PHOT-XIIS

Model 505

DENTAL X-RAY

INSTRUCTIONS FOR USE

(for Canada)

Wall Mount Type.....WK

⚠ WARNING

This X-ray equipment may be dangerous to patients and operators unless safe exposure factors, operating instructions and maintenance schedules are observed.

Belmont

INDEX

[1] INTRODUCTION

1. GENERAL

This manual provides information for the operation and maintenance procedures and technical specifications for the PHOT-X IIs Model 505 dental x-ray. The instructions contained in this book should be thoroughly read and understood before operation.

The PHOT-X IIs Model 505 has no user serviceable items. Repair should be performed by qualified dealer service personnel.

2. INTENDED USE OF THE PRODUCT

The PHOT-X IIs Model 505 is a extraoral source dental radiographic x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with resultant image recorded on intraoral dental x-ray film or image receptor.

3. PARTS IDENTIFICATION OF X-RAY SYSTEM "PHOT-X IIs Model 505"

a. Tube housing assembly : 505-H
b. X-ray controls : 505-CM (main controller), 505-CS (sub controller)
c. Cones : 505-R (regular), 505-L (long)
d. Collimator : 505-REC (rectangular)
e. Balance arm : 505-A

4. COMPLIANCE WITH STANDARD

BELMONT PHOT-X IIs Model 505 x-ray unit complies with the following standard.

a. Electrical and Mechanical Safety
IEC60601-1:2005+A1;A2, CSA-C22.2 No.60601-1:2014 Ed.3+A2

b. Radiation Safety
IEC60601-1-3:2008 Ed.2+A1, CSA-C22.2 No.60601-1-3:2009 Ed.2,
IEC60601-2-65:2012 Ed.1+A1

5. CLASSIFICATION

5-1. According to Medical Device Regulations in Canada, the BELMONT PHOT-X IIs Model 505 is classified as CLASS II Medical Device.

5-2. According to IEC60601-1, the BELMONT PHOT-X IIs Model 505 is classified as follows.

a. Protection against electric shock : Class I Equipment
b. Protection against ingress of water : Ordinary
c. Mode of operation : Non continuous (Duty Cycle = 1 : 30,
Max. ON time: 2.0 sec., Min. OFF time: 12 sec.)
d. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

6. SAFETY

This X-ray Unit may be dangerous to patient and operator, if safe exposure factors, operating instructons and maintenance schedules are not observed.

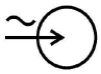
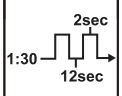
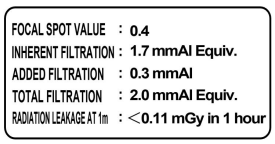
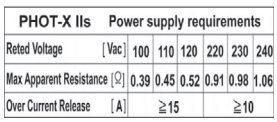
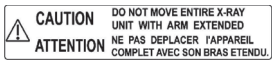
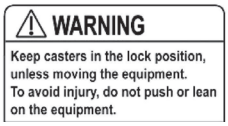
Only qualified and authorized personnel may operate this equipment observing all laws and regulations concerning protection against x-ray radiation.

The operator must :

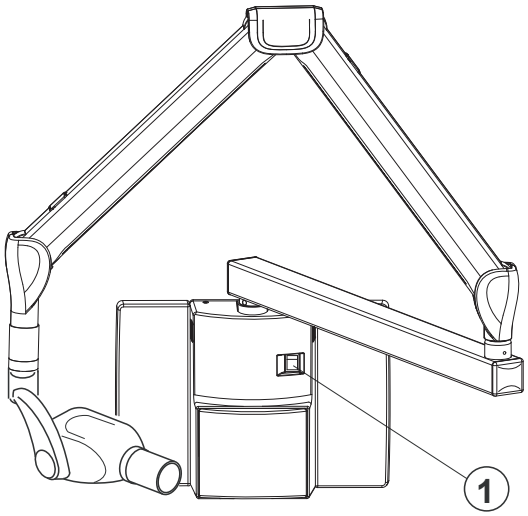
- have means for audio and visual communication with the patient.
- have full view of kV, mA, timer selections and exposure warning light.
- be at least 2 m away from the x-ray head and patient and out of the path of the x-ray beam or be positioned behind a protective device.
- fully use all radiation protection devices, accessories and procedures available to protect the patient and operator from x-ray radiation.

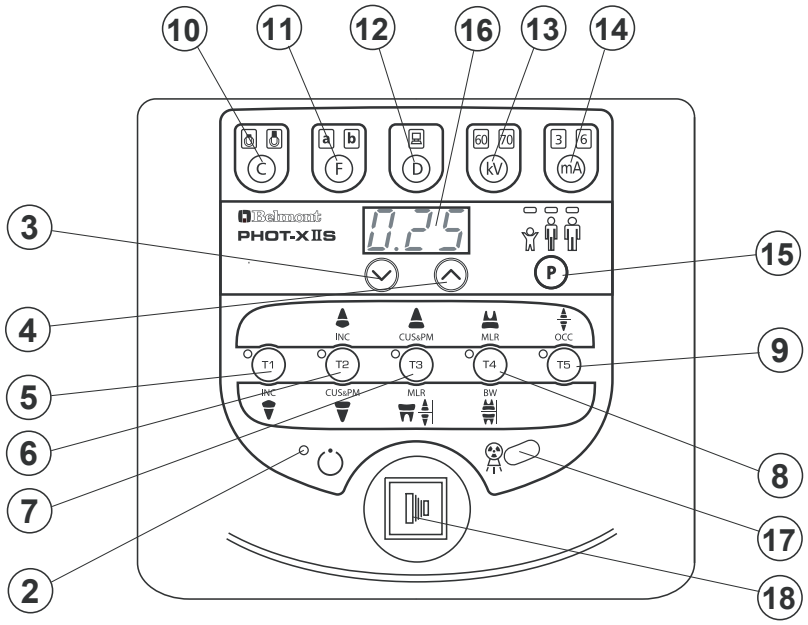
7. SYMBOL

In this book, on the labels or on the control panel of PHOT- X IIs Model 505, following symbols and graphics are used. Confirm the meaning of each symbol and graphic.

	Follow Instructions for use		X-radiation warning sign		ON (POWER)		OFF (POWER)
	Protection Grounding		Exposure Switch		X-ray Emission		Ready
	Upper Incisor		Upper Cuspid & Pre Molar		Upper Molar		Occlusal
	Lower Incisor		Lower Cuspid & Pre Molar		Lower Molar & Bite Wing		Bite Wing
	Digital Imaging		Patient Child		Patient Adult		Patient Large Adult
	Regular Cone		Long Cone		Electronic instructions for use	SN	Serial Number
	Manufacturer		Date of Manufacture		Manufactured in Japan (used with date symbol)	REF	Catalogue Number
COMP	Identification for each component	TYPE	Type of the device		Rated input to the device	OUTPUT	Rated output from the device
	Duty cycle : 1:30 Max. On time : 2 s Min. Off time : 12 s	Belmont	Brand symbol of Takara Belmont group		Importer		
TUBE	X-ray tube	SSD	Source to skin distance			FOCAL SPOT VALUE INHERENT FILTRATION ADDED FILTRATION TOTAL FILTRATION RADIATION LEAKAGE AT 1m	
EXIT FIELD SIZE		X-ray field size at cone end					
		Power supply requirements Rated Voltage [Vac] Max Apparent Resistance [Ω] Over Current Release [A]				CAUTION DO NOT MOVE ENTIRE X-RAY UNIT WITH ARM EXTENDED.	
		CAUTION ! DO NOT RELEASE THIS BAND UNTIL X-RAY HEAD IS INSTALLED.				WARNING Keep casters in the lock position, unless moving the equipment. To avoid injury, do not push or lean on the equipment.	

[2] LAYOUT OF CONTROLS





① **Main Power Switch**
② **Ready Light**
③ **ExposureTime Adjusting Switch (Down)**
④ **ExposureTime Adjusting Switch (Up)**
⑤ **Tooth Selection Switch (T1)**
⑥ **Tooth Selection Switch (T2)**
⑦ **Tooth Selection Switch (T3)**
⑧ **Tooth Selection Switch (T4)**
⑨ **Tooth Selection Switch (T5)**
⑩ **Cone Type Selection Switch**
⑪ **Film Speed Selection Switch**
⑫ **Digital Imaging Switch**
⑬ **kV Selection Switch**
⑭ **mA Selection Switch**
⑮ **Patient Size Selection Switch**
⑯ **ExposureTime Display Window**
⑰ **ExposureWarning Light**
⑱ **Exposure Switch**

[3] FUNCTION OF CONTROLS

① Main Power Switch

Pushing the upper side of this switch to the ON position energizes the x-ray unit. (Ready light and pre-select lights for cone type, film or digital, kV, mA, and patient size illuminate.)
It is recommended to keep this switch OFF when the unit is not in use, in order to prevent an accidental exposure.

IMPORTANT : To prevent the risk of an accidental exposure, push the lower side of this switch to the OFF position, when the unit is not in use.

② Ready Light

This light illuminates when the line voltage is within operable range (108 ~ 132Vac).
When this light is not on, exposure can not be made.

③④ Exposure Time Adjusting Switches

By momentarily pushing the ⌃ (or ⌄) switch, the exposure time displayed increases (or decreases) by one increment. By keeping the switch depressed more 2 sec., the exposure time displayed increases (or decreases) continuously until the switch is released.
Model 505 has the following 37 exposure time settings :

0.00, 0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.07, 0.08, 0.09, 0.10, 0.11, 0.13, 0.14, 0.16, 0.18, 0.20, 0.22, 0.25, 0.28, 0.32, 0.36, 0.40, 0.45, 0.50, 0.56, 0.63, 0.71, 0.80, 0.90, 1.00, 1.12, 1.25, 1.40, 1.60, 1.80, 2.00(sec.)

⑤ ~ ⑨ Tooth Selection Switches (T1 ~ T5)

Pushing one of these switches sets the exposure time automatically for the following ⑩ ~ ⑮ .

⑤ T1 : Incisor of Mandible
⑥ T2 : Incisor of Maxilla, Cuspid & Premolar of Mandible
⑦ T3 : Cuspid & Premolar of Maxilla, Molars of Mandible, Bitewing
⑧ T4 : Molar of Maxilla, Bitewing Molars
⑨ T5 : Occlusal

If the T1 switch ⑤ is depressed more than 3 sec. unit goes into " Lock Mode". In lock mode, the only functional switch is the power switch. To exit from the lock mode, depress the T1 switch more than 3 sec. again.

⑩ Cone Type Selection Switch

By depressing this switch for less than 2 sec., selected cone type can be confirmed. If round cone is selected, "rnd" is displayed. If the cone with rectangular collimator is selected, "rEC" is displayed. Depressing this switch more than 2 sec. changes the cone type by the following order.

Short cone (Round) --> Short cone with rectangular collimator --> Long cone (Round) --> Long cone with rectangular collimator --> Short cone (Round) --> continued

⑪ Film Speed Selection Switch

a. PHOT-X IIs has 16 film speed settings. (F.00 ~ F.15)
Two speed settings are pre-set at the factory (a & b) and can be selected with switch ⑪.
a = Film speed No. F.09 (equivalent to ISO speed group " D", or Kodak Ultra-Speed film)
b = Film speed No. F.05 (equivalent to ISO speed group " F/E", or Kodak InSight film)
Including these two speeds, the PHOT-X IIs Model 505 x-ray can provide 16 different film speeds (F.00 ~ F.15) and any two of them can be programmed for easy selection. If doctor uses a different film speed, or prefers darker (or lighter) radiographs, the new speed can be programmed as follows. Higher speed settings make films darker. If film speed is increased by 1, exposure time becomes 25 % longer.

1. Keep the kV selection switch and mA selection switch depressed simultaneously for more than 3 seconds. Release the switches if the ready light starts to flash.

2. Push F switch momentarily until the "a" light above the F switch illuminates. The exposure time display window shows the present film speed for "a" setting. (The factory default setting, F.09 should be displayed.) By depressing ⌃ or ⌄ switch, increase or decrease film speed number until desired number for "a" setting is displayed.
3. To change the "b" setting from the factory default, F.05, push F switch momentarily until the "b" light illuminates. By depressing ⌃ or ⌄ switch, increase or decrease film speed until the desired number for "b" setting is displayed.
4. Press T1 switch to store these settings, then turn the main power switch off.

b. Pushing **Film Speed Selection Switch** ⑪ momentarily displays the selected film speed setting in the **Exposure Time Display Window** ⑯
Depressing this switch for more then 2 sec. changes the film type being selected.

c. If the **Digital Imaging Switch** ⑫ is depressed, both of the film speed indicating lights (a & b) are turned off.

⑫ **Digital Imaging Switch**

If a digital imaging system is used, shorter exposure time is often required. PHOT-X IIs has 16 speeds for digital imaging (d.00 ~ d.15). Pushing this switch momentarily displays the speed being selected in the **Exposure Time Display Window** ⑯. With the factory speed setting d.10, the exposure time becomes half of F.10 setting.

As the sensitivity is different according to each manufacturer of digital imaging sensors, this setting should be adjusted. To get a darker image, increase the speed setting and to get a lighter image, decrease the speed setting. If the speed setting is increased by 1, exposure time becomes 12 % longer.

1. Keep kV selection switch and mA selection switch depressed simultaneously for more than 3 seconds.
2. Push D switch momentarily until the light above the D switch illuminates and the exposure time display window shows the present speed setting. (The factory default setting d.10 should be displayed.)
3. By depressing ⌃ or ⌄ switch, increase or decrease speed until the desired number is displayed.
4. Press **T1 switch** to store these settings, then turn the main power switch off.

⑬ **kV Selection Switch**

Momentarily depressing this switch will change the tube potential to 60 or 70 kV. If either the Film Speed Switch ⑪ or Digital Imaging Switch ⑫ is depressed, 60kV is automatically selected.

⑭ **mA Selection Switch**

Momentarily depressing this switch will change the tube current setting (3 or 6 mA). If the Digital Imaging Switch ⑫ is depressed, 3 mA is automatically selected and if the Film Speed Switch ⑪ is depressed, 6 mA is automatically selected.

TABLE 1. Speed Setting and Exposure Time (Short Cone) [unit : sec.]

Speed Setting	kV	mA	Child					Adult					Large Adult				
			T1	T2	T3	T4	T5	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5
F. 09	60	3	0.20	0.25	0.28	0.32	0.50	0.32	0.40	0.50	0.56	0.80	0.40	0.50	0.63	0.71	1.00
		6	0.10	0.11	0.14	0.16	0.25	0.16	0.20	0.25	0.28	0.40	0.20	0.25	0.28	0.36	0.50
	70	3	0.14	0.16	0.20	0.22	0.36	0.25	0.28	0.36	0.40	0.56	0.28	0.36	0.45	0.50	0.71
		6	0.07	0.08	0.10	0.11	0.18	0.11	0.14	0.18	0.20	0.28	0.14	0.18	0.22	0.25	0.36
F. 05	60	3	0.08	0.10	0.11	0.14	0.20	0.14	0.16	0.20	0.22	0.32	0.18	0.20	0.25	0.28	0.40
		6	0.04	0.05	0.06	0.07	0.10	0.07	0.08	0.10	0.11	0.16	0.09	0.10	0.13	0.14	0.20
	70	3	0.06	0.07	0.08	0.10	0.14	0.10	0.11	0.14	0.16	0.25	0.13	0.14	0.18	0.20	0.28
		6	0.03	0.04	0.04	0.05	0.07	0.05	0.06	0.07	0.08	0.11	0.06	0.07	0.09	0.10	0.14
d.10	60	3	0.13	0.14	0.18	0.20	0.28	0.20	0.25	0.28	0.36	0.50	0.25	0.32	0.36	0.40	0.63
		6	0.06	0.07	0.09	0.10	0.14	0.10	0.13	0.14	0.16	0.25	0.13	0.16	0.18	0.22	0.32
	70	3	0.09	0.11	0.13	0.14	0.22	0.14	0.18	0.22	0.25	0.36	0.18	0.22	0.25	0.32	0.45
		6	0.04	0.05	0.06	0.07	0.11	0.07	0.09	0.11	0.13	0.18	0.09	0.11	0.13	0.16	0.22

TABLE 2. Speed Setting and Exposure Time (Long Cone) [unit : sec.]

Speed Setting	kV	mA	Child					Adult					Large Adult				
			T1	T2	T3	T4	T5	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5
F. 09	60	3	0.40	0.50	0.63	0.71	1.00	0.71	0.80	1.00	1.12	1.60	0.90	1.00	1.25	1.40	2.00
		6	0.20	0.25	0.28	0.36	0.50	0.36	0.40	0.50	0.56	0.80	0.45	0.50	0.63	0.71	1.00
	70	3	0.28	0.36	0.45	0.50	0.71	0.50	0.56	0.71	0.80	1.25	0.63	0.71	0.90	1.00	1.40
		6	0.14	0.18	0.22	0.25	0.36	0.25	0.28	0.36	0.40	0.56	0.32	0.36	0.45	0.50	0.71
F. 05	60	3	0.18	0.20	0.25	0.28	0.40	0.28	0.36	0.40	0.45	0.71	0.36	0.45	0.50	0.56	0.90
		6	0.09	0.10	0.13	0.14	0.20	0.14	0.18	0.20	0.25	0.36	0.18	0.22	0.25	0.28	0.45
	70	3	0.13	0.14	0.18	0.20	0.28	0.20	0.25	0.28	0.32	0.50	0.25	0.32	0.36	0.40	0.63
		6	0.06	0.07	0.09	0.10	0.14	0.10	0.13	0.14	0.16	0.25	0.13	0.16	0.18	0.22	0.32
d.10	60	3	0.25	0.32	0.36	0.45	0.63	0.45	0.50	0.63	0.71	1.00	0.56	0.63	0.80	0.90	1.25
		6	0.13	0.16	0.18	0.22	0.32	0.22	0.25	0.32	0.36	0.50	0.28	0.32	0.40	0.45	0.63
	70	3	0.18	0.22	0.28	0.32	0.45	0.32	0.36	0.45	0.50	0.71	0.40	0.45	0.56	0.63	0.90
		6	0.09	0.11	0.13	0.16	0.22	0.16	0.18	0.22	0.25	0.36	0.20	0.22	0.28	0.32	0.45

⑮ **Patient Size Selection Switch**

This switch alters the selection of patient type/size to be radiographed (child→adult→large adult →child) and sets the exposure time automatically. If the weight of child is less then 20kg, press ⌄ switch once after setting to child. If the weight of child is over 30kg and less than 50kg, press ⌃ switch once after setting to child. If the weight of child is over 50kg and less than 70kg, press ⌃ switch twice after setting to child. If the weight of child is over 70kg, set to adult.

NOTE: Setting or adjusting the exposure time manually (with ⌃ or ⌄ switch) supersedes ⑤～⑮ functions.

⑯ **Exposure Time Display Window**

This window displays the selected exposure time. Estimated air kerma (radiation output) at distal end of cone can be displayed in this window by manual operation or automatically after the exposure. If an abnormal condition exists or a malfunction occurs, an Error Code is also displayed in this window. (See Section :**[9] ERROR CODES)**

⑰ **Exposure Warning Light**

Illumination of this light indicates the unit is producing x-radiation.

⑱ **Exposure Switch**

This switch initiates radiographic exposure. When making an exposure, depress and hold this switch until the **Exposure Warning Light**⑰ and the audible warning shut off. Failure to keep this switch depressed will result in the premature termination of the exposure and an error code E.00 will be displayed in **Exposure Time Display Window** ⑯.

[4] OPERATING PROCEDURES

1. Turn ON the Main Power Switch ①.
2. Confirm that Ready Light ② is illuminated.

NOTE : The ready light will not illuminate unless the incoming line voltage is correct and within the x-ray's operable range (108 ~ 132V AC).

3. Select the appropriate tooth type (⑤ ~ ⑨), and confirm the pre-selected conditions (cone type, film or digital, kV, mA and patient size) are suitable for exposure.

NOTE : To manually set the exposure time, depress either of the Manual Exposure Time Adjusting Switches (⌃ or ⌄) until the desired exposure time appears in the Exposure Time Display Window ⑯ . While the unit is in manual mode, other selection switches (⑤ ~ ⑮) do not affect exposure time. (All of the tooth selection lights are off.) To return to the automatic exposure time selection mode, depress any one of Tooth Selection Switches (⑤ ~ ⑨).

4. Depress the Exposure Switch ⑱. When the Exposure Switch is depressed, the Exp. Warning Light ⑰ illuminates and the audible warning sounds. Do not release the Exposure Switch until the Exposure Warning Light and audible warning automatically shut off. Failure to keep the switch depressed will result in exposure being terminated prematurely.

5. To continue to radiograph other teeth, just select appropriate Tooth Selection Switches (⑤ ~ ⑨).

IMPORTANT : To protect x-ray tubehead from heat accumulation, wait for a time interval that is equal to 30 times the selected exposure time before making additional exposures. (Example : a 15 sec. wait is necessary between exposures that are 0.5 sec. in duration.)

6. Turn OFF the Main Power Switch ① in order to prevent accidental exposures when the unit is not in use.

NOTE : If the unit left over 8 min. without being operated and the Main Power Switch ① is kept on, figure "1" runs through the Exposure Time Display Window ⑯. This does not mean that malfunction of the unit has occurred ; this is an energy saving feature. The unit returns to ready condition by pressing any one of the switches, except the Exposure Switch ⑱.

[5] ESTIMATED AIR KERMA

Estimated air kerma (radiation output) at distal of cone can be displayed in the exposure time window by depressing the patient switch for more then 1 second. Unit for this value is mGy and this value is calculated by kV, mA, Exposure time and Cone type selected at that time.
Patient type display lamps and displayed value in the window are flashing in this mode and if either of the manual exposure time adjusting switch is depressed during this mode, accumulated air kerma will be displayed. Accumulated value will be reset when the power switch is turned off or leave the x-ray unit more than 8 minutes without depressing any switch. To return to normal mode, press the patient switch for more than 1 second again or leave the controller untouched for more than 10 seconds.

[6] OPTIONAL HAND EXPOSURE SWITCH

An optional hand exposure switch can be connected to the sub controller. Since this exposure switch has a coiled cord, operators can stand in the most suitable position for operation. As controller has separate connector for this exposure switch, both exposure switch ⑱ on the front panel of sub controller and this hand exposure switch can be used.
If local code prohibits use of both, aks installer to disconnect the connector of either switch.

[7] DIGITAL IMAGING SYSTEM

No x-ray image receptor is integrated into the PHOT-X IIs Model 505 x-ray system. If an image receptor is used with the PHOT-X IIs Model 505, the type and performance of the receptor should be as follows.

1.Type of receptor : CCD(charge-coupled device), CMOS(complimentary metal oxide semi-conductor) or PSP (photostimulable phosphor plate) receptor for dental intraoral use.
2.Adequate amount of x-radiation for the receptor should be between 0.02mGy and 23.6mGy.
3.Use the receptor holder and receptor cover recomended by the manufacturer of image receptor.
4.Receptor holder should hold the image receptor firmly in position and work as the x-ray beam alignment device.

⚠ WARNING

The use of ACCESSORY equipment not complying with the equivalent safety requirements of the PHOT-X IIs Model 505 may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include :
· use of the accessory in the PATIENT VICINITY
· evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC60601-1 and/or IEC60601-1 harmonized national standard.

[8] DISINFECTION AND CLEANING

1. DISINFECTION
   (a) X-ray operators are required to wear disposable gloves when taking radiographs and handling contaminated film packets or digital detector cover. Gloves should be changed for each patient to avoid cross contamination. X-ray head, main controller and sub controller should be covered by single use barriers.
   (b) If you use film holders or digital detector holders that go into patient's mouth, properly sterilize them. Follow the sterilization procedures indicated by each manufacturer.
2. CLEANING
   In order to ensure proper hygiene and cleaning of the equipment, the following procedures must be followed.

⚠ CAUTION

Before cleaning the unit, turn off the main power switch and breaker on the branch line. This is required because some internal parts remain connected to main voltage even when the main power switch has been turned off.
Never use the corrosive disinfectants, such as povidone iodine or sodium hypochlorite.
Do not pour or spray solvent or liquid directly on the x-ray unit.
Be careful not to allow solvents to run or drip into the x-ray unit.

Limitations on reprocessing : Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.
Point of use : Remove excess soil with disposable cloth / paper wipe.
Preparation for cleaning : Turn off the main power switch and breaker on the branch line. Disassembly is not required.
Cleaning : Wipe the outside surface with a paper towel dampened with a disinfectant solution or household, non abrasive cleaner.
Disinfection : To ensure proper cleaning of the parts that may come in contact with skin, periodic disinfection with a non corrosive surface disinfectant is recommended.
Recommended disinfectant : FD333 (Durr Dental), OPTIM33TB (SciCan Ltd.)
Drying : Allow surface to air dry before turning breaker and main switch back on.

[9] ERROR CODES

If an abnormal condition exists in the unit, or a malfunction occurs, an error code is displayed in the Exposure Time display window. Please refer to the table below.

<table>
<tr><th>Error Code</th><th>Condition</th><th>Step to be Taken</th><th>Possible Solution</th></tr>
<tr><td>E. 00</td><td>Exposure switch was released before exposure termination.</td><td>All the tooth selection lights blink. Touch one of the tooth switches.</td><td>Release the exposure switch after the exposure warning indication disappears.</td></tr>
<tr><td rowspan="2">E. 01</td><td>Exposure switch was pressed within 10 sec. of previous exposure.</td><td rowspan="2">A 10 sec. delay is built in between each exposures and 3 sec. delay is built in after the power is on.</td><td>There should be a "wait" interval of 30 times the exposure time between successive exposures.</td></tr>
<tr><td>Exposure time was set and exposure switch was pressed within 3 sec. after the power switch being turned on.</td><td>Wait for a minimum 3 sec. after the main power switch is turned on before pressing the exposure switch.</td></tr>
<tr><td>E. 02</td><td>Line voltage was less than 90% of rated voltage.</td><td rowspan="2">Line voltage should be in the range of ±10% of rated voltage.</td><td rowspan="2">Confirm that ready lamp is on before exposure. Ask service personnel to check the line voltage.</td></tr>
<tr><td>E. 03</td><td>Line voltage was more than 110% of rated voltage.</td></tr>
<tr><td>E. 05</td><td>Tube current at last portion of exposure was less than 2 mA at 3 mA setting or less than 4.5 mA at 6 mA setting</td><td rowspan="13">Turn off the main power switch and wait for approx. 2 min. Turn on the main power switch again.</td><td rowspan="3">If the same error code is displayed, call service personnel.</td></tr>
<tr><td>E. 06</td><td>Tube current at last portion of exposure was more than 4 mA at 3 mA setting or more than 7.5 mA at 6 mA setting</td></tr>
<tr><td>E. 07</td><td>During the exposure, tube current becomes less than 1.5 mA at 3mA setting or less than 3 mA at 6 mA setting.</td></tr>
<tr><td>E. 08</td><td>During the exposure, tube current becomes more than 20 mA.</td><td>Make an exposure at 60kV, 3mA, 0.1s. If the same error occurs, repeat the exposures until the error doesn't come. If it is not solved within 20 shoots, call service personnel.</td></tr>
<tr><td>E. 09</td><td>Setting for pre-heating time is out of range.</td><td rowspan="5">If the same error code is displayed, call service personnel.</td></tr>
<tr><td>E. 10</td><td>Exposure switch or exposure circuit had been ON, when main power switch is turned on.</td></tr>
<tr><td>E. 11</td><td>Tube current is detected during pre-heating.</td></tr>
<tr><td>E. 12</td><td>Tube current is detected when main power switch is turned on.</td></tr>
<tr><td>E. 14</td><td>Tube potential at last portion of exposure was less than 50 kV at 60 kV setting or less than 60 kV at 70 kV setting.</td></tr>
</table>

Error Code	Condition	Step to be Taken	Possible Solution
E. 15	Tube Potential at last portion of exposure was more than 70 kV at 60 kV setting.	Turn off the main power switch and wait for approx. 2 min. Turn on the main power switch again.	If the same error code is displayed, call service personnel.
E. 16	1. During the exposure, tube potential becomes less than 40 kV at 60 kV setting or less than 50 kV at 70 kV setting. 2. 2P connector between the main power board and arm or between the arm and tube head is disconnected.		
E. 17	During the exposure, tube potential becomes more than 80 kV.		
E. 18	Excess current was detected in primary circuit of filament transformer.		
E. 19	Excess current was detected in primary circuit of high voltage transformer.		
E. 20	1. Exposure switch was depressed when tube head temperature was over 60 C. 2. 8P connector between the main power board and arm or between the arm and tube head is disconnected.	Wait until the temperature goes down.	
E. 22	Failure of electrical communication between the power PCB and timer PCB.	Turn off the power switch and wait for approx. 2 min. Turn on the power switch again.	
E. 23	Some switch had been on, when the main power switch is turned on. (Except the exposure switch.)		

[10] MAINTENANCE

PHOT-X IIs Model 505 x-ray unit requires post installation confirmation and periodic maintenance checks to be performed by dealer service personnel. These procedures ensure that the x-ray unit is functioning within the manufacture's specifications and remains in compliance with the Standard.

It is responsibility of the owner of the unit to see that these maintenance checks are correctly performed. The specific instructions to perform these checks are located within the PHOT-X IIs Model 505 Installation manual.

a. Maintenance personnel : Qualified dealer service personnel who has the experience with Belmont's x-ray or has been trained by Belmont. But item 7 - 10 of the maintenance check list on page 11 should be verified routinely by treatment room personnel.

b. Specification of the parameters to be monitored and monitoring frequency : Refer to the maintenance check list on page 11.

c. Acceptance limit : Refer to the Maintenance check list on page 11.

d. Required action when failed : Refer to the Maintenance check list on page 11.

e. Tools to maintain quality control logs : Use the check list on page 11.

f. Training material : Operator's instructions, Installation instructions and Service manual

MAINTENANCE CHECK LIST

Parameter	Acceptance limit	Frequency	Procedures when failed	OK/NG
1. Line voltage	Confirm the line voltage is within 120V±10%. Also confirm the voltage drop during exposure is within 5%.	Yearly	Connect to the power supply within 120V±10%. Check disconnection of wire or connection failure. Repair cable connection as needed.	
2. Tube current	Confirm the measured mA value indicated on the LED window is within the rated value ± 1 mA.	Yearly	Perform MA adjustment. (Refer to page 25 of Installation manual.)	
3. Tube potential	Confirm the measured kV value indicated on the LED window is within the rated value ±10%.	Yearly	Check the tube potential compensation (CP) values are same as the values on the label in the head yoke.	
4. Timer	Confirm the error of the measured value by noninvasive exposure time meter is within ±5% or 20mS at 0.01 and 2.0 seconds exposure. *The non invasive time meter should be calibrated to measure the radiation from dental x-ray.	Yearly	Exchange the power PC board to new one and check the result.	
5. Wall mounting plate	Confirm the wall plate is firmly fixed to the wall.	Yearly	If bolts are loose, find the reason why bolts became loose and take counter measure that prevents bolts from becoming loose.	
6. Arm mounting bracket	Make sure that the arm bracket is firmly attached to the wall plate.	Yearly	If bolts that fix the arm bracket to the wall plate are loose, find the reason why bolts became loose and take counter measure that prevents bolts from becoming loose.	
7. Dosimetry	Save the image that was taken under appropriate conditions as a reference image. Compare a newly taken image with a reference image to assure the image quality.	Weekly	If the image quality is found poor comparing to a reference image, check the condition of image receptor (film, sensor or imaging plate), image developer (developing fluid, dental film developer, PC or scanner). If they are OK, then set appropriate film / sensor speed by referring to page 27 of installation manual.	
8. Horizontal arm	Confirm that horizontal arm is firmly inserted to the arm bracket. Make sure the retaining bolt is firmly inserted to the arm bracket.	Daily (before use)	If the retaining bolt is loose, find the reason why bolt became loose and take counter measure that prevents the retaining bolt from becoming loose.	
9. Head	Confirm the head can be smoothly positioned.	Daily (before use)	Adjust the brake screws by referring to page 17 of installation manual.	
10. Balance arm	Confirm the balance arm moves smoothly without making noise.	Daily (before use)	Adjust the tension of the balance arm by referring to page 17 of installation manual. If the balance arm makes noise, apply grease.	

[11] TECHNICAL DATA

1. X-ray tube (Stationary Anode) ---------- D-046 or KL11-0.4-70 (See the label on head)
   a. Nominal focal spot value ---------- 0.4 (IEC60366)
   b. Target Material ---------- Tungsten
   c. Target angle ---------- 12.5 deg (D-046), 12 deg (KL11-0.4-70)
   d. Maximum anode heat content ---------- 4.3 kJ (6.1 kHU)
2. Maximum x-ray tube assembly heat content ---------- 293 kJ (413 kHU)
3. Rated peak tube potential ---------- 60 kV / 70 kV selectable
4. Rated tube current ---------- 3 mA / 6 mA selectable
5. Maximum rated peak tube potential ---------- 70 kV
6. Rated line voltage ---------- 120 VAC, 60 Hz, Single phase, 1.2 kVA
7. Line voltage range ---------- 108 VAC ~ 132 VAC
8. Range of line voltage regulation ---------- 0 ~ 5 % (Apparent resistance 0.52 ohm)
9. Rated line current ---------- 10 A at 70 kV, 6 mA
10. Maximum line current ---------- 11 A at 70 kV, 6 mA
11. Exposure time ---------- 0.01 ~ 2.0 sec.
12. Inherent filtration ---------- 1.7 mm Al Equivalent
13. Added filtration ---------- 0.3 mm Al
14. Minimum filtration permanently in useful beam ----- 2.0 mm Al Equivalent at 70 kV
15. Nominal radiation output ---------- Refer to the nominal radiation output table on the next page for every combination of kV, mA, exposure time and cone. The values in the table are measured at the distal end of the cone.
16. Nominal electrical output of H.V. generator ---------- 0.42 kW at 70 kV, 6 mA
17. Cone

	Source to skin distance	Field size
a. Regular cone	8 inches (203 mm)	58 mm dia., circular
b. Long cone (option)	12 inches (305 mm)	58 mm dia., circular
c. Rectangular collimator	SSD of cone + 40mm	32 x 40 mm, rectangular

18. Maximum symmetrical radiation field ---------- 60 mm dia. at distal end of cone
19. Leaking technique factor ---------- 70 kV / 0.19 mA (697mAs at 1 hour)
    (0.19 mA is maximum rated continuous current for 6mA with a duty cycle 1:30)
20. Duty cycle ---------- 1 : 30 (0.5 sec. exposure with 15 sec. interval)
21. Maximum deviation of tube potential, tube current and exposure time
    a. Below 0.1 sec. setting ---------- ±10 kV, ±2 mA, ±5 msec.
    b. 0.1 sec. setting & up ---------- ±5 kV, ±1 mA, ±10 msec.
22. Measurement base of technique factors
    a. peak tube potential ---------- Average of peak tube potentials during one exposure
    b. tube current ---------- Average of tube current during one exposure
    c. exposure time ---------- Time period during x-ray is emitted
23. Half value layer ---------- 1.5 mm Al over
24. Source to the base of cone distance ---------- 94 mm
25. Environmental condition for storage ---------- -20 ~ 70 °C, 10 ~ 100 %, 500 ~ 1060 hPa
26. Environmental condition for operation ---------- 10 ~ 40 °C, 30 ~ 70 %, 700 ~ 1060 hPa
27. Dose area product ---------- Estimated air kerma displayed [mGy] x 26.4 [cm^2] (for regular and long cone)
    Estimated air kerma displayed [mGy] x 12.8 [cm^2] (for rectangular collimator)

Nominal Radiation Output Table

Exp. Time [sec.]	Nominal Radiation Output															
	without Rectangular Collimator								with Rectangular Collimator							
	60kV				70kV				60kV				70kV			
	Regular Cone		Long Cone		Regular Cone		Long Cone		Regular Cone		Long Cone		Regular Cone		Long Cone	
	3mA	6mA	3mA	6mA	3mA	6mA	3mA	6mA	3mA	6mA	3mA	6mA	3mA	6mA	3mA	6mA
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
0.01	0.05	0.09	0.02	0.04	0.06	0.12	0.03	0.05	0.03	0.06	0.02	0.03	0.04	0.08	0.02	0.04
0.02	0.09	0.18	0.04	0.08	0.12	0.24	0.05	0.10	0.06	0.13	0.03	0.06	0.08	0.16	0.04	0.08
0.03	0.14	0.27	0.06	0.12	0.18	0.35	0.08	0.16	0.10	0.19	0.05	0.09	0.12	0.25	0.06	0.12
0.04	0.18	0.37	0.08	0.16	0.24	0.47	0.10	0.21	0.13	0.26	0.06	0.13	0.16	0.33	0.08	0.16
0.05	0.23	0.46	0.10	0.20	0.30	0.59	0.13	0.26	0.16	0.32	0.08	0.16	0.21	0.41	0.10	0.20
0.06	0.27	0.55	0.12	0.24	0.35	0.71	0.16	0.31	0.19	0.38	0.09	0.19	0.25	0.49	0.12	0.24
0.07	0.32	0.64	0.14	0.28	0.41	0.83	0.18	0.37	0.22	0.45	0.11	0.22	0.29	0.58	0.14	0.29
0.08	0.37	0.73	0.16	0.32	0.47	0.94	0.21	0.42	0.26	0.51	0.13	0.25	0.33	0.66	0.16	0.33
0.09	0.41	0.82	0.18	0.36	0.53	1.06	0.24	0.47	0.29	0.57	0.14	0.28	0.37	0.74	0.18	0.37
0.10	0.46	0.91	0.20	0.41	0.59	1.18	0.26	0.52	0.32	0.64	0.16	0.32	0.41	0.82	0.20	0.41
0.11	0.50	1.01	0.22	0.45	0.65	1.30	0.29	0.58	0.35	0.70	0.17	0.35	0.45	0.91	0.22	0.45
0.13	0.59	1.19	0.26	0.53	0.77	1.53	0.34	0.68	0.41	0.83	0.21	0.41	0.54	1.07	0.27	0.53
0.14	0.64	1.28	0.28	0.57	0.83	1.65	0.37	0.73	0.45	0.89	0.22	0.44	0.58	1.15	0.29	0.57
0.16	0.73	1.46	0.32	0.65	0.94	1.89	0.42	0.84	0.51	1.02	0.25	0.51	0.66	1.32	0.33	0.65
0.18	0.82	1.65	0.36	0.73	1.06	2.12	0.47	0.94	0.57	1.15	0.28	0.57	0.74	1.48	0.37	0.73
0.20	0.91	1.83	0.41	0.81	1.18	2.36	0.52	1.05	0.64	1.28	0.32	0.63	0.82	1.65	0.41	0.82
0.22	1.01	2.01	0.45	0.89	1.30	2.60	0.58	1.15	0.70	1.40	0.35	0.70	0.91	1.81	0.45	0.90
0.25	1.14	2.29	0.51	1.01	1.48	2.95	0.65	1.31	0.80	1.60	0.40	0.79	1.03	2.06	0.51	1.02
0.28	1.28	2.56	0.57	1.13	1.65	3.30	0.73	1.46	0.89	1.79	0.44	0.89	1.15	2.31	0.57	1.14
0.32	1.46	2.93	0.65	1.30	1.89	3.78	0.84	1.67	1.02	2.04	0.51	1.01	1.32	2.64	0.65	1.31
0.36	1.65	3.29	0.73	1.46	2.12	4.25	0.94	1.88	1.15	2.30	0.57	1.14	1.48	2.97	0.73	1.47
0.40	1.83	3.66	0.81	1.62	2.36	4.72	1.05	2.09	1.28	2.55	0.63	1.27	1.65	3.29	0.82	1.63
0.45	2.06	4.12	0.91	1.82	2.66	5.31	1.18	2.35	1.44	2.87	0.71	1.42	1.85	3.71	0.92	1.84
0.50	2.29	4.57	1.01	2.03	2.95	5.90	1.31	2.61	1.60	3.19	0.79	1.58	2.06	4.12	1.02	2.04
0.56	2.56	5.12	1.13	2.27	3.30	6.61	1.46	2.93	1.79	3.57	0.89	1.77	2.31	4.61	1.14	2.29
0.63	2.88	5.76	1.28	2.55	3.72	7.43	1.65	3.29	2.01	4.02	1.00	1.99	2.59	5.19	1.29	2.57
0.71	3.25	6.49	1.44	2.88	4.19	8.38	1.86	3.71	2.27	4.53	1.12	2.25	2.92	5.85	1.45	2.90
0.80	3.66	7.32	1.62	3.24	4.72	9.44	2.09	4.18	2.55	5.11	1.27	2.53	3.29	6.59	1.63	3.27
0.90	4.12	8.23	1.82	3.65	5.31	10.6	2.35	4.70	2.87	5.74	1.42	2.85	3.71	7.4	1.84	3.67
1.00	4.57	9.15	2.03	4.05	5.90	11.8	2.61	5.23	3.19	6.38	1.58	3.16	4.12	8.2	2.04	4.08
1.12	5.12	10.2	2.27	4.54	6.61	13.2	2.93	5.85	3.57	7.1	1.77	3.54	4.61	9.2	2.29	4.57
1.25	5.72	11.4	2.53	5.06	7.38	14.8	3.27	6.53	3.99	8.0	1.98	3.96	5.15	10.3	2.55	5.10
1.40	6.40	12.8	2.84	5.67	8.26	16.5	3.66	7.32	4.47	8.9	2.21	4.43	5.77	11.5	2.86	5.72
1.60	7.32	14.6	3.24	6.48	9.44	18.9	4.18	8.36	5.11	10.2	2.53	5.06	6.59	13.2	3.27	6.53
1.80	8.23	16.5	3.65	7.29	10.6	21.2	4.70	9.41	5.74	11.5	2.85	5.70	7.41	14.8	3.67	7.35
2.00	9.15	18.3	4.05	8.10	11.8	23.6	5.23	10.5	6.38	12.8	3.16	6.33	8.24	16.5	4.08	8.17

unit : [mGy] ±50%

[12] ELECTROMAGNETIC COMPATIBILITY (EMC)

This product conforms to EMC standard IEC 60601-1-2:2014+AMD1:2020.

1. Caution to EMC and Compliance with information in attached document

Medical electrical equipment requires special attention to EMC and it must be installed and used according to the EMC information provided in this instruction manual. Do not install in the vicinity of the electrosurgical device being output or electromagnetically shielded room of ME system for MRI diagnostic imaging because the electromagnetic interference intensity is high.

⚠ WARNING

a. Use of this equipment adjacent to or stocked with other equipment should be avoided because it should result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

b. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

c. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the PHOT-X IIs Model 505, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

2. Electromagnetic emissions

Emissions test	Test procedure	Compliance	Note :
Conducted and radiated RF emissions	CISPR11	Group 1 Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re- orienting the equipment.
Harmonic distortion	IEC 61000-3-2	N/A (*1)	
Voltage fluctuations and flicker	IEC 61000-3-3	Clause 5	

(*1) : The test is not applicable since professional equipment is rated power 1kW or more.

3. Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst 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 IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -
Proximity magnetic field IEC 61000-4-39	134.2 kHz 65A/m Pulse Modulation 2.1 kHz 13.56 MHz 7.5 A/m Pulse Modulation 50kHz	134.2 kHz 65A/ m Pulse Modulation 2.1 kHz 13.56 MHz 7.7A m Pulse Modulation 50kHz	Proximit magnetic fields should be at levels characteristic of a typical location in a professional healthcare facilit environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	dips 0 %Ut: 0.5 cycle (0,45,90,135,180,225,270 and 315 degree) 0 %Ut: 1 cycle (0 degree) 70 %Ut: 25/30 cycles (0 degree) short interruptions 0 %Ut: 250/300 cycles Ut: Rated voltage of EUT	dips 0 %Ut: 0.5 cycle (0,45,90,135,180,225,270 and 315 degree) 0 %Ut: 1 cycle (0 degree) 70 %Ut: 25/30 cycles (0 degree) short interruptions 0 %Ut: 250/300 cycles Ut: Rated voltage of EUT	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PHOT-X IIs Model 505 x-ray requires continued operation during power mains interruptions, it is recommended that the PHOT-X IIs Model 505 x-ray be powered from an uninterruptible power supply or a battery.
Conducted RF IEC 61000-4-6	AC/DC power and Signal input/output 0.15 MHz - 80 MHz: 3V 6 V in ISM bands between 0.15 MHz - 80 MHz (unmodulated, r.m.s.) 80 % AM (1 kHz)	AC/DC power and Signal input/output 0.15 MHz - 80 MHz: 3V 6 V in ISM bands between 0.15 MHz - 80 MHz (unmodulated, r.m.s.) 80 % AM (1 kHz)	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the PHOT-X IIs Model 505, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	80 MHz - 2700 MHz: 3V/m (unmodulated, r.m.s.) 80 % AM (1kHz)	80 MHz - 2700 MHz: 3V/m (unmodulated, r.m.s.) 80 % AM (1kHz)	
Proximity fields from RF wireless communication equipment IEC 61000-4-3	385 MHz 27 V/m (unmodulated, r.m.s.) Pulse modulation 18 Hz	385 MHz 27 V/m (unmodulated, r.m.s.) Pulse modulation 18 Hz	
	450 MHz 28 V/m (unmodulated, r.m.s.) FM ± 5 kHz deviation 1 kHz sine or Pulse modulation 18 Hz	450 MHz 28 V/m (unmodulated, r.m.s.) FM ± 5 kHz deviation 1 kHz sine or Pulse modulation 18 Hz	
	710 MHz, 745 MHz, 780 MHz 9 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	710 MHz, 745 MHz, 780 MHz 9 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	
	810 MHz, 870 MHz, 930 MHz 28 V/m (unmodulated, r.m.s.) Pulse modulation 18 Hz	810 MHz, 870 MHz, 930 MHz 28 V/m (unmodulated, r.m.s.) Pulse modulation 18 Hz	
	1720 MHz, 1845 MHz, 1970 MHz 28 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	1720 MHz, 1845 MHz, 1970 MHz 28 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	
	2450 MHz 28 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	2450 MHz 28 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	
	5240 MHz, 5500 MHz, 5785 MHz 9 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	5240 MHz, 5500 MHz, 5785 MHz 9 V/m (unmodulated, r.m.s.) Pulse modulation 217 Hz	

4. Essential performance

Unless the exposure switch is pressed, x-ray is not exposed.

If the Essential performance is lost or deteriorated, the device may operate inadvertently and may harm the patient, the operator, and the surrounding people.

[13] DISPOSAL

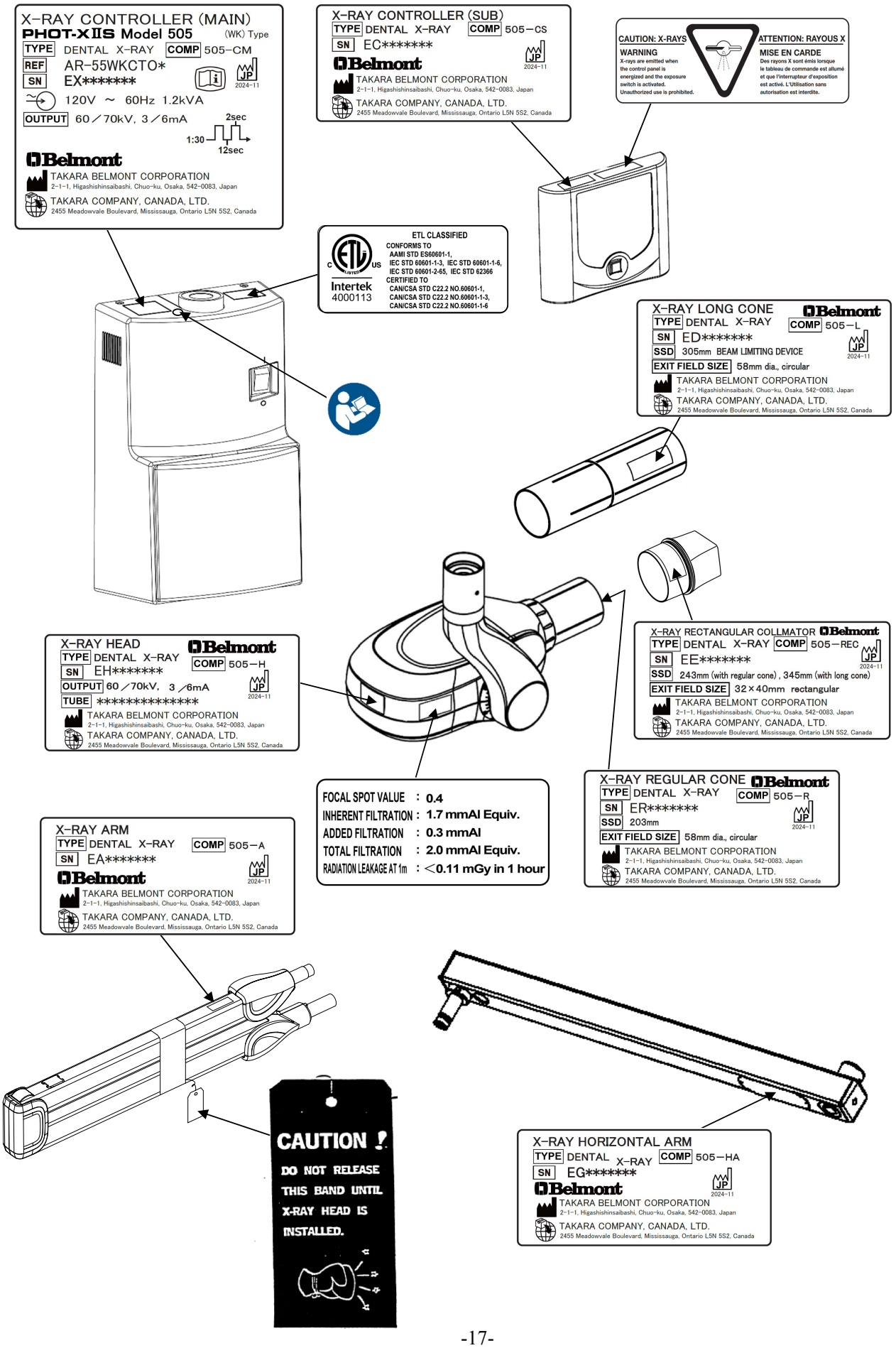
1. Disposal of x-ray unit or components

The tube head of this x-ray unit contains the lead for x-ray shield and oil, which is refined mineral oil and does not contain the carciongenic substances such as PCBs, for the insulation. When disposing the x-ray unit or components, appropriatly dispose complying with all current applicable regulations and local codes.

2. Disposal of used film and CCD cover

Dispose the used film covers and CCD sensor covers appropriately, according to precedures indicatated by each manufacturer and all current applicabel regurations and local codes.

[14] LABEL LOCATION



NOTE

Importer / Distributor

TAKARA COMPANY, CANADA, LTD.

2455 Meadowvale Boulevard, Mississauga, Ontario L5N 5S2, Canada TEL: (905) 816-8965 FAX: (905) 816-8999

www.belmont.ca

Manufacturer

TAKARA BELMONT CORPORATION

2-1-1, Higashishinsaibashi, Chuo-ku, Osaka, 542-0083, Japan TEL: (81) 6-6213-5945 FAX: (81) 6-6212-3680

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