PHOT-XIIS

Model 505

DENTAL X-RAY

OPERATOR'S INSTRUCTIONS

(for Canada)

Floor Mobile Type.....FM

⚠ 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 PHOT-XIIs Model 505 dental x-ray. The instructions contained in this book should be thoroughly read and understood before operation.

PHOT-XIIs Model 505 has no user serviceable items. Maintenance and repair should be performed by qualified dealer service personnel.

2. INTENDED USE OF THE PRODUCT

PHOT-XIIs 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-XIIs Model 505"

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

4. COMPLIANCE WITH STANDARD

BELMONT PHOT-XIIs MODEL 505 x-ray unit complies with the following standard.

a. Electrical and Mechanical Safety
IEC60601-1:2005, IEC60601-1-3:2008, IEC60601-1-65:2012
UL60601-1:2003
b. Radiation Safety
21 CFR 1020.30

5. CLASSIFICATION

5-1. According to Section 513 of Federal Food, Drug and Cosmetic Act and 21 CFR Part 806, BELMONT PHOT-X IIs Model 505 is classified as CLASS II Medical Device.

5-2. According to IEC60601-1, 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)
d. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

6. SYMBOL

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

	Consult written Instructions in Manuals		Digital Imaging		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
	Regular Cone		Patient Child		Patient Normal		Patient Obese
	Long Cone						

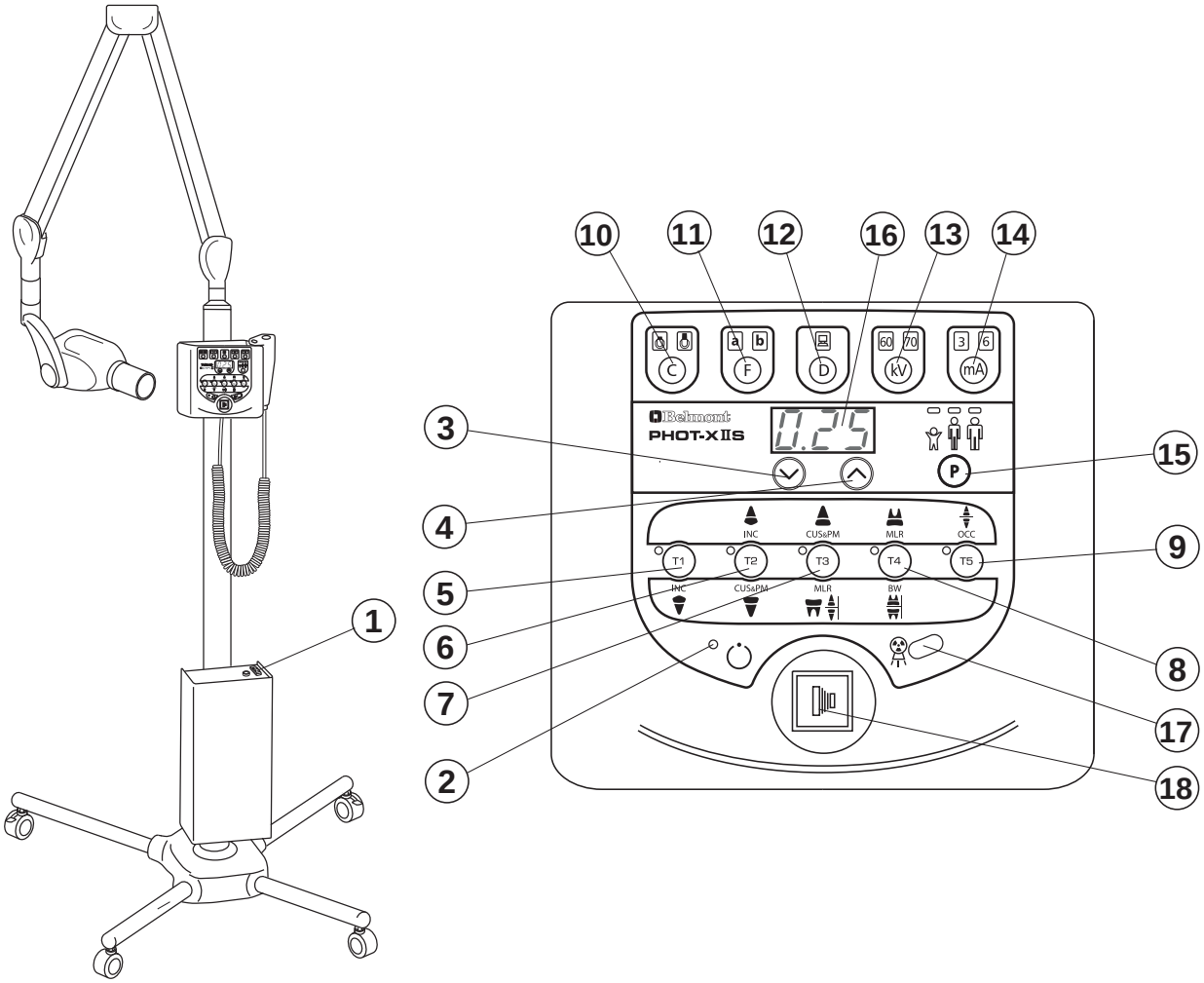
7. SAFETY

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.

- The operator must at all times remain 6ft. (2m) from the X-ray head for operator protection.
- Fully use all radiation safety features of the equipment.
- Fully use all radiation protection devices, accessories and procedures availabel to protect the patient and operator from x-ray radiation.

[2] LAYOUT OF CONTROLS



⚠CAUTION

When moving mobile type (FM) x-ray on the floor, close the balance arm and keep holding the balance arm.
Unless you move the equipment, always lock casters. Do not push the equipment nor lean on the equipment to avoid injuries.

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

Depressing this switch for more than 2 sec. selects the cone type : 8" standard cone or 12" optional long cone. (If the optional rectangular cone is to be used, select the 8" standard cone setting.)

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)

b. Pushing this switch momentarily displays the selected film speed setting in the **Exposure Time Display Window** ⑯
Depressing this switch for more than 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.11, the exposure time becomes half of F.06 setting.

TABLE 1. Speed Setting and Exposure Time (Regular 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.11	60	3	0.16	0.18	0.22	0.25	0.36	0.25	0.32	0.36	0.45	0.63	0.32	0.40	0.45	0.56	0.80
		6	0.08	0.09	0.11	0.13	0.18	0.13	0.16	0.18	0.22	0.32	0.16	0.20	0.22	0.28	0.40
	70	3	0.11	0.13	0.16	0.18	0.28	0.18	0.22	0.28	0.32	0.45	0.22	0.28	0.32	0.40	0.56
		6	0.06	0.07	0.08	0.09	0.13	0.09	0.11	0.13	0.16	0.22	0.11	0.14	0.16	0.20	0.28

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	0.56	0.63	0.80	0.90	1.25	0.90	1.12	1.25	1.40	*	1.12	1.40	1.60	1.80	*
		6	0.28	0.32	0.40	0.45	0.63	0.45	0.56	0.63	0.71	1.12	0.56	0.63	0.80	0.90	1.40
	70	3	0.40	0.45	0.56	0.63	0.90	0.63	0.80	0.90	1.00	1.60	0.80	1.00	1.12	1.25	2.00
		6	0.20	0.28	0.36	0.40	0.45	0.32	0.40	0.45	0.50	0.80	0.40	0.50	0.56	0.63	1.00
F.05	60	3	0.22	0.28	0.32	0.36	0.56	0.36	0.45	0.56	0.63	0.90	0.45	0.56	0.63	0.80	1.12
		6	0.11	0.13	0.16	0.18	0.28	0.18	0.22	0.28	0.32	0.45	0.22	0.28	0.32	0.40	0.56
	70	3	0.16	0.20	0.22	0.25	0.40	0.25	0.32	0.40	0.45	0.80	0.40	0.50	0.56	0.71	1.00
		6	0.08	0.10	0.11	0.13	0.20	0.13	0.16	0.20	0.22	0.32	0.16	0.20	0.25	0.28	0.40
d.11	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	0.32	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	0.63	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	0.63	0.32	0.36	0.45	0.50	0.71

⑬ kV Selection Switch

Momentarily depressing this switch will change the tube potential to 60 or 70 kV. Since the tube potential is constant DC, a 60 kV setting the PHOT-X IIs is similar to a 70 kVp setting on a conventional x-ray. 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,

⑮ Patient Size Selection Switch

This switch alters the selection of patient type/size to be radiographed (child→adult→obese→child) and sets the exposure time automatically.

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 : **[4] 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 eigher 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.

⚠CAUTION

When moving mobile type (FM) x-ray on the floor, close the balance arm and keep holding the balance arm.
Unless you move the equipment, always lock casters. Do not push the equipment nor lean on the equipment to avoid injuries.

[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 the loading factors (kV, mA and Exposure time) selected at that time. Patient type display lamps and displayed value in the window are flashing in this mode and if eighter 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.

[6] DIGITAL IMAGING SYSTEM

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

1.Type of receptor : CCD(charge-coupled device), CMOS(complimentary metal oxide semi-conductor) or PSP (photostimulabel 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 keep the image receptor firmly at the position and works as the x-ray beam alignment device.

⚠ WARNING

The use of ACCESSORY equipment not complying with the equivalent safety requirements of 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.

[7] DISINFECTION AND CLEANING

1. DISINFECTION

(a) X-ray operator is required to wear disposable groves when taking radiographs and handling coutaminated film packet or digital detector cover. Groves 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 strilization procedures indicate by each manufacturer.

2. CLEANING

In order to ensure proper hygiene and cleaning of the equipment, the following procedure 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 metal corrosive disinfectant, 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 normally determined by wear and damage due to use.

Point of use : Remove excess soil with disposable cloth / pager 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 in contact with skin, periodic disinfection with a non corrosive surface ininfectant is recommended.
Recommended disinfectant : FD333 (Durr Dental)

Drying : Allow survace to air dry before turningbreaker and main switch back on.

[8] 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.
Depress one of the tooth switches.</td><td>Release the exposure switch after the exposure lamp turns off.</td></tr>
<tr><td rowspan="2">E.01</td><td>Exposure switch was depressed within 10 sec. of previous exposure.</td><td rowspan="3">A 10 sec. delay is built in between each exposure.

Release the exposure switch.</td><td>There should be a "wait" interval of 30 times the exposure time between successive exposure.</td></tr>
<tr><td>Exposure time was set and exposure switch was depressed within 3 sec. of the power switch being turned on.</td><td>Wait 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">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="10">Turn off the main power switch and wait for approximately 2 min. Turn on the main power switch again.</td><td rowspan="10">If 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 4.5 mA at 3mA setting or more than 9 mA at 6 mA setting.</td></tr>
<tr><td>E.09</td><td>Setting for pre-heating time is out of range.</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 period.</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 approximately 2 min. Turn on the main power switch again.	If same error code is displayed, call service personnel.
E.16	During the exposure, tube potential becomes less than 40 kV at 60 kV setting or less than 50 kV at 70 kV setting.		
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	Exposure switch was depressed when tube head temperature was over 60ûC.	Release the exposure switch,	
E.22	Failure of electrical communication between the power PCB and timer PCB.	Turn off the main power switch and turn on again.	
E.23	Some switch had been on, when the main power switch is turned on. (Except the exposure switch.)		

[9] 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 isfunctioning 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 done once a year and that they are performed by a trained, certified service technician. The specific instructions to perform these checks are located within the PHOT-X IIs Model 505 Installation manual.

A. Line voltage confirmation
B. Tube potential and Tube current confirmation
C. Inspection of arm and head movement
D. Mechanical safety
   1. The leg bars should be checked to confirm that it is securely attached to the pole base.
   2. Check and verify that the balance arm and pole bushing are not raising up nor out of the position. This should be verified routinely by treatment room personnel.
   3. Check the swing angle of the balance arm matches with the angle of the two long legs.
   4. Check the casters and balance arm and confirm they move smoothly and without noize.

[10] 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 for 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.

[11] TECHNICAL DATA

1. X-ray tube ---------- Toshiba D-046 (Stationary Anode)
   a. Focal spot value ---------- 0.4
   b. Target Material ---------- Tungsten
   c. Target angle ---------- 12.5deg
   d. Maximum anode heat content ---------- 4.3kJ (6.1kHU)
2. Maximum x-ray tube assembly heat content ---------- 293 kJ (413kHU)
3. Rated peak tube potential ---------- 60 kV / 70 kV selectable
4. Rated tube current ---------- 3mA / 6 mA selectable
5. Maximum rated peak tube potential ---------- 70 kV
6. Rated line voltage ---------- 120 VAC, 60Hz, 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

	60 kV		70 kV		
	3 mA	6 mA	3 mA	6 mA	
a. Distal end of regular cone ----------	4.6	9.1	5.9	11.8	mGy/sec. ± 40%
b. Distal end of long cone ----------	2.0	4.1	2.6	5.2	mGy/sec. ± 40%

   (Data obtained by direct measurement in the useful beam)
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 cone (option) ----------	10 inches (243 mm)	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 ~ 70deg, 10 ~ 100%, 500 ~ 1060hPa
26. Environmental condition for operation ---------- 10 ~ 40deg, 30 ~ 70%, 700 ~ 1060hPa
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 cone)

[12] ELECTROMAGNETIC COMPATIBILITY(EMC)

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect medical electrical equipment. The equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emissions		
The PHOT-XIIs 505 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the PHOT-XIIs 505 x-ray should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PHOT-XIIs 505 x-ray uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The PHOT-XIIs 505 x-ray is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The PHOT-XIIs 505 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the PHOT-XIIs 505 x-ray should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic file. 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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25cycle <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25cycle <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PHOT-XIIs 505 x-ray requires continued operation during power mains interruptions, it is recommended that the PHOT-XIIs 505 x-ray be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to applications of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The PHOT-XIIs 505 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the PHOT-XIIs 505 x-ray should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the PHOT-XIIs 505 x-ray, including cables,than the recommended separation distance calculated from the equation applications to the Frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by adsorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PHOT-XIIs 505 x-ray is used exceeds the applicable RF compliance level above, the PHOT-XIIs 505 x-ray should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PHOT-XIIs 505 x-ray.

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

Essential performance (purpose of IMMUNITY testing)

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

Recommended separation distances between
Portable and mobile RF communications equipment and the PHOT-XIIs 505 x-ray

The PHOT-XII 505 x-ray is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PHOT-XIIs 505 x-ray can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PHOT-XIIs 505 x-ray as recommended below, according to the maximum output power of the communications equipment.

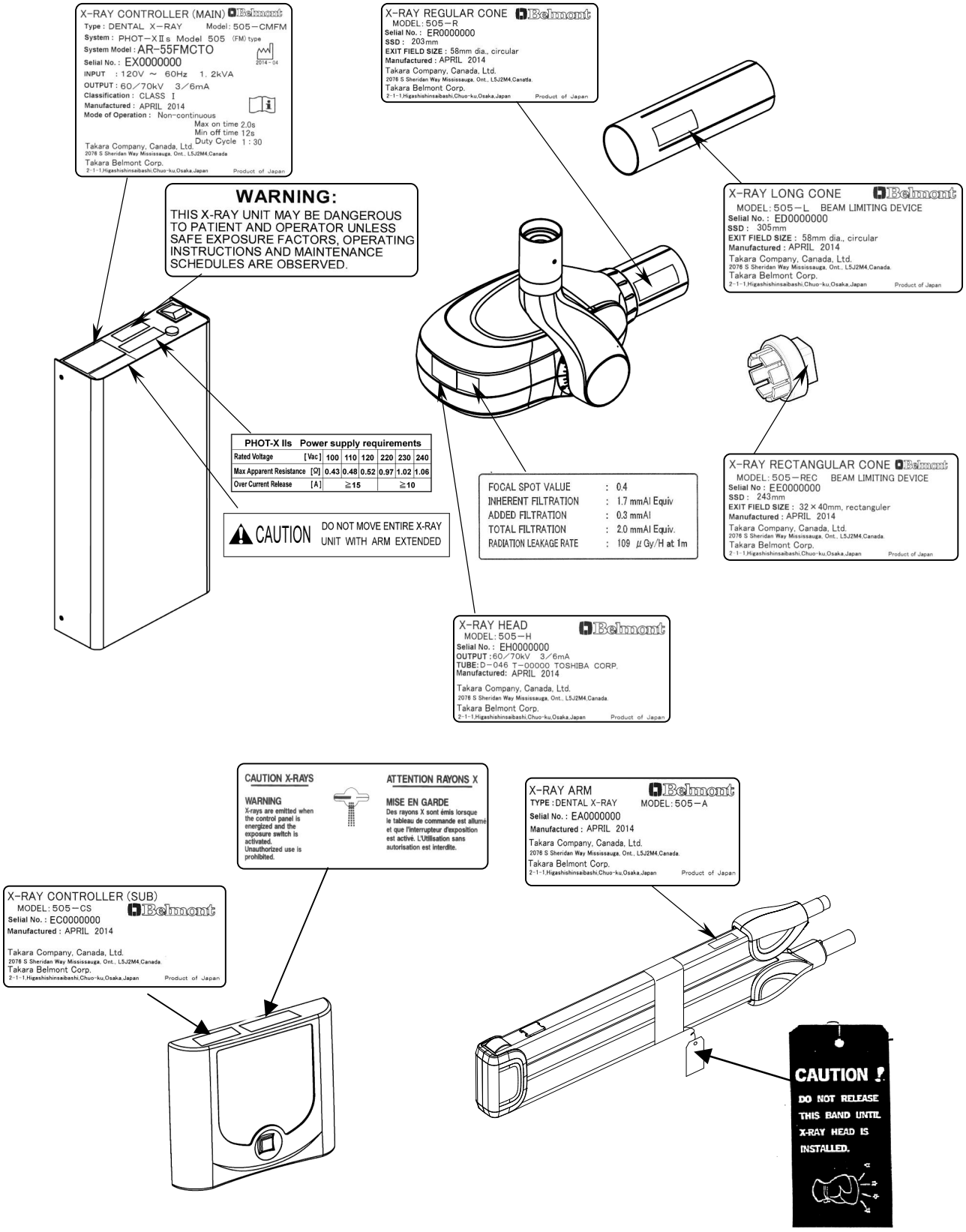
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12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

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

NOTE 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These quidelines may not apply in all situations. Electromagnetic propagation is affected by adsorption and reflection from structures, objects and people.

[13] LABEL LOCATION



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