World's Best Dental Imaging Company

PaX-Flex3D

Installation Manual

Dental Pioneer

VATECH

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General Information

This manual covers the installation procedures of the **PaX-Flex3D** dental X-ray unit.

An installation manual and user manual are shipped with each hardware equipment.

These manuals and future updates will be released upon request.

Thorough review of this manual is recommended before installation to make the most effective use of its contents. *The information contained in this manual may be subject to change without notice to persons whom may be concerned*.

For the further information that are not covered in this manual and others, please contact us via the following methods:

Telephone: **+82-1588-9510**

E-Mail: **gcs@vatech.co.kr**

Address: **23-4, Seogu-dong, Hwaseoung-si, Gyeonggi-do, KOREA**

Conventions in this guide

The following symbols will be used throughout this manual for the users to keep better comprehension of their meaning. Make sure that you fully understand them and obey the instructions they contain.

This symbol indicates a *note* to help you get the best performances from the system. Carefully read these notes to bring about the best performance possible.

It means there is a case or situation that demands prompt but careful action, remedy or emergency. Disregarding this reading may cause slight or moderate physical injury or damage to equipment.

This symbol indicates a *warning* that should be obeyed with extreme cares. When missed, it may cause severe damages or physical injuries or death.

This radiation symbol warns you about radiation dangers.

This indicates a compulsory action or instruction.

	**X-Rays can be harmful and dangerous if not used properly. The instructions and warnings contained in this manual must be carefully followed.** **As a manufacturer of radiology equipments that conform to stringent protection standards in force throughout the world, we guarantee a maximum degree of protection against radiation hazards. The room in which your radiology unit is to be installed must comply with all official regulations applicable to protection against radiation. You must install your radiology unit in a room protected against x-ray emission.**

Installation Cautions

	**Do not install or use this system in any place where there is an explosive danger.**

- To maintain the safety, the installer must read and follow this manual carefully.
- The installer must confirm the system is installed as described in this manual and perform the appropriate procedures therein.
- Only a VATECH technician or a qualified technical expert can install the system.
- Applying pressure or spraying liquid on the system can cause fire and electrical accident.
- Do NOT install the system in an environment exposed to volatile gas or vapor.
- For a stable power supply avoid using the system simultaneously with other system of high electrical capacity, and make sure to ground the system.
- If there is any doubt on operation or condition, do NOT install the system until a VATECH customer support team confirms the reliability.

Guidelines for Protection against Radiation

The X-ray system may cause injury to the patients if used improperly. The instructions contained in this manual must be read and followed when operating PaX-Flex3D. The world standard regulations pertaining to radiation safety must be observed.

When exposing X-ray, User must be behind the protective wall, or take other protective actions. When a breakdowns or troubles appear, User keeps at least 2m (7feet) away from the X-ray system to release the exposure switch while observing patient and capture-progress.

User must provide the protective clothes to the patient. Before capturing, pregnant women must always consult with doctors.

Responsibilities of the Manufacturer

When the following instructions are observed strictly in the installation steps , the manufacturer has the responsibilities for the safe and proper working of the system, only if

- The system is installed as per installation manual.
- User uses the system as per user manual and instructions on the program.
- User software is installed as per software installation manual.
- Repairs are made by manufacturer's engineers and/or trained engineers from the manufacturer.
- User uses authorized components or approved components.

NOTE	**The manufacturer reserves the right to amend and/or update this manual at any time without notice.**

Standards and Regulations

This product is designed and produced to meet the following standards:

IEC/EN 60601-1, IEC/EN 60601-1-3, IEC/EN 60601-2-7, IEC/EN 60601-2-28,
IEC/EN 60601-2-32, IEC/EN 60601-2-44, IEC/EN 60601-1-2
IEC/EN ISO 9001, IEC/EN ISO 13485

CE 0120

CE symbol grants the product compliance to the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.

1 PaX-Flex3D Imaging System Overview

1.1 System features

PaX-Flex3D is an advanced digital dental diagnostic system that provides 3D CT imaging, panoramic, and Cephalometric imaging capabilities into one system. This equipment is based on digital and computed tomography. Specifically, its advanced digital imaging process allows for a considerably more efficient diagnosis, well-rounded management of information, and a real-time sharing of image information over a network. It is equipped with state-of-the-art CT sensor technology to capture 3-D Computed Tomogram X-ray images.

The followings are the prominent features of the equipment:

1. Consolidates Panoramic, One-shot Cephalometric, and CT imaging into a single system and provides the ability to acquire high quality digital images with ease.
2. Features a 3 in 1 system that provides all the necessary dental images for diagnostic analysis.
3. Has Metal Reduction function that minimizes the effects of metal artifact, in order to acquire a much clearer image.
4. Adapts Auto-focusing (optional) algorithm that enables the system to:
    - focus automatically on the object, using artificial intelligence algorithm
    - acquire high quality images, regardless of the arch shape and positioning of the patient
5. Provides wide touch screen of 10.4" to streamline series of procedures from patient positioning, to image saving to image reading, thus leading to easier-to-manipulation than ever before.(optional)
6. Improved reliability and dependability by adopting CAN (controlled area network) protocol that is generally used in areas like airplane leading to greatly reduced problem occurrences.
7. Supports various imaging modes in consideration of the individual characteristic of each patient.
8. Generates HD quality panoramic images (optional).
9. Employs stitching capability to obtain an image, which is larger than the physical sensor could provide.

1.2 Examination programs supported

The PaX-Flex3D has been designed to carry out the following radiological examinations:

- Panoramic (Basic, Intelligent, Ultra HD)
- Dental CT
- Cephalometric

The following table summarizes the anatomical programs that PaX-Flex3D supports:

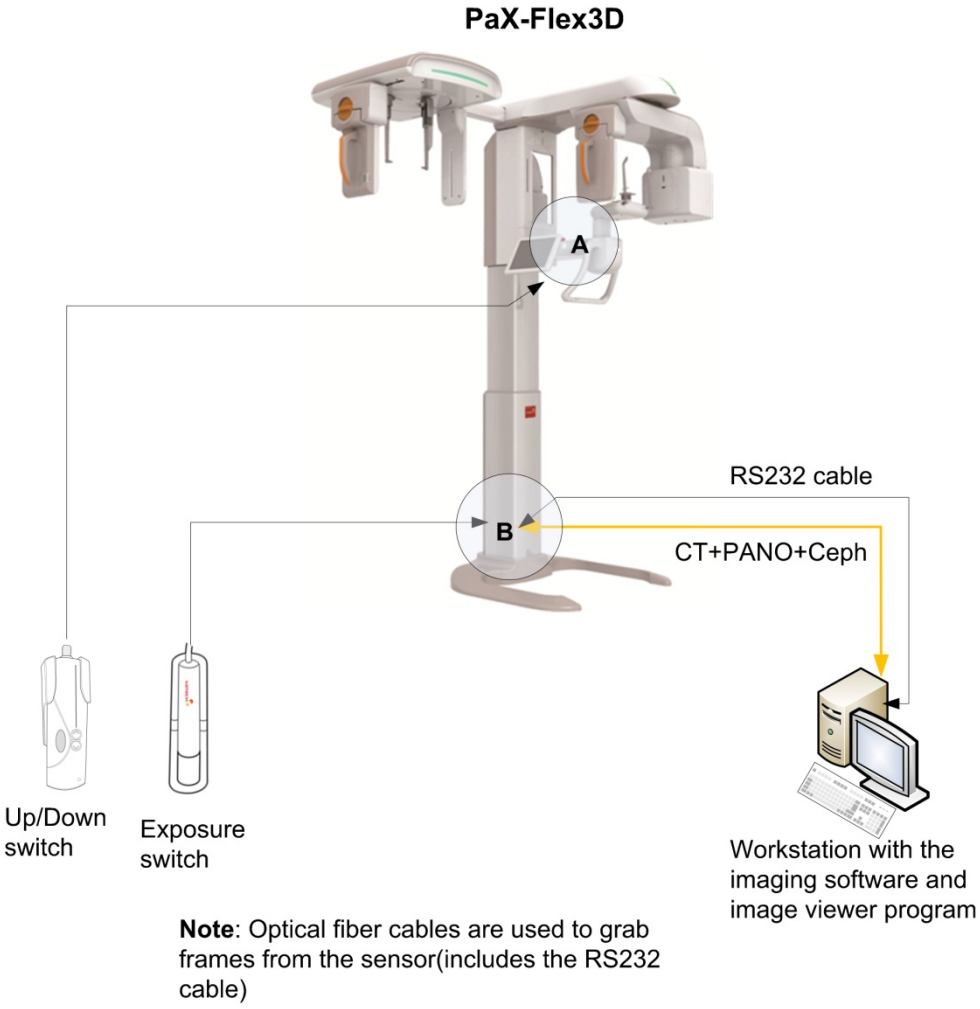
<table>
<tr><th rowspan="2">Mode</th><th colspan="6">Panoramic</th></tr>
<tr><th colspan="2">Basic</th><th colspan="2">Intelligent (optional)</th><th colspan="2">Ultra HD (optional)</th></tr>
<tr><td rowspan="8">Standard</td><td rowspan="4">Normal</td><td>Adult (Normal)</td><td rowspan="4">Normal</td><td rowspan="2">Adult</td><td rowspan="4">Normal</td><td rowspan="2">Adult</td></tr>
<tr><td>Adult (Wide)</td></tr>
<tr><td>Adult (Narrow)</td><td rowspan="2">Child</td><td rowspan="2">Child</td></tr>
<tr><td>Child</td></tr>
<tr><td rowspan="4">Fast</td><td>Adult (Normal)</td><td rowspan="4">Fast</td><td rowspan="2">Adult</td><td rowspan="4">Ultra HD</td><td rowspan="2">Adult</td></tr>
<tr><td>Adult (Wide)</td></tr>
<tr><td>Adult (Narrow)</td><td rowspan="2">Child</td><td rowspan="2">Child</td></tr>
<tr><td>Child</td></tr>
<tr><td rowspan="7">Special</td><td colspan="2">Frontal</td><td colspan="2">Orthogonal</td><td colspan="2">Orthogonal Ultra HD</td></tr>
<tr><td colspan="2">TML (Lateral)</td><td colspan="2">Bitewing</td><td colspan="2">Bitewing Ultra HD</td></tr>
<tr><td colspan="2">TMJ (PA)</td><td colspan="2">Frontal</td><td colspan="2">Frontal</td></tr>
<tr><td colspan="2">Sinus (PA)</td><td colspan="2">TMJ (Lateral)</td><td colspan="2">TMJ (Lateral)</td></tr>
<tr><td colspan="2" rowspan="3"></td><td colspan="2">TMJ (PA)</td><td colspan="2">TMJ (PA)</td></tr>
<tr><td colspan="2">Sinus (PA)</td><td colspan="2">Sinus (PA)</td></tr>
<tr><td colspan="2">Sinus (Lateral)</td><td colspan="2">Sinus (Lateral)</td></tr>
</table>

NOTE	**: Intelligent (Auto-focusing) mode is supported.** **: Ultra HD (High Definition) mode is supported.**

Mode	Sub mode
Cephalometric	Lateral
	PA
	SMV
	Carpus
CT	Maxillary (Left, Center, Right)
	Mandible (Left, Center, Right)
	Occlusion (Left, Center, Right)
	TMJ (Left, Right)
	Stitching [5x5(default), 8x5(optional)]

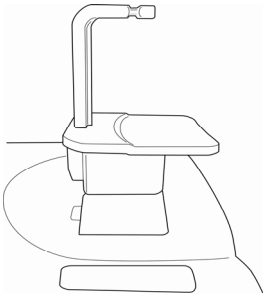
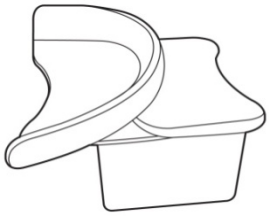
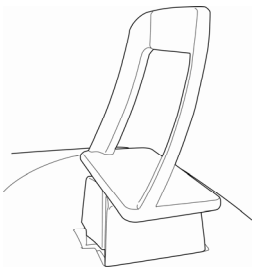
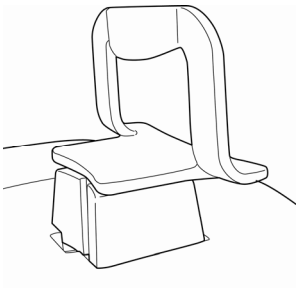
1.3 Imaging system structure

The following illustration shows the direct connection diagram to acquire, process, and view an image.



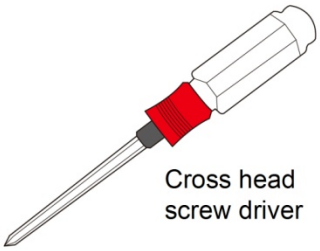
NOTE	**Real-time communication between the touchpad screen (optional) and the PC is established via the RS-232.**

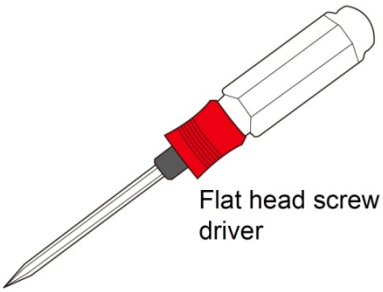
1.4 Replaceable parts and positioning accessories

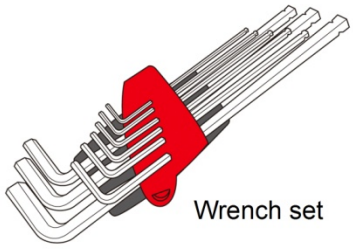
Accessory	Description
	Normal bite
	Support for the edentulous patient
	TMJ support
	Sinus support

1.5 Tools required

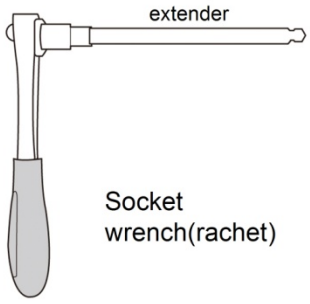
The following tools are required to expedite the installation of the PaX-Flex3D with ease.


Cross head screw driver


Flat head screw driver


Wrench set


Rubber hammer



Socket wrench(rachet)

Multi-meter(up to 1500VDC/15A)


Spirit level

2 Preparing for the installation

2.1 Space Requirements for the installation

Recommended Minimum Space

- PaX-Flex3D w/o Cephalometric unit: **2000(L) * 2000(W) * 2500(H) mm**
- PaX-Flex3D w/ Cephalometric unit: **2300(L) * 2000(W) * 2500(H) mm**

Above space is considered for the movement of both system operator and patient.
The system is normally installed beside a wall, and operator uses the system on left.

Width of Door

The width of door is more than 800mm for system movement into X-ray room.

Installation site

The condition of ground should be flat for system balance.
Ground should support a min. 500KG of weight.

Power Supply

For the stable operation, please allow the following power supply at minimum
(Depending on the local power distribution system)

- Input voltage AC 110/230V ± 10%
- Phase single
- Frequency 50/60 Hz
- Power rating 1.8KVA

	**For the stable operation of the equipment, never use the same main power outlet, used by other power devices. Always use the dedicated power outlet.**

Protection against radiation

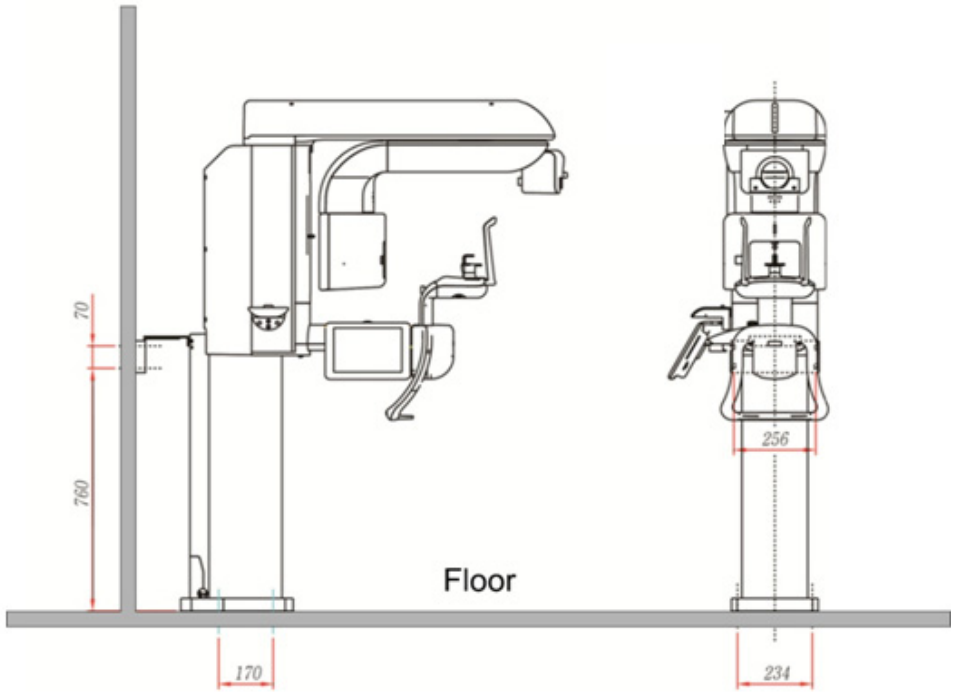
For protection against radiation follow the government or local standards.

Safety Zone

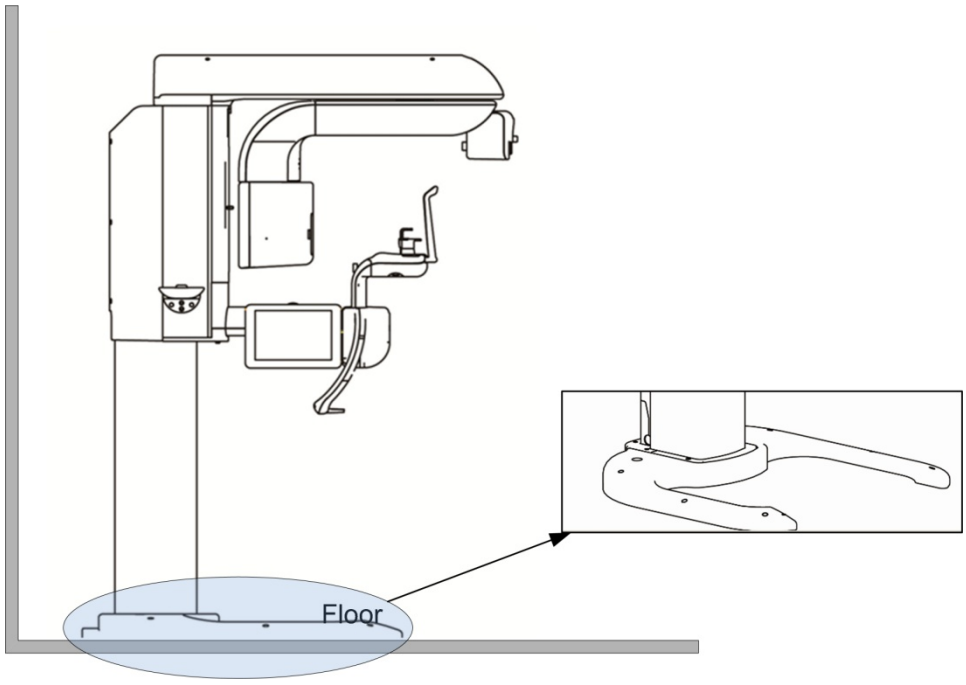
Check the safety zone.

2.2 The installation versions

A. Wall mount version (without Cephalometric function): Optional



B. Floor standing type: Default



2.3 Checking the ShockWatch status

Each carton is attached with the ShockWatch to monitor its conditions, while being delivered, from vibration, shocks and various impacts.
Please follow the next steps before opening the carton.

1. Check visually whether the "**ShockWatch**" indicator on the carton has turned red.
2. If the indicator is red, do not open the carton.
3. Report immediately this fact to your Delivery Company, agent, or VATECH.

This sticker affixed on the box in pair with ShockWatch

Indicator:this turns red when affected

WARNING	**Please check the color of ShockWatch on the carton. Even if the indicator is red, it does not necessarily mean that the unit had been damaged. However, immediately contact the Delivery Company, agent, or VATECH.**

2.4 Unpacking the cartons

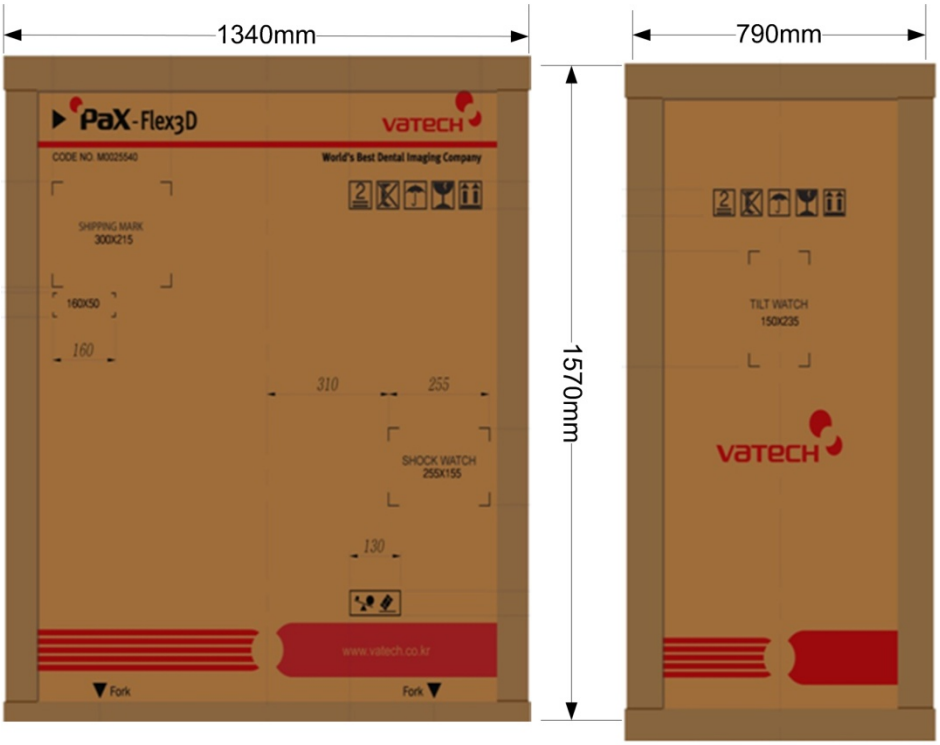
A. Models and physical specifications

1. PaX-Flex3D-P type

(Panoramic only)

C/T No.	Components included	Dimension(mm)	Weight
1	Column, Vertical unit and Rotating units	1340(L)x790(W)x1570(H)	140Kg
2	Base unit	1100x1100x180	50Kg

Column and Rotating units



Front view

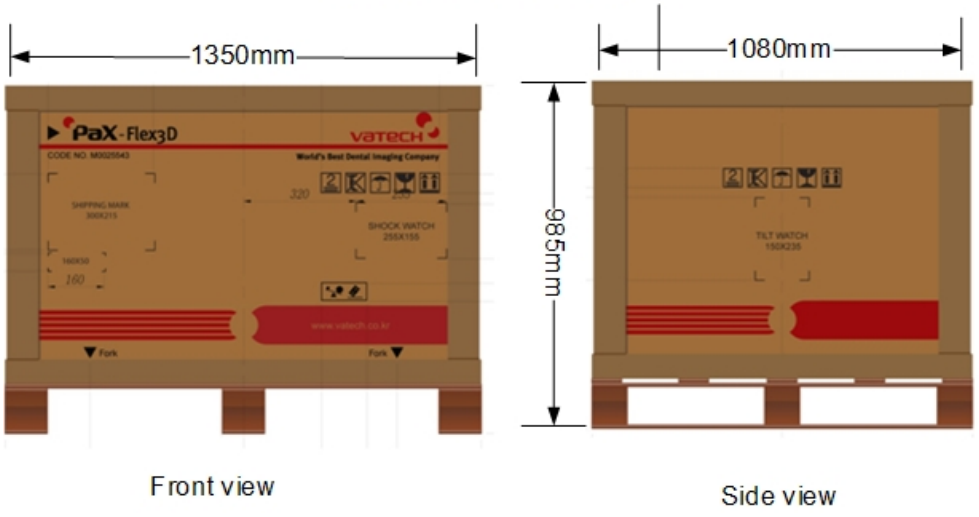
Side view

2. PaX-Flex3D-C type

(With Cephalometric unit)

C/T No.	Components included	Dimension(mm)	Weight
1	Column, Vertical unit and Rotating units	1340x790x1520	140Kg
2	Cephalometric and Base units	1350x1080x985	90Kg

Cephalometric and Base units

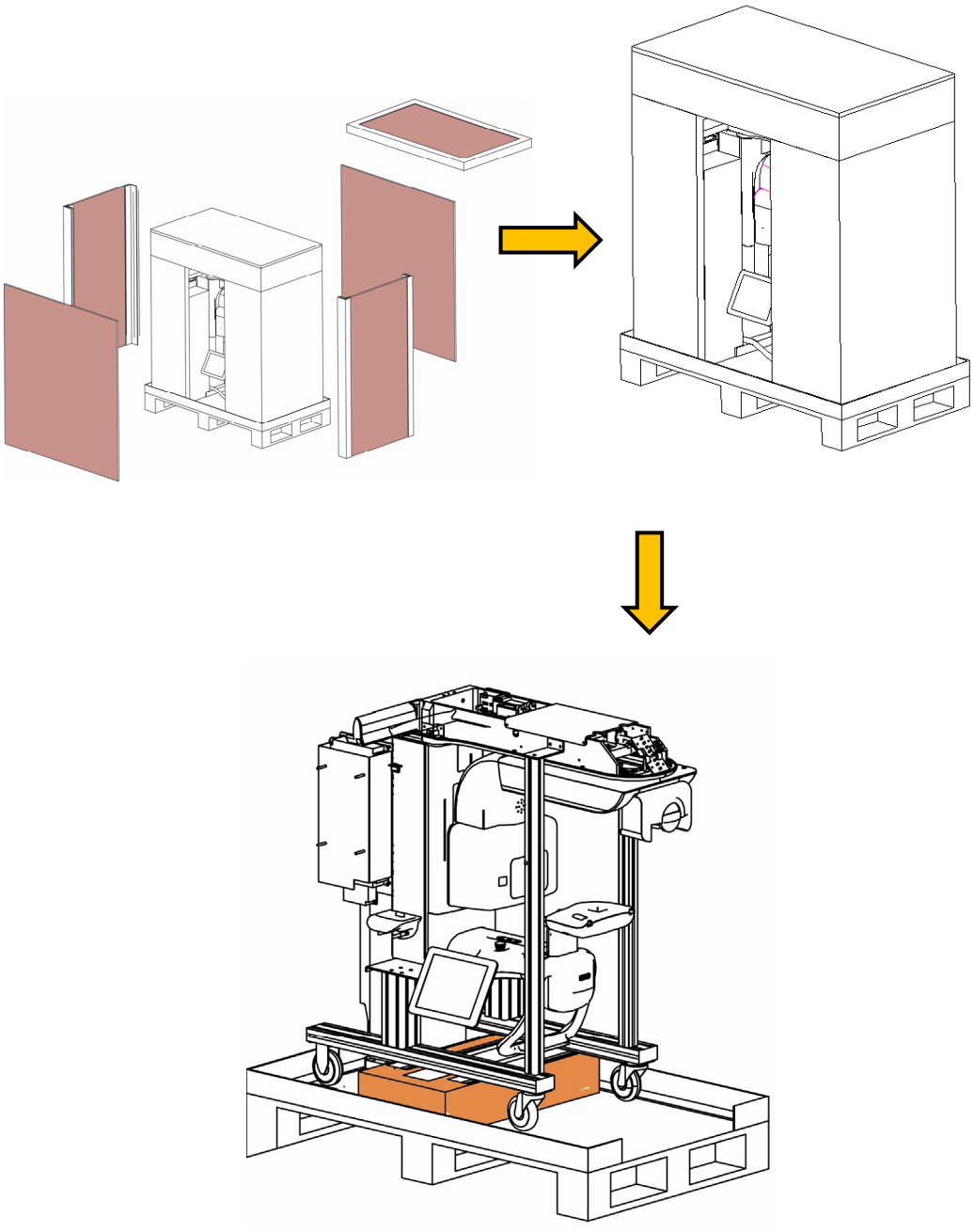


B. Unpacking the box

1. Locate the carton No.1 which contains the main unit.

2. Move this carton near the installation site and open the top cover of the carton.

3. Remove four side cardboards one by one.



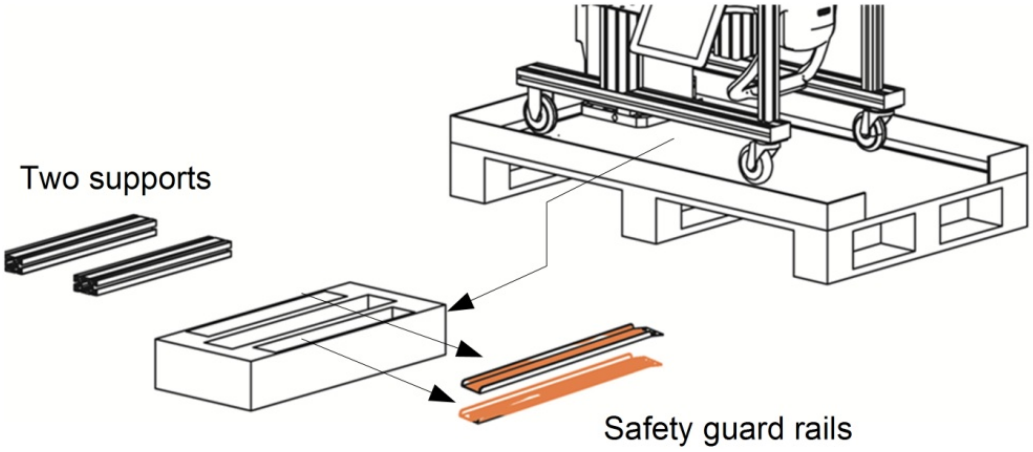
The view after unpacking the box

4. Check that the following parts are contained in the box.

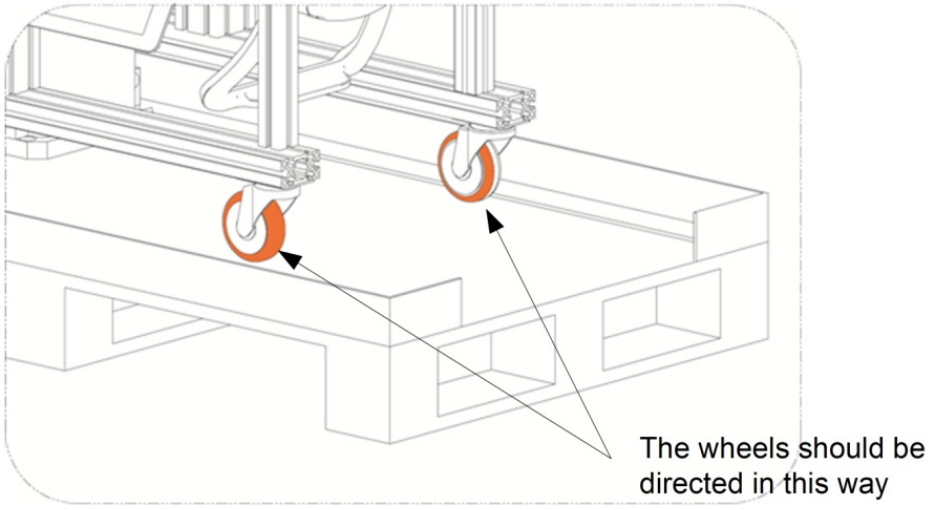
NO	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
1	COLUMN, VERTICAL UNIT, ROTATING UNIT(ASSEMBLED)			1
1-1	VERTICAL TOP CASE	Kit		1
	SENSOR CRADLE ASS'Y			1
1-2	CRADLE BLOCK			1
	WRENCH BOLT M6x12			2
1-3	CASE COLUMN REAR	Kit		2

C. Unloading the equipment

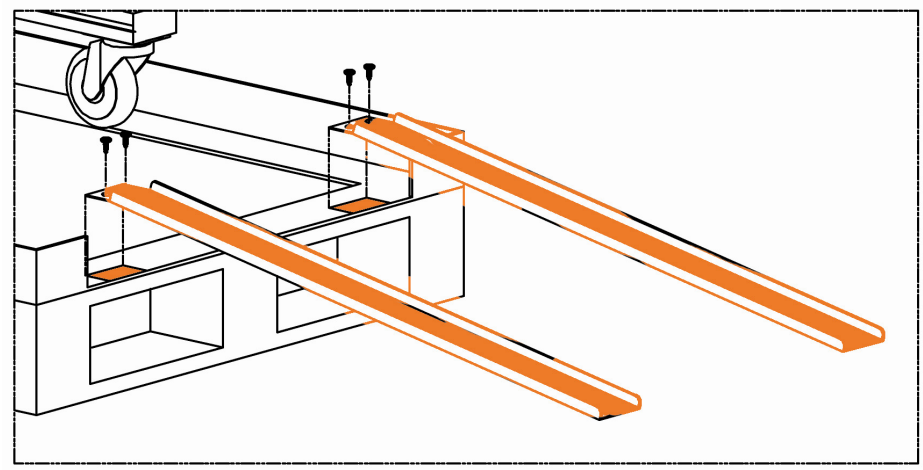
1. Take two safety guard rails out of the box which is placed under the equipment.

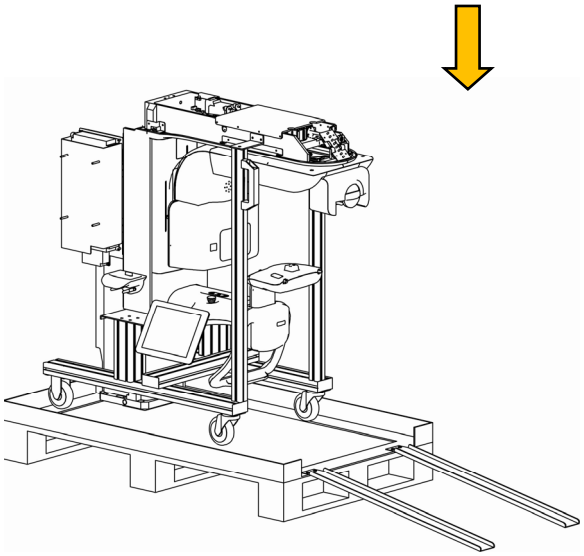


2. Make sure that the wheels should face the direction, as shown in the following figure.



3. Place two guard rails onto the printed area(colored area in the following figure) and tighten them firmly using four screws(**M4x20: Part No.:43**)



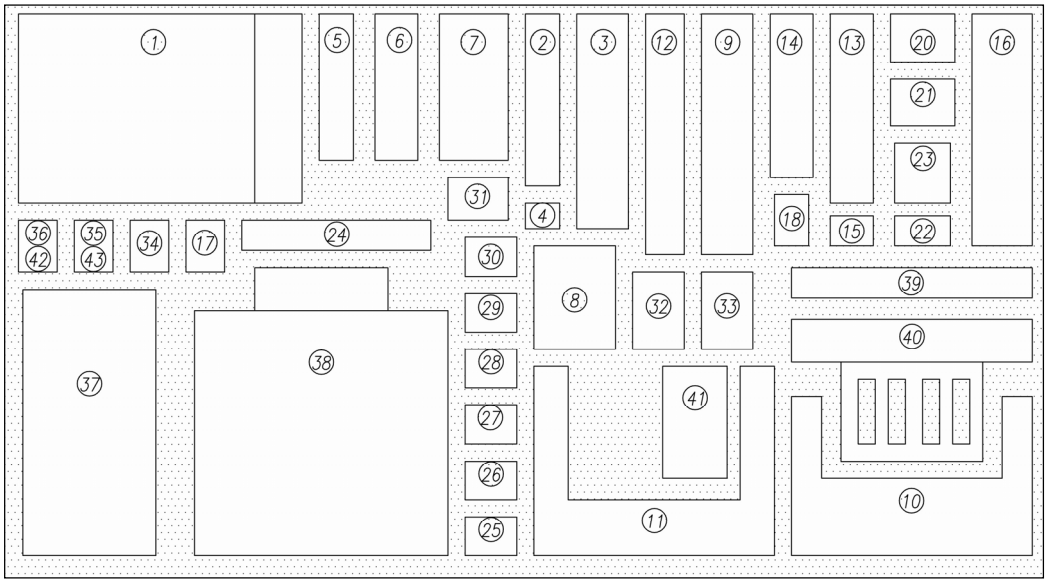


View upon completion

4. Unload the equipment from the crate and move it near the installation site.

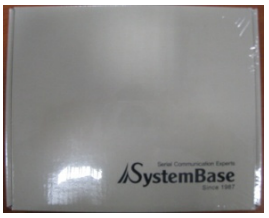
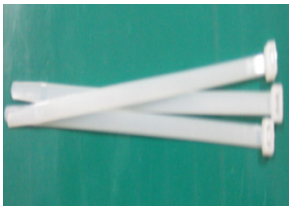
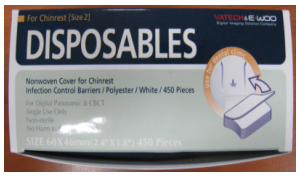
2.5 Checking parts and accessories

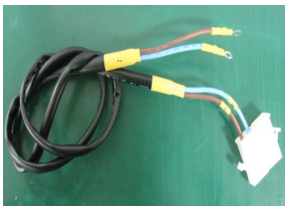
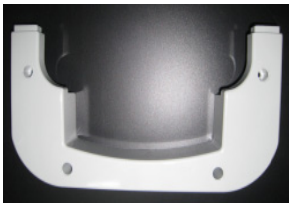
A. Location layout of the parts and assembly units supplied

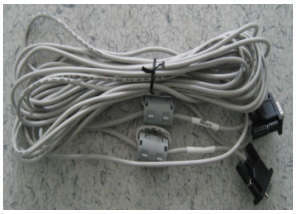


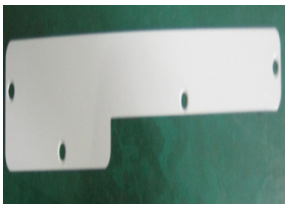
B. Parts list

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
	USER MANUAL & INSTALL CD			1each
1	HANDREST	(Optional) Use for the Cephalometric		1
	MOUSE PAD			1

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
2	SERIAL CARD	M-19/232A1		1
3	FRAMEGRABBER CARD	OPTIC2		1
4	RESCONSTRUNTION KEY			1each
	Ez3D2009 VIEWER KEY			1each
5	TIE	Cable tie, middle		10
6	COLUMN REAR SUB COVER	ABS		1
7	Non-woven cover	60		1

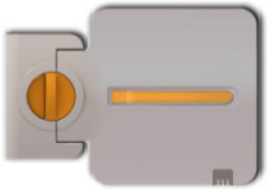
No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
8	INSTALL Cable			1each
9	CASE COLUMN MID	ABS		1
10	COLUMN FLOOR COVER	ABS		1
11	BASE CASE COVER-F	ABS		1
12	BASE CASE COVER-R	ABS		1
13	TEMPLE SUPPORTS (RIGHT, LEFT)	PC		1 set

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
14	UP DOWN SWITCH			1
15	UP DOWN SWITCH HOLDER			1
16	RS232 CABLE	P5065A		1
16	EXPOSURE SWITCH			1
17	EXPOSURE SWITCH HOLDER	ABS		1
	SILICON CAP(WHITE)	Silicon Cap - A		1
18	BITE COVER			1

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
19	CHIN SUPPORT	ABS		1
20	NON CHIN	PC		1
21	SINUS CHIN			1
22	TMJ CHIN	PC		1
23	NORMAL CHIN BITE CHIN	PC		1
	BITE CHIN			1
24	CEPH ARM BOTTOM CASE	AL, (EP033K)		1

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
25	TRUSS BOLT	M4 x 8		18
26	FLAT HEAD BOLT	M4 x 8		4
27	FLAT HEAD BOLT	M4 x 16		4
28	ROUND HEAD BOLT	M5 x 10		4
29	WRENCH BOLT	M6 x 25, CEPH ARM		4
30	WRENCH BOLT	M8 x 50, COLUMN fixing		8
	FLAT WASHER	M8 TYPE, COLUMN fixing		8
	SPRING WASHER	M8 TYPE, COLUMN fixing		8

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
31	WRENCH BOLT(WITH FLAT & SPRING WASHER)	M10 x 40		4
32	TAPPING SCREW (FLAT HEAD)	M4 L=30		4
	KAL BLOCK SET	M4 TYPE		4
33	CAP EAR-L/R-CHIN	Silicon		2 sets
34	CAP EAR	For the Ceph.		4
35	SILICON CAP(WHITE)	Silicon Cap - A		10
36	SILICON CAP(Beige)			14

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
37	ANYPANO	NP/SP MODEL(Optional)		1
	ANYCEPH	NC/SC MODEL(Optional)		1
38	COLUMBUS PLUS	SP/SC MODEL, FOV 5x5		1
		SP/SC MODEL, FOV 8x5		1
	CONCORD 1	SP/SC MODEL, FOV 8.5x8.5		1
		SP/SC MODEL, FOV 12x8.5		1
39	This numbered slot left empty intentionally			
40	WALL BRACKET 1 ,2-SPC 4.0T (ZnW)	WALL-MOUNT TYPE		1
	WRENCH BOLT(WITH FLAT & SPRING WASHER)+	M8 x 20		4 sets

No.	ITEMS	SPECIFICATION	PICTURE	Q'ty(EA)
	WRENCH BOLT(WITH FLAT & SPRING WASHER)	M6 x 20 (WALL-MOUNT TYPE)		2
	HEX HEAD BOLT + FLAT WASHER(M9 TYPE)	3/8" x 3" (THREAD TYPE : WOOD)	(Optional item) For U.S market only	4
	ANCHOR BOLT SET	M8 (WALL-MOUNT TYPE)		8
41	POWER S/W			1
42	WRENCH BOLTS	M8 X40		4
43	SELF-TAPPING PHILLIPS HEAD SCREWS	M4 X20		4

3 Installing the equipment

3.1 Assembling the base and the main units

NOTE	**Please make sure that ground on which equipment is to be installed is flat and dry before installation.**

NOTE	**The recommended location for the unit to be installed is where high visibility with the patient is available and distance to the patient is as close as possible.**

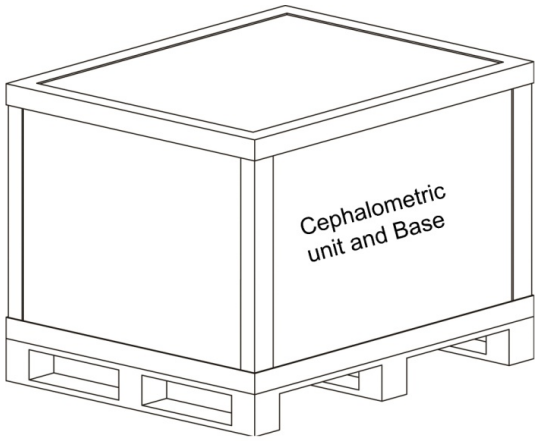
NOTE	**Please keep a minimum of 300mm distance from the wall because you need enough space to maneuver for cabling and covering works on the backside.**

A. Open the accessory box that comes with the unit to be ready to use.

B. Remove the protective plastic that wraps around the rotating unit.

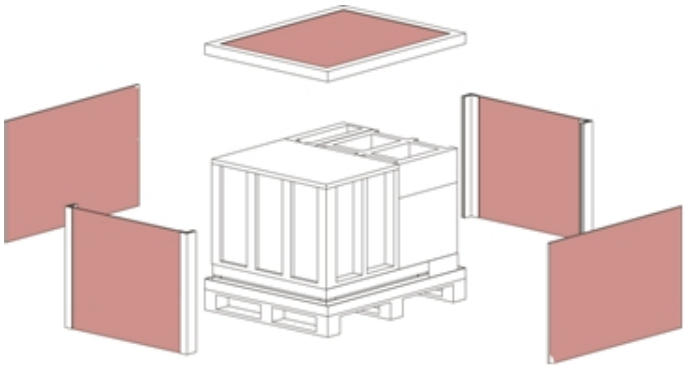
C. Take the *base unit* out of the 2nd box

1. Locate the 2nd box.

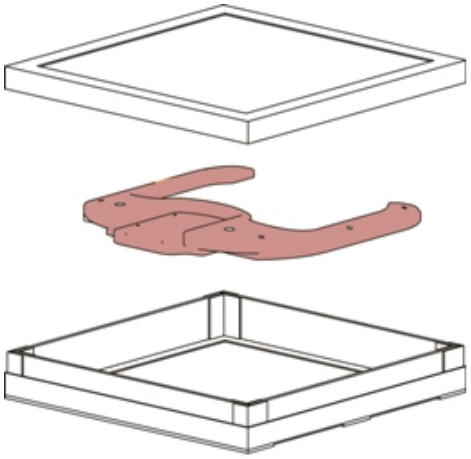


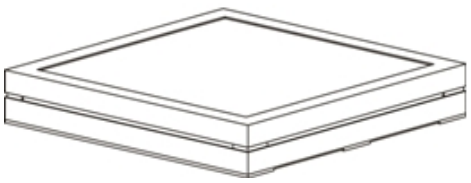
If the equipment is without Cephalometric function, this box contains only the base unit

2. Remove four side cardboards and a top cover.

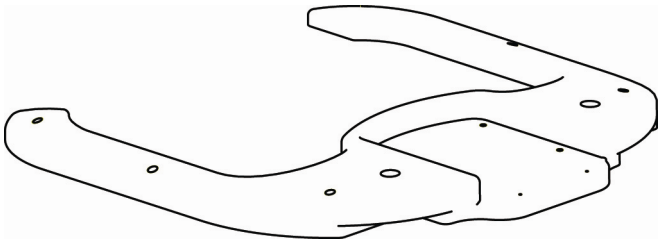


3. Take the base unit out.



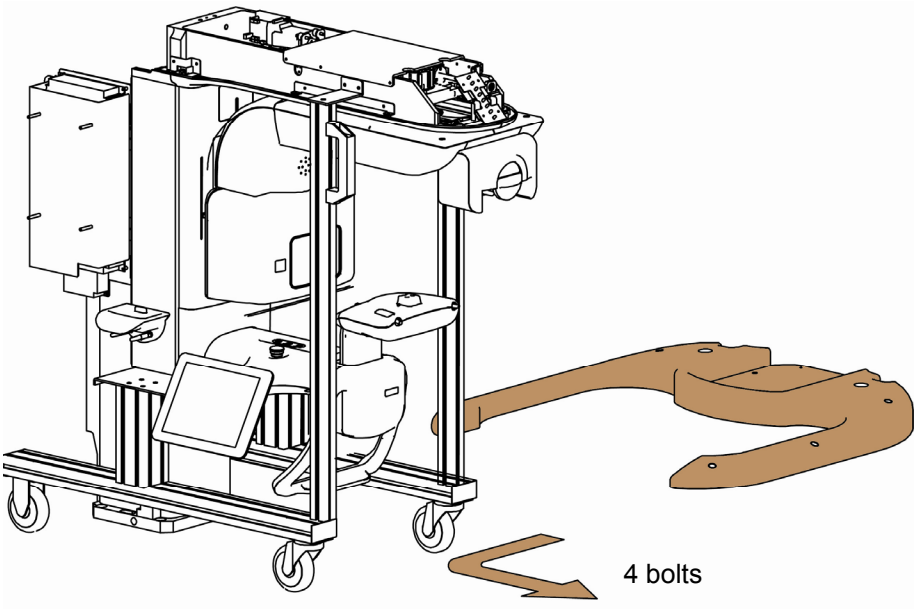


4. Place the base unit where the equipment will be installed.

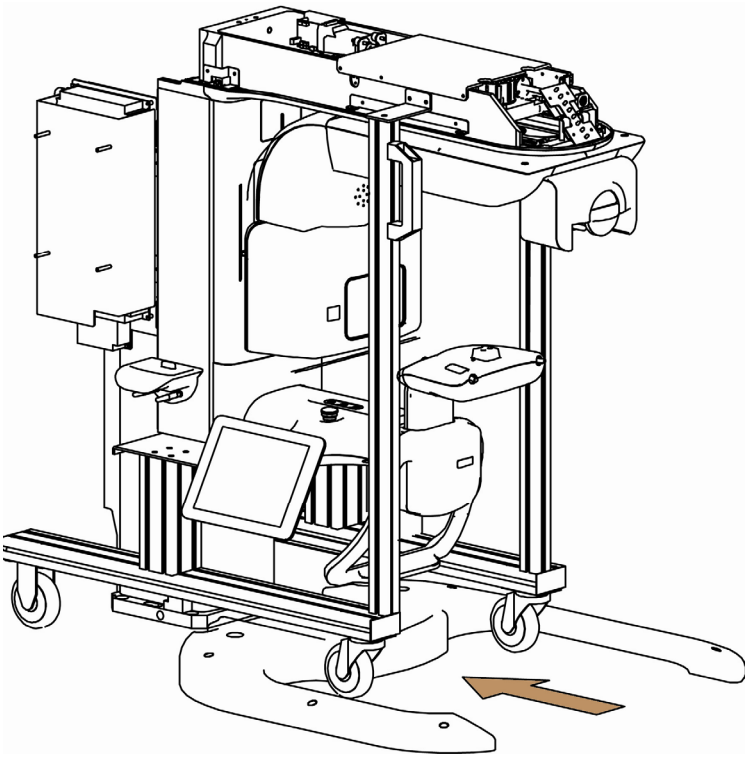


NOTE	**For the wall mount version, the base unit is not necessary.**

D. Push the base unit through the space under the equipment, as shown in the following figure.



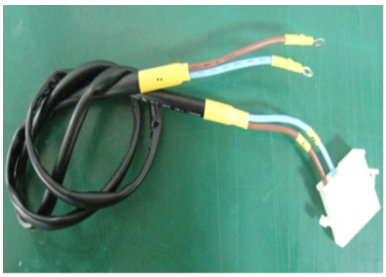
E. Slide (push) the base unit to the rear close enough until four holes are matched, as shown in the figure.



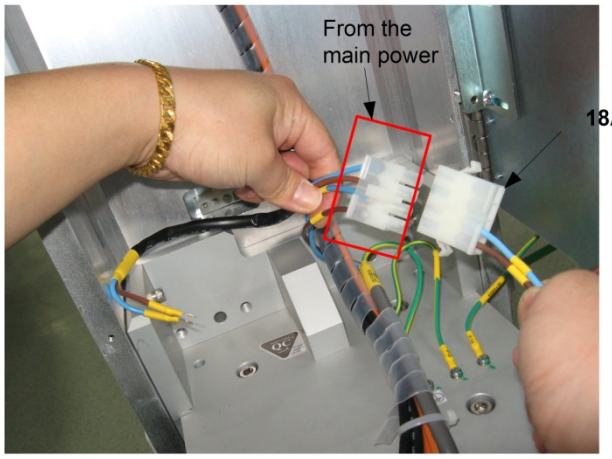
F. Wiring the cables to apply the ***temporary power*** for the column movement

WARNING	**Extreme care must be taken to assure safety to the installer and the equipment for this wiring. Thus double- check the wiring conditions before applying power.**

Do take the numbered steps.

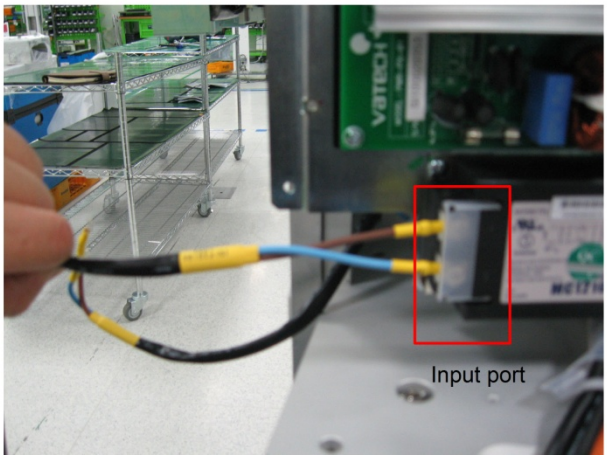


1. Locate the power cable in the parts box(**part No.: 8**)



18A cable(supplied)

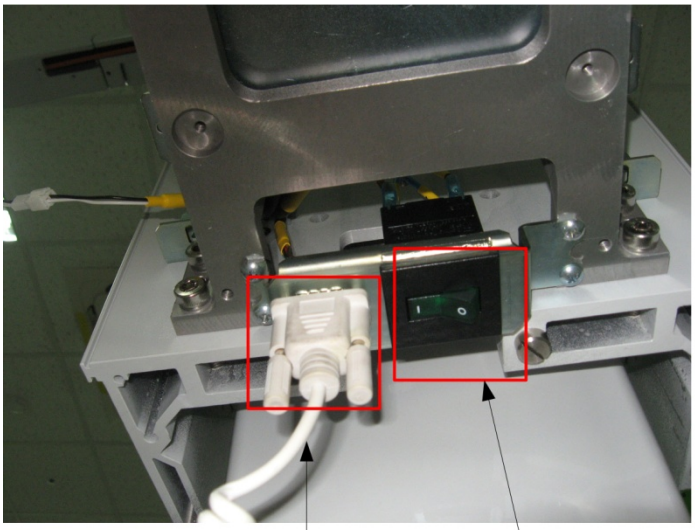
2. Connect the cable **18A** with the main power supply



3. Connect the other end of cable **18A** With the input port

G. Connect the UP/DOWN switch and plug the power cable and turn ON the equipment.

WARNING	**Before applying power to the equipment, check the main outlet voltage meets the requirement specified in the technical data.**

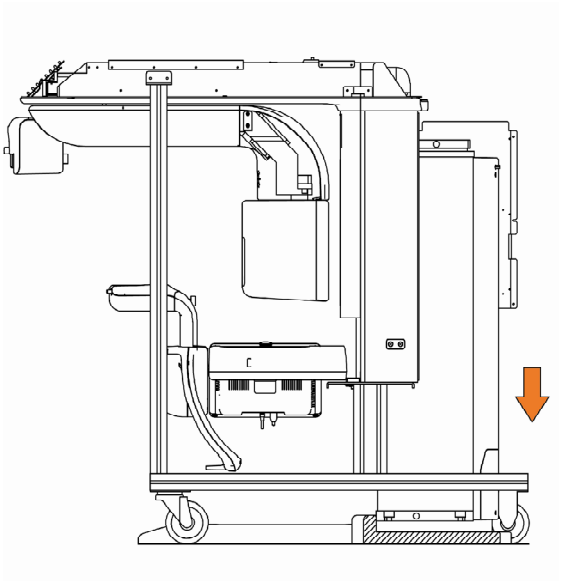


1. Connect the UP/DOWN switch, as shown in left figure

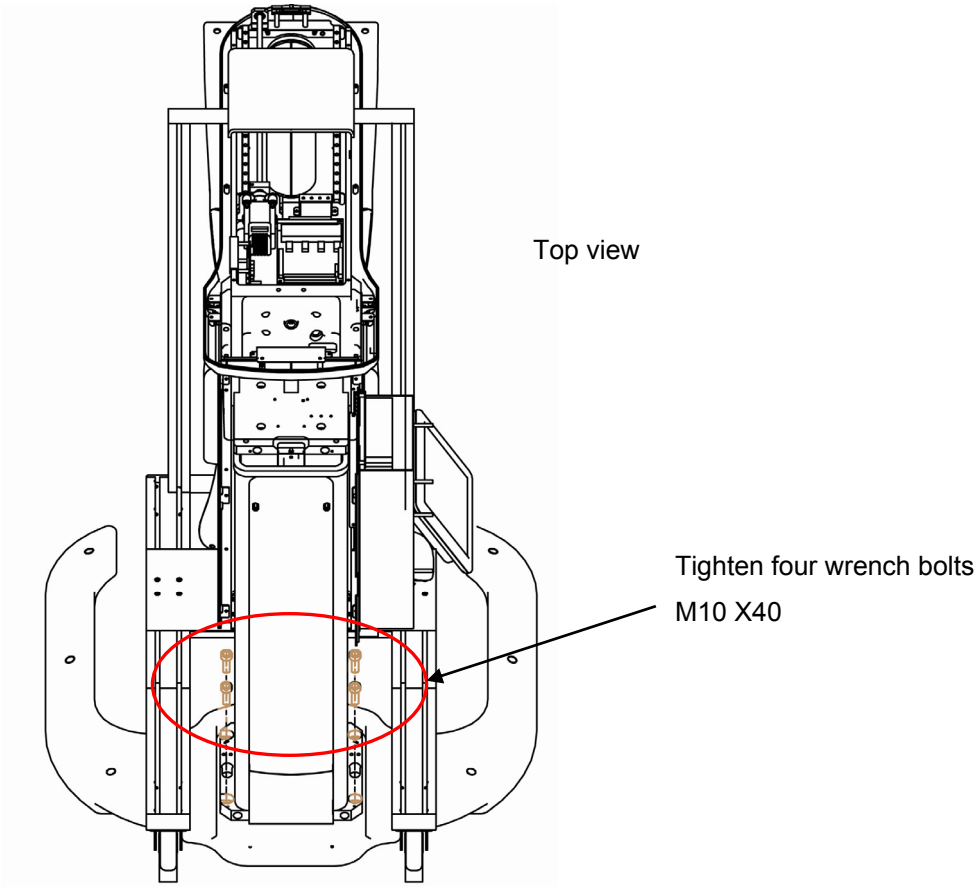
2 .Plug the main power cable into the outlet

3. Turn on the equipment. ON/OFF switch is located on the right side of the UP/DOWN switch

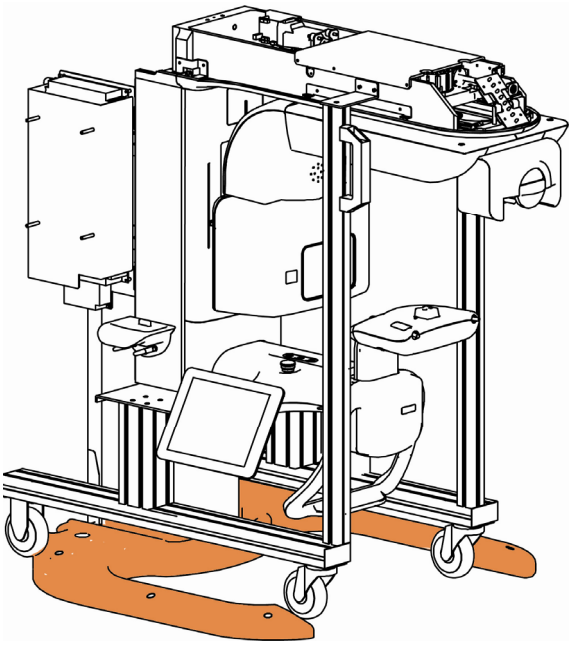
H. Lower it slowly using the UP/DOWN switch until they(column and base units) touch each other barely.



I. Align four holes to make them matched and screw the main unit and the base unit using four wrench bolts (M10X40: **Part No.:31**) firmly.

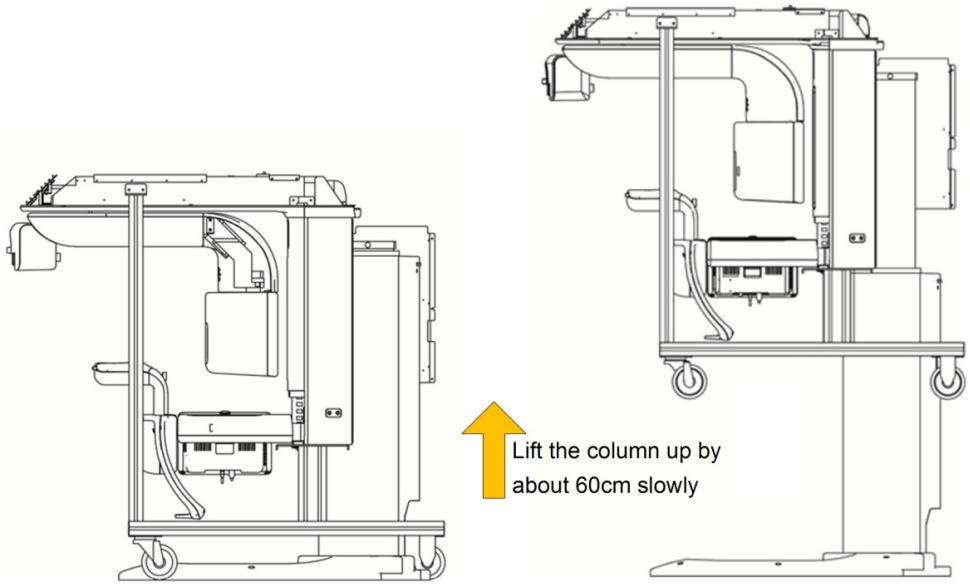


The following figure shows the resulting assembly of the base unit with the main unit.

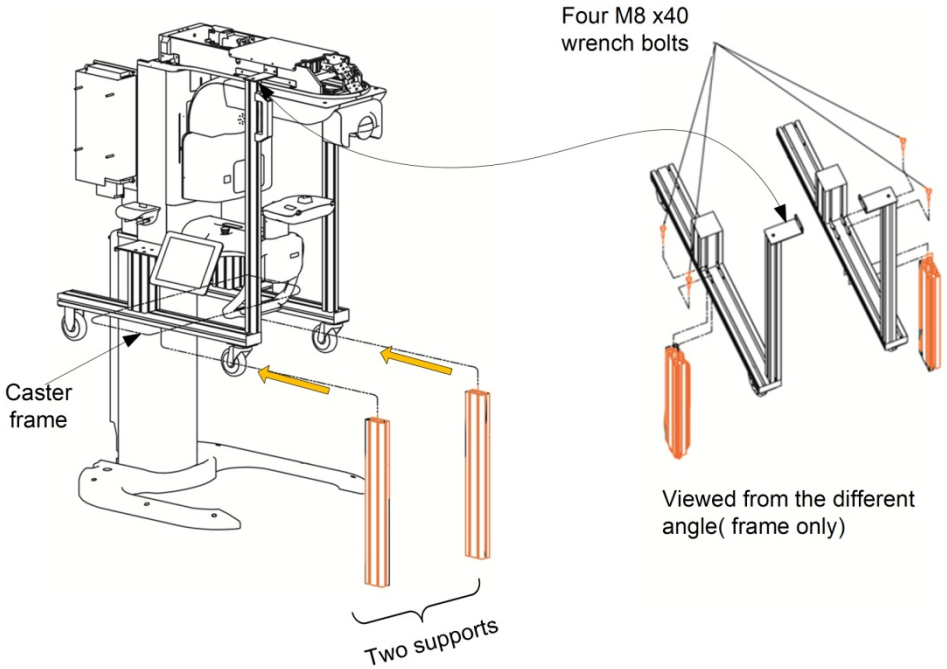


WARNING	**Be careful not to scratch any surface around the column while working on this step.**

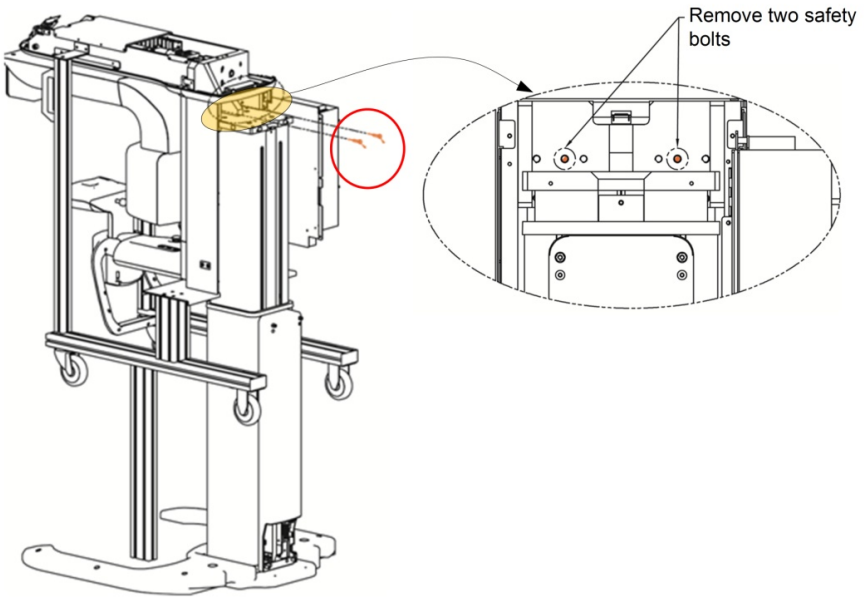
J. Now raise the column up by about 60cm slowly, using the UP/DOWN switch.



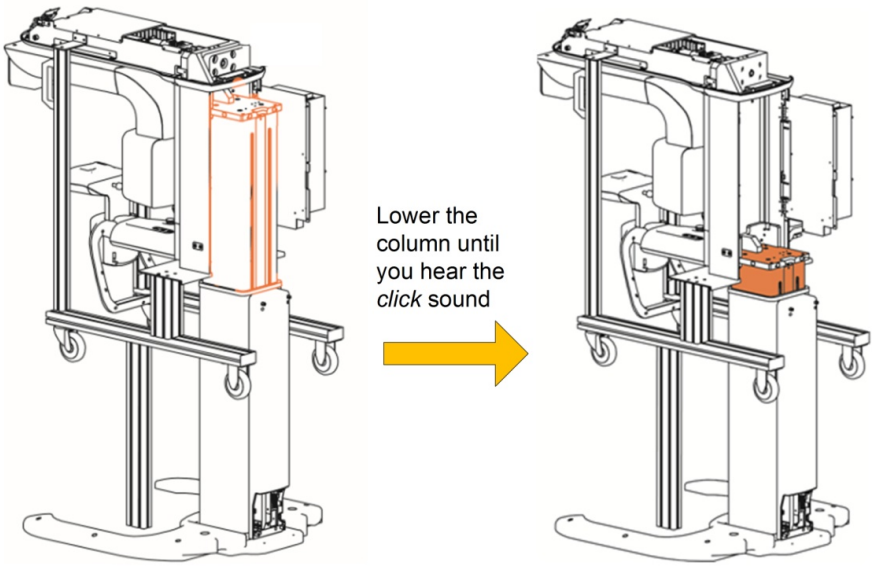
K. Assemble two supports and the support frame(caster frame) on both sides, as illustrated in the following figures with four wrench bolts (**M8 x40: Part No. 42**).



L. Remove two transportation bolts that hold the rotating unit and column in position—installed to prevent the equipment from tipping forward, due to the center of gravity.



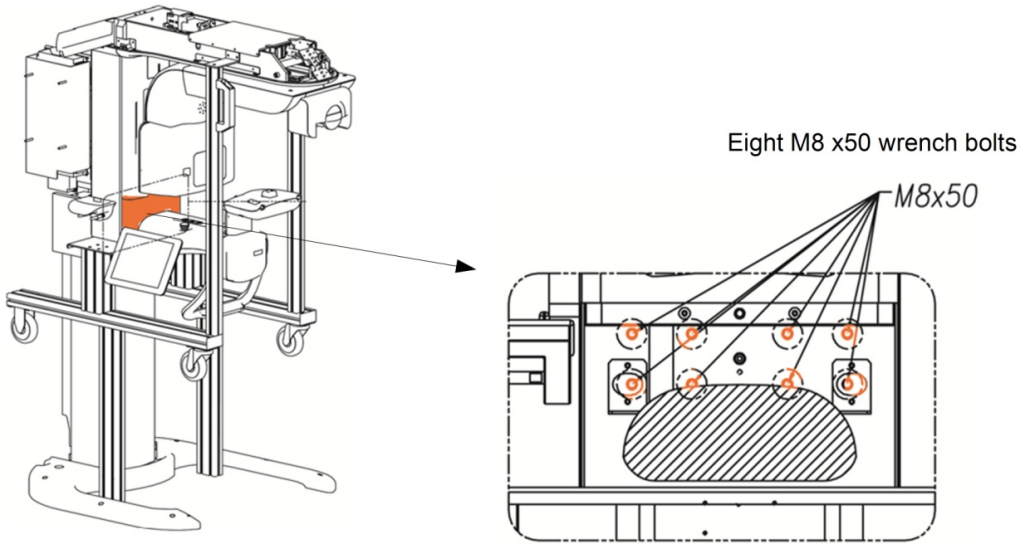
M. Lower slowly the column with the UP/DOWN switch until the ***click*** sound is heard.
At this moment (point), the holes for four wrench bolts —which will hold column and main unit together— are aligned for the next work.



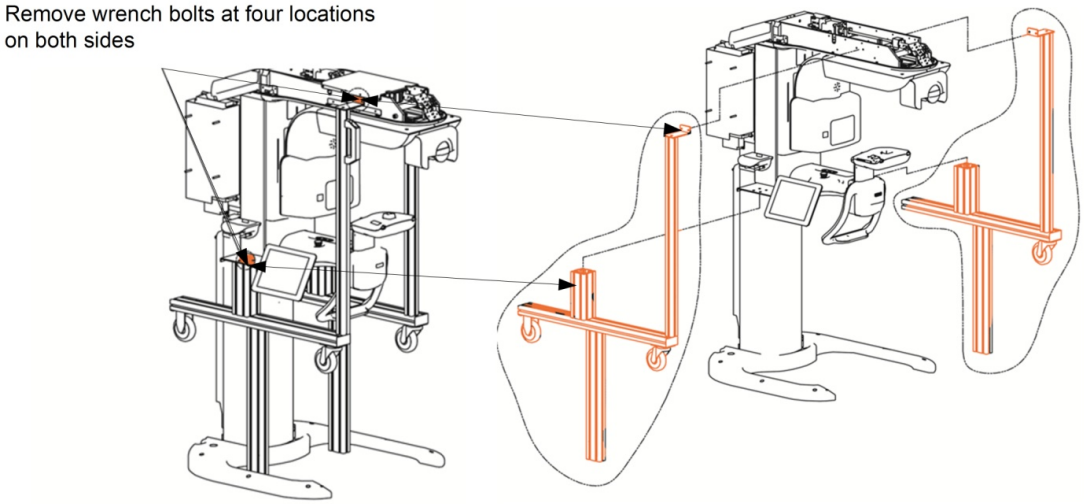
WARNING	Do not keep lowering even after the *click* sound is heard, lest it cause damage to the equipment

WARNING	**It could cause severe damages to the equipment when, even after the *click* sound heard, the column is kept on being lowered beyond this point.**

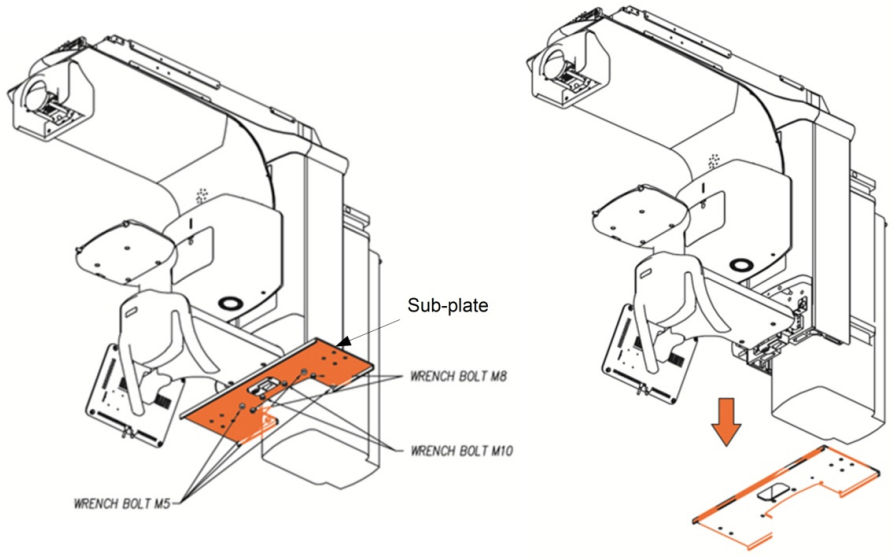
N. Tighten eight wrench bolts (**M8x50: Part No.:30)**. We suggest **tightening** them evenly. Don't screw them down all the way one at a time. Tighten each one a little at a time.



O. After raising the column up by about 5 cm, remove the wrench bolts on both sides to separate the support frames (colored) from the equipment.

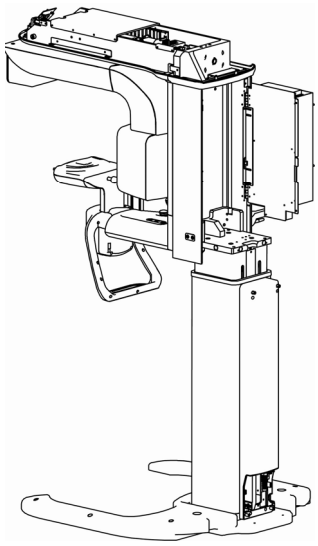


P. Finally separate the sub-plate from the equipment, as illustrated in the following figure.



WARNING	**Be careful not to drop the sub-plate. To avoid this situation, unscrew the bolts, while holding the sub-plate until the last bolt is removed. The failure to comply with this warning could do scratch on the equipment.**

The following figure shows the resulting view of assembling the *base* and the *main* units after removing the support frames and transportation barrow wheels.

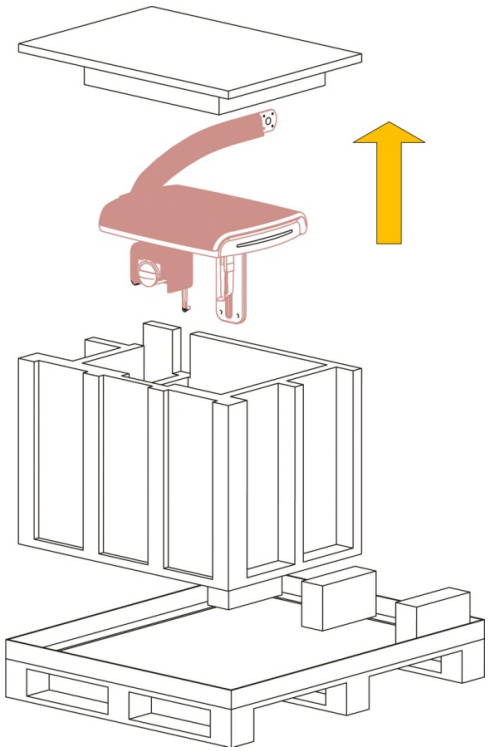


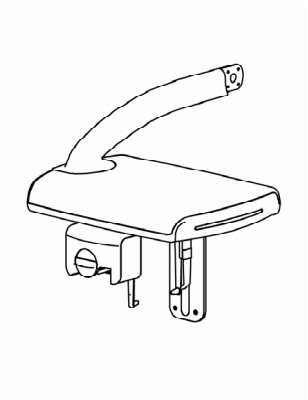
View at oblique angle

Q. If at this installation time the Cephalometric unit and wall mount are not installed, *go to the clause 3.4 directly.*

3.2 Assembling the Cephalometric and column units (Optional)

A. Take the Cephalometric unit out from the 2nd box.

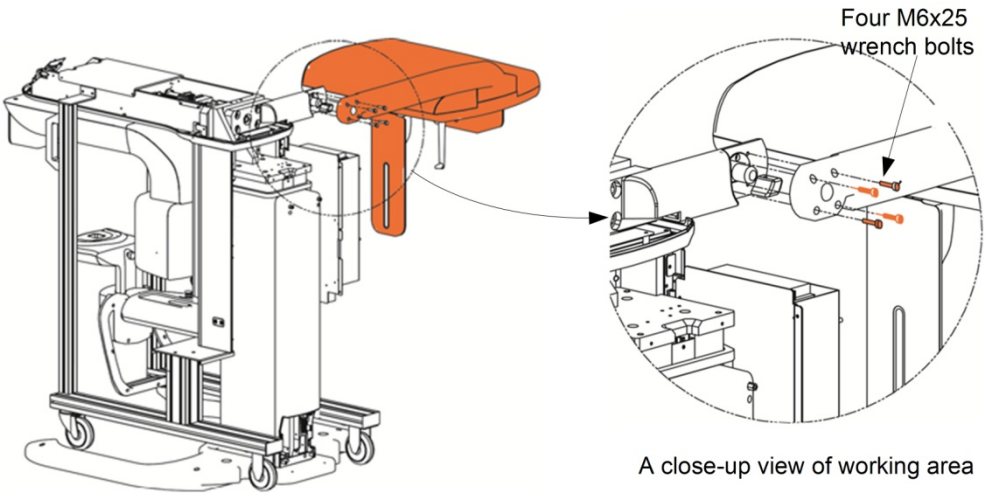




Cephalometric unit

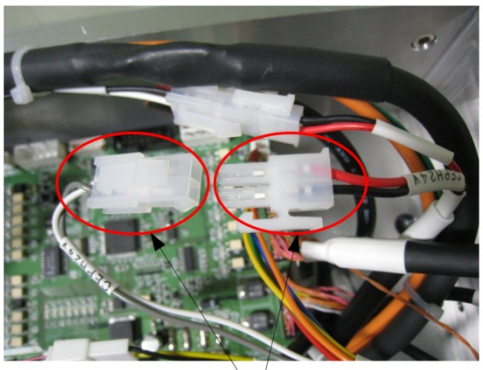
B. Pull three cables out from the Cephalometric unit to make connection work easier later.

C. Mount this unit on the column and tighten four bolts **(M6x25: Part No.: 29)** firmly.



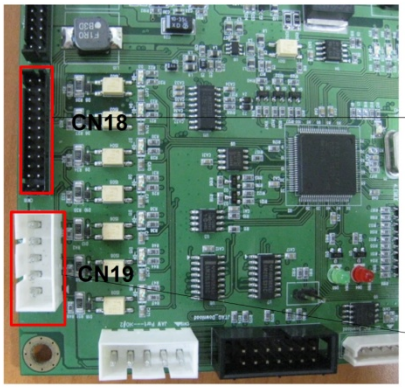
A close-up view of working area

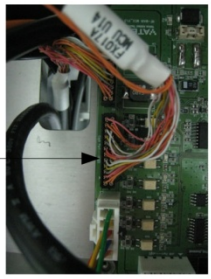
D. Connect the cables with four connectors in order, as illustrated in the following figure.



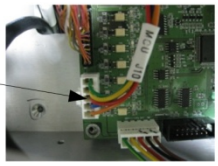
1. Connect the cables named CEPH 24V

Cable name: CEPH 24V

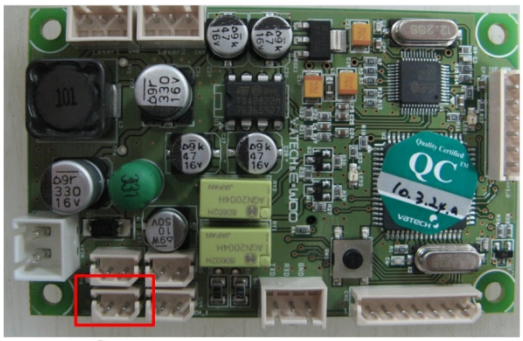




2. Connect FX017A MCU CN18 into the connector CN18

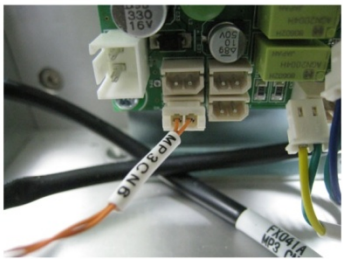


3. Connect MCU CN19 cable into the CN19

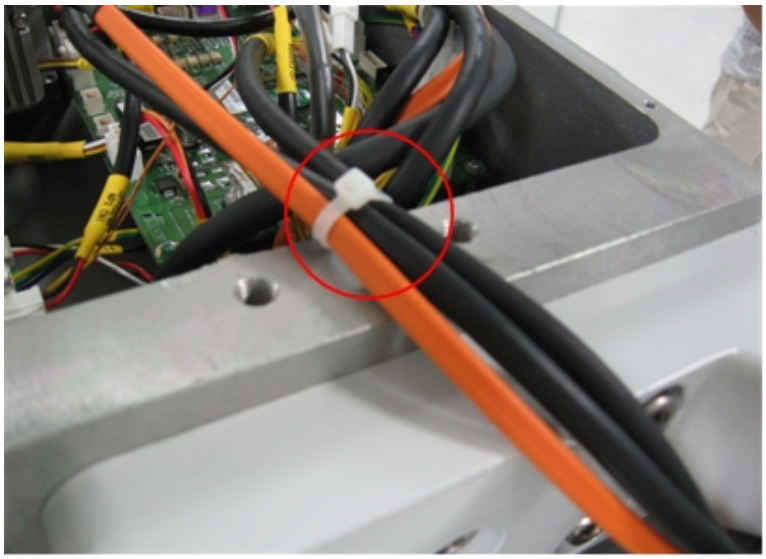


4. Connect the cable MP3CN6 into the connector CN6

CN6



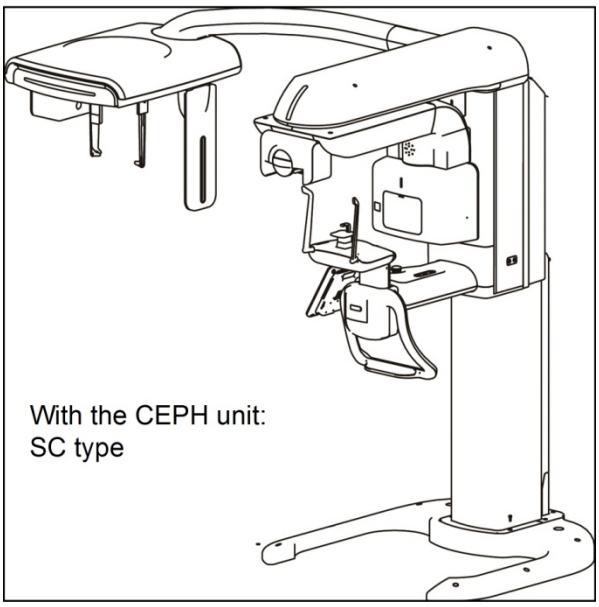
5. Tie the cables with the cable tie (**Part No.:5**) together.



E. Separate the support frames from the column unit to finish the installation of the Cephalometric unit. For this work, see the steps from **K** to **P** in the clause **3.1**.

This completes the installation of the Cephalometric unit.

The finished appearance



F. If the installation is not the wall mount version, *go to the clause 3.4 directly.*

3.3 Installing the equipment of the wall mount version (Optional)

IMPORTANT	**You are advised to plan and study carefully in advance before proceeding, since the installation involves drilling the wall and floor. Accurate measurement is of critical importance to successful installation.**

NOTE	**This equipment is assumed to be installed on the concrete wall and floor.**

NOTE	**The common procedures found in those of the base unit installation are omitted intentionally here to make the manual brief, with no ambiguity in understanding.**

A. Unpack and unload the main unit in the box No.1. The steps from unpacking to unloading the box are identical with those of the base unit installation version: that is, see **Unpacking the box** and **unloading the equipment** on pages 19 and 22, respectively.

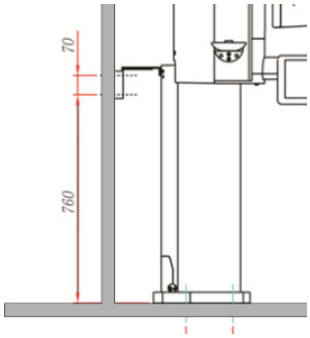
B. Move the equipment to where it is supposed to be installed.

C. Prepare the bracket (**part No.: 40**) to make it ready to be used.

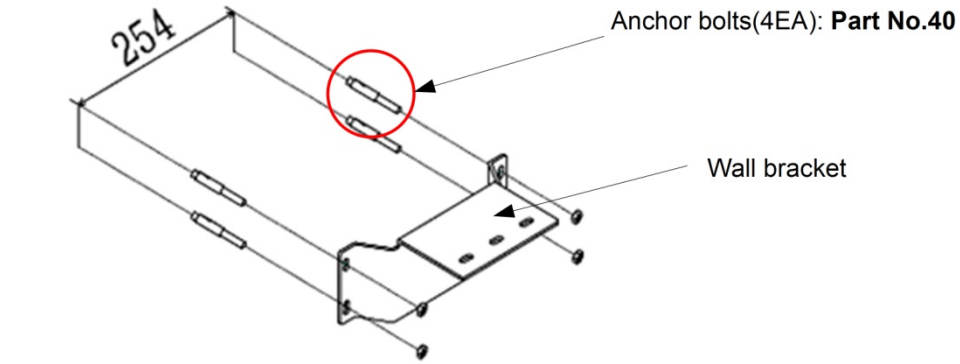
D. Installing the wall mount bracket.

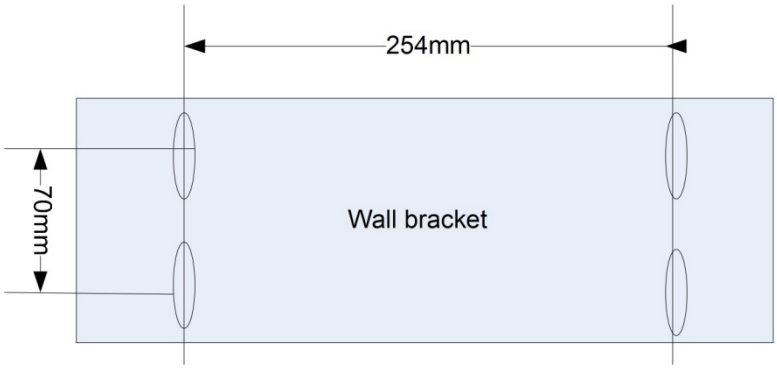
1. Get the proper position on the wall where the wall mount bracket is to be installed.

2. Mark the position at height 760mm above the floor.



3. Mark four hole positions on the wall to where the bolts are to be anchored.

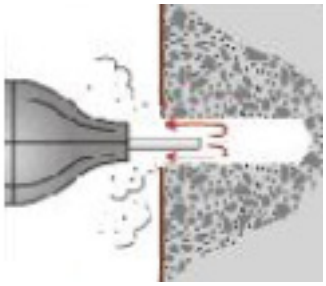




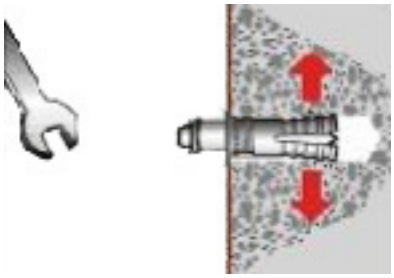
4. Drilling four holes on **the wall** in the following order.

   i. Drill holes of size 10.5mm x 30mm (depth) using the concrete drill.

   ii. Remove the debris and clean the holes using the dust pump.

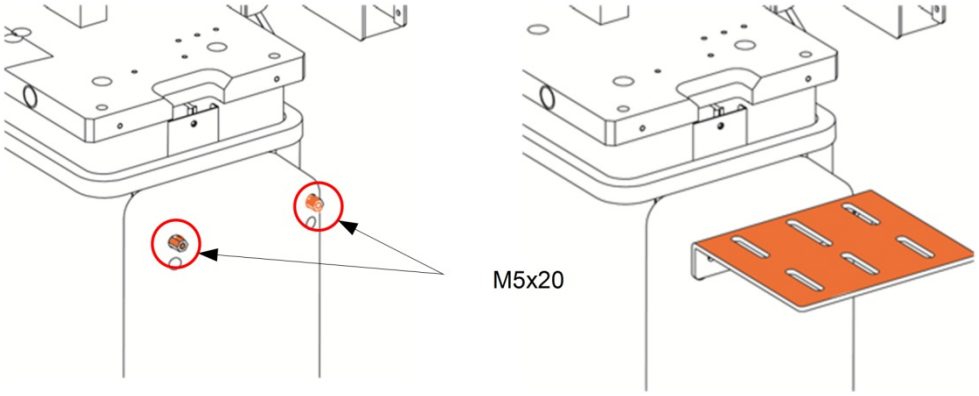


   iii. Insert the anchor bolts (**M4 L=30, Part No. 32**) into the holes using the hammer. Verify that the anchors are secured.



5. Attach and tighten the wall bracket (**Part No. 40**) to the wall, with the anchor bolts (**M8: Part No.:40**).

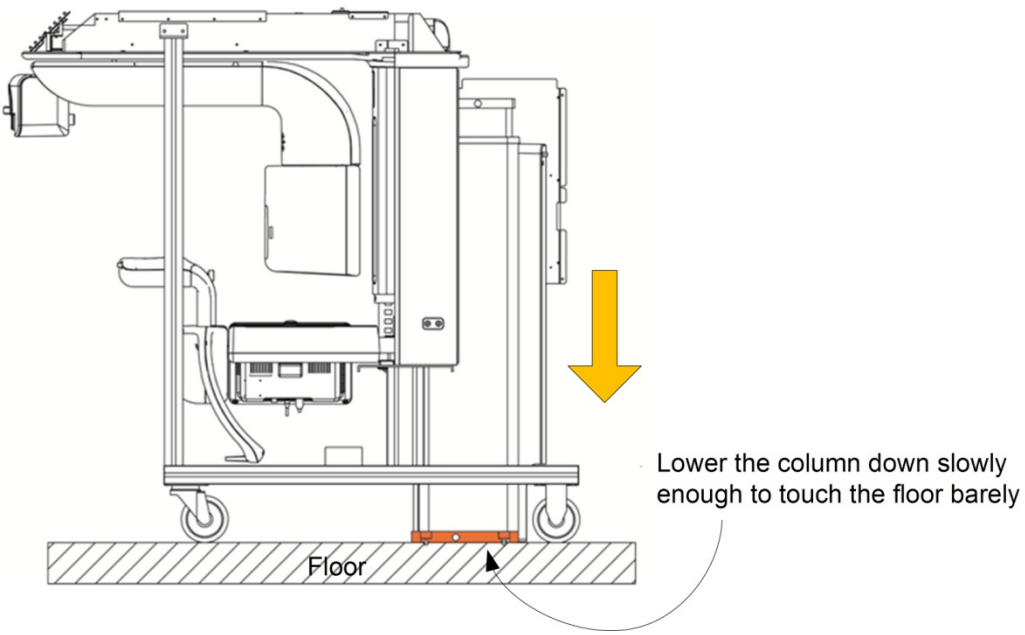
E. Attach the column bracket to the back of the column with the wrench bolts (**M5x20: Part No.:40)**.



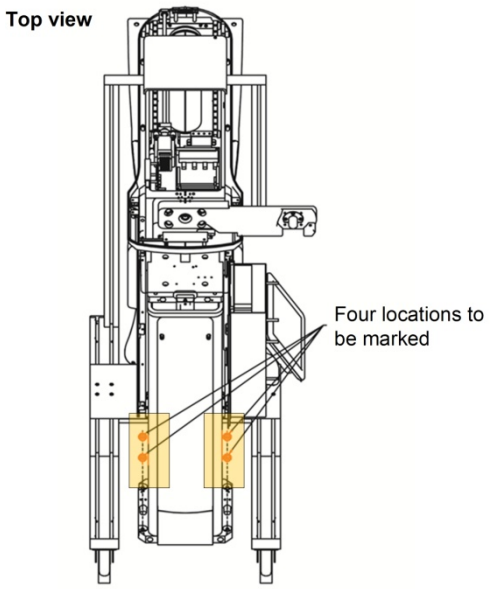
F. Wiring the cables to apply the ***temporary power*** for the column movement.
For this works, see the step F on page 36 in the clause 3.1.

G. Connect the UP/DOWN switch and plug the power cable and turn ON the equipment.
For this works, see the step G on page 37 in the clause 3.1.

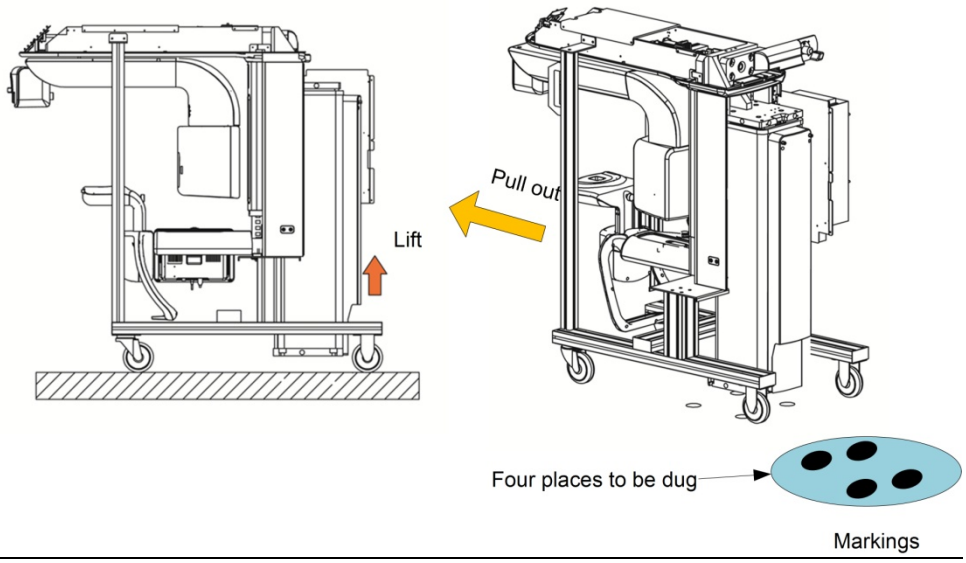
H. Move the column down slowly and carefully to touch the floor barely, while watching the wall bracket alignment.



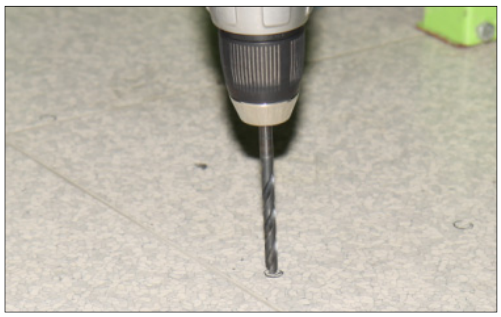
I. Mark four holes locations where the bolts are to be anchored.



J. Move the equipment up slowly and pull it out



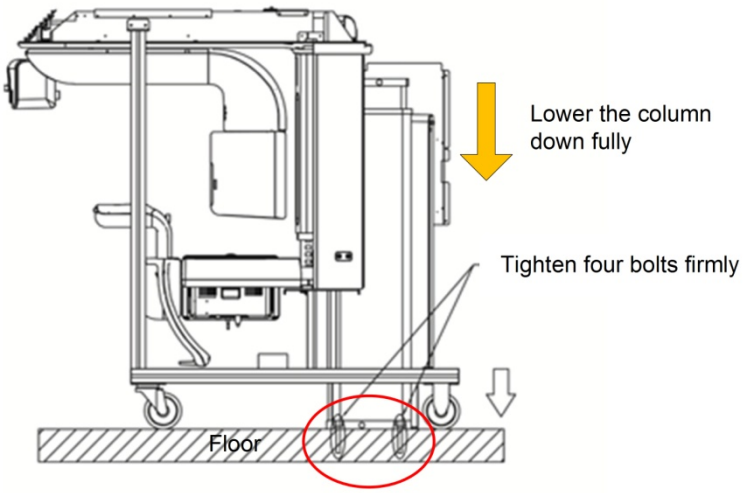
K. Drill four floor holes marked at the **step K** where the equipment is to be installed, as stated in the following figure.



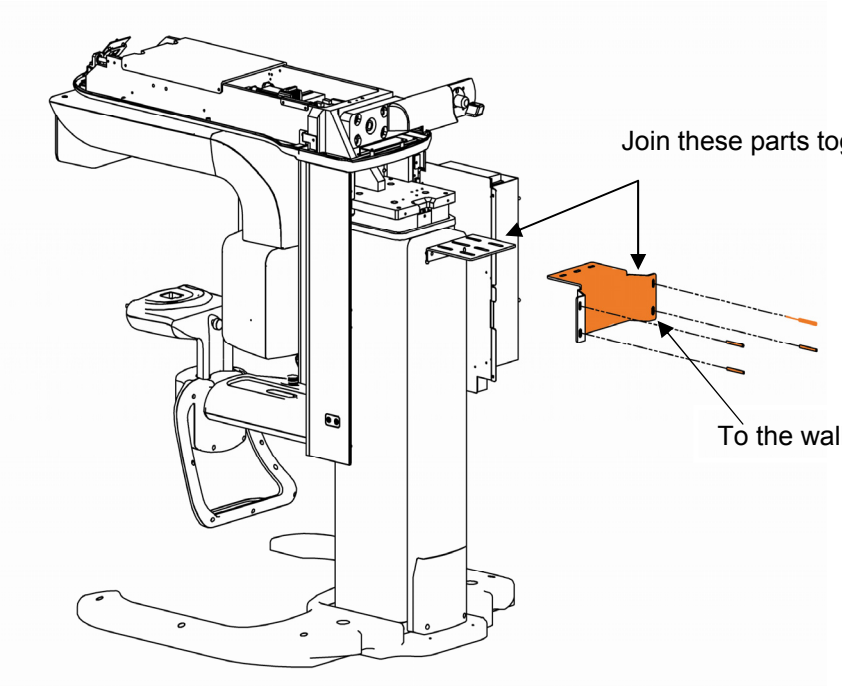
L. Anchor four bolts provided (**M8: Part No.40**) into those holes.

M. Fixing the equipment to the wall and floor.

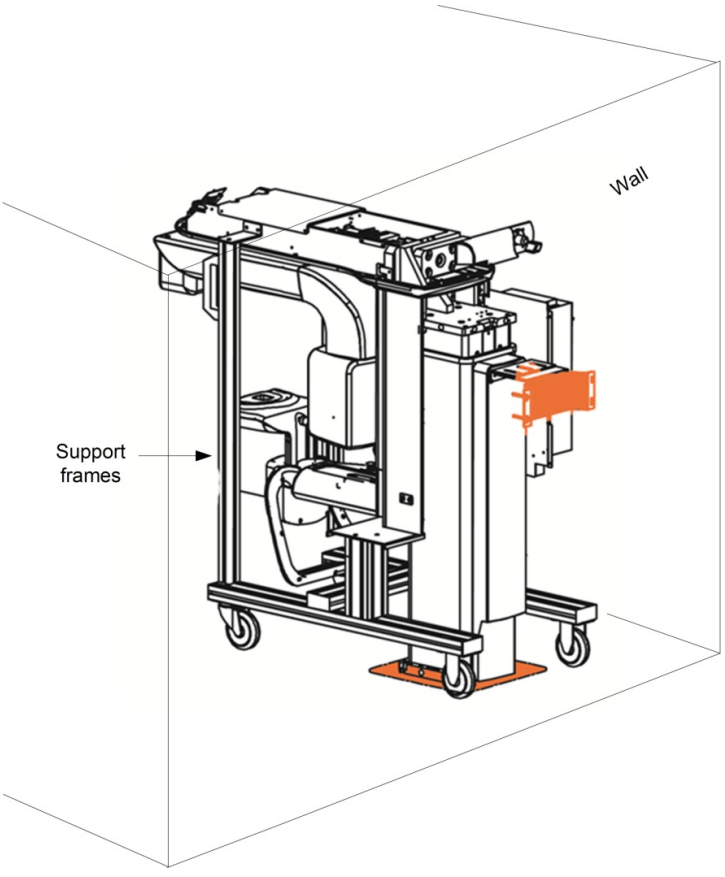
1. Move the equipment *again* to site where four bolts are anchored and lower it down slowly to floor and fix them firmly using the anchor bolts(**M8: Part No.: 40**)



2. Fasten the wall mount bracket with the equipment using the bolts (come with the bracket)



3. The following figure shows the 3-dimensional view after the floor anchors and wall mount bracket are installed.

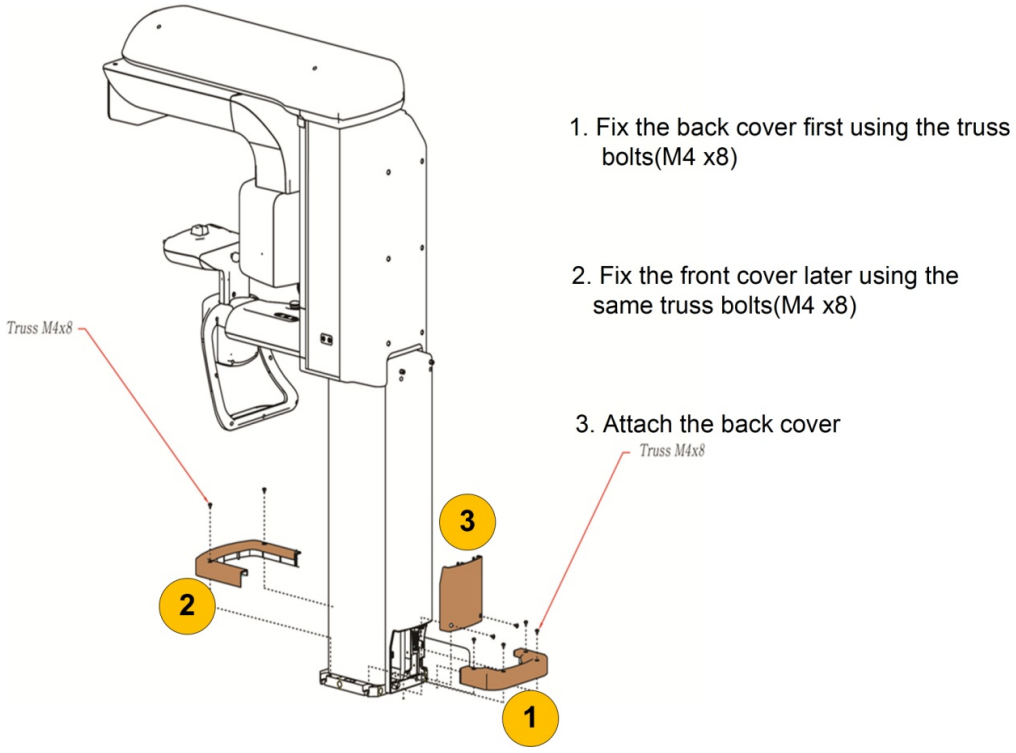


N. Now separate the transportation barrow wheels and support frames from the column unit by removing eight bolts (M10x2, M8x4, and M5x2).
For this work, see the step O on page 41.

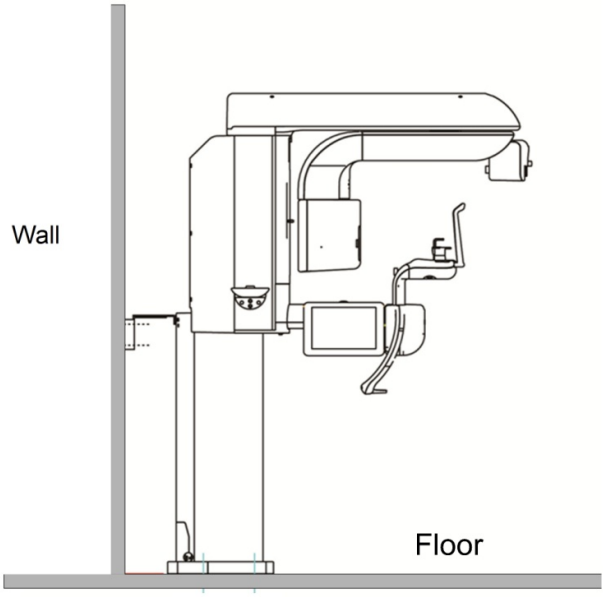
O. Move the equipment up fully and then pull the transportation barrow wheel out and keep it in safe place for the next use.

P. Remove the sub-plate from the system.
See the step P on page 42.

Q. Fix the base covers (front and rear) using truss bolts (**M4x8: Part No.:25**), placing the back cover first and the front one later. To do that, follow the ordered steps.

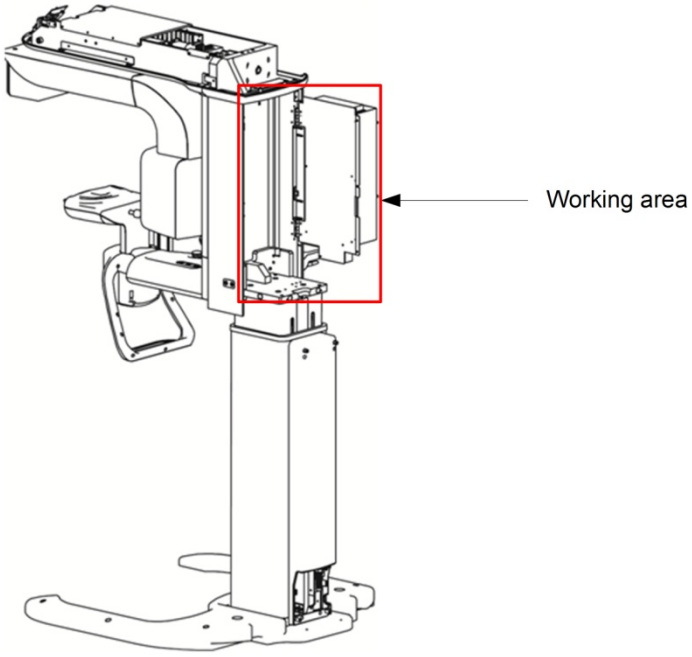


R. The next figure shows the view of the final works.

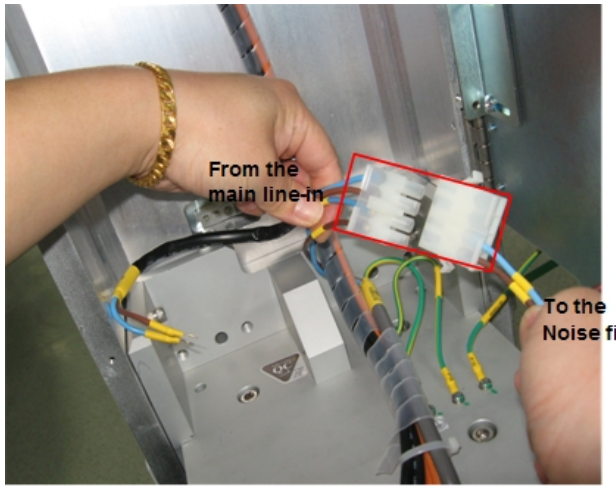


3.4 Assembling the power board bracket

The circled area in the following figure indicates the location where we are to work now.

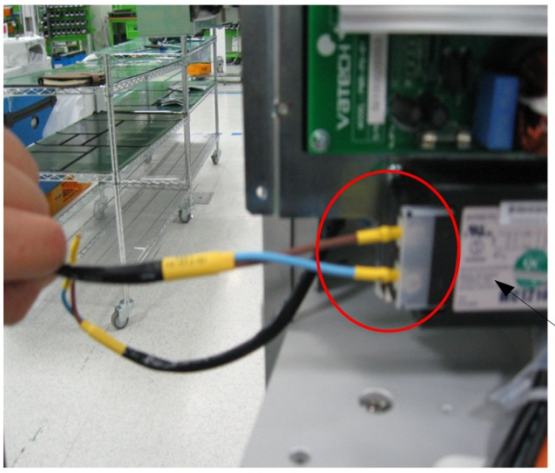


A. Thus far, the temporary power supply wiring has been used to provide power to move the column up or down. Now it is time to put this wiring back into the normal connection.



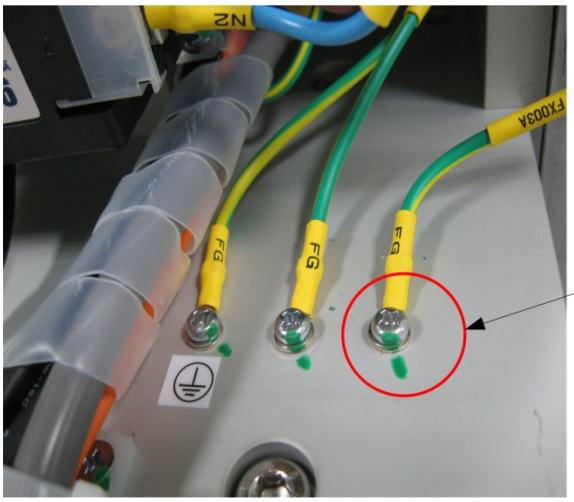
1. Reconnect these connectors again

WARNING	**To do this work, unplug the main power cable completely from the outlet.**



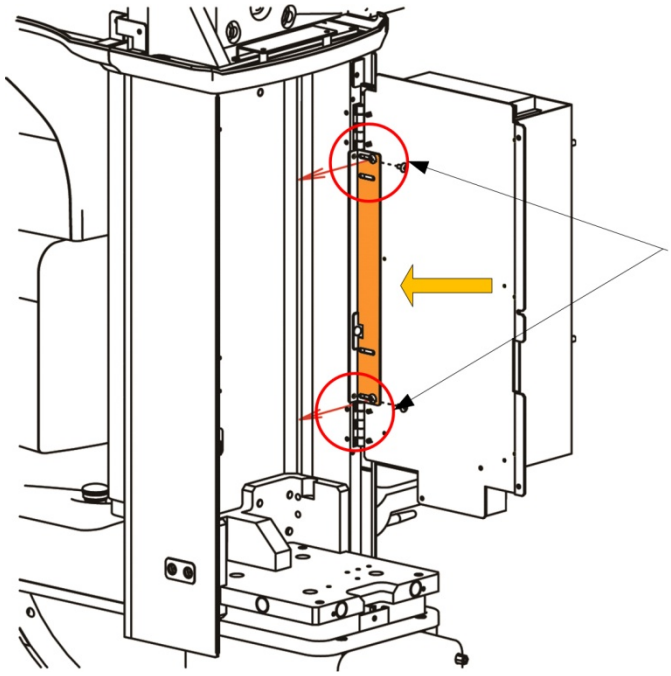
2. Connect firmly two ends of wires

Line noise filter



3. Fasten this ground cable onto the frame firmly to make perfect contact

B. Assembling the power board bracket.

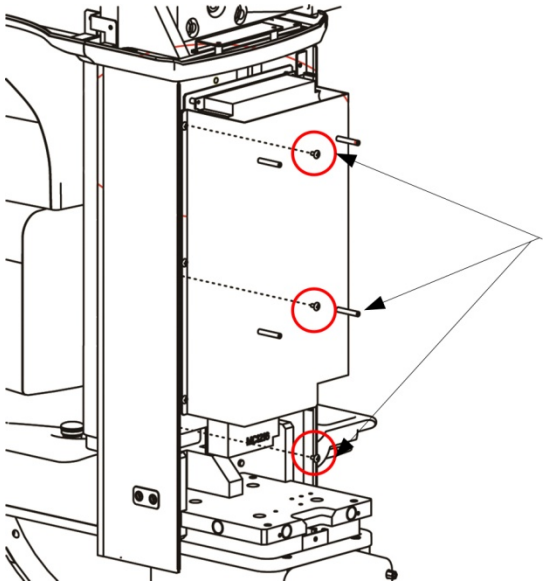


1. Loosen these two screws to make the bracket movable

2. Move the bracket to far left

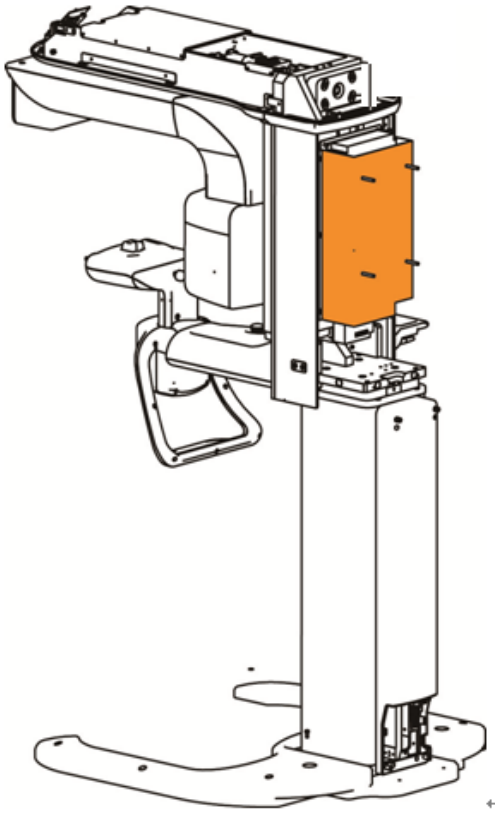
3. Tighten the loose bracket firmly again

4. Fix this bracket to the column using two bolts(M4 x8, **part #: 25**)



4. Tighten three truss bolts(M4 x8)

The following figure shows the view of the final assembly of the power board bracket.

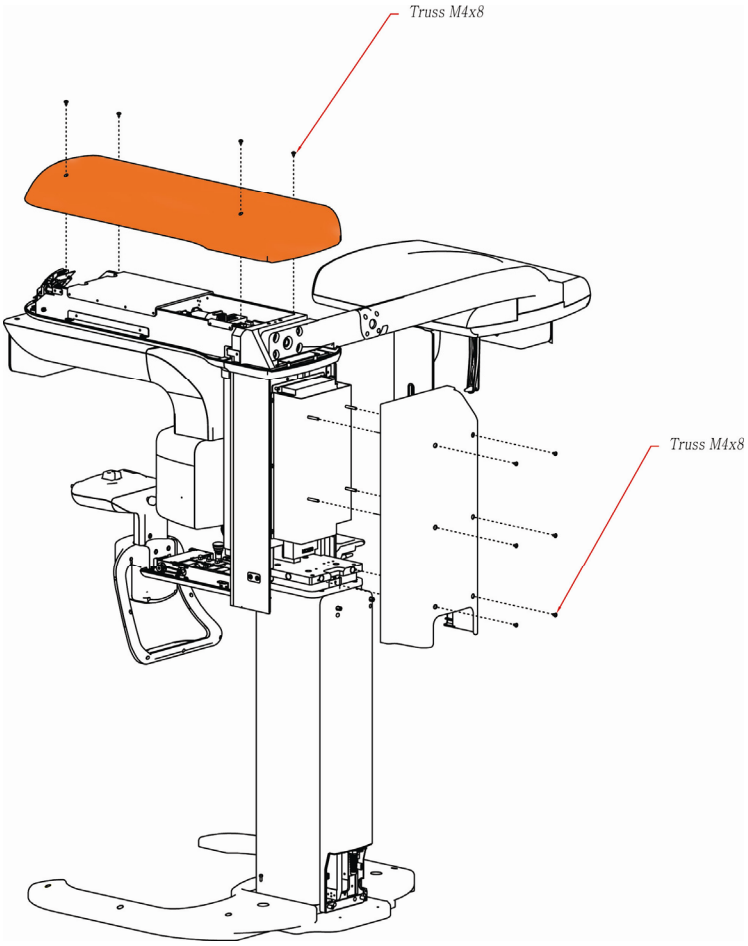


C. Go to the next sub chapter 3.5.

3.5 Assembling the covers

NOTE	**Covering works in this section is the same whether or not the Cephalometric unit is installed. Thus in this regard there are no elements of confusion.**

A. Close the vertical top case using four truss bolts. **(M4x8: part No. 25)**



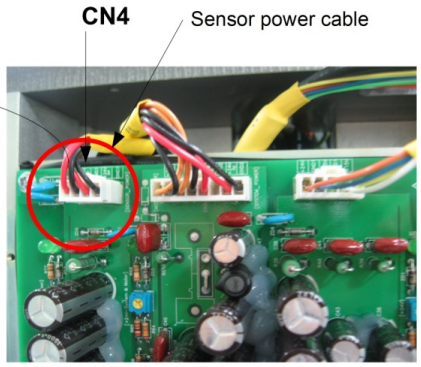
B. Connecting the power cable for the **Sensor power board** with the connector **CN4**.

This unit is shipped with the sensor power cable unplugged from connector **CN4** on the main power board.

This job should be done before assembling the case column rear. (**Part No.1-3)**

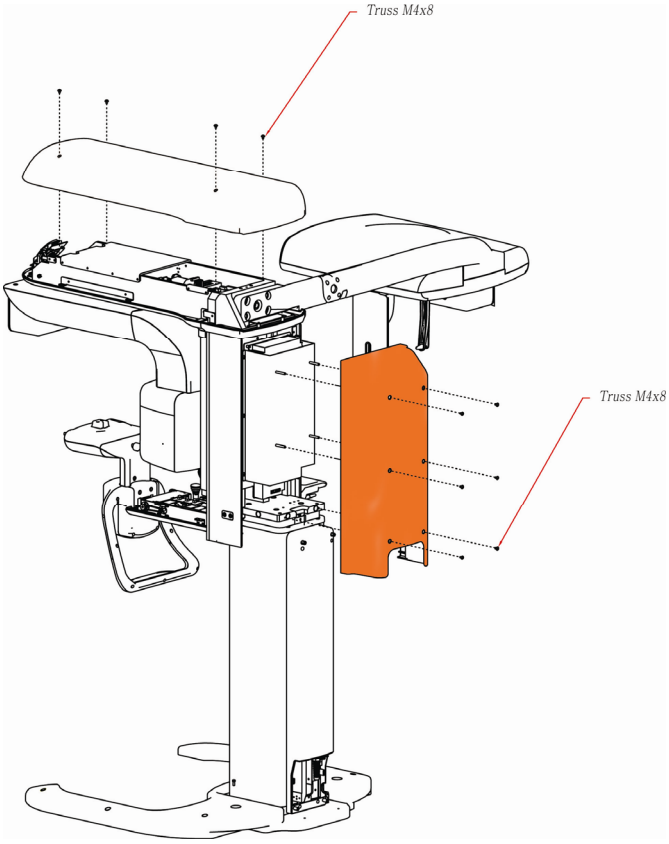
1. Locate the **CN4** on the main power board. (See the following figure)
2. Identify the power cable to the sensor board.
3. Plug cable carefully without exerting too much force.

Main power board on the back of the column

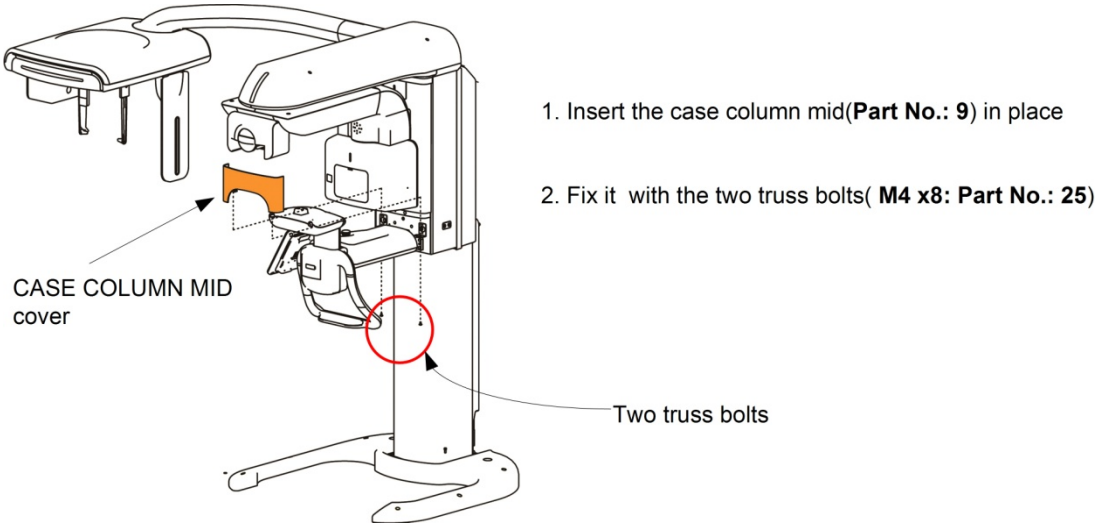


Work: connect the sensor power cable to the CN4

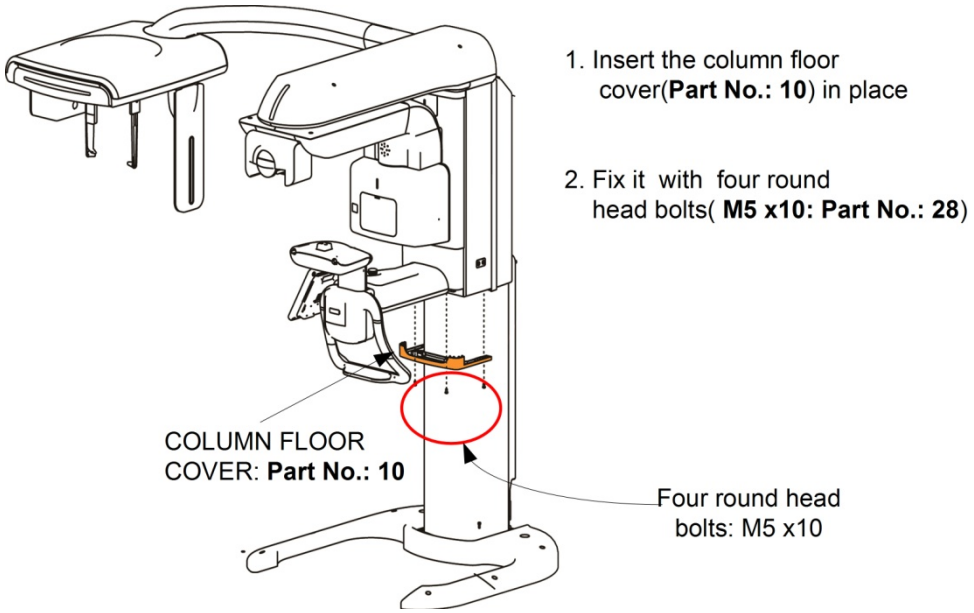
C. Assemble the case column rear **(Part No.: 1-3)** using the six truss bolts.



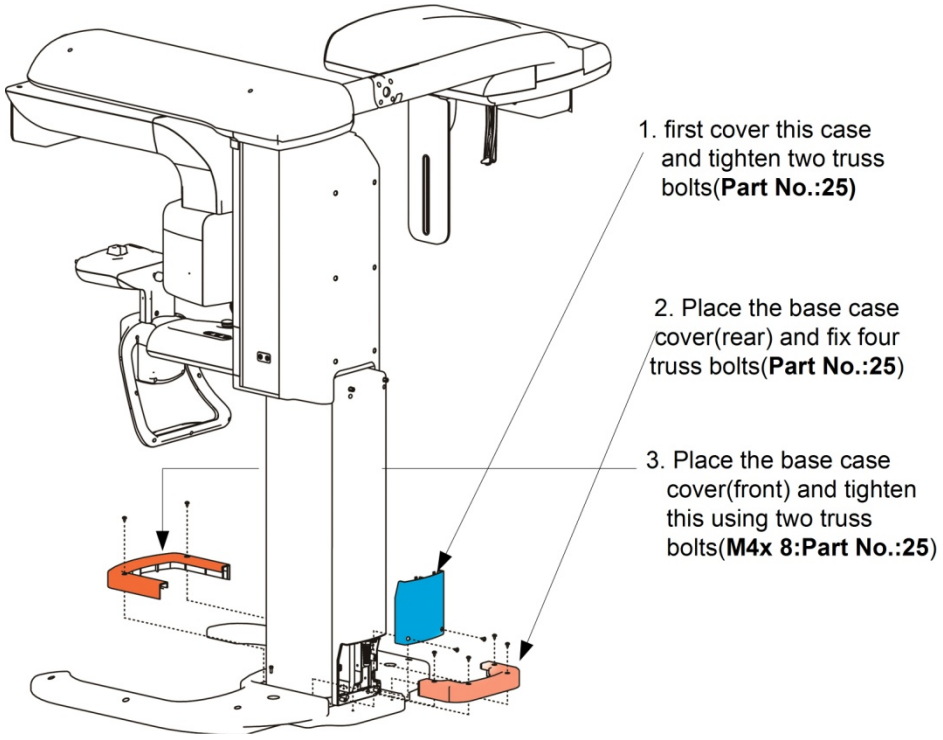
D. Attach the Column mid cover, as described in the following figure.



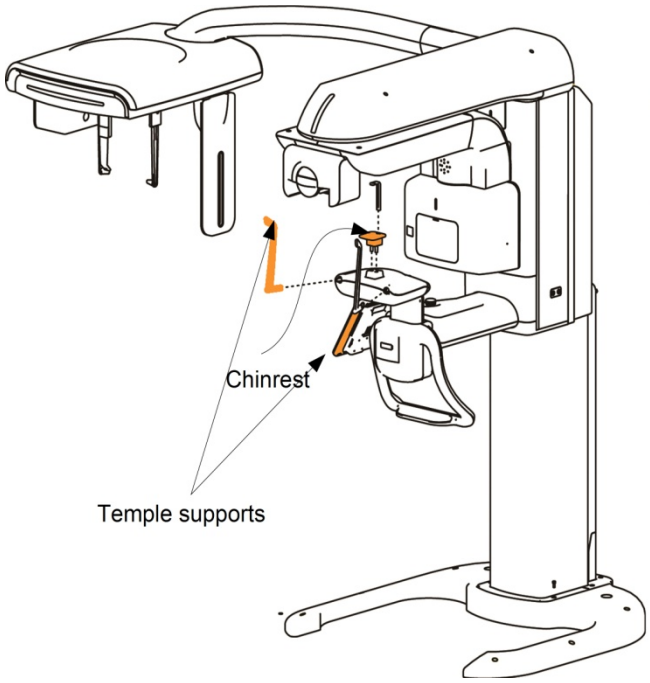
E. Attach the COLUMN FLOOR COVER.



F. Please install two base covers **(Parts No. 11** and **12)** in a way that the rear base cover is installed first and front base cover installed later, so that the front base cover can be stacked onto the rear one.(See the colored parts)



G. Install the temple support and the chinrest.

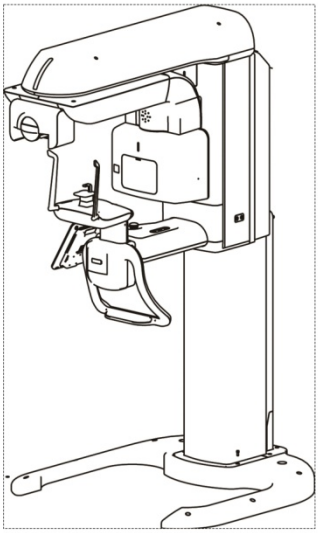


1. Insert the chinrest in place **(part No. 19)**

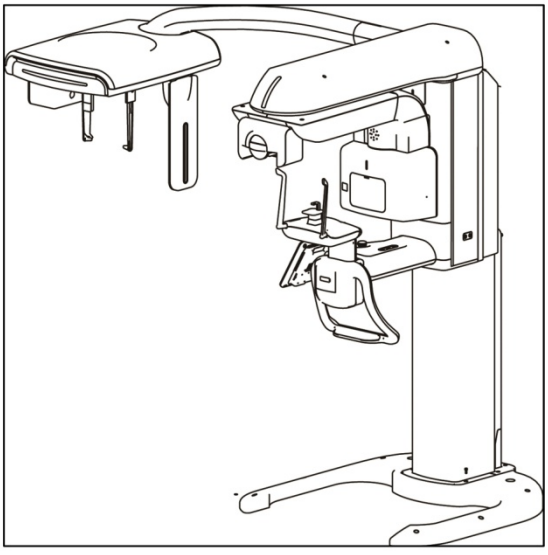
2. Insert two temple supports**(part No. 13**)

H. The installation has just finished.

The finished appearance



Without the CEPH. unit:
SP type

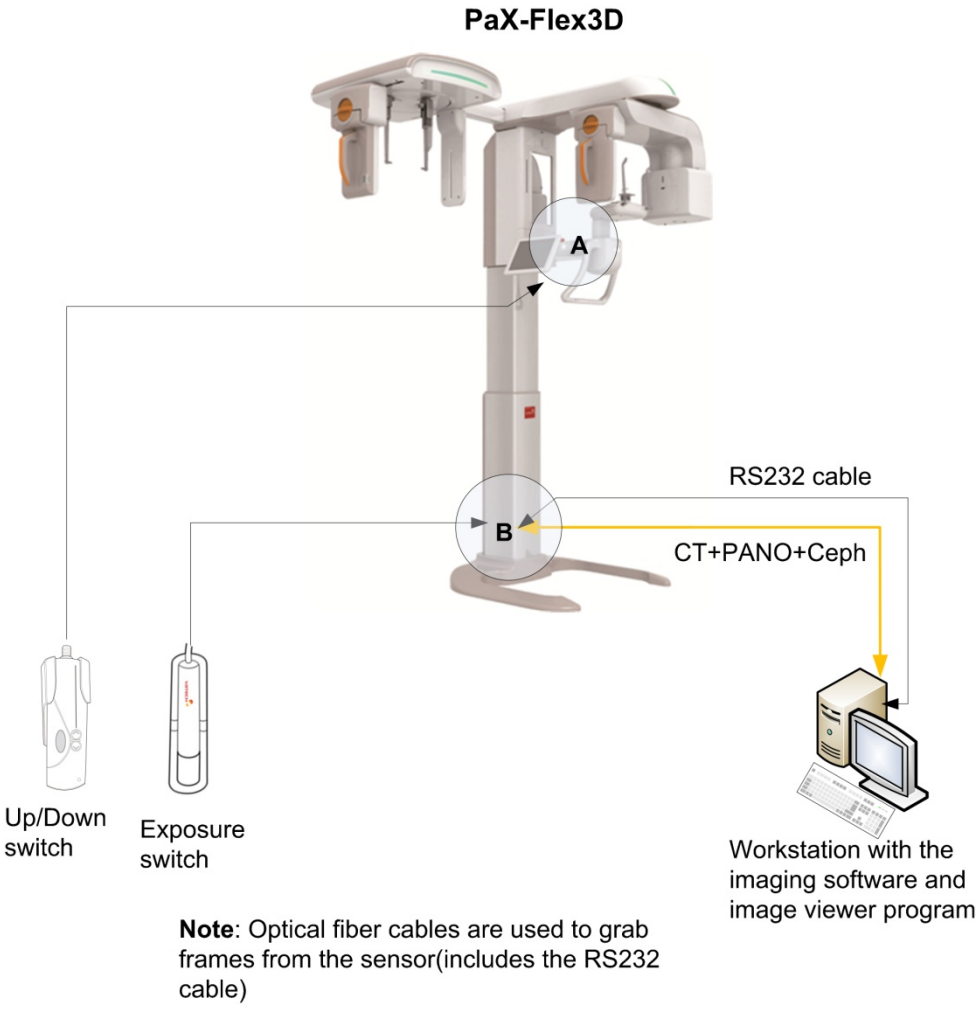


With the CEPH unit:
SC type

4 Installing the peripheral devices

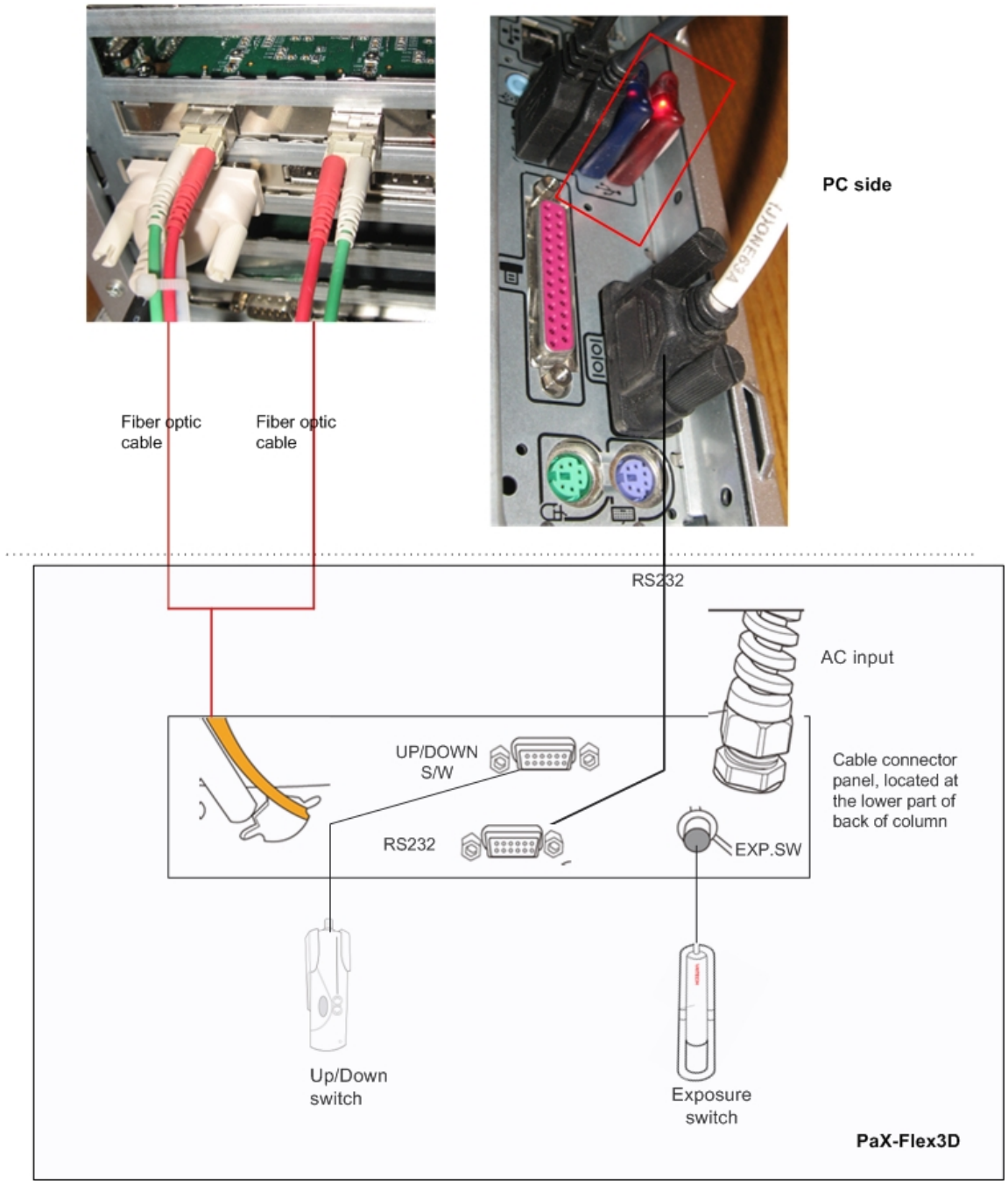
4.1 Image acquisition system

The following figure is the overall diagram of the image acqusition system.



NOTE	**RS232 protocol is employed to let the serial communication to occur between touchpad screen and PC in real time.**

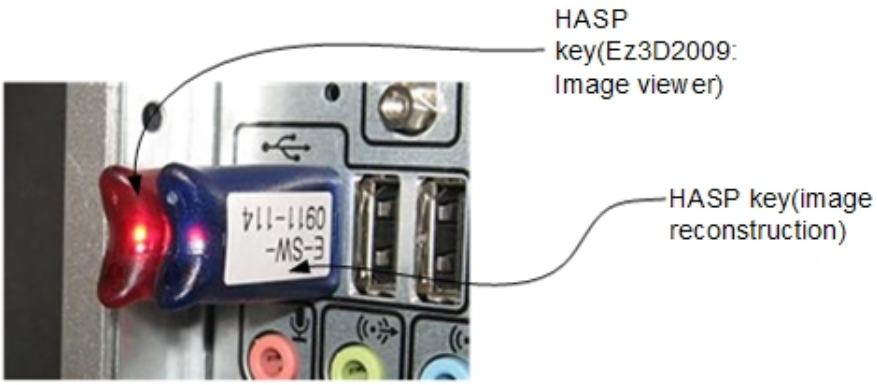
4.2 Connecting the external peripherals



4.3 Installing the USB-Type HASP keys

Two USB typed HASP keys are necessary to reconstruct and display image taken.

1. Insert HASP keys into the USB ports.



NOTE	**To install the driver software later successfully, these two USB-type HASP keys should be installed in advance.**

5 Installing the imaging software

Three different software programs are used with the PaX-Flex3D.

- 2D Viewer and processing : EasyDent or Dental Sherpa
- 3D Viewer and processing: Ez3D2009
- Imaging program

NOTE	**It is strongly recommended that the EasyDent or Dental Sherpa image viewer program be installed prior to the InstallShield installation.**

5.1 PC system requirements (recommended)

The following specifications are recommended minimum requirements that enable the operation to be stable in processing and viewing image.

WARNING	**The PC system plays a great role for processing and viewing quality image. In other words it means there may be image quality deterioration from lack of resources. Thus observe the requirement guideline specified the following tables.**

Items	Descriptions	Comments
CPU	Intel Core 2 Duo E8400 3.0 Ghz or higher	
RAM	2GB or higher DDR-2 ECC type	RAM has a major impact on system performance.
HDD	500 GB SATA 3Gb/s NCQ 7200	
Graphic card	NVIDIA Quadro FX580 512MB video RAM	The video RAM has major impact on image processing performance

Items	Descriptions	Comments
Monitor	19" or larger 1280 x 1024 minimum screen resolution - 32 bits color mode	Monitor is a vital in displaying quality images. Low-quality screens will prevent you from proper diagnoses and treatment
Ethernet card	100/1000Mbps	
USB port	USB 2.0 supported	
Serial card	1 RS232 port	
CD/DVD drive	DVD +-RW SUPERMULTI SATA x16	
Operating system	Genuine Windows XP Home Basic SW or higher version	Windows vista OS

NOTE	**Although the manual update continues on an as-needed basis, this section may not contain the explanation for the latest version. But there should be no ambiguity as long as installation is concerned. Please ask the technical support staff for the latest information.**

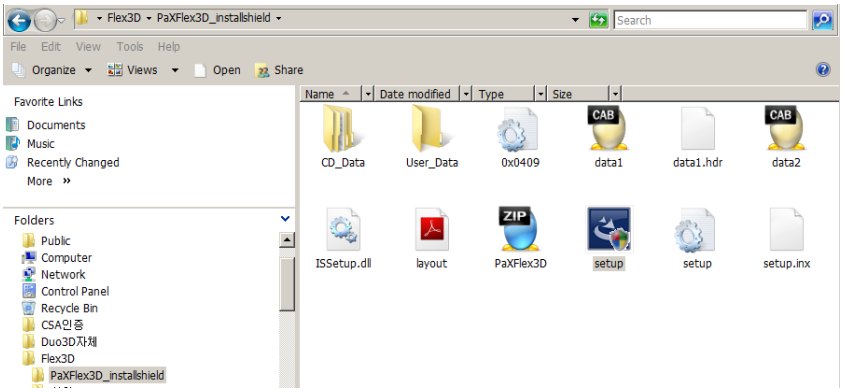
5.2 Installing the InstallShield

The installShield program contains the imaging software and some other programs like the hardware drivers. In order for them to work properly, these software should be installed in advance.

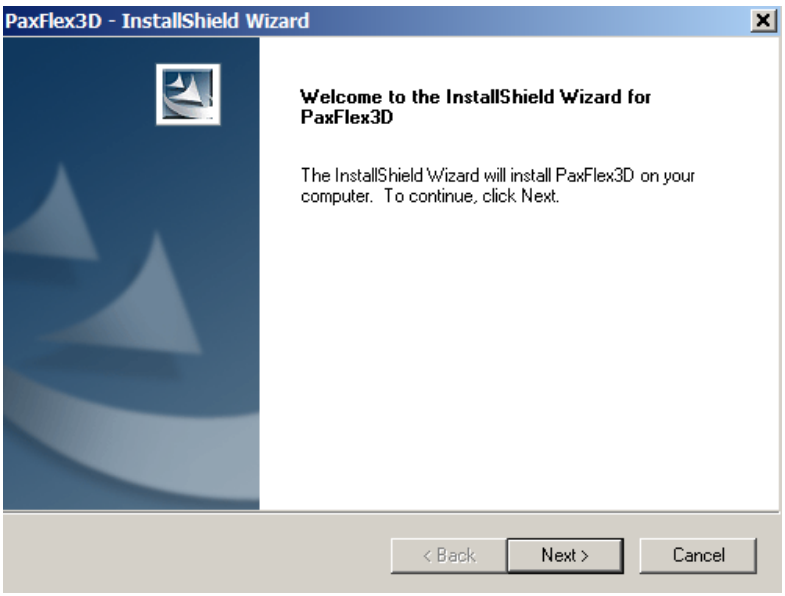
NOTE	**Although the programs to be installed could be selected individually, select all for the first time installation.**

Insert the CD that comes with the equipment. It will run automatically if autorun is enabled. Otherwise, move to the directory where the following files are in.

1. Please focus on the **setup.exe** and double-click it.



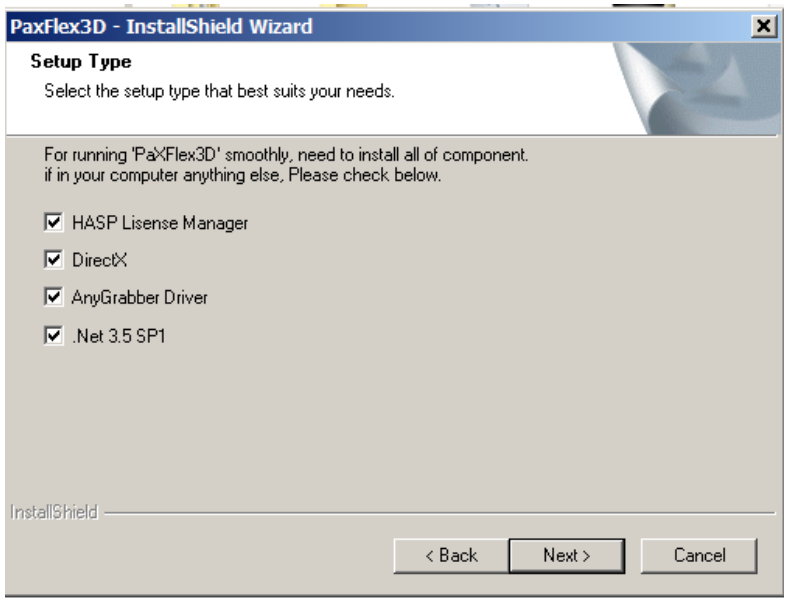
2. If the following figure appears a few seconds later, double-click **Next**.



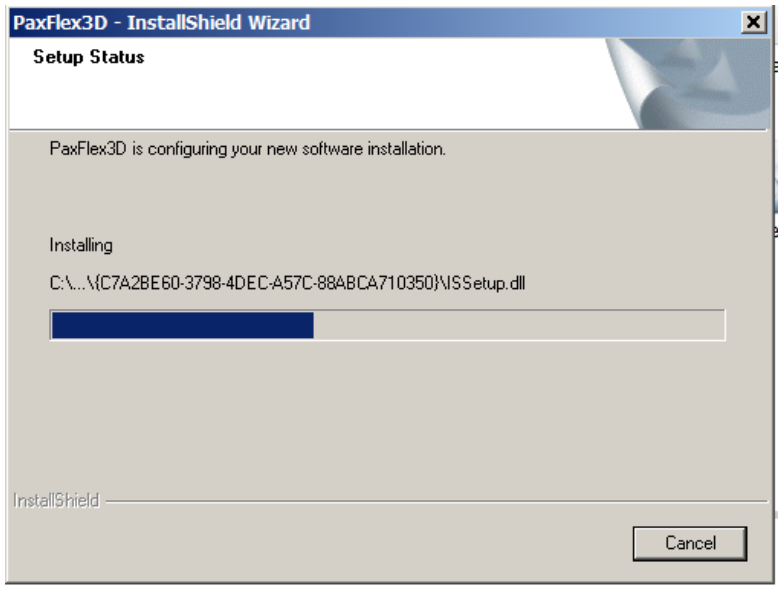
3. Then the following figure shows the list of software to be installed. For the first time installation since the equipment setup, select all of them.

   The drivers can be installed later individually.

NOTE	**. Net 3.5 SP1** is installed with the **EasyDent** or **Dental Sherpa** installation. Therefore, you don't necessarily need to choose it this time.

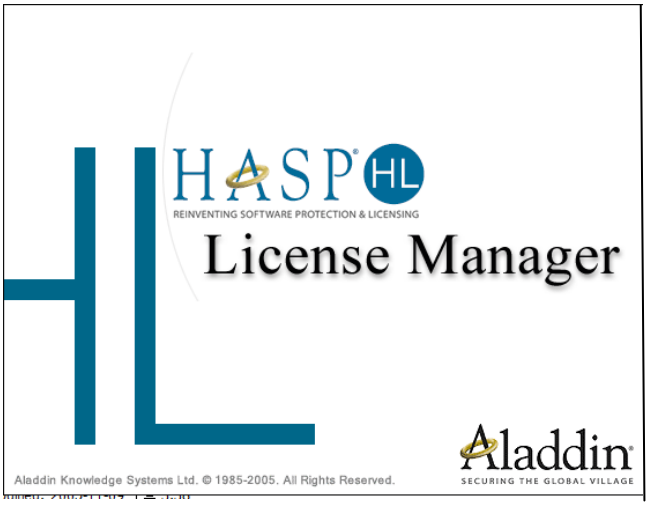


4. Entering the internal configuration stage and installing the related program modules.

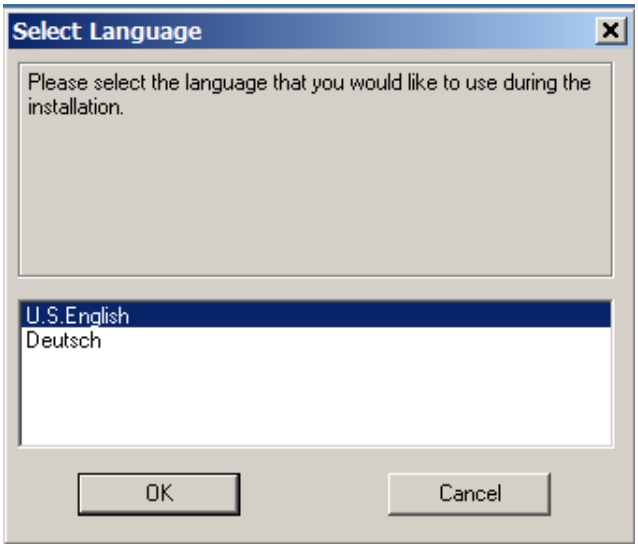


5.3 Installing the HASP key driver and its license manager

1. If the HASP driver is selected, the following screen will come up automatically.



2. Please select the language and then click **OK**.

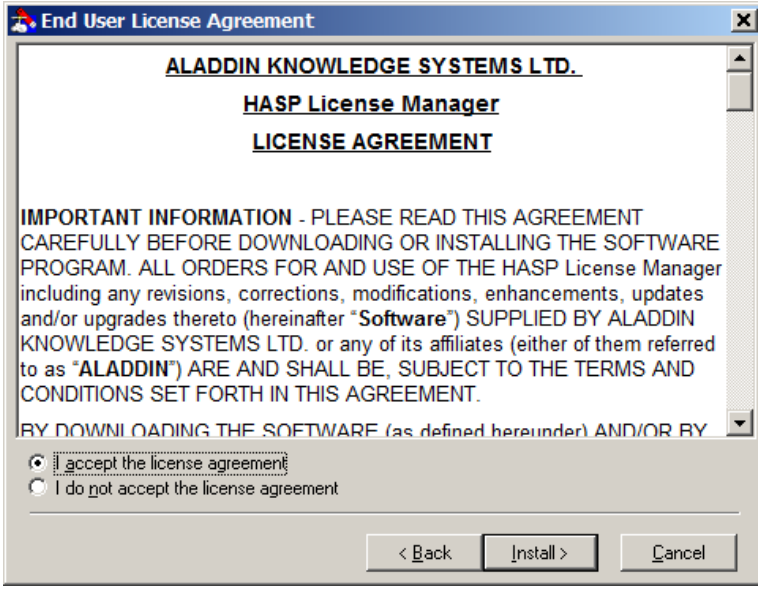


3. You are welcome to continue to install the license manager.

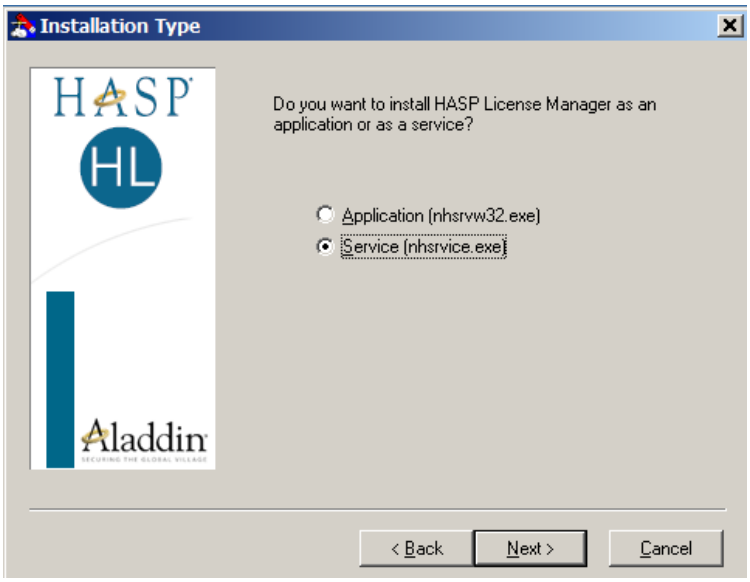
   From this screen, make sure that its current version is **8.31**. Then click **Next** to continue.

NOTE	**If the license manger is running at the time of installation, terminate this program first. And try again to install program.**

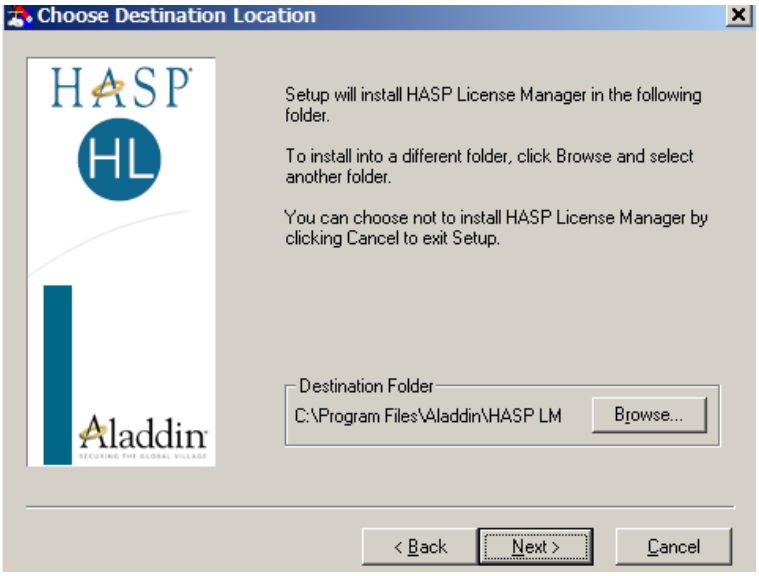
4. Select **"I accept the license agreement"** click **Install**.



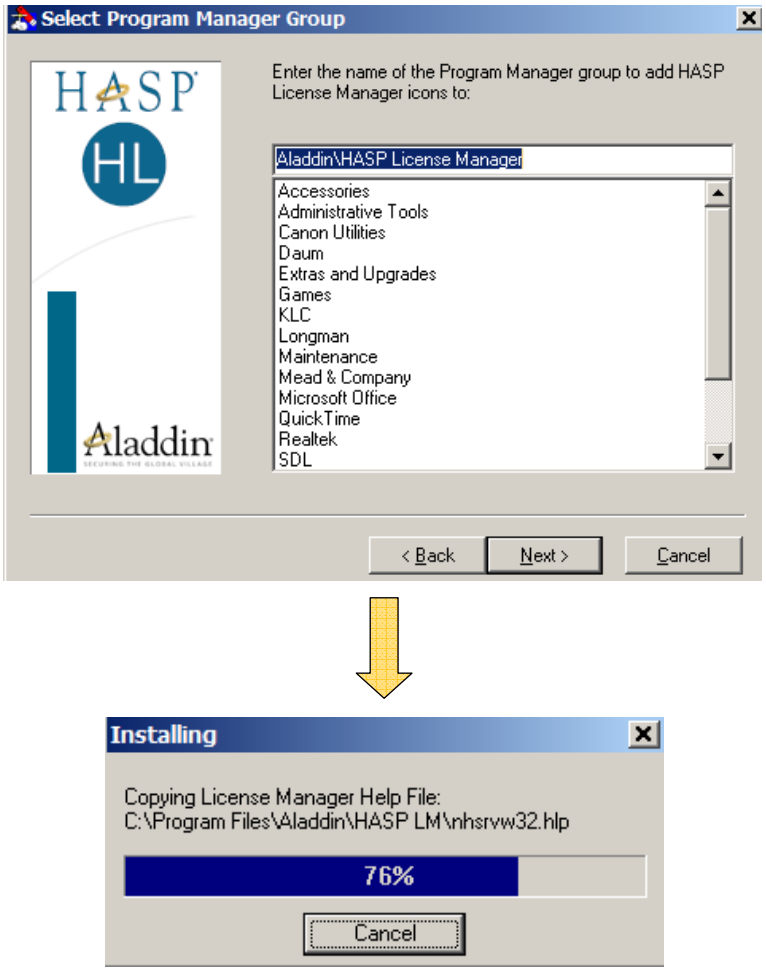
5. Select the default from the following figure and click **Next** to continue.



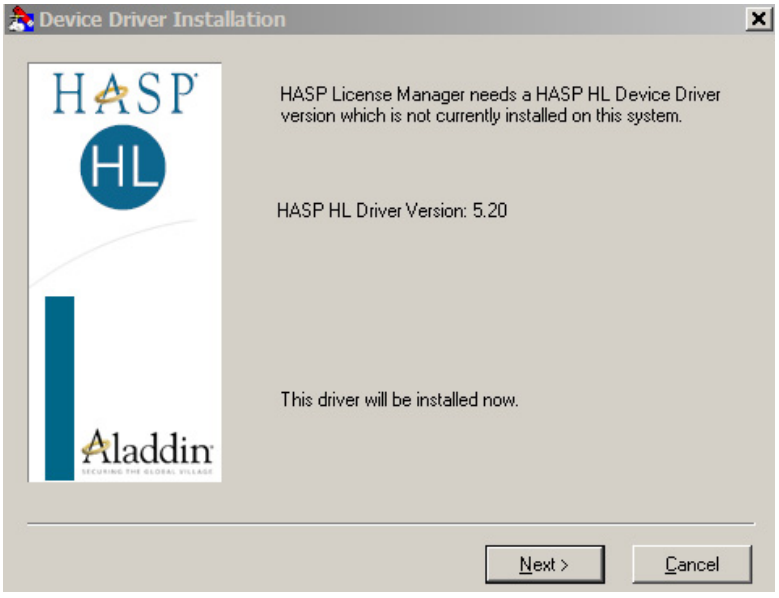
6. Select the folder in which the programs are to be installed. If the other user-defined folder is preferred, click **Browse** to change and click **Next**.



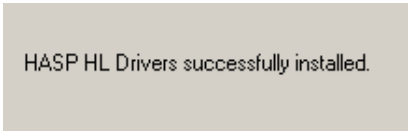
7. Leave the default group in the windows program manager. Click **Next**.



8. Make sure that the driver version for the HASP key that is already installed is 5.20. Click **Next**.

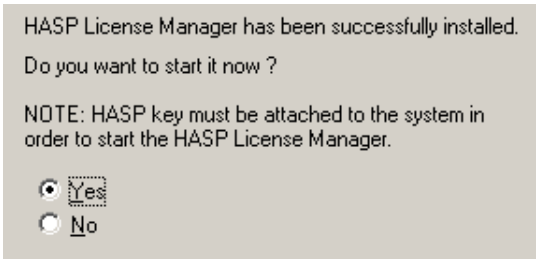


9. The driver installation has completed.



10. It is time to reboot the PC system. Click **Finish** to reboot system.

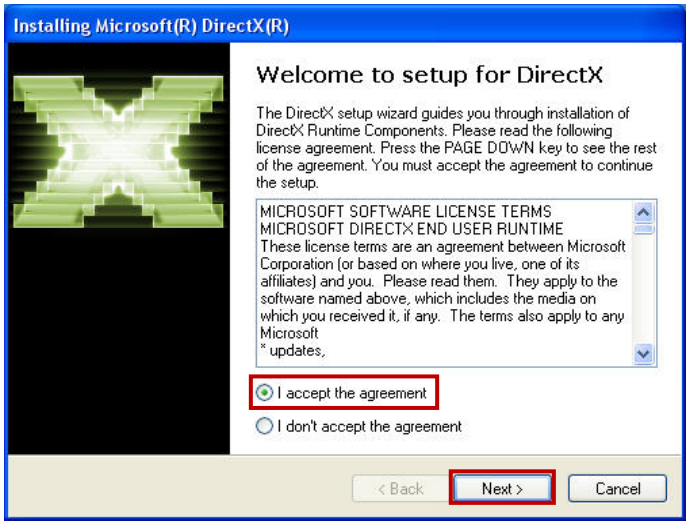
    Keep in mind that rebooting the system should be done — with the HASP keys being inserted in the USB ports. Otherwise, the license manager will not work properly.



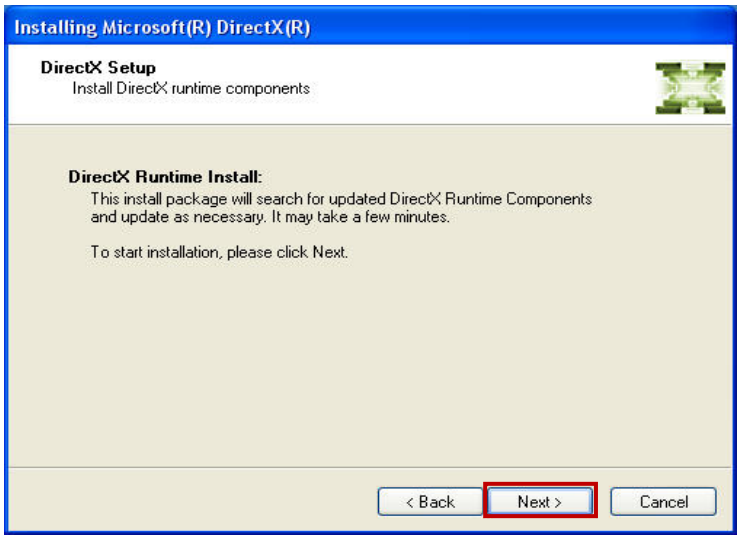
5.4 Installing the DirectX driver

If the **DirectX** is selected in the setup list, following setup screen will come up automatically.

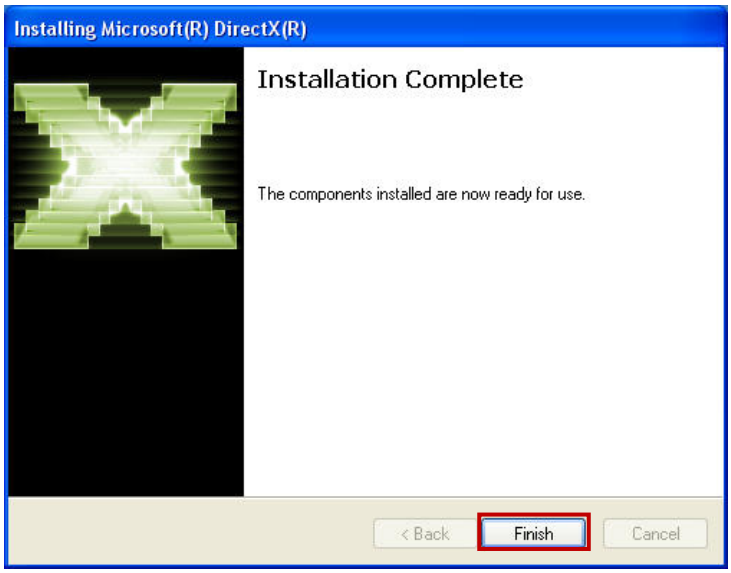
1. Select "**I accept the agreement**" and click **Next** to continue.



2. Click **Next** to continue.



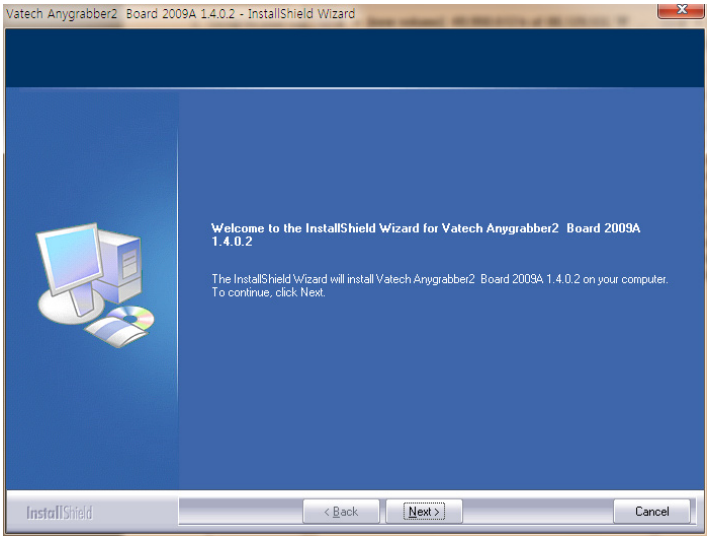
3. From the next screen, click **Finish.**



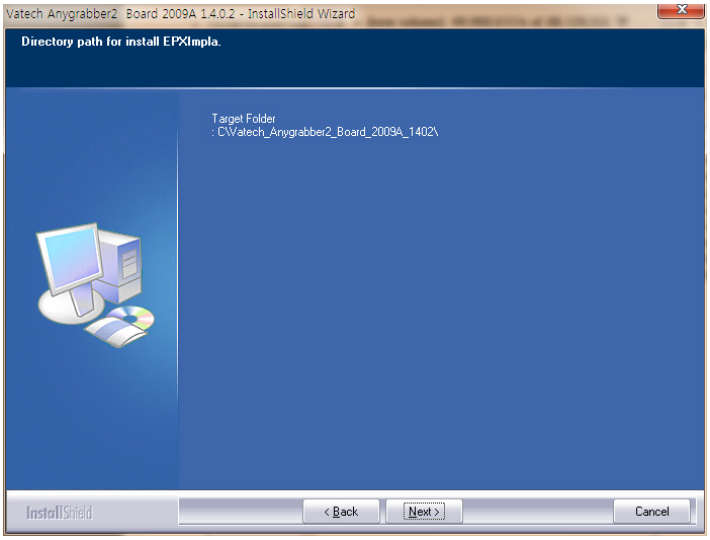
5.5 Installing the Frame grabber driver

If the frame grabber driver was selected from the list of set-up, frame grabber setup window will appear automatically after completing the installing of pre-Installation software.

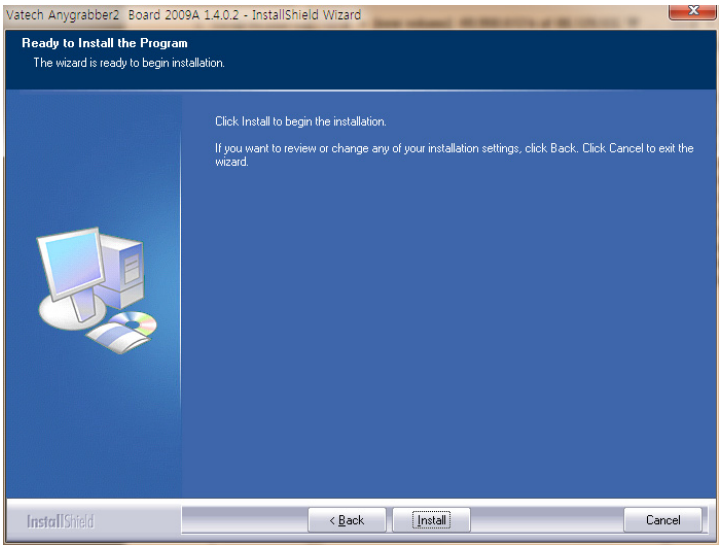
1. You are welcome to the frame grabber driver installation with the following screen. Click **Next** to continue.



2. Identify the target folder where the program is to be installed and click **Next**.

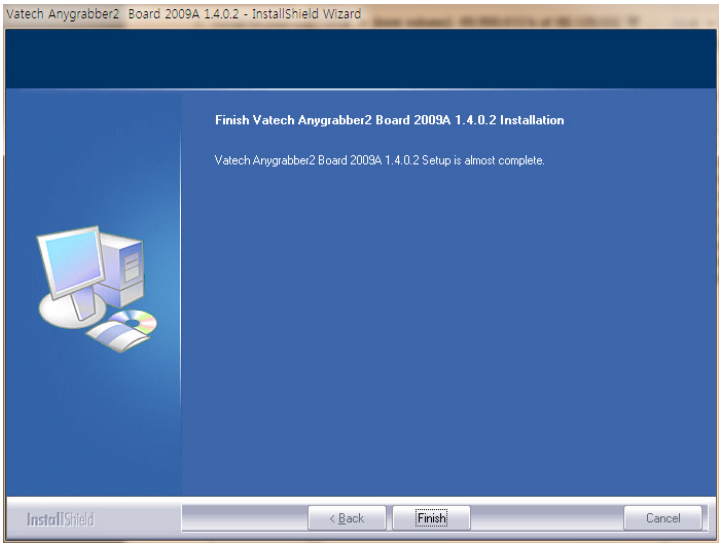


3. Click **install** to continue.



Progressing

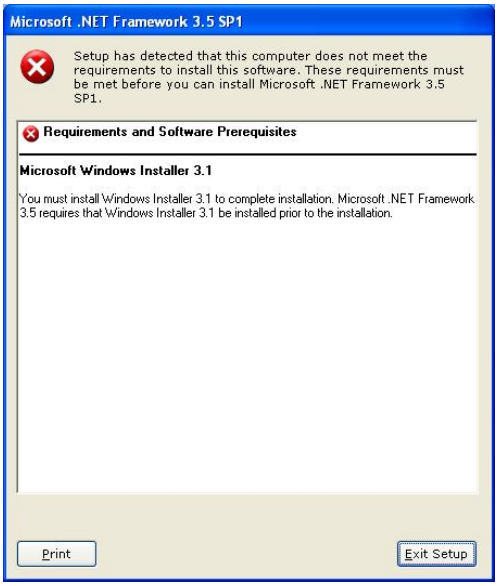
4. The driver installation has just completed. Click **Finish** to end.



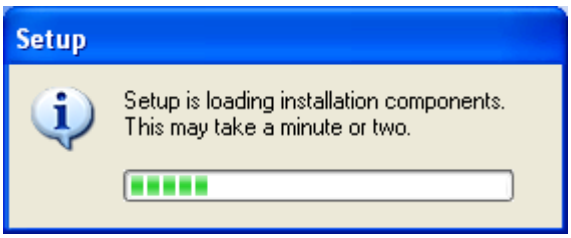
5.6 Installing the. NET Framework 3.5

NOTE	**1. Windows installer 3.1 should be installed prior to .NET Framework 3.5 installation. Otherwise, the error message will be displayed.** **2. If Dental Sherpa or EasyDent was installed already, so was the .NET Framework 3.5. Otherwise, install this separately, as shown in the following order.**

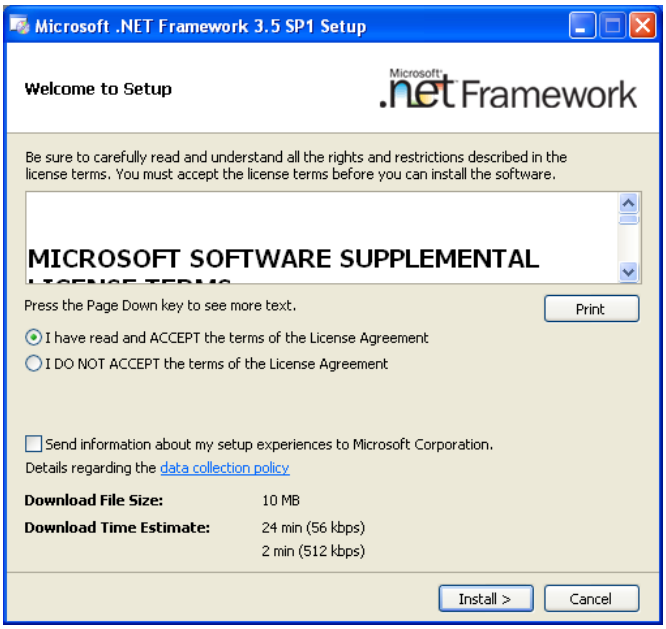
1. Upon selection of. **NET Framework 3.5** from the set-up list, the following installation screen will appear automatically. It is assumed that **Windows installer 3.1** is installed in advance. Otherwise, the following error message will be displayed. Resume installation of. **NET Framework 3.5 installation** after **Windows installer 3.1** installation.



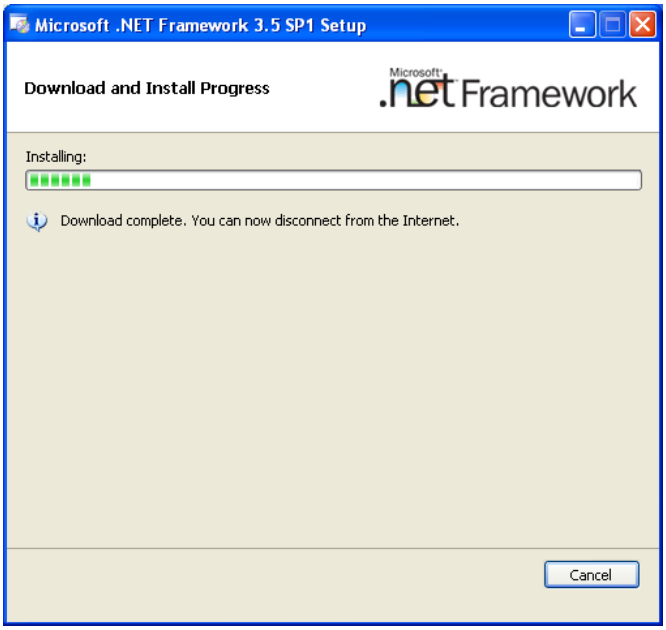
2. Loading the required files for installation.



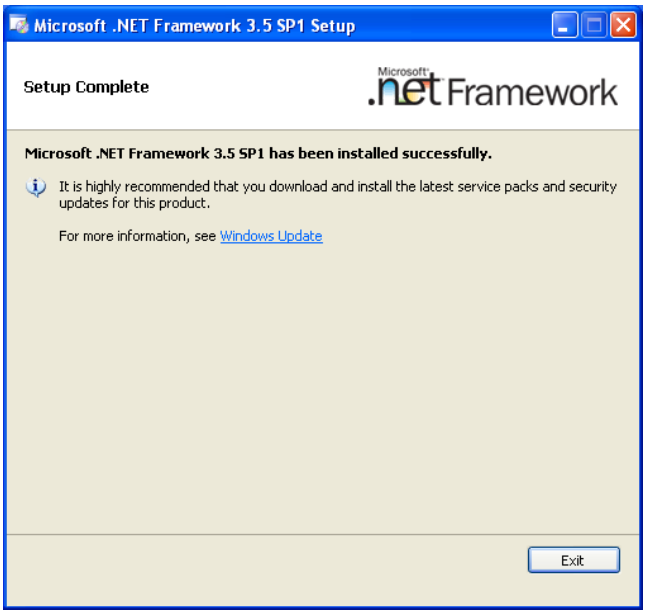
3. Select **“I accept the terms of the License Agreement”** click **Install**.



4. Installing.

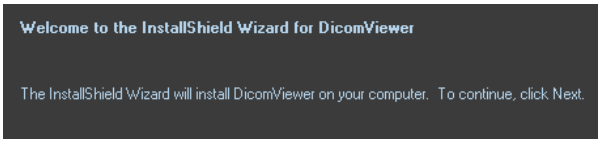


5. The installation has finished. Click **Exit** to finfish.

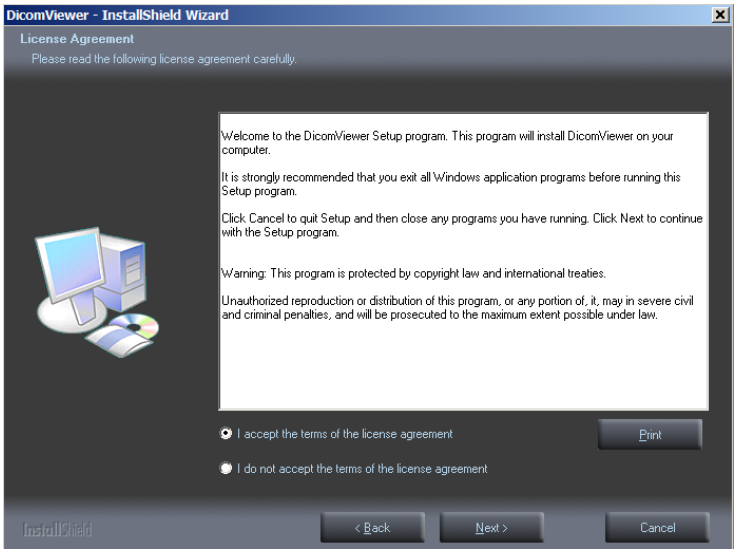


5.7 Installing the DICOM Viewer

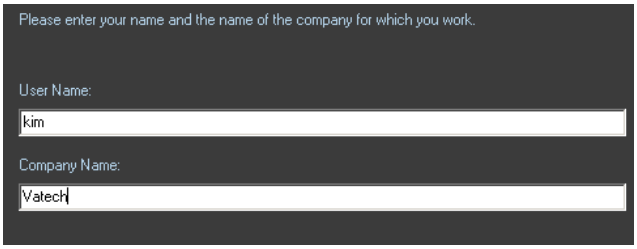
A. Once the installation for **.Net frame work 3.5** completed, DICOM Viewer installation screen will come up. Click **Next** to continue.



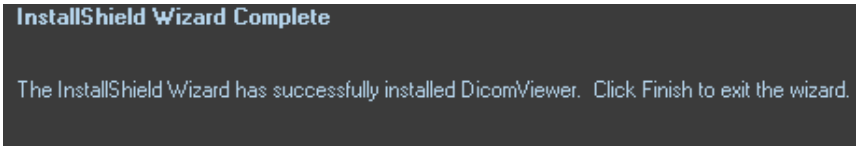
B. Select **"I accept the terms of license agreement"** and click **Next**.



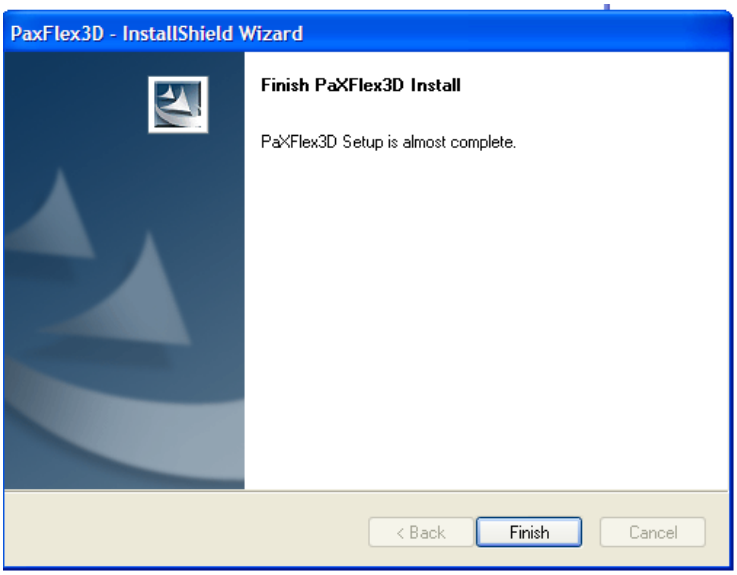
C. Enter **the User name** and **company name** and click **Next**.



D. The installation has completed. Click **Finish** to end.



E. Finally, the InstallShield installation for the PaX-Flex3D has finished**.** Click **Finish**.



6 Exiting the packing mode

IMPORTANT	**PaX-Flex3D has a unique feature— packing mode— built in the system to prevent the unit from being damaged while shipping and transporting. Thus it is in the packing mode by factory default. The unit is required to exit the packing mode at this step for successful installation.**

NOTE	**The following steps should be carried out after all the hardware and software-related set-ups have completed.**

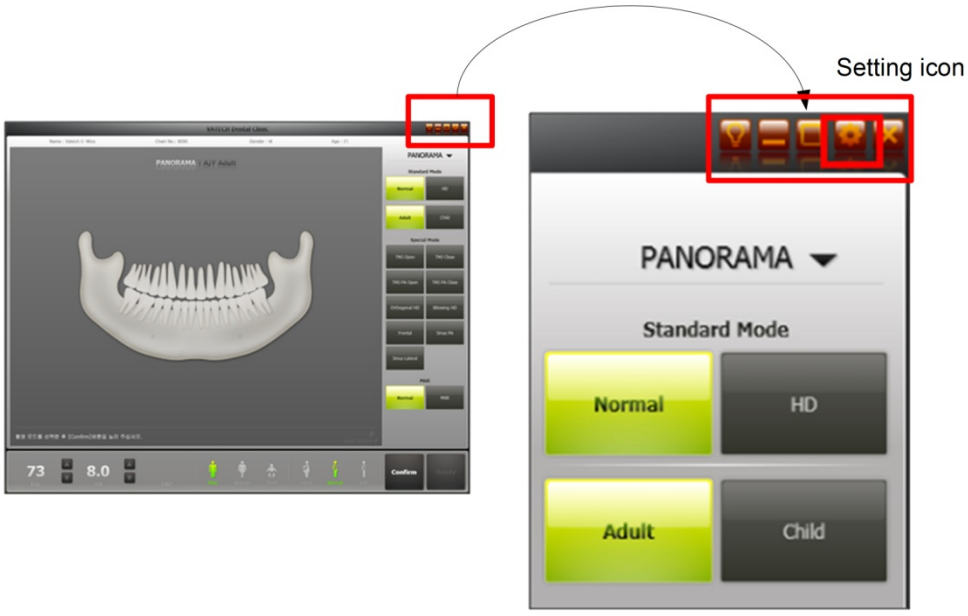
CAUTION	**Unless the packing mode disabled, no operation will happen even after the equipment is turned on.**

A. Run the imaging software after setting up the hardware and software installation.

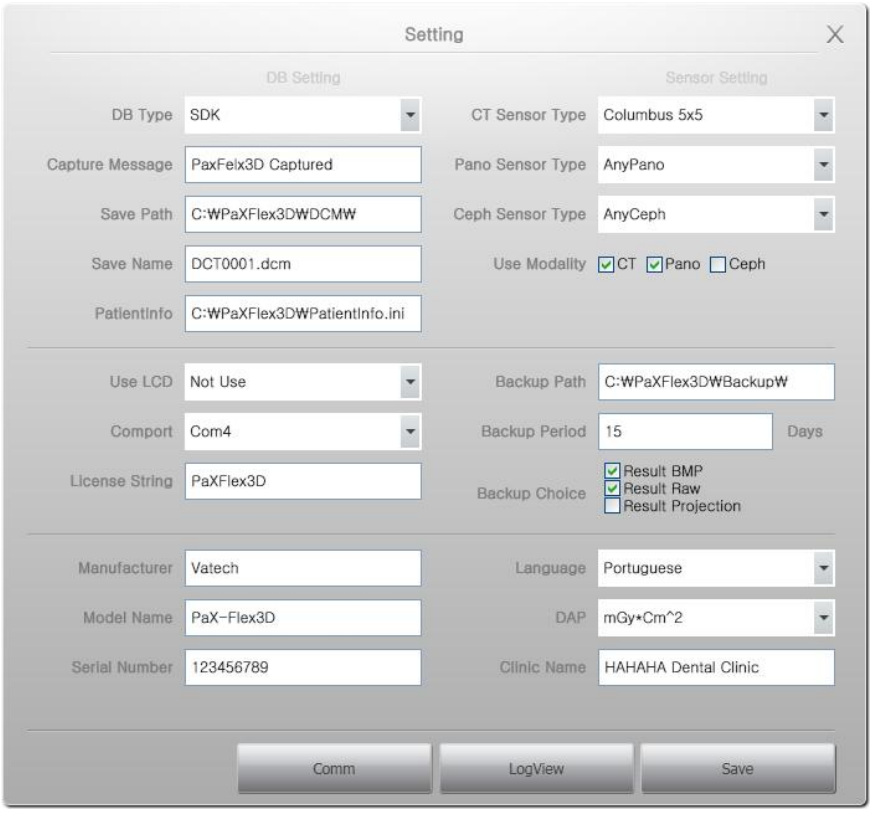
(It is assumed that the InstallShield program has already been installed successfully)

Imaging software main screen

B. Click  (setting icon) located at the upper right corner.

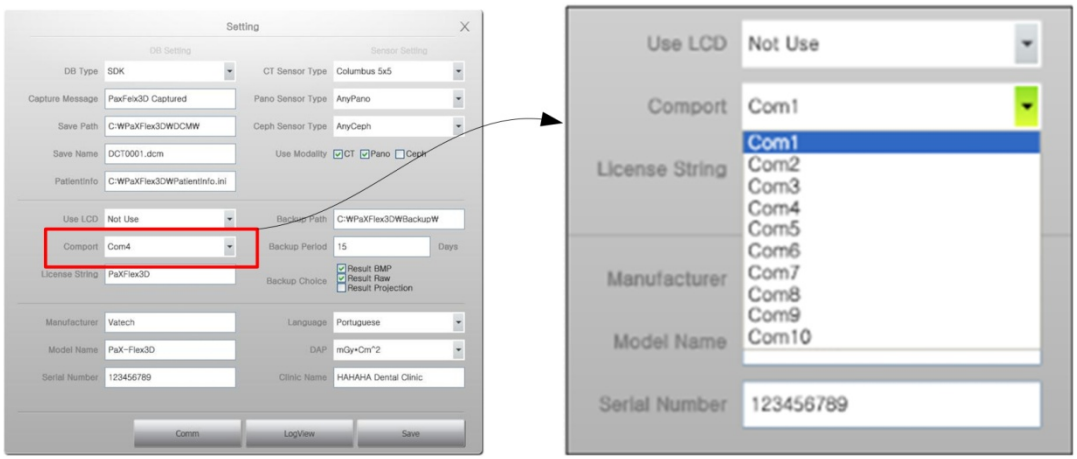


C. The following active screen will come up to allow the users to set variable parameters.

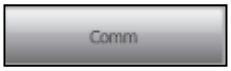


D. Select the **COM** port.

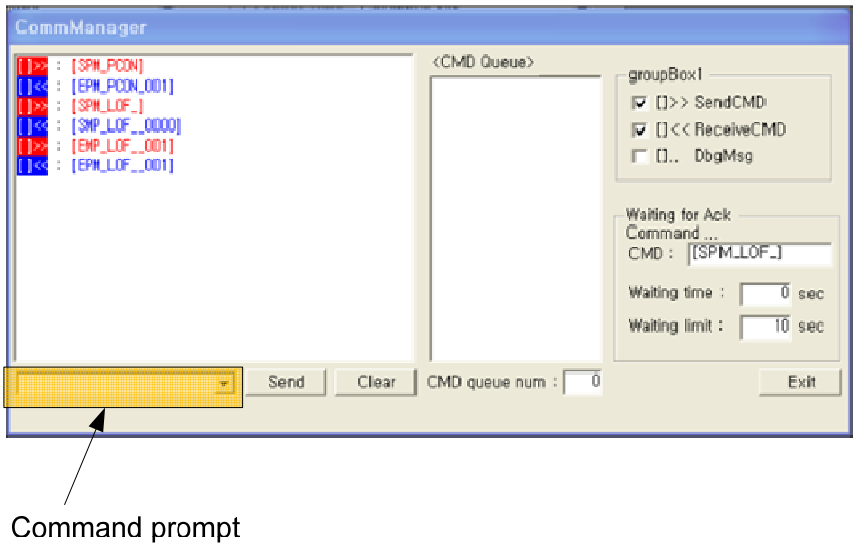
IMPORTANT	**The same COM ports should be assigned to the PaX-Flex3D and PC.** **Ex) Equipment→ COM1← PC**



Ex): COM 1 assigned

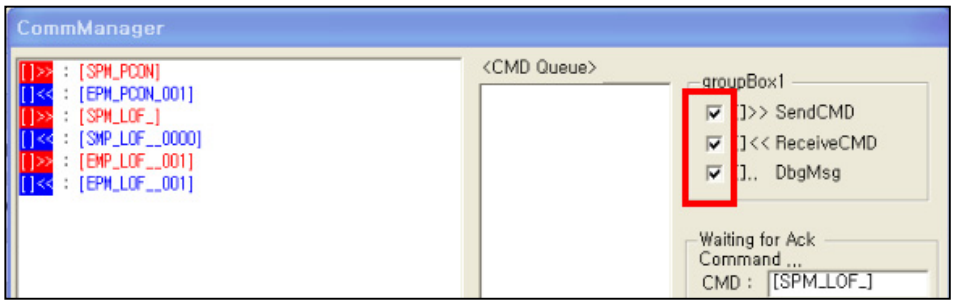
E. Open the **command manager** by clicking 

button from the above **setting** screen.



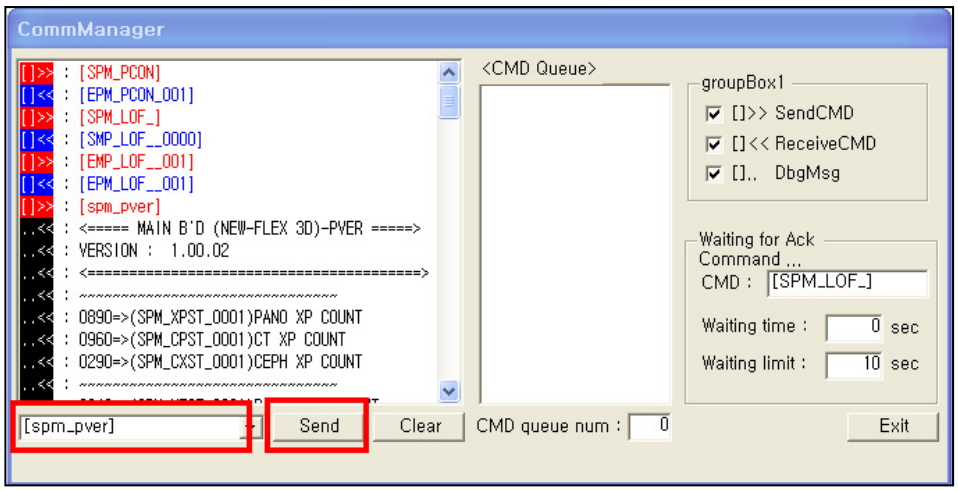
Command Manager Screen

F. Check all the items in the **groupBox1** from the command manger screen.

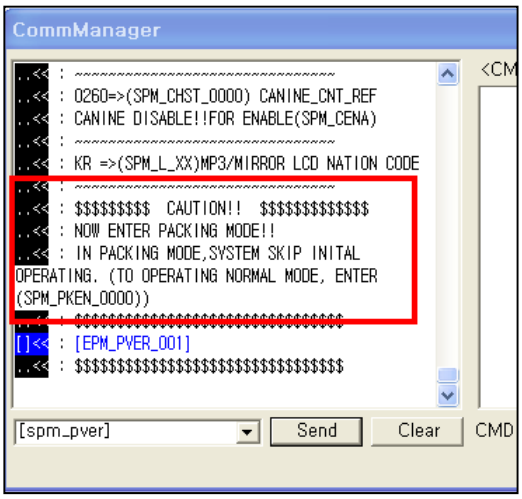


G. Enter **[spm_pver]** in the command prompt, followed by **Send** button.

(**[spm_pver]** is a command sent to the equipment to identify the current version of the main board)



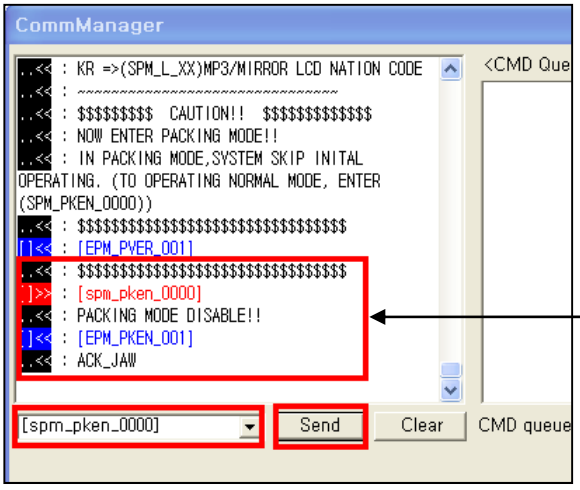
H. Identify the following information message by scrolling down the window.



This message indicates that currently equipment is in the packing mode

$$$$$$$$$ CAUTION!! $$$$$$$$$$$$$
NOW Enter Packing Mode!!
In packing mode,system skip inital operating. (To operating normal mode, Enter (spm_pken_0000))
$$$$$$$$$$$$$$$$$$$$$$$$$$$$$$$$[epm_pver_001]

I. Now enter **[spm_pken_0000]** and click **Send** to exit the packing mode. Then read carefully the echoed texts.



Now indicates the equipment is out of the packing mode

NOTE	**In case of the re-entry into the packing mode, use the command [spm_pken_0001].**

7 (Optional)Setting the power management options

NOTE	**This chapter is intended for the PC which is running on the Windows Vista. For the Windows XP users, there would be some differences in the screen captures and instructions.**

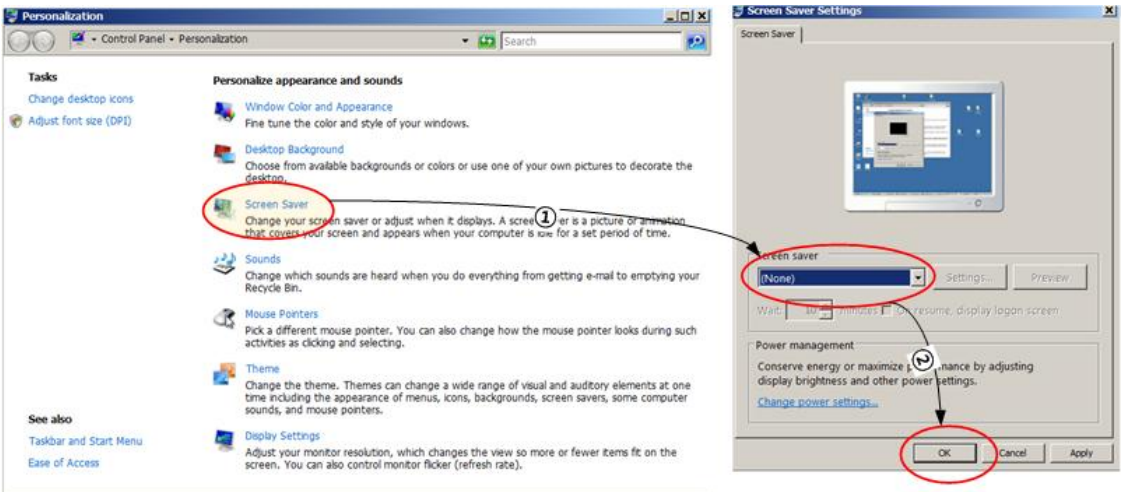
The following statements are based on the windows vista environment. Depending on the operating system employed, the figures and instructions on your system may appear different slightly.

To avoid disruptive and abnormal operation while acquiring image, it is required to reconfigure some parameters on the Windows operating system.

A. Disable the screen saver

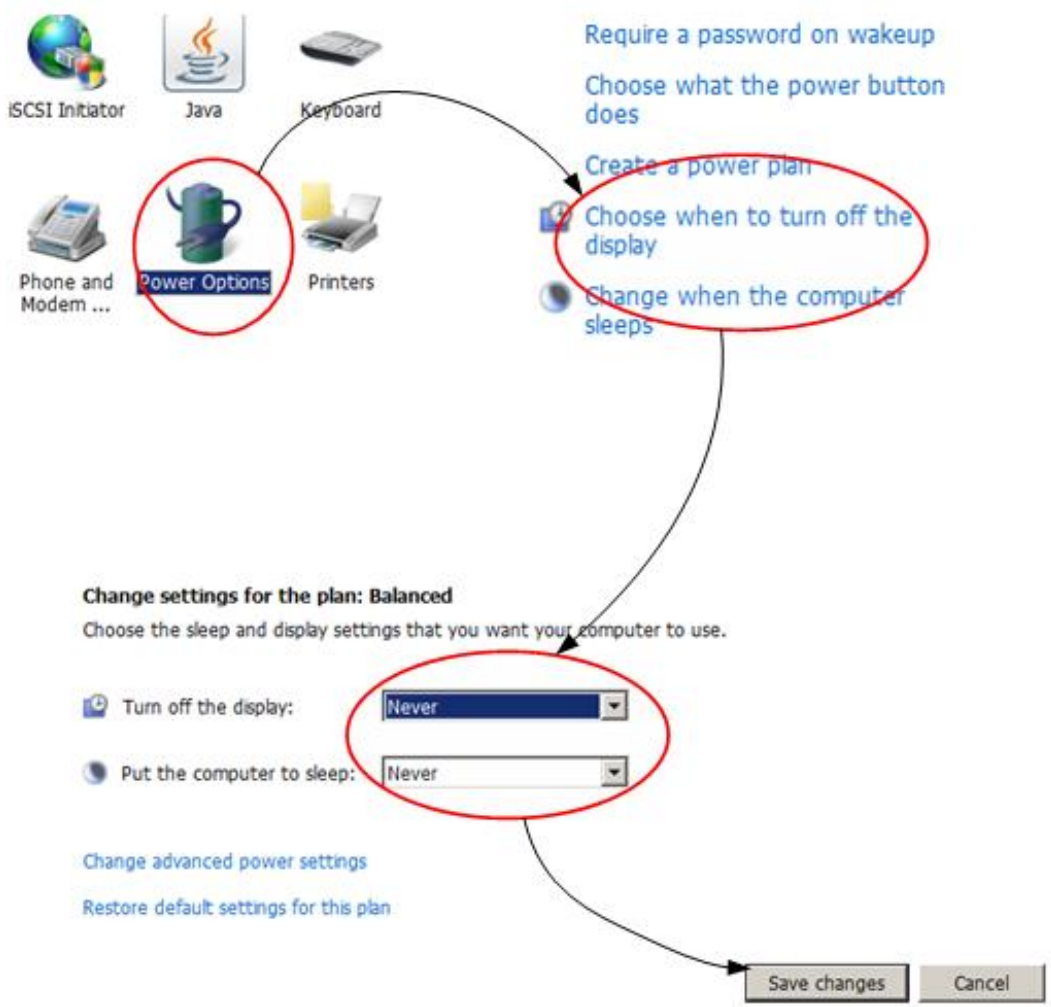
On the desktop, click the right mouse button.

1. Locate and click the screen saver. Then the screen saver setting window will appear.
2. Select **"None"** in the pull-down menu.
3. Click **"OK"**.



B. Select “Never” at the “ turn off the display” and “put the computer to sleep”

1. Go to the control panel
2. Locate the power options icon.
3. Select “choose when to turn off the display”
4. Select **“Never”** among the list for each item.
5. Do the same for “Put the computer to sleep”.
6. Click **“Save changes”**



8 Technical specifications

8.1 General specification

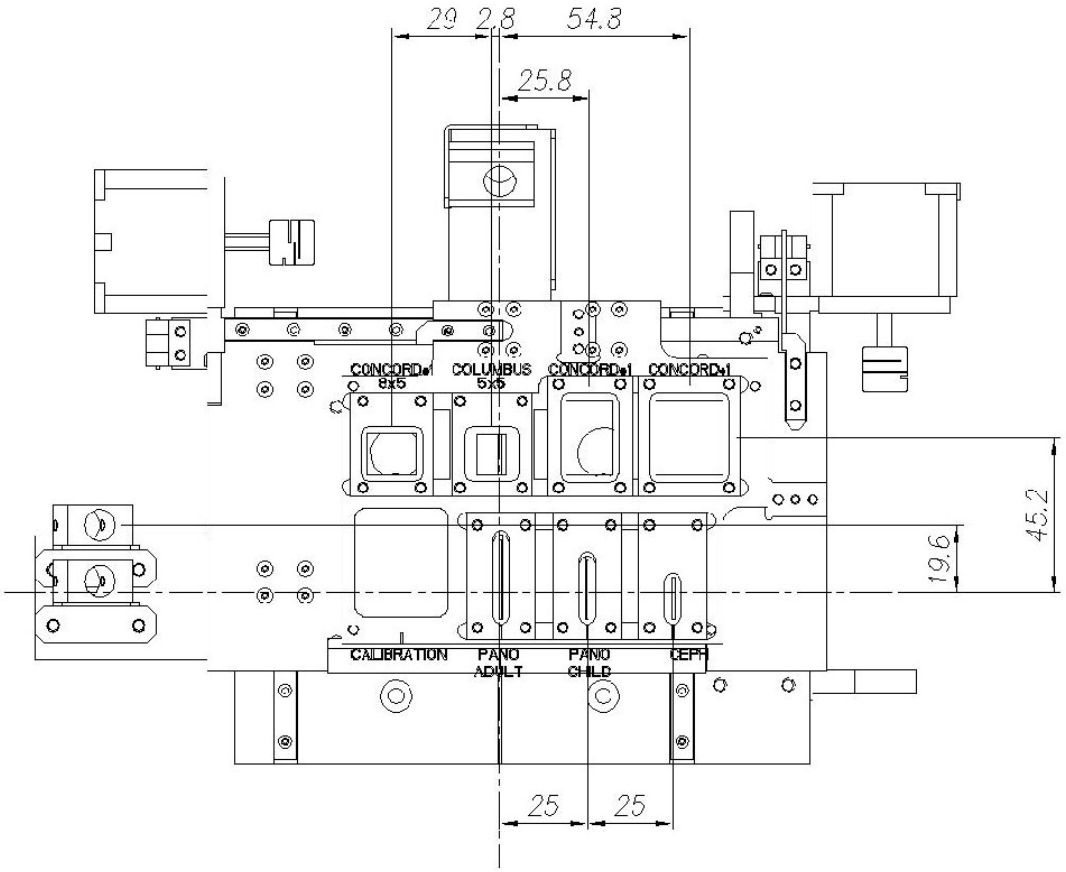
Specification		PaX-Flex3D		
		Panoramic	**CT**	**Ceph**
X-Ray beam			Cone beam	
Detector		CMOS sensor with Cesium Iodie (CsI) scintillated screen	CMOS photodiode array (Active Pixel Sensor: APS)	CMOS sensor with Cesium Iodide (CsI) scintillator
Grayscale Resolution(bit)		14bit	12bit	14bit
Exposure time		Fast mode: 9.8 sec Normal: 13.5 sec HD mode: 18 sec	24 sec	
FOV size			5x5/ 8x5/ 12x8.5	
Reconstruction time	**Normal Mode**		Depends on the PC	
	High Mode			
Voxel Sizes (mm)			0.12mm~0.25mm	
Patient position		Standing/Wheelchair Accessible		
Focal spot		0.5mm		
Max. Anode Voltage to ground		90 kVp		
Max. tube current		10 mA		
Image magnification		1.33	1.569	1.14

Specification		PaX-Flex3D		
		Panoramic	**CT**	**Ceph**
FOD (mm)		439.7	409.7	1,524
ODD (mm)		148.5	233.2	221
FDD (mm)		588.2	642.9	1,745
Weight (kg)		Pano / CT / Ceph : 180, Base : 50 = **Total : 230**		
		Pano / CT :140, Base : 50 = **Total : 190**		
Height (mm)	**Max.**	2,328		
	Min.	1,628		
Length(mm) **x Width**(mm)		Pano/CT : 1,000 x 1,535		
		Pano/CT/Ceph : 1,944 x 1,535		
Power supply		110/230V~ 50/60 Hz 1.8KVA		

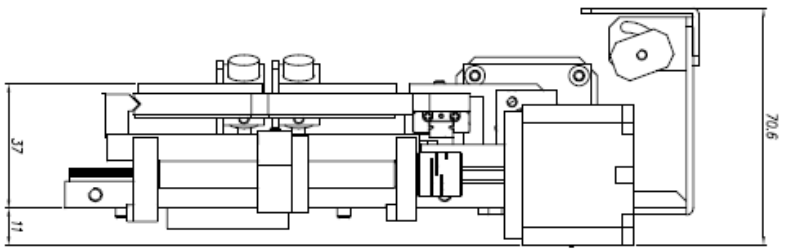
8.2 X-Ray generator specifications

item	details		Data
	Output power rating		0.9kW
High voltage generator	Type		40kHz inverter type
	Normal/pulse	kV	50~90kV(resolution of 1kV)
		mA	4~10mA(resolution of 0.1mA)
		sec	0.5~20(resolution of 0.5sec)
	cooling		Natural /Protect ≥60°C
	Added filtration		1.5 mm Al
	Total filtration		2.8 mm Al
X-Ray tube	Manufacturer		Toshiba
	Model		D-052SB(Stationary Anode type)
	Focal spot		0.5 x0.5mm(IEC 60336)
	Target angle		5°
	inherent filtration		At least 0.8mm Al equivalent at 50kV
	X-Ray coverage		95 x380 mm at SID 550mm
	Anode heat content		35kJ
	duty cycle		1:60 (exposure time :interval time) or more

8.3 Collimator: Beam limiting device

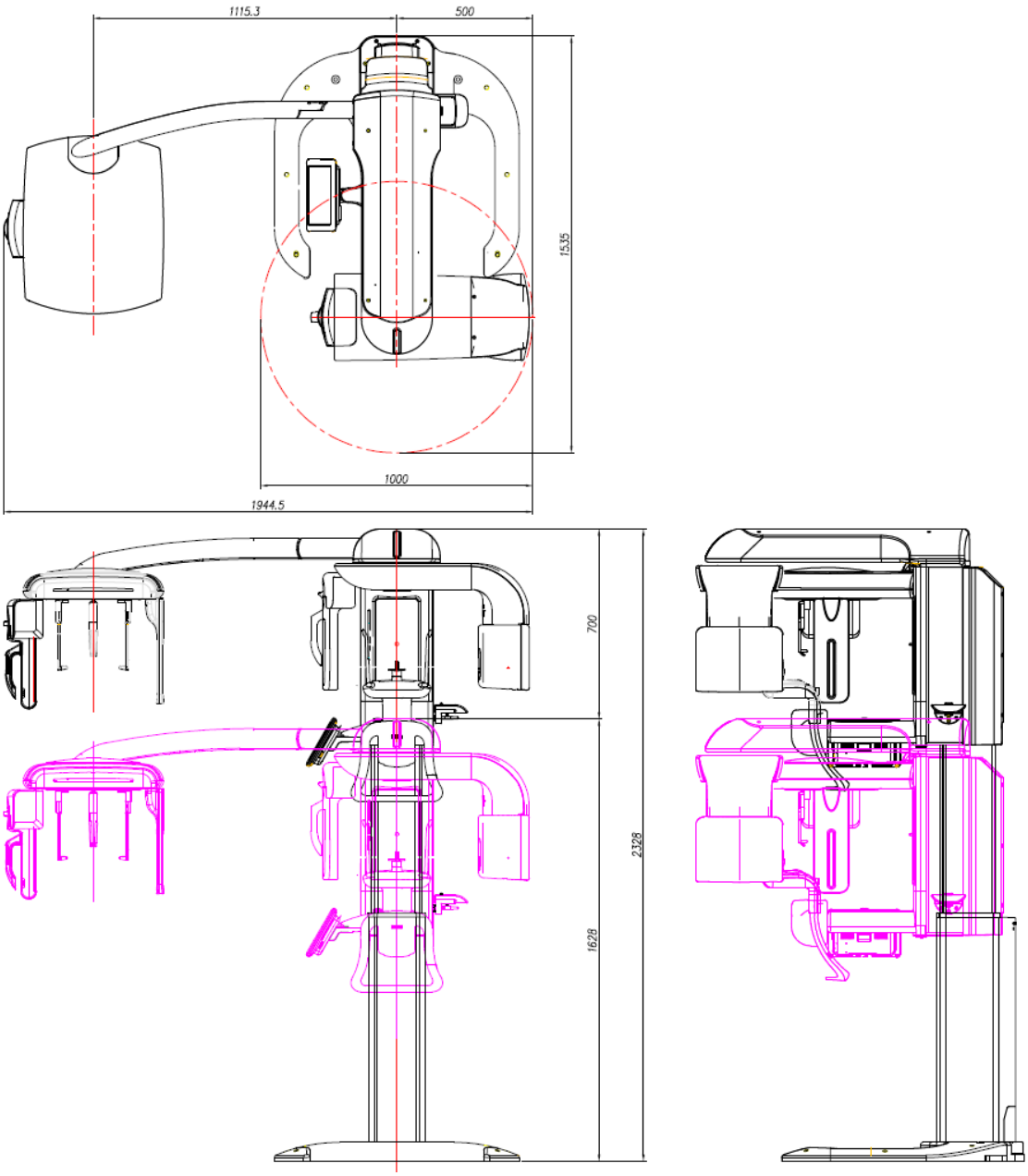


<Front view>



<Side view>

8.4 Physical dimensions



(Unit: mm)

NOTE

Sensor	PANO.	CEPH	CT
Distance from the X-Ray source	588.2mm	1745mm	642.9mm

8.5 Environmental specifications

	Details			Data
Mechanical	Weight	(PANO+CT)/CEPH.		(140Kg)/180Kg
		Base		50Kg
		Total		(190Kg)/230Kg
	Height	Max.	In operation	2328mm
		Min.		1628mm
		Min.	Packing	1178mm
	Length x Width	W/CEPH.		1944mm x 1535mm
		w/o CEPH		1000mm x 1535mm
	Installation type			Standing
Electrical	Input voltage rating			AC 110/230V ± 10%
	Frequency			50/60 Hz
	Phase			Single
	Power consumption			1.8 kVA
Environmental	in service	ambient temperature		18 ~ 28℃
		relative humidity		30 ~ 75%
		atmospheric pressure		700 ~ 1060 hPa
	Transportation and storage	ambient temperature		0 ~ 35℃
		relative humidity		< 90% non-condensing
		atmospheric pressure		500 ~ 1060 hPa

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CE 0120

CE symbol grants the product compliance to the European Directive for Medical Devices 93/42/EEC as amended by 2007/47/EC as a class IIb device.

EC REP

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