Manual No.:S514-E010
Revision :B

CEILING TUBE SUPPORT

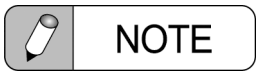
CH-200M

SPECIFICATIONS

SHIMADZU

About the Symbols Appearing in this Specifications

Throughout the text in this specifications, warnings and other information essential when using this unit, such as cautionary or prohibited items, appear classified as per the following:

Mark	Description
	Indicates an imminently hazardous situation which, if not avoided, will result in serious injury or death.
	Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or possibly death.
	Indicates a potentially hazardous situation which, if not avoided, may result in minor to moderate injury or equipment damage.
	Emphasizes additional information that is provided to ensure the proper use of this product.

Contents

Chapter 1 Outline

Chapter 2 Specifications

Dimensions

This page is intentionally left blank.

1

Outline

This chapter describes the applications, features and usage environment of the ceiling tube support CH-200M.

1.1 Applications

The CEILING TUBE SUPPORT CH-200M is a system used for image-based diagnosis in which forms, characteristics and movements inside the body are made visible using X-rays.

It is used to hold the X-ray tube and collimator to position the X-ray tube unit and determine the radiography area after locating the radiography area of patient in front of the system.

In combination with an X-ray high-voltage generator, a radiography stand and a radiography table, it enables radiography of patients either while they are standing or laying down.

1.2 Features

Operation Panel

- The X-ray tube can be positioned by operation from the operation panel.
- Position information such as the angle of rotation are displayed on the operation panel's screen.
- The button arrangement on the operation panel can be modified when installing the equipment.
- The X-ray tube support can be moved and lighted exposure field lamp using the rear operation panel.
  (3-directional moving, rotation around the vertical axis lock release functions and exposure field lamps)

Function

- The rotation around the vertical axis of the X-ray tube support can be unlocked with the operation panel enabling even radiography at difficult angles demanded in orthopedic operations. (Radiography with general radiography technique)
- The X-ray tube support can be moved vertically within a 1600 mm range. Without using a footstool, it can perform radiography at a low position, such as the knees, with the patient in a standing position.
- The vertical position of the X-ray tube support is selectable at the time of installation making it suitable even for examination rooms with high ceilings.
- Aluminum rails are standard equipment enabling the quiet and smooth movement of the X-ray tube support. They also enable accurate positioning for conducting radiography.
- The magnetic brakes reduce noises upon locking.

1.3 Principle

By releasing the locks on all system motions and manually operating the X-ray tube in longitudinal motion, transverse motion, vertical motion, horizontal rotation and vertical rotation, you can set the radiography position.
Note also that position information such as the exposure distance and angle of rotation are displayed using a position detection mechanism.

1.4 Environmental Conditions

To obtain proper performance, be sure to use the equipment under the specified environmental conditions.

1.4.1 Operating Environment

Use the equipment under the environmental conditions listed below:

The installation of a dedicated air-conditioner in the examination room is recommended if the building air-conditioning cannot meet the necessary environmental conditions.

Do NOT use the equipment in an oxygen-rich environment.
The use of the equipment in an oxygen-rich environment may cause fatal or serious injuries or damage to the equipment due to easy ignition.

Even under the prescribed conditions, avoid rapid changes of temperature or humidity.
Condensation may occur and cause failure. Also, rust or corrosion may occur inside the equipment.

Item	Specifications
Atmosphere	No explosive or corrosive gases
Ambient Temperature	10 to 40 °C
Relative Humidity	30 to 85 % (with no condensation)
Atmospheric Pressure	800 hPa to 1060 hPa
Environment Luminosity	150 to 500 lx
Ambient Noise Level	Under 70 dB

1.4.2 Transportation and Storage Environment

Item	Specifications
Ambient Temperature	-10 to 60 °C
Relative Humidity	10 to 95 % (with no condensation)
Atmospheric Pressure	700 hPa to 1060 hPa

1.4.3 Power Supply

Item	Specifications
Phase	Single phase AC
Frequency	50/60 Hz
Standard Voltages	100 V
Voltage Fluctuation Range	±10 % of nominal voltage
Supply Capacity	0.7 kVA

DANGER

Be sure to use the power supply specified in the specifications.
Using a power supply other than the one specified may cause equipment malfunction or serious accidents such as fire, smoke emission, or explosions.

1.4.4 Ground

Grounding to the ground resistance of less than 100 W with annealed copper wire of 1.6 mm in diameter for grounding wire.

WARNING

Be sure to connect the equipment only to a (commercial) power outlet with a ground terminal.
If the outlet does not have a ground terminal, electric shock may occur.

1.5 Classification of Equipment

This system is classified as follows, based on safety standards for electrical medical equipment.

■ Protection Method Against Electric Shock

Class I equipment

■ Classification of Applied Parts

No applied parts

■ Operation Mode

Continual operation with intermittent loading

■ Degree of Protection Against Liquid Ingress

Ordinary equipment

■ For Use in an Oxygen-rich Environment

WARNING

Do NOT use the equipment in an oxygen-rich environment.
The use in an oxygen-rich environment may cause fatal or serious injuries or damage to the equipment due to easy ignition.

■ For Use in Flammable Atmosphere

Not to be used in presence of flammable anaesthetic gas

DANGER

Do NOT use the equipment or system in the presence of flammable anesthetics gas.
It may cause an explosion.

■ Classification of Installation Type

Permanently installed equipment

2

Specifications

This chapter describes specifications.

2.1 Environmental Conditions of EMC (Electromagnetic Compatibility)

The equipment satisfies the EMC (Electromagnetic Compatibility) standard below:

IEC 60601-1-2:2007

CAUTION

Pay attention to the electromagnetic circumstances at the installation site.
The equipment may be affected by the electromagnetic environment at the installation site.

Also, the installation of the equipment may affect other existing equipment.

Classification of EMI in Accordance with EN/IEC60601-1-2: 2007

Group 1, Class A

The system uses radio-frequency energy only for its internal function and is not intended to deliver energy to the patient. But little leakage radio-frequency energy does harm to highsensitive equipment.

The system main power line in the clinical site should be connected to the domestic power sources which are separated from the public main network.

CAUTION

For replacement parts of internal components, make sure to apply the cables supplied by Shimadzu.
The use of non-cable devices, accessories, or cables other than those sold by Shimadzu as replacement parts for the internal components may result in increased emissions or decreased immunity of the equipment.

Performance to be EMC immunity tested (Essential performance)

Essential performances of this equipment are as followings;

- Supporting X-ray tube assembly
- Positioning of X-ray field

List of Cables

Cable Name	Cable Length (MAX)	Shield	Note (Manufacturer/Part No)
POWER CABLE A	20 m	U	Shimadzu/503-59610-20
EARTH CABLE	20 m	U	Shimadzu/503-58132-20

S: Shielded / U: Unshielded

NOTE

The cables listed above are the parts specified to be compliant with the standards.
These parts are not provided to the equipment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The Ceiling Type X-ray Tube Support CH-200M is intended for use in the electromagnetic environment specified below. The customer or the user of the Ceiling Type X-ray Tube Support CH-200M should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions EN 55011/ CISPR11	Group 1	The Ceiling Type X-ray Tube Support CH-200M uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011/ CISPR11	Class A	The Ceiling Type X-ray Tube Support CH-200M is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2/ IEC 61000-3-2	Not applicable (Combined total system's RATED input current exceeds 16 A per phase)	
Voltage fluctuations/ flicker emissions EN 61000-3-3/ IEC 61000-3-3	Not applicable (Combined total system's RATED input current exceeds 16 A per phase)	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The Ceiling Type X-ray Tube Support CH-200M is intended for use in the electromagnetic environment specified below. The customer or the user of the Ceiling Type X-ray Tube Support CH-200M should assure that it is used in such an environment.			
Immunity test	**EN/IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2/ IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst EN 61000-4-4/ IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5/ IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11/ IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Not applicable <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ceiling Type X-ray Tube Support CH-200M requires continued operation during power mains interruptions, it is recommended that the Ceiling Type X-ray Tube Support CH-200M be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8/ IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE • U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The Ceiling Type X-ray Tube Support CH-200M is intended for use in the electromagnetic environment specified below. The customer or the user of the Ceiling Type X-ray Tube Support CH-200M should assure that it is used in such an environment.			
Immunity test	**EN/IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF EN 61000-4-6/ IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 230 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Ceiling Type X-ray Tube Support CH-200M, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF EN 61000-4-3/ IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 351.2 MHz 800 MHz 1980 MHz 2412 MHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey*1, should be less than the compliance level in each frequency range*2. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

*1: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ceiling Type X-ray Tube Support CH-200M is used exceeds the applicable RF compliance level above, the Ceiling Type X-ray Tube Support CH-200M should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ceiling Type X-ray Tube Support CH-200M.

*2: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

List of the transmitters or equipment used as RF test sources and the frequency and modulation characteristics of each source

Kind of equipment	Type	Manufacturer	Spot check frequencies	Modulation
Digital Transceiver	IC-DPR5	ICOM	351.2 MHz	FSK (frequency shift keying)
Cellular Telephone	P251S/ F212i	Panasonic/ Fujitsu	800 MHz	PM (Phase modulation)
Cellular Telephone	812SH	Sharp	1980 MHz	PM (Phase modulation)
Wireless LAN Station	WHR-HP-G	BUFFALO	2412 MHz	OFDM (Orthogonal Frequency-Division Multiplexing)

WARNING

When using the devices at frequencies other than the tested frequencies, be sure to check the electromagnetic influence.
The equipment is tested for radiated RF immunity only at particular frequencies. Note that the test is not necessarily performed over the entire frequency range from 80 MHz to 2.5 GHz.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the Ceiling Type X-ray Tube Support CH-200M

The Ceiling Type X-ray Tube Support CH-200M is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the Ceiling Type X-ray Tube Support CH-200M can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Ceiling Type X-ray Tube Support CH-200M as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTE

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.2 Specifications

2.2.1 Specification

Table 2.1 Specifications

Item		Description	
Max, allowable mass of suspension		39 kg	
Balancing system		Spring-balancing type	
Ceiling fixture	Rail	Fixed rail of 4 m or 5.5 m length	
		Moving rail of 2 m, 2.6 m or 3.3 m length	
Movement of X-ray tube assembly	Vertical	160 cm	Electro-magnetic lock
	Longitudinal	295 cm*1	
	Transversal	140 cm*1	
Rotation of X-ray tube assembly	Around vertical axis	± 180° *2 Stops at every 90° angle. The equipment can be fixed at an intended angle with the electro-magnetic lock.	
	Around horizontal axis	-180° to +120° Stops at 0° and ± 90° when the setting position lock mode is enabled. The equipment can be fixed at an intended angle with the electro-magnetic lock.	
Display range	SID (Option)	0 to 999 cm	
	Rotation angle	Ceiling tube support mount position	(Unit: °) (+: clockwise, -: counterclockwise)
		Upper left	0 to +120, 0 to -180
		Lower left	0 to +120, 0 to -180
		Upper right (Standard)	0 to +180, 0 to -120
		Lower right	0 to +180, 0 to -120
Tube support (option)*3	Front mount	Tube support of standard type with control panel attached to the front of the X-ray tube unit.	
	Rear mount	Tube support of type with control panel attached to the opposite side of the X-ray tube unit. Eases operations when the ceiling tube support is installed against the wall of the examination room.	
	Low ceiling type	Tube support of front mount type with X-ray tube unit attached 150 mm higher. Maintains SID in supine position radiography in examination rooms with low ceilings.	
	Front mount L	Tube support of front mount type with X-ray tube unit attached 80 mm lower. Eases positioning by preventing interference between the lower edge of the tube support and the tabletop during lateral radiography using the radiography table.	
Installation requirement	Standard height of ceiling	285 cm*4	
	Installation area	A square of 250 cm x 450 cm or more, with door opening of 60 cm width.	
	Gross mass	250 kg	
	Power supply	Single phase AC100V, 0.7 kVA, 50/60 Hz	

*1: In the case of a 4 m fixed rail and a 2 m moving rail. For rails of other dimensions, refer to Table 5.2.

*2: -90° to +30° for Low-ceiling type

*3: Additions and changes to the tube support option offer ways to maintain operability when the layout of the examination room has changed.

*4: The ceiling height of 285 cm satisfies the specification of the CH-200M (The recommended ceiling height for Low-ceiling type is 270 cm.); but the height can be less than this dimension but the vertical travel range may be restricted.

Table 2.2 Length of the rail and the moving range of device (Unit: m)

Rail		Moving range of device	
Fixed rail	Moving rail	Longitudinal	Transversal
4	2	2.95	1.4
4	2.6	2.95	2.0
4	3.3	2.95	2.7
5.5	2	4.45	1.4
5.5	2.6	4.45	2.0
5.5	3.3	4.45	2.7

2.2.2 Distance from spot to reception area

Distance from spot to reception area varies according to the unit combination.

Unit combination			Distance from spot to reception area (mm)
X-Ray Tube Unit	Collimator	X-Ray Radiography table	
CH-200M (Ceiling height: 2850 mm)	R-20J	BK-12HK	337-1374
		BK-120MK	337-1524
		BK-200	343-1530

2.3 Statement of Compliance [For Europe]

2.3.1 Regulatory Information

For Europe:

The product complies with the requirement of the Medical Device Directive 93/42/EEC

Product Name:	CEILING TYPE X-RAY TUBE SUPPORT
Model Name:	CEILING TYPE X-RAY TUBE SUPPORT CH-200M
Parts Number:	503-58100
Manufacturer:	SHIMADZU CORPORATION Medical Systems Division
Address:	1, NISHINOKYO-KUWABARACHO, NAKAGYO-KU, KYOTO, 604-8511, JAPAN
Authorized Representative in EU:	SHIMADZU EUROPA GmbH
Address:	Albert-Hahn-Strasse 6-10, 47269 Duisburg, F.R. Germany

2.3.2 Company's Quality System

The company's Quality System is satisfied with Annex II, Article 3 for 93/42/EEC as amended by 2007/47/EC, which is certified by TUV Rheinland LGA Products GmbH; Tillystrasse 2, D-90431 Nurnberg, Germany (Notified under No. 0197) as Registration No.: HD 60029841 0001

2.3.3 International Standards

This equipment conforms the following international standards.

- IEC 60601-1:2005 / EN 60601-1:2006
- IEC 60601-1-2:2007 / EN 60601-1-2:2007
- IEC 60601-1-3:2008 / EN 60601-1-3:2008
- IEC 60601-1-6:2010 / EN 60601-1-6:2010
- IEC 60601-2-54:2009 / EN 60601-2-54:2009
- ISO 10993-1:2009 / EN ISO 10993-1:2009
- ISO 14971:2007,Corrected version / EN ISO 14971:2009
- IEC 62304:2006 / EN 62304:2006+AC:2008
- IEC 62366:2007 / EN 62366:2008
- EN 980:2008
- EN 1041:2008

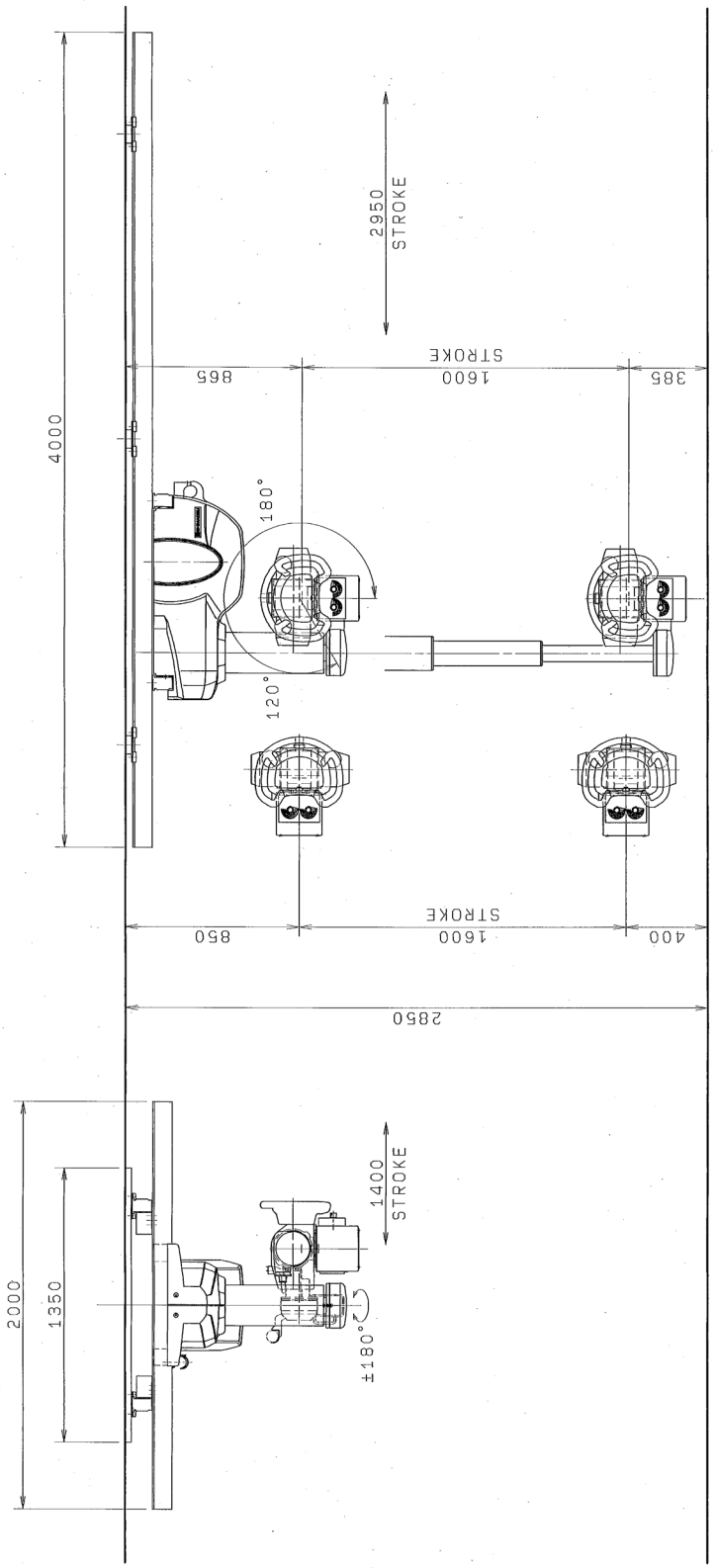
2.4 Statement of Compliance with Standards

- X-RAY EQUIPMENT for RADIOGRAPHY ... CEILING TYPE X-RAY TUBE SUPPORT CH-200M IEC 60601-2-54:2009
- X-RAY EQUIPMENT for RADIOGRAPHY ... CEILING TYPE X-RAY TUBE SUPPORT CH-200M EN 60601-2-54:2009

2.5 Manufacturer Information

Manufacturer:	SHIMADZU CORPORATION Medical Systems Division
Address:	1, NISHINOKYO-KUWABARACHO, NAKAGYO-KU, KYOTO, 604-8511, JAPAN

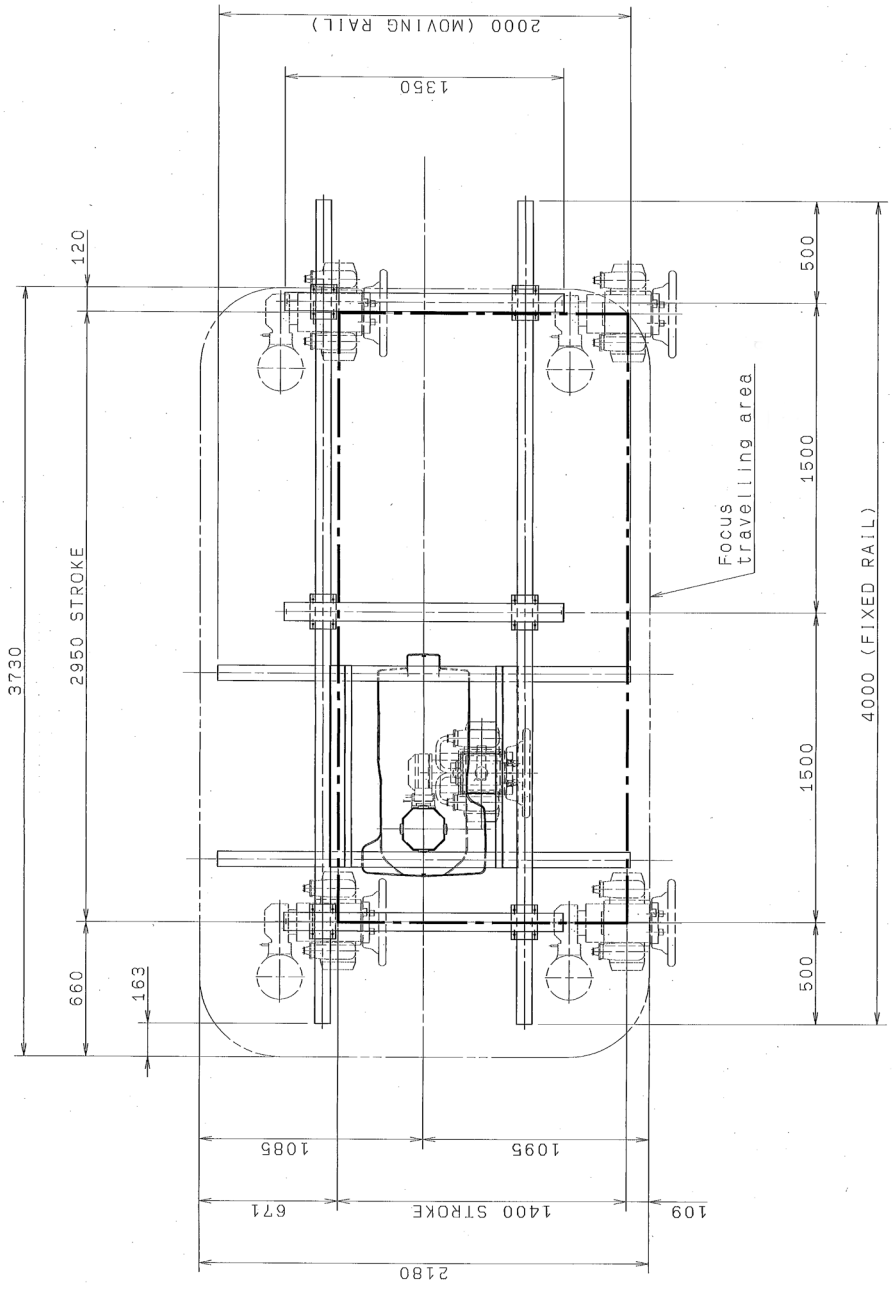
Dimensions

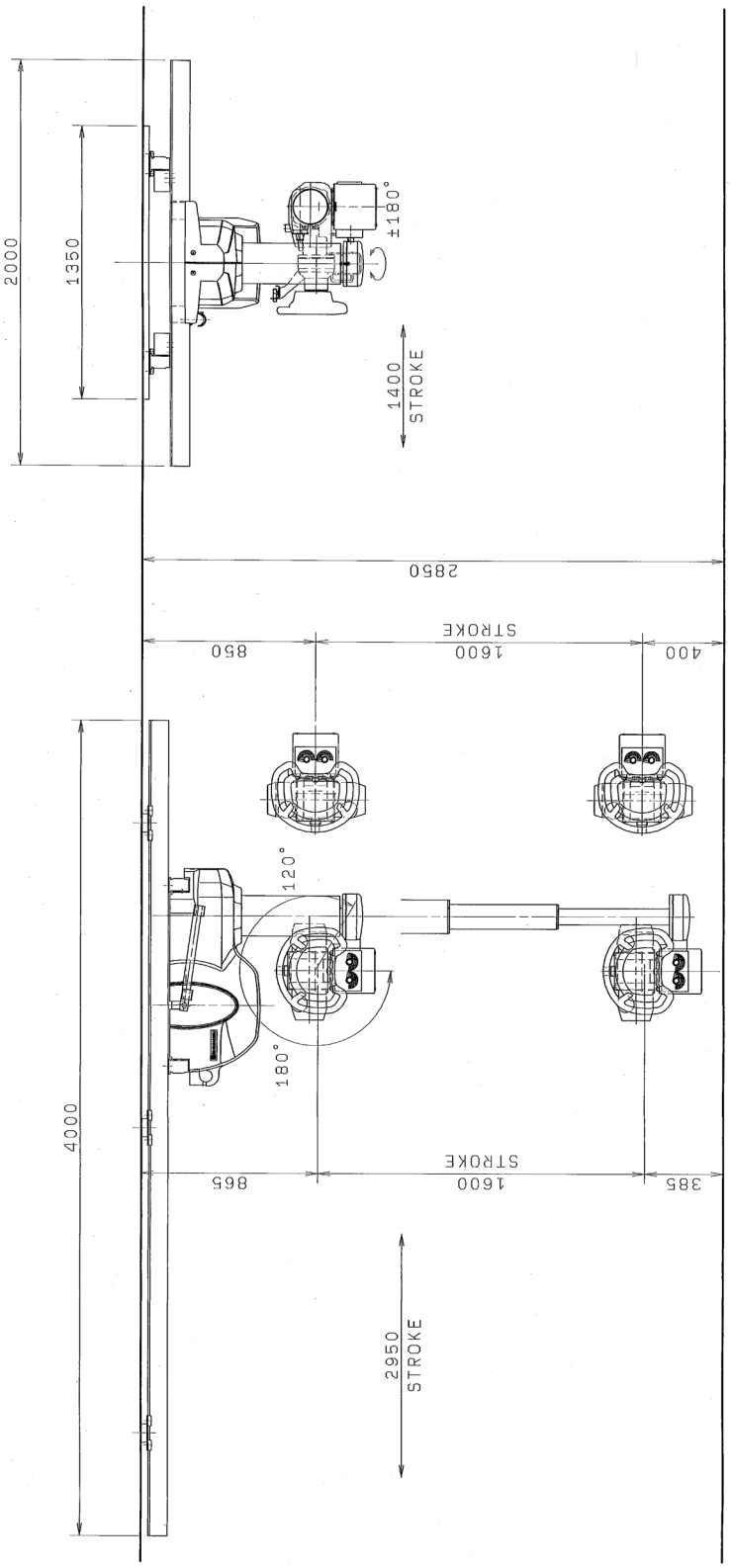


CH-200M
Fixed rail 4M
Moving rail 2M

※ The height of focus is 10mm less if wide fixed rail are used.

CH-200M (Moving range of device)
Fixed rail 4M
Moving rail 2M

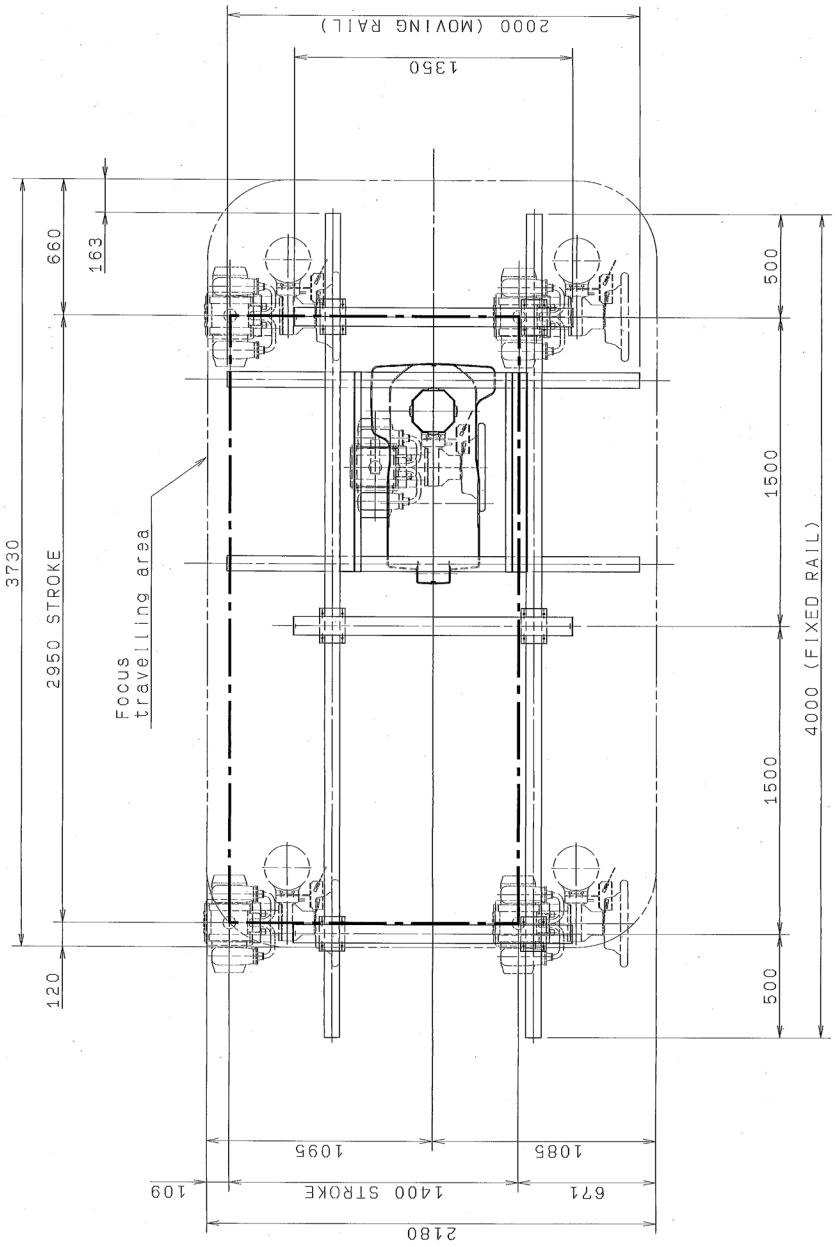


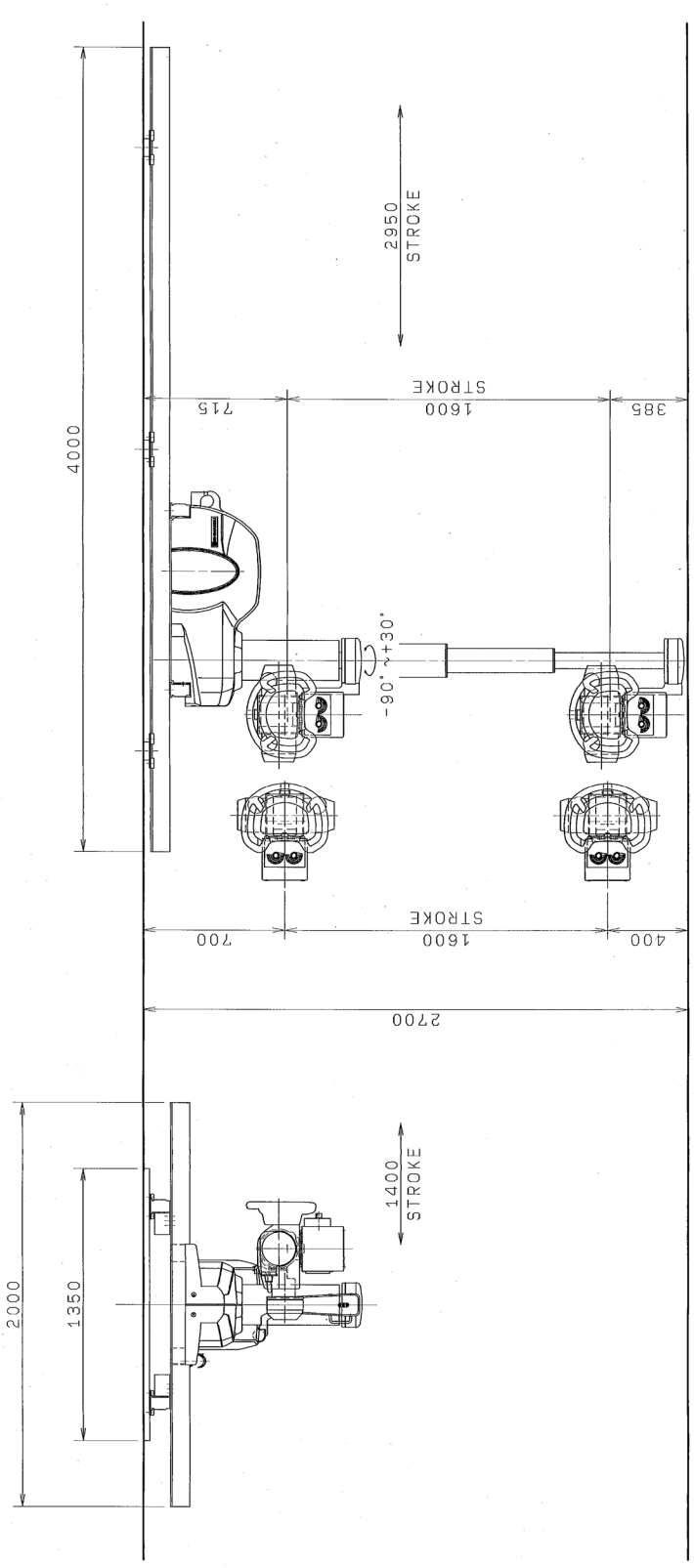


CH-200M (Rear mount type)
Fixed rail 4M
Moving rail 2M

※ The height of focus is 10mm less if wide fixed rail are used.

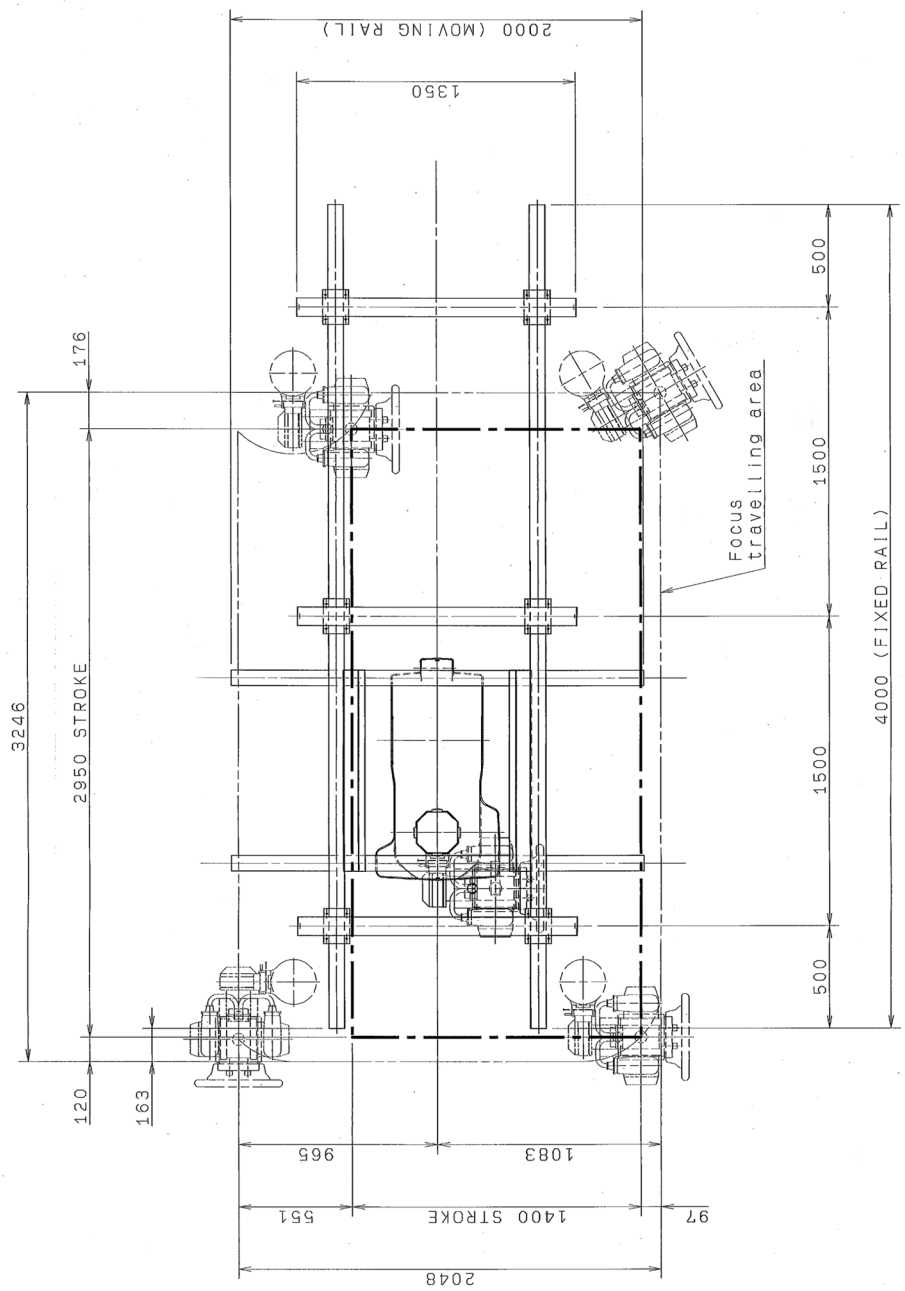
CH-200M (Moving range of rearmount type)
Fixed rail 4M
Moving rail 2M



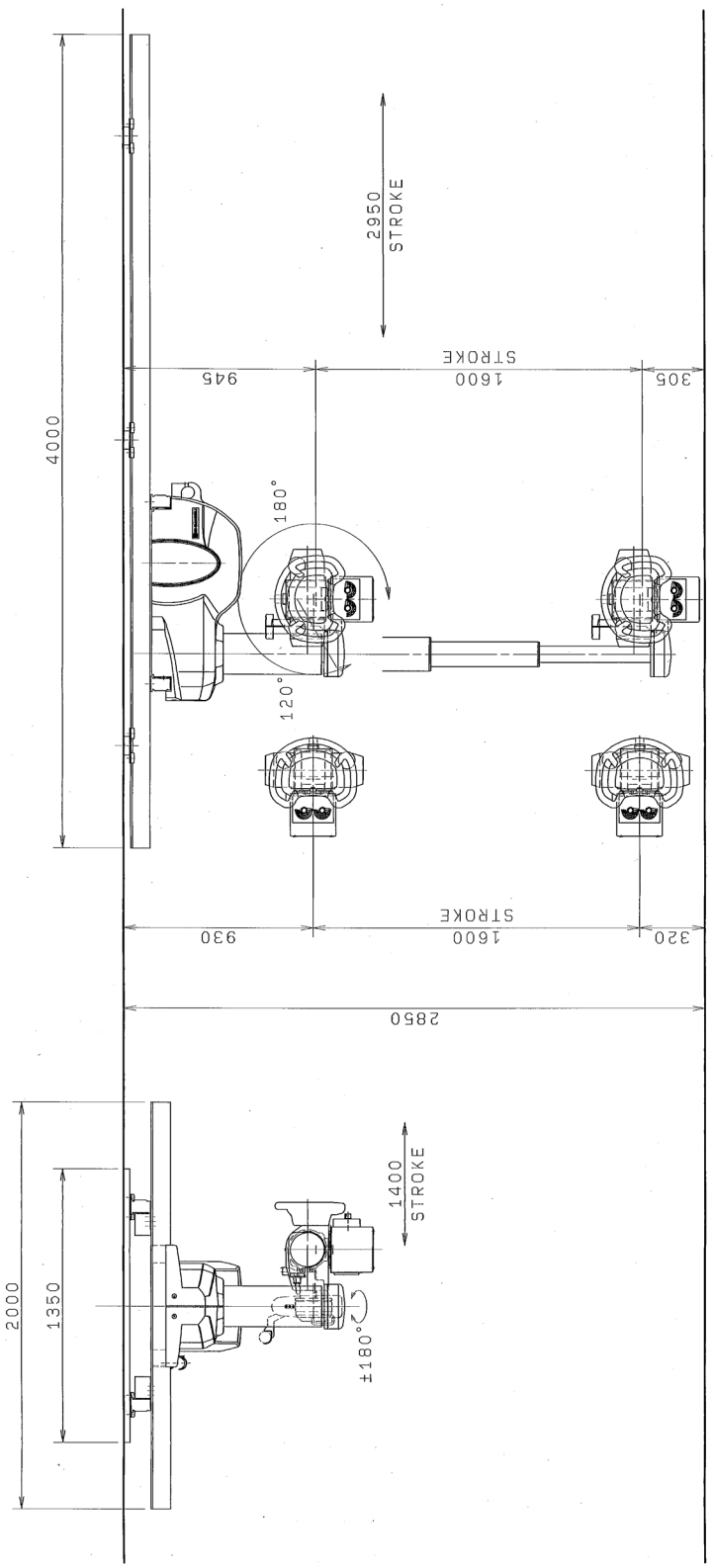


CH-200M (Low-ceiling type)
Fixed rail 4M
Moving rail 2M

※ The height of focus is 10mm less if wide fixed rail are used.

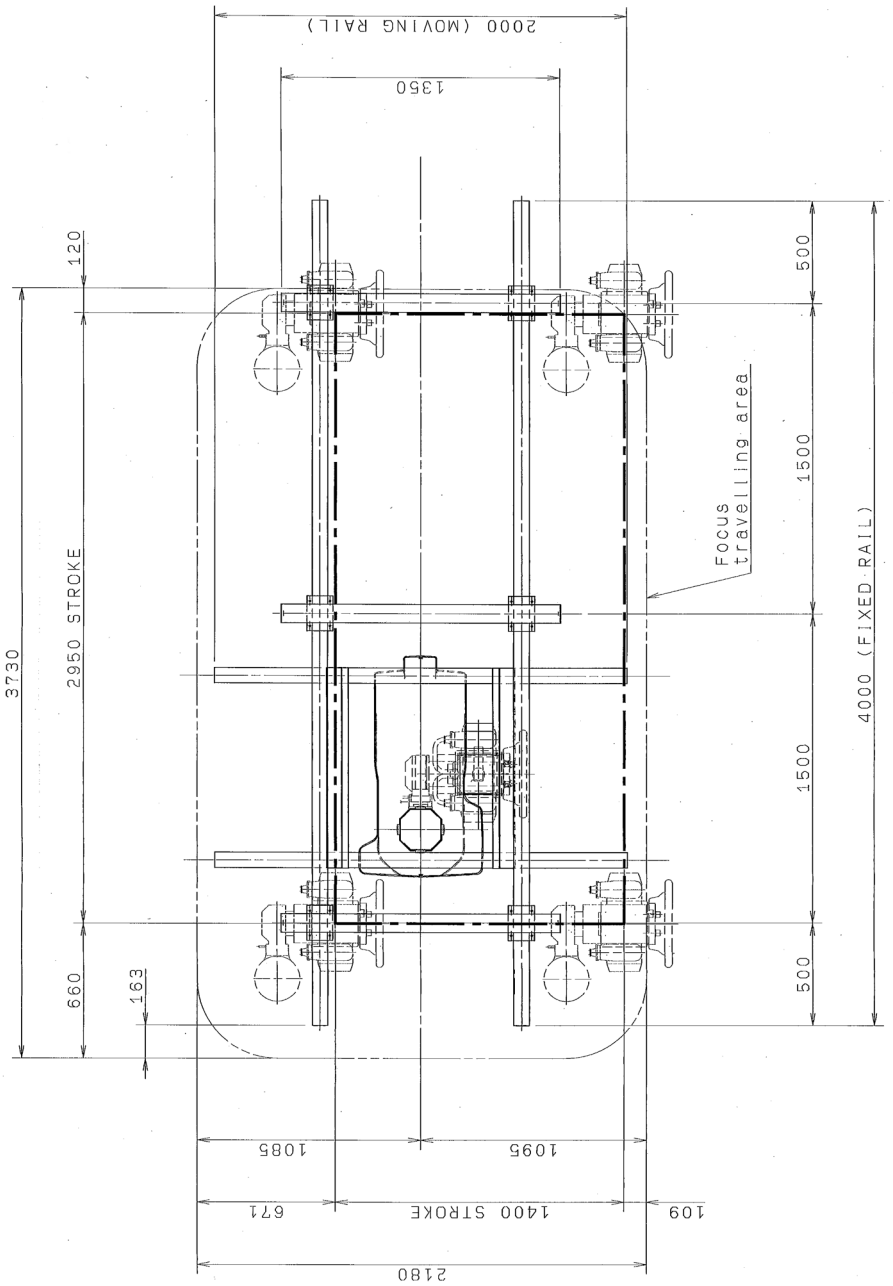


CH-200M (Moving range of low-ceiling type)
Fixed rail 4M
Moving rail 2M



CH-200M (Front L type)
Fixed rail 4M
Moving rail 2M

※ The height of focus is 10mm less if wide fixed rail are used.


CH-200M (Moving range of front L type)
Fixed rail 4M
Moving rail 2M
2000 (MOVING RAIL)
1350
120
500
Focus
travelling area
1500
4000 (FIXED RAIL)
3730
2950 STROKE
1500
660
163
500
1085
1095
671
1400 STROKE
109
2180

This page is intentionally left blank.