for applying epoxy resin (reusable).
(2) Adhesive tape (product number 252, 18 mm × 35 m)	4 rolls	Used to fix the plastic L-angle plates.
(3) Cutter	2	Used to remove the floor covering
(4) Saw	1	Used to cut the plastic L-angle plates.
(5) Basin (60 cm in diameter) or bucket	1	Used for mixing epoxy resin.
(6) Ladle	1	Used for mixing epoxy resin.
(7) Caulking compound (joint sealant) Silicone sealant Cemedine 8060 clear	1	Used to prevent leakage of the epoxy resin.
(8) Caulking gun	1	Used to apply caulking compound.
(9) Tape measure	2	Used to measure dimensions and to draw lines.
(10) Spatula	1	For caulking
(11) Epoxy resin (Epichlon 830)	1 can	18 liters/can
(12) Diluted solution (Epichlon 520)	1 can	18 liters/can
(13) Winter-use hardener (Epichlon B-065)	1 can	18 liters/can
(14) Rags	1 bundle	
(15) Grinder	1	
(16) Technodisk (external diameter 100 mm)	1	
(17) Plastic sheet (2 m x 2 m)	1	
(18) Spray lubricant (CRC-556)	1	Used for epoxy resin finishing.
(19) Electric mixer (BMV-150A) manufactured by Toshiba	1	It is recommended that an electric mixer be used to mix the resin.

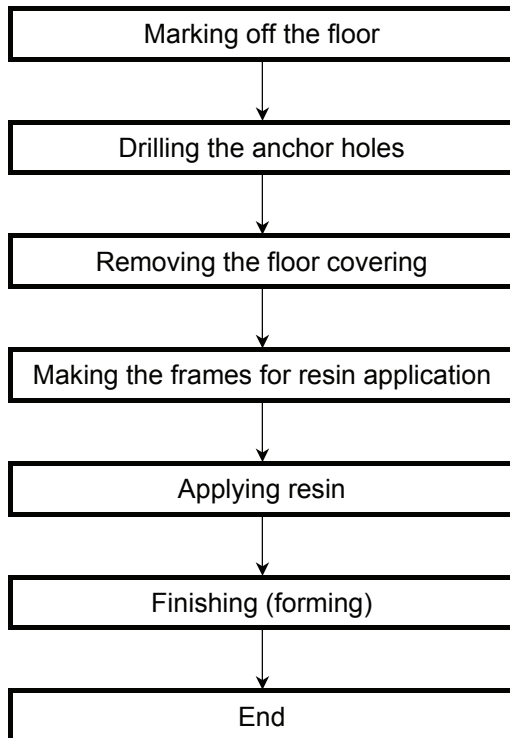
<Supplier of the epoxy resin>

Epoxy resin and hardener: Dai-Nippon Ink & Chemicals, Inc.

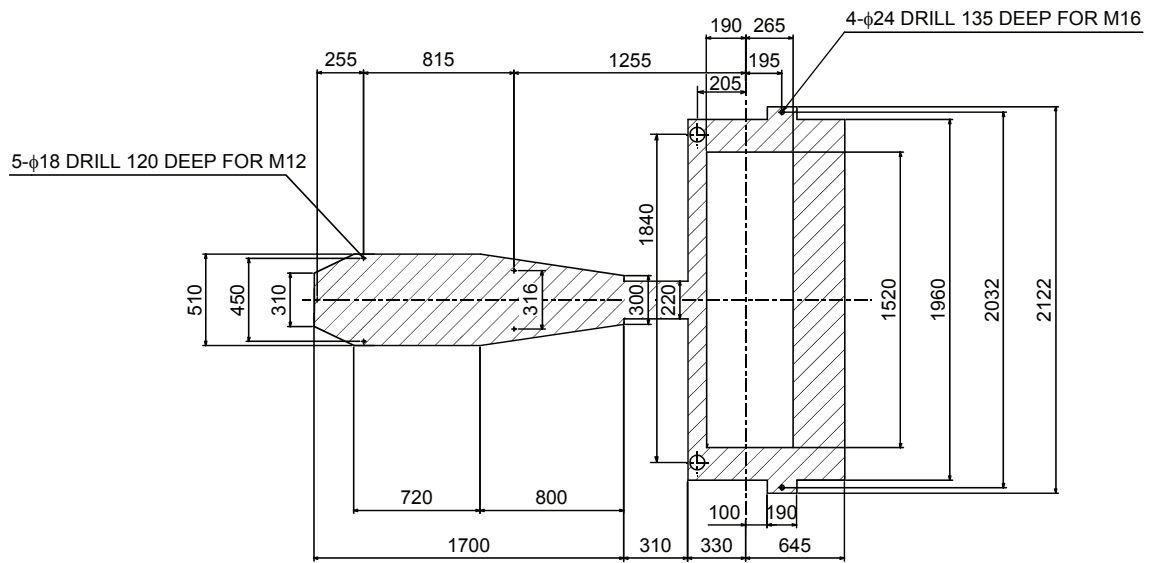
⚠ CAUTION: Although two different hardeners are available for the epoxy resin (winter-use hardener and summer-use hardener), the winter-use hardener (B-065) must be used.
The summer-use hardener is not suitable for work in hospitals or clinics because it requires a long hardening time and, in some cases, the application of heat may be necessary to achieve hardening.

3. WORK PROCEDURES

The main work procedures are as follows:



The following shows the application area. (It is recommended that the full-scale gauge be used for marking and anchor hole drilling work.)



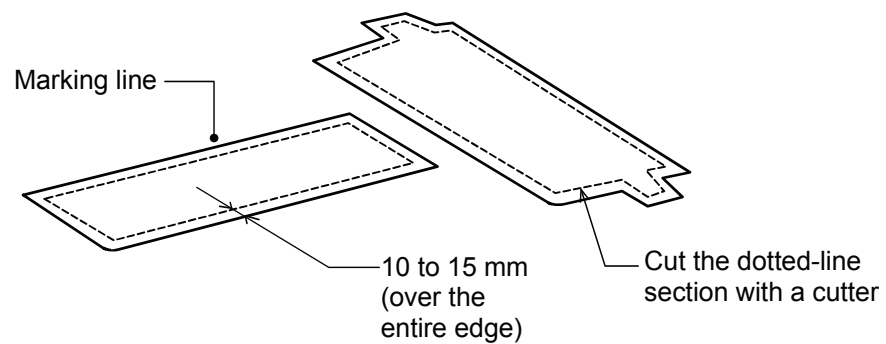
Unit: mm

3.1 Marking

- (1) Determine the installation locations for the gantry and the patient couch (refer to appended figures 2-1 and 2-2).
- (2) Mark off the resin application areas on the floor sections of the determined installation locations.

3.2 Drilling the Anchor Holes and Removing the Floor Covering

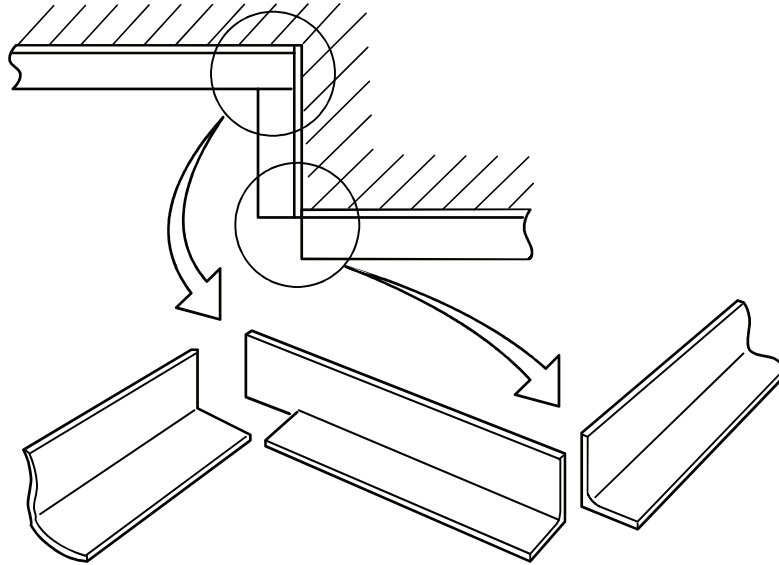
- (1) Drill the anchor holes at the marked positions using an electric drill with 24-mm and 18-mm bits.
- (2) Cut a slit 10 to 15 mm inside the marking line on the floor using a cutter.



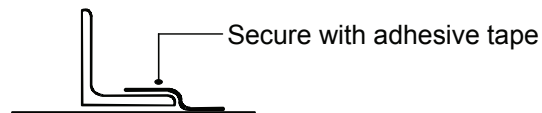
- (3) Remove the floor covering inside the marking line. (Entire area inside the marking line)
- (4) Clean the area from which the floor covering has been removed.

3.3 Making the Frames for Resin Application

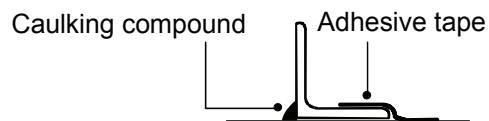
- (1) Cut off the plastic L-angle plates along the marking line using a saw. Treat the corners as shown below.



- (2) Tape along the marking line of the plastic L-angle plates that have been cut off.
- (a) Tape the outside of the plastic L-angle plate to secure it.



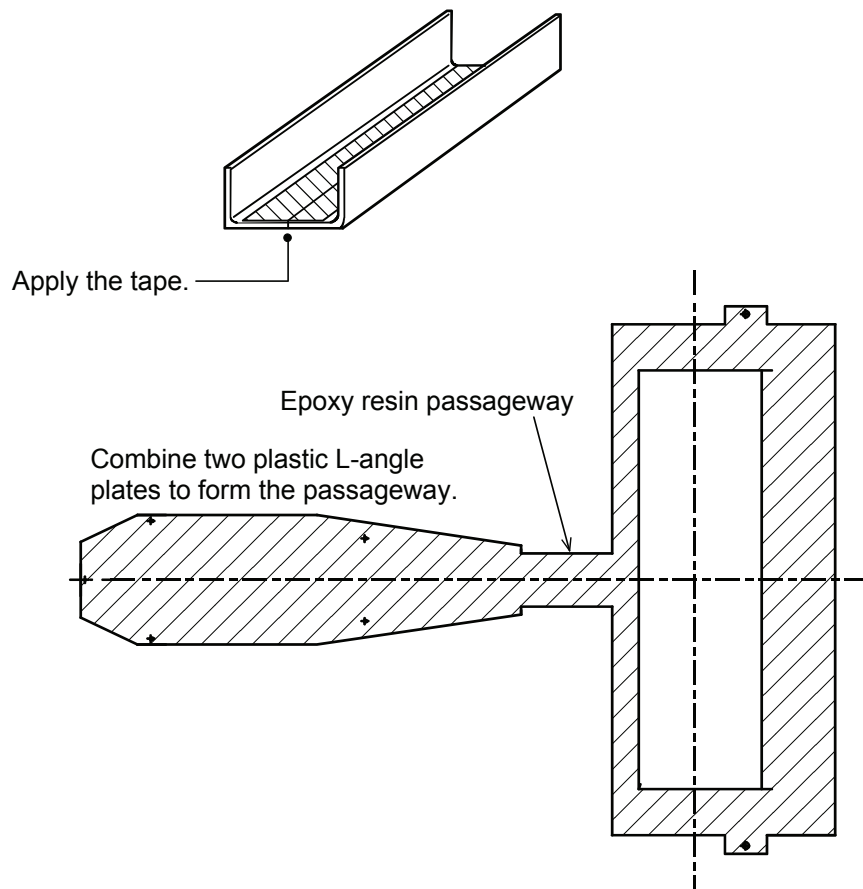
- (b) Use the spatula to spread the caulking compound all over the corner inside the L-angle plate.



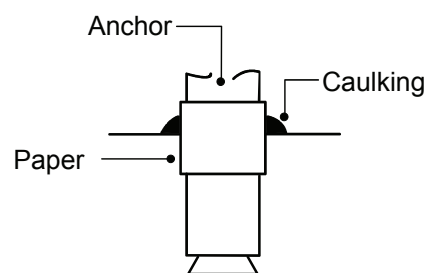
- (c) Tape outside sections of the corners between the plastic L-angle plates.
- (d) Cut out part of the plastic L-angle plates for the gantry and the patient couch to make an epoxy resin passageway.

(This job must be performed to ensure that the bottoms of the gantry and the patient couch are flush.)

- (e) Using a spatula, apply caulking compound (joint sealant) to all sections where the resin may leak, such as the connections at the corners of, and the joints between, the plastic L-angle plates, the clearances between the installation surface and the base, etc.



- (f) Wind paper on the anchor a couple of times and fix it using the tape. Insert this anchor into the anchor hole and perform caulking.



⚠ CAUTION: The anchor must be well caulked to prevent the epoxy resin from being intruded into the anchor hole. The paper wound on the anchor must be higher than the epoxy resin depth.

3.4 Applying Resin

- (1) Place epoxy resin (major agent), hardener, and pigment into a basin, and mix them thoroughly using a ladle.

Mixture ratio : Epoxy resin: hardener = 3:1 (w/w)

Specific gravity : Epoxy resin 1.20
Hardener 1.20

⚠ CAUTION:

1. This job must be performed with a plastic floor-covering sheet laid on the floor.
2. Before mixing the liquid agents, they must be accurately weighed using an oil replenishment container.
3. The oil replenishment container that has been used for weighing must not be used to apply the resin.
4. Gloves, eye protection, etc. must be worn when handling the resin.
5. During handling of the resin, good ventilation must be provided since it is a volatile chemical.

- (2) Pour the liquid mixture into the frames.

Since the resin has a certain degree of viscosity, the mixture must be poured evenly. The amount of mixture poured should be such that the minimum thickness of the resin is about 5 mm.

- (3) Allow about one hour after the start of pouring to observe closely for leakage of the resin from the frames. If leakage is seen, immediately seal the leak using adhesive tape or caulking compound (joint sealant).
- (4) After pouring has been completed, apply a spray lubricant CRC-556 to the epoxy resin surface. This eliminates any bubbles from the resin surface to ensure a smooth finish.

3.5 Finishing the Resin Surface

- (1) After allowing the resin to stand for 48 hours or more, check that the surface has become hard (press the surface with a push-pull gauge and confirm that the surface is not dented).
- (2) Remove the frames. Remove the gantry-to-couch epoxy resin passageway using a saw.
- (3) Remove any rough edges or bulges from the corners and the surface using a grinder. Finish the entire surface so that it is flat and smooth.

TOSHIBA



LEGAL MANUFACTURER

TOSHIBA MEDICAL SYSTEMS CORPORATION

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