# PHOT-XIS Model 505 DENTAL X-RAY COD OPERATOR'S INSTRUCTIONS (for USA)

Wall Mount Type.....WK

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

A CAUTION Federal law restricts this device to sale by or on the order of a dentist.



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# [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.

Installation, assembly, calibration and certification procedures are written in the separate manual titled "Installation Instructions". Both "Operator's Instructions" and "Installation Instructions" are included in each PHOT-X IIs model 505 package.

## 2. INTENDED USE OF THE PRODUCT

The PHOT-X IIs Model 505 is an extraoral source dental radiographic x-ray unit. This unit works as 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-Н
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

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

- a. Electrical and Mechanical Safety IEC60601-1:2005, IEC60601-1-3:2008, IEC60601-2-65:2012 AMMI ES60601-1:2005
- 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, 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)
  - 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 the PHOT- X IIs Model 505, following symbols are used. Confirm the meaning of each symbol.

i	Consult written Instructions in Manuals	M	Date of Manufacture	I	ON (Power)	Ο	OFF (Power)
	Protection Grounding	00	Exposure Switch		X-ray Emission	Ü	Ready
	Maxillary Incisor		Maxillary Cuspid & Pre Molar		Maxillary Molar		Maxillary Occlusal
Ţ	Mandibular Incisor	¥	Mandibular Cuspid & Pre Molar		Mandibular Molar		Mandibular Occlusal
<b>•</b>	Bite Wing (Incisor & Pre Molar)		Bite Wing (Molar)	0	Short Cone		Long Cone
×	Patient Child	ŕ	Patient Adult	Ē	Patient Large Adult	Ą	Brightness of Backlight
(((•••)))	Non-ionizing Radation	$\Box$	Loudness of Speaker	$\bigotimes$	Mute	<b>_</b> 00	Level Control
Ø	Setting Mode		Store to Memory		Turn down		Turn up
	Film	ŗ	Digital Sensor	Ρ	Phosphor Plate	$\langle X  $	Delete
V	Decrease	^	Increase	Ð	Return		

## 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 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 indication.
- 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.

# [2] LAYOUT OF CONTROLS



- 3) Exposure Time Adjustment Switch (Down)
- 4) Exposure Time Adjustment Switch (Up)
- (5) Tooth Selection Switch (Maxilla)
- (6) Tooth Selection Switch (Mandible)
- (7) Tooth Selection Switch (Bitewing)
- (8) Tooth Selection Switch (Bitewing Molars)
- (9) Tooth Selection Switch (Occlusal)
- (10) Cone Type Selection Switch

- (14) mA Selection Switch
- (15) Patient Size Selection Switch
- (16) Exposure Time Display Window
- (17) Exposure Warning Indication
- (18) Exposure Switch
- (19) Radiation Dose Indication
- (20) Setting Mode 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.

## **(2)** Ready Indication

This indication becomes green when the exposure time is set and the line voltage is within operable range ( $108 \sim 132$ Vac). When this indication is white, exposure cannot be made.

## **3**(4) Exposure Time Adjusting Switches

By momentarily touching the  $\bigotimes$  (or  $\bigotimes$ ) switch, the exposure time displayed increases (or decreases) by one increment. By keeping the switch touched more than 2 sec., the exposure time displayed increases (or decreases) continuously until the switch is released. PHOT-X IIs 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

Touching one of these switches sets the exposure time to the optimum value according to the tooth type and the following settings ( $(10 \sim 15)$ ). Selected tooth is illuminated in orange.

- (5) Maxilla : Incisor, Cuspid & Premolar or Molar
- 6 Mandible : Incisor, Cuspid & Premolar or Molar
- (7) Bitewing : Incisor and Cuspid & Premolar
- 8 Bitewing : Molar
- (9) Occlusal : Maxilla and Mandible

### **10** Cone Type Selection Switch

This switch indicates the cone type being selected at the time. Momentarily touching this switch will open the cone type selection window. This window closes when one of cones is selected.



Cone type selection window

## **(1)** Image Receptor Selection Switch

To get optimal images the exposure timer adjustment according to the sensitivity of image receptor is important. The PHOT-X IIs has 16 density settings for each three kinds of image receptors, i.e.



Image Receptor Selection windows

film, digital sensor and phosphor plate. For film, two different sensitivities can be selected as film-a and film-b and those can be switched easily.

(1) Film

Following two speed (=sensitivity) settings are pre-set at the factory.

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 as film-a and film-b.

Film speed number being selected at the time can be confirmed by touching switch (1).

If doctor uses a different film speed, or prefers darker (or lighter) radiographs, the new speed can be programmed as follows. Larger speed number makes films darker. If film speed number is increased by 1, exposure time becomes 25 % longer. The method to change the film speed setting is as follows.

- 1. Go to the setting mode by touching the switch (20).
- 2. Select "Image receptor sensitivity setting" at page 2/3 in "Setting mode".
- 3. If new film is used, select the "Preset setting", select "film-a" or "film-b" and select the manufacturer and model name of the film.
- If darker (or lighter) radiographs are preferred or film name is not listed in "Preset setting", select the "Manual setting" and by touching or or switch, increase or decrease film speed until the desired number is displayed. Touch the memory icon to store the setting.
- (2) Digital sensor and Phosphor Plate

If a digital imaging system is used, shorter exposure time is often required compared with film. PHOT-X IIs has 16 speeds for digital sensor and phosphor plate ( $d.00 \sim d.15$ ).

Factory settings for digital sensor and phosphor plate are both d.10, but it is necessary to change according to the sensitivity of each model of digital sensor or phosphor plate. The density number selected can be checked by touching switch (11). The method to change the density setting for digital sensors or phosphor plate is same as film.







#### Preset setting mode



Manual setting mode

Speed					Child					Adult				La	rge Adu	ılt	
Setting	kV	mA	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5
	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
E 00	60	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
г. 09		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
	70	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
	(0)	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
E 05	60	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
г. 05	- 0	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
	70	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
	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
d 10	60	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
u.10		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
	/0	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 1. Speed Setting and Exposure Time (Short Cone)

[unit : sec.]

 TABLE 2. Speed Setting and Exposure Time (Long Cone)

[ unit : sec.]

Speed					Child					Adult				La	rge Adı	ult	
Setting	kV	mA	T1	T2	Т3	T4	T5	T1	T2	T3	T4	T5	T1	T2	Т3	T4	T5
		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
E 00	60	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
Г. 09		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
	70	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
		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
E 05	60	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
г. 05	-0	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
	70	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
		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
d 10	60	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
<b>u</b> .10		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
	//0	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

# 13 kV Selection Switch

Momentarily touching this switch will open the kV selection window. This window closes when either 60 or 70 kV is selected.

## (14) mA Selection Switch

Momentarily depressing this switch will open the mA selection window. This window closes when either 3 or 6 mA is selected.



These switches alter the selection of patient type/size to be radiographed (child, adult or large adult) and sets the exposure time

automatically. If the weight of child is less then 20kg, press  $\bigotimes$  switch once after setting to child. If the weight of child is over 50kg and less than 70kg, press  $\bigotimes$  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.

# **(b)** Exposure Time Display Window

This window displays the selected exposure time.

# (17) Exposure Warning Indication

This indication appears while 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 Indication (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.



KV Selection Window





### **19** Radiation Dose Indication

Estimated air kerma (radiation dose) at distal end of cone can be displayed below the exposure time display window. This value is calculated by kV, mA, exposure time and cone type selected at the moment. The value displayed below the ready indication is sum of estimated air kerma of each exposure after the power switch has been turned on.

The units of these values can be selected from mGy or mGycm<sup>2</sup>. And also to display these values or not can be selected by the following procedures.

- 1. Go to the setting mode by touching switch 20.
- 2. Select "Estimated air kerma display setting" at 2/3 page of setting mode.
- 3. Select "Display ON" or "Display OFF".
- 4. If "Display ON" is selected, you can select "mGy" or "mGycm<sup>2</sup>" on next menu.

#### **20** Setting Mode Switch

By touching this switch the normal operation mode will be changed to the setting mode or service mode. At the setting mode, following settings can be changed. Refer to section [5] for detail. Service mode is restricted to the qualified dealer service personnel and requires password.

Page 1/3: Parameter Selection at Power ON Loudness of Electronic chime Brightness of LCD Sensitivity of touch panel Language selection

- Page 2/3: Estimated air kerma display setting Image receptor sensitivity setting Standard density for each tooth Calibration of Tube Current Color of background
- Page 3/3: Standby display setting Nameplate setting Photo display setting Color of background

# [4] OPERATING PROCEDURES

- 1. Turn ON the Main Power Switch ①.
- 2. Select the appropriate tooth type  $(5 \sim 9)$ , and confirm the pre-selected conditions (cone type, film or digital, kV, mA and patient size) are suitable for exposure.
- 3. Confirm that Ready Indication (2) is illuminated on green.

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

- 4. Position the x-ray tube head to the patient using the standard positioning procedures.
- 5. Depress the Exposure Switch (18). When the Exposure Switch is depressed, the Exp. Warning Indication (17) appears and the audible warning sounds. Do not release the Exposure Switch until the Exposure Warning Indication and audible warning automatically shut off. Failure to keep the switch depressed will result in exposure being terminated prematurely.
- 6. To continue to radiograph other teeth, just select appropriate Tooth Selection Switches ( $(5) \sim (9)$ ).
  - **IMPORTANT** : To protect x-ray tube head 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.)
- 7. Turn OFF the Main Power Switch (1) in order to prevent accidental exposures when the unit is not in use.
  - NOTE : If the unit is left without being operated and the Main Power Switch (1) is kept on, display will go into one of the following four standby display modes.
    - a. Energy saving mode
    - b. Fixed display of one photo
    - c. Slide-show of photos
    - d. Nameplate display

Transition time to the standby display mode can be set by 5 minutes steps and making switch enable and disable during standby mode is also selectable.

## [5] SETTING MODE

By touching the setting mode switch at bottom left corner, the normal operation mode can be changed to the setting mode or service mode. There are 13 setting modes and each purposes of those settings are as follows.

#### 1. Parameter Selection at Power ON

Factory default settings are

kV selection: 60 kVmA selection: 6 mAImage receptor: Digital sensorPatient type: AdultCone type: Short cone (round)

If necessary, these settings can be changed. For example, in case of pedodontistry, patient type should be changed to Child. For the image receptor, as the sensitivity of each receptor is different, please set the sensitivity as on page 5.

If the same settings before the power switch is turned off sould be set at power on, select "Same Selection befor Power OFF".

#### 2. Loudness of Electronic Chime

Loudness of electronic chime can be selected from 9 levels including off setting. The loudness of the sound for exposure warning and error warning cannot be adjusted.

#### 3. Brightness of LCD

Brightness for backlight of LCD display can be selected from 10 levels.

#### 4. Sensitivity of Touch panel

Sensitivity of touch switch on the panel can be selected from 3 levels.

#### 5. Language Selection

Language can be selected from English, French, Spanish or Japanese.

#### 6. Estimated Air Kerma Display Setting

Whether to display the estimated air kerma (radiation output) or not to display can be selected. If displaying is selected, the unit of the values can be selected from mGy or mGycm<sup>2</sup>.

#### 7. Image receptor sensitivity setting

Manual setting or preset setting can be selected.

- Manual setting: Two film speeds can be selected from 16 speeds as film-a and film-b. One digital sensor sensitivity can be selected from 16 steps and one phosphor plate sensitivity can be selected form 16 steps. Refer to page 5 for detail.
- Preset setting: For each 4 types of image receptors, standard sensitivity can be set by selecting the manufacturer and model name of the image receptor.

#### 8. Standard density for each tooth

The exposure time ratio between each tooth is preprogrammed. If doctor want to change this ratio, it can be done by this setting. Exposure time for each tooth can be increased (or decreased) by 4 steps individually. One step increase is corresponding to 25% increase of exposure time.

### 9. Calibration of Tube Current

Tube current can be adjusted to be the rated value by making several exposures at this mode. This calibration is necessary at the installation and at the annual maintenance checks.

#### **10. Color of Background**

The default color of the back panel at the normal operation mode is blue. This color can be changed to green or pink. And also there are two patterns for pink.

#### 11. Standby display setting

If the unit is left without being operated and the main power switch is kept on, display will go into standby display mode. You can select one of following four kinds of standby display modes.

- a. Energy saving mode: Backlight of LCD becomes minimum in this mode.
- b. Fixed display of one photo: One of ten photos pre-stored is displayed. You can overwrite your original photos on the pre-stored photos.
- c. Slide-show of photos: ten photos are displayed in turn continuously.
- d. Nameplate display: Any name within 20 characters with a photo is displayed.

Transition time from normal mode to the standby display mode can be set to  $5 \sim 30$  minutes in 5 minutes step. Enabling or disabling of touch switch function during standby mode is also selectable.

#### 12. Nameplate setting

Nameplate creation: Four kinds of nameplates can be created and stored. To check the nameplate already created, touch the mountain icon at right side. To modify or create new name, touch the name or "New Name Input" at left side. Maximum 20 characters can be used for the name of nameplate. After the name is fixed, you can use preinstalled photo or your original photo for that nameplate. If you want to use your own photo, USB flash drive containing your photo data should be connected to the right side connector of LCD controller. The file name of your photo should be the same as indicated on the screen and data format should be 16 bit BMP with 800 x 400 pixels.

Nameplate selection: One of the nameplates created should be selected for the standby display.

#### 13. Photo display setting

Ten photos are pre-stored. One of ten photos is used for "fixed display of one photo" and ten photos are used for "Slide-show of photos" at standby display mode.

Stored photo can be checked by touching the mountain icon at right side. If you want to store your own photo, touch one of the bar named "FF00" to "FF09". Connect USB flash drive containing your photo data to the right side connector of LCD controller. The file name of your photo should be the same as indicated on the screen and data format should be 16 bit BMP with 800 x 480 pixels.

## [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, ask 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 semiconductor) 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.

# 

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.

# 

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)

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, code condition, and the possible solution are displayed on the LCD screen. Please refer to the Table below.

Error Code	Condition	Step to be Taken	Possible Solution	
E.00	Exposure switch was released before exposure termination.	All the tooth selection lights blink. Depress one of the tooth switches.	Release the exposure switch after the exposure lamp turns off.	
F 01	Exposure switch was depressed within 10 sec. of previous exposure.	A 10 sec. delay is	There should be a "wait" interval of 30 times the exposure time between successive exposure.	
2.01	Exposure time was set and exposure switch was depressed within 3 sec. of the power switch being turned on.	built in between each exposure. Release the exposure switch.	Wait for a minimum 3 sec. after the main power switch is turned on before pressing the exposure switch.	
E.02	Line voltage was less than 90% of rated voltage.	*	Confirm that ready lam is on before exposure.	
E.03	Line voltage was more than 110% of rated voltage.		Ask service personnel to check the line voltage.	
E.05	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			
E.06	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			
E.07	During the exposure, tube current becomes less than 1.5 mA at 3mA setting or less than 3 mA at 6 mA setting.	Turn off the main power	If same error code is	
E.08	During the exposure, tube current becomes more than 4.5 mA at 3mA setting or more than 9 mA at 6 mA setting.	switch and wait for approximately 2 min. Turn on the main power	displayed, call service personnel.	
E.09	Setting for pre-heating time is out of range.	switch again.		
E.10	Exposure switch or exposure circuit had been ON, when main power switch is turned on.			
E.11	Tube current is detected during pre-heating period.			
E.12	Tube current is detected when main power switch is turned on.			
E.14	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.	* 		

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.	T. 00.41	
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.	switch and wait for approximately 2 min.	If same error code is displayed, call service personnel.
E.17	During the exposure, tube potential becomes more than 80 kV.	switch again.	1
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 60°C.	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.)		

## [10] MAINTENANCE

The 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 maintenace check list on page 14 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 14.
- c. Acceptance limit : Refer to the Maintenance check list on page 14.
- d. Required action when failed : Refer to the Maintenace check list on page 14.
- e. Tools to maintain quality control logs : Use the check list on page 14.
- f. Training material : Operator's instructions, Installation manual and Service manual

# [11] 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 insulation oil, which is refined mineral oil and does not contain the carcinogenic substances such as PCBs. 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.

## MAINTENANCE CHECK LIST

Parameter	Acceptance limit	Frequency	Procedures when failed	OK/NG
1. Line voltage	Confirm the line voltage is within $120V\pm10\%$ . 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 $\pm 1$ mA.	Yearly	Perform MA calibration. (Refer to page 26 of Installation manual.)	
3. Tube potential	Confirm the measured kV value indicated on the LED window is within the rated value $\pm 10\%$ .	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 5 of this book.	
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 16 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 16 of installation manual. If the balance arm makes noise, apply grease.	

# [12] 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	$-0 \sim 5\%$ (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	$-0.01 \sim 2.0$ 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
1	3 mA 6 mA 3 mA 6 mA
a. Distal end of regular cone	- 4.6 9.1 5.9 11.8 mGy/sec. $\pm 40\%$
b. Distal end of long cone	- 2.0 4.1 2.6 5.2 mGy/sec. $\pm 40\%$
(Data obtained by direct measurement in the useful	ıl 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 collimator (option)	- 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 a	and exposure time
a. Below 0.1 sec. setting	$\pm 10$ kV, $\pm 2$ mA, $\pm 5$ msec.
b. 0.1 sec. setting & up	$\pm 5$ kV, $\pm 1$ mA, $\pm 10$ 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 <sup>2</sup> ] (for regular and long cone)
	Estimated air kerma displayed [mGy]
	x 12.8 [cm <sup>2</sup> ] (for rectangular collimator)

# [13] 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.

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

Guidance and manufacturer's declaration – electromagnetic immunity							
The PHOT-X IIs model 5	The PHOT-X IIs model 505 x-ray is intended for use in the electromagnetic environment specified below. The						
customer or the user of the PHOT-X IIs model 505 x-ray should assure that it is used in such an environment.							
	Í						

Immunity toot	IEC 60601	Compliance lovel	Electromagnetic environment -
minumity test	test level	Compliance level	guidance
Electrostatic	±6 kV contact	±6 kV contact	Floors should be wood, concrete or
discharge (ESD)	±8 kV air	±8 kV air	ceramic tile. If fl oors are covered
IEC 61000-4-2			with synthetic material, the relative
			humidity should be at least 30%.
Electrical fast	±2 kV for power	±2 kV for power	Mains power quality should be that
transient/burst	supply lines	supply lines	of a typical commercial or hospital
IEC 61000-4-4	±1 kV for input/output	±1 kV for input/output	environment.
	lines	lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	of a typical commercial or hospital
			environment.
Voltage dips, short	$<5\% U_{\rm T}$	$<5\% U_{\rm T}$	Mains power quality should be
interruptions and	$(>95\% \text{ dip in } U_{\rm T})$	$(>95\% \text{ dip in } U_{\rm T})$	that of a typical commercial
voltage variations	for 0.5 cycle	for 0.5 cycle	or hospital environment. If the
on power supply	$40\% U_{\rm T}$	$40\% U_{\rm T}$	user of the PHOT-X IIs model 505
input lines	$(60\% \text{ dip in } U_{\mathrm{T}})$	$(60\% \text{ dip in } U_{\mathrm{T}})$	x-ray requires continued operation
IEC 61000-4-11	for 5 cycle	for 5 cycle	during power mains interruptions,
	$70\% U_{\rm T}$	$70\% U_{\rm T}$	it is recommended that the
	$(30\% \text{ dip in } U_{\rm T})$	$(30\% \text{ dip in } U_{\rm T})$	PHOT-X IIs model 505 x-ray be
	for 25cycle	for 25cycle	powered from an uninterruptible
	<5% U <sub>T</sub>	<5% U <sub>T</sub>	power supply or a battery.
	(>95% dip in $U_{\rm T}$ )	(>95% dip in $U_{\rm T}$ )	
	for 5 s	for 5 s	
Power frequency	3 A/m	0.3 A/m	Power frequency magnetic fields
(50/60 Hz)			should be at levels characteristic
magnetic field			of a typical location in a
IEC 61000-4-8			typical commercial or hospital
			environment.
NOTE <i>U</i> is the a.c. t	mains voltage prior to applica	tions of the test level	

 $U_{\rm T}$  is the a.c. mains voltage prior to applications of the test NOTE

Guidance and manufacturer's declaration – electromagnetic immunity					
The PHOT-X IIs model 505 x-ray is intended for use in the electromagnetic environment specified below. The					
customer or the user of the PHOT-X IIs model 505 x-ray should assure that it is used in such an environment.					
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance		
			Portable and mobile RF communications equipment		
			should be used no closer to any part of the		
			PHOT-X IIs model 505 x-ray, including cables, than		
			the recommended separation distance calculated		
			from the equation applications to the frequency of		
			the transmitter.		
			Recommended separation distance		
Conducted RF	3 Vrms	3 Vrms	$d = 1.2\sqrt{P}$		
IEC 61000-4-6	150 kHz to 80 MHz				
	outside ISIVI bands				
Radiated RF	3V/m	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz		
IEC 61000-4-3	80 MHz to 2.5 GHz		$d = 2.3\sqrt{P}$ 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, <sup>a</sup> should		
			be less than the compliance level in each frequency		
			range. <sup>D</sup>		
			Interference may occur in the vicinity of equipment		
			marked with the following symbol:		
			((( <b>_</b> )))		
			<b>`▲</b> ′		

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 absorption 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-X IIs model 505 x-ray is used exceeds the applicable RF compliance level above, the PHOT-XIIs model 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-X IIs model 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-X IIs model 505 x-ray

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

Rated maximum output	Separation distance according to frequency of transmitter			
power of transmitter W	<b>150 kHz to 80 MHz</b> $d = 1.2\sqrt{P}$	<b>80 MHz to 800 MHz</b> $d = 1.2\sqrt{P}$	<b>800 MHz to 2.5 GHz</b> $d = 2.3\sqrt{P}$	
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 absorption and reflection from structures, objects and people.

# [14] LABEL LOCATION





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