DENTAL X-RAY

PHOT-XIS 505

OPERATOR'S INSTRUCTIONS

| ·Wall Mount Type | . <i>WK</i> |
|--------------------|------------------|
| Floor Mount Type | . <i>FK1/FK2</i> |
| Mobile Type | .FM |
| Room Mount Type | . RK |
| Ceiling Mount Type | . <i>CK</i> |



MWARNING

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



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[1] INTRODUCTION

1 GENERAL

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

PHOT-X IIs 505 has no user serviceable items. Repair should be performed by qualified dealer service personnel. Any part of this x-ray unit shall not be maintenanced or serviced while in use with a patient.

2 INTENDED USE OF THE PRODUCT

PHOT-X IIs 505 is a diagnostic dental x-ray system designed to generate and control x-ray beams. The absorption pattern of x-ray beam is used for general-purpose, routine, dental radiography examinations of diseases of the teeth, jaw and oral cavity structures. The sensor, film or phosphor plate is placed in the mouth, the purpose being to visualize a limited region in detail.

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

PHOT-XIIs 505 x-ray unit complies with the following directive and standard.

Medical Device Directive 93/42/EEC, RoHS Directive 2011/65/EU,

EN60601-1:2006/A1:2013, EN60601-1-3:2008/AC:2010, EN60601-2-65:2013

5. CLASSIFICATION

5-1. According to Medical Device Directive: 93/42/EEC, PHOT-X IIs 505 is classified as CLASS IIb Medical Device.

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

a. Protection against electric shock : Class I Equipment

b. Type of applied parts : Type B (RK type only)

c. Protection against ingress of water: Ordinary

d. Mode of operation : Non continuous (Duty Cycle = 1 : 30,

Max. ON time: 2.0 sec, Min. OFF time: 12 sec.)

e. 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 unless safe exposure factors, operating instructons and maintenance schedules are observed.

Only qualified and authorized personnel may operate this equipment observing all laws and regulations concerning protection. The operator must:

- · heve 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 505, following symbols are used. Confirm the meanings of each symbol by the table below.

| i | Consult written Instructions in Manuals | ∱ | Protection against electric shock: Type B | | ON (POWER) | 0 | OFF (POWER) |
|-------------|---|-----------------|---|--------|--|----------|------------------------|
| | Protection Grounding | | Exposure Switch | | X-ray Emission | Ċ | Ready |
| \triangle | Upper Incisor | \triangle | Upper Cuspid & Pre Molar | 20 | Upper Molar | | Occlusal |
| | Lower Incisor | | Lower Cuspid & Pre Molar | | Lower Molar & Bite Wing | <u> </u> | Bite Wing |
| 且 | Digital Imaging | ¥ | Patient Child | ·F | Patient Adult | Ť | Patient Large Adult |
| Ō | Regular Cone | | Long Cone | EC REP | Authorized Representative in The European Community | | Manufacturer |
| ((•)) | Non-ionizing Radiation | M | Date of Manufacture | SN | Serial Number | REF | Catalogue Number |
| | Separate Collection for Electrical and Electronic Equipment | (E 0197 | Compliance with European directive required | | | | |

[2] MAJOR COMPONENTS

1. FOOR MOUNT TYPE (FK1/FK2)

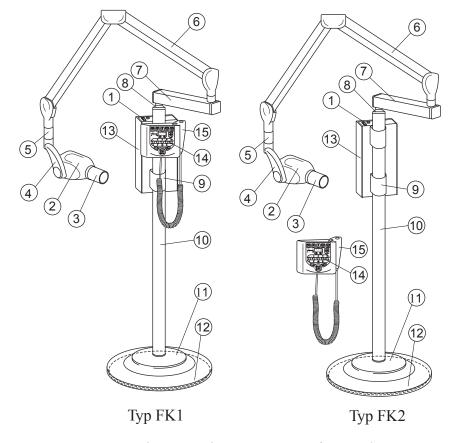


Fig.2-1 Major Components for FK1/FK2

- 1 Main Power Switch
- (2) X-Ray Head
- (3) Cone
- 4 Yoke
- (5) Arm Collar
- 6 Balance Arm
- 7 Horizontal Arm (300mm)
- (8) Pole Bush
- 9 Back Supporter
- 10 Pole
- 11) Base Cover
- (12) Mounting Plate
- (13) Main Controller
- (14) Sub Controller
- (15) Hand Exposure Switch

2. MOBILE TYPE (FM)

- (1) Main Power Switch
- 2 X-Ray Head
- (3) Cone
- 4 Yoke
- (5) Arm Collar
- (6) Balance Arm
- (7) Pole Bush
- (8) Pole
- **9** Pole Base
- 10 Leg Bar (long)
- 11 Leg Bar (Short)
- (12) Lock Caster
- (13) Standard Caster
- (14) Main Controller
- (15) Sub Controller
- **16** Hand Exposure Switch

MARNING

Keep casters in the lock position, unless moving the equipment. To avoide injury, do not push or lean on the equipment.

⚠CAUTION

Do not move entire x-ray unit with arm extended.

3. ROOM MOUNT TYPE (RK)

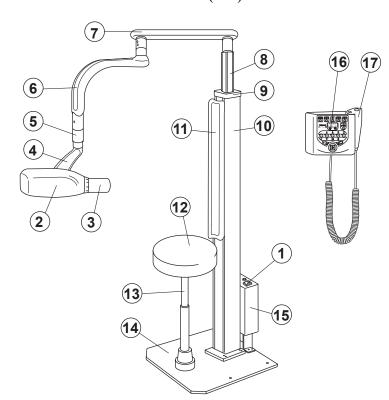


Fig.2-3 Major Components for RK

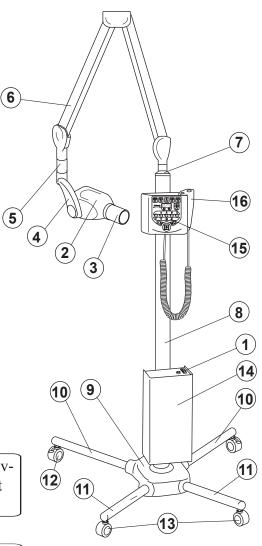


Fig.2-2 Major Components for FM

- (1) Main Power Switch
- 2 X-Ray Head
- (3) Cone
- (4) Yoke
- (5) Arm Collar
- **6** Swing Arm 1
- (7) Swing Arm 2
- (8) Sliding Post
- (9) Column Cover
- (10) Colum
- (11) Backrest Cushion (applied part)
- **12** Seat (applied part)
- (13) Gas Cylinder
- (14) Base Plate
- (15) Main Controller
- (16) Sub Controller
- 17 Hand Exposure Switch(option)

4. WALL MOUNT TYPE (WK)

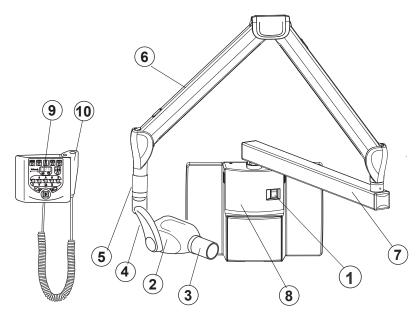
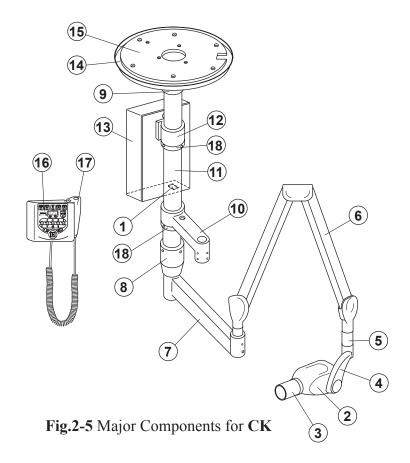


Fig.2-4 Major Components for WK

- (1) Main Power Switch
- 2 X-Ray Head
- (3) Cone
- (4) Yoke
- (5) Arm Collar
- (6) Balance Arm
- (7) Horizontal Arm
- (8) Main Controller
- Sub Controller
- 10 Hand Exposure Switch (Option)

5. CEILING MOUNT TYPE (CK)



- (1) Main Power Switch
- 2 X-Ray Head
- (3) Cone
- 4 Yoke
- (5) Arm Collar
- (6) Balance Arm
- **7** Swing Arm
- 8 Swing Post
- **9** Cover Ring
- 10 Light Arm (Option)
- (1) Ceiling Pole
- (12) Main Controller Bracket
- (13) Main Controller
- **14** Ceiling Cover
- **15** Ceiling Mounting Plate
- **16** Sub Controller
- 17 Hand Exposure Switch(Option)
- (18) Support Ring

6. SUB CONTROLLER

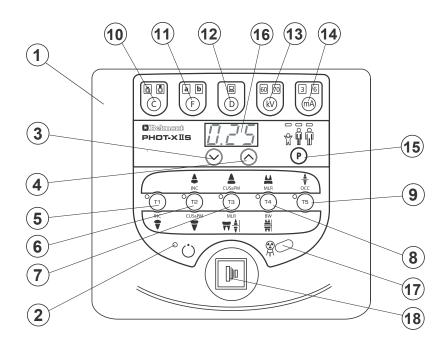


Fig.2-6 Sub Controller Switches

- 1 Sub controller front panel
- (2) Ready Light
- (3) Exposure Time Adjusting Switch (Down)
- (4) Exposure Time 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** Exposure Time Display Window
- **17** Exposure Warning 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 ($207 \sim 253 \text{Vac}$). When this light is not on, exposure can not be made.

(3)(4) Exposure Time Adjusting Switches

By momentarily pushing the \bigcirc (or \bigcirc) 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.

Phot-X IIs 505 has the following 37 exposure time settings:

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

$(5) \sim (9)$ Tooth Selection Switches (T1 ~ T5)

Pushing one of these switches sets the exposure time automatically for the following $(0) \sim (15)$.

- (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.

(1) Cone Type Selection Switch

Depressing this switch for more than 2 sec. selects the cone type: 203mm standard cone or 305mm optional long cone.

(1) Film Speed Selection Switch

a. PHOT-X IIs 505 has 16 film speed settings. (F.00 \sim F.15)

Two speed settings are pre-set at the factory (a & b) and can be selected with switch (1). 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, PHOT-X IIs 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** ① momentarily displays the selected film speed setting in the **Exposure Time Display Window** ⑥
 - Depressing this switch for more then 2 sec. changes the film type being selected.
- c. If the **Digital Imaging Switch** (2) is depressed, both of the film speed indicating lights (a & b) are turned off.

(2) 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 ($d.00 \sim d.15$). Pushing this switch momentarily displays the speed being selected in the **Exposure Time Display Window** (6). 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 (1) 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 (Reguler Cone)

| Speed | kV mA | | kV mA Child | | | | | | Adult | | | | | Large Adult | | | |
|---------|-------|----|-------------|------|------|------|------|------|-------|------|------|------|------|-------------|------|------|------|
| Setting | K V | шл | T1 | T2 | Т3 | T4 | T5 | T1 | T2 | Т3 | T4 | T5 | T1 | T2 | Т3 | 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 |
| F. 09 | 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 |
| 1.07 | 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 |
| | 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 |
| | 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 |
| F. 05 | 00 | 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 |
| 1.03 | 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 |
| | 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 | 00 | 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 | 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 |
| | 70 | 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 |

[unit:sec.]

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

| Speed | kV | mA | Child | | | | | Adult | | | | | Large Adult | | | | |
|---------|-----|--------|-------|------|------|------|------|-------|------|------|------|------|-------------|------|------|------|------|
| Setting | K V | 1117 1 | T1 | T2 | Т3 | T4 | T5 | T1 | T2 | Т3 | T4 | T5 | T1 | T2 | Т3 | T4 | T5 |
| | 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 |
| F. 09 | 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 |
| 1.09 | 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 |
| | 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 |
| | 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 |
| F. 05 | 00 | 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 |
| 1.03 | 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 |
| | 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 |
| | 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 |
| d.10 | 00 | 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 |
| u.10 | 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 |
| | 70 | 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 \rightarrow adult \rightarrow large adult \rightarrow child) and sets the exposure time automatically. If the weight of child is less then 20kg, press \odot switch once after setting to child. If the weight of child is over 30kg and less than 50kg, press \odot switch once after setting to child. If the weight of child is over 50kg and less than 70kg, press \odot 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 \odot or \odot switch) supersedes \bigcirc \bigcirc \bigcirc 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** 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** (6).

[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 $(207 \sim 253 \text{Vac})$.

- 3. 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.
 - NOTE: To manually set the exposure time, depress either of the Manual Exposure Time Adjusting Switches (\bigcirc or \bigcirc) until the desired exposure time appears in the Exposure Time Display Window (\bigcirc). While the unit is in manual mode, other selection switches (\bigcirc \bigcirc) 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 (\bigcirc \bigcirc).
- 4. Depress the Exposure Switch (8). When the Exposure Switch is depressed, the Exp. Warning Light (7) 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 $(5 \sim 9)$.
 - 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 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 either of the manual exposure time adjusting switches 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] 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 (8) 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.

NOTE: This hand exposure switch is included with FM and FK1/FK2 type x-ray unit.

[7] DIGITAL IMAGING SYSTEM

No x-ray image receptor is integrated in PHOT-X IIs 505 x-ray system. If image receptor used with PHOT-X IIs 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 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 505 may lead to a reduced level of safety of the resulting system.

Consideration relating to the choice shall include:

- · accessory should be CE marked
- · 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 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. If the sub controller is not covered by a barrier and incorrect disinfectant is used, the exposure switch may be damaged by direct contact with disinfectants.
 - (b) If you use film holders or digital detector holders that go into patient's mouth, properly sterilize them. Follow the sterilization procedures indicate by each manufacturer.

2. CLEANING

In order to ensure proper hygiene and cleaning of the equipment, the following procedure must be followed.

A 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 / 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 in contact with skin, periodic disinfection with a non corrosive surface infectant is recommended.

Recommended disinfectant: FD333 (Durr Dental GmbH)

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.

| 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. | | | |
| E.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. | | | |
| L.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 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 lampis 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 (C.4) | | | |
| 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. | Turn off the main power switch and wait for approximately 2 min. Turn on the main power | If same error code is displayed, call service personnel. | | |
| E.17 | During the exposure, tube potential becomes more than 80 kV. | switch again. | | | |
| 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

PHOT-X IIs 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 505 Installation instructions.

- 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 14 of the maintenace check list on page 13 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 13.
- c. Acceptance limit: Refer to the Maintenance check list on page 13.
- d. Required action when failed: Refer to the Maintenace check list on page 13.
- e. Tools to maintain quality control logs: Use the check list on page 13.
- f. Training material: Operator's instructions, Installation instructions 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 oil, which is refined mineral oil and does not contain the carcinogenic substances such as PCBs, for the insulation. When disposing the x-ray unit or components, appropriately dispose them complying with all current applicable regulations and local codes. In EU area, EU directive 2012/19/EU on waste electrical and electronic equipment (WEEE) is applied on this product. In this directive, environment conscious recycling / abandonment is obligated.

2. Disposal of used film and CCD cover

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

MAINTENANCE CHECK LIST

| Parameter | Acceptance limit | Frequency | Procedures when failed | OK/NG |
|---|--|-----------------------|---|-------|
| 1. Line voltage | Confirm the line voltage is within 230V±10%. Also confirm the voltage drop during exposure is within 3%. | Yearly | Connect to the power supply within 230V±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 installation instructions.) | |
| 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. Mounting plate for wall (WK), ceiling (CK) or floor (FK1/FK2) | Confirm the plate is firmly fixed to the wall (WK), ceiling (CK) or floor (FK1/FK2). | Yearly | If bolts are loose, find the reason why bolts became loose and take counter measure that prevents bolts become loose. | |
| 5. Arm mounting bracket (WK) | Make sure that the arm bracket is firmly attached to the wall or wall plate. | Yearly | | |
| 6. Pole (FK1/FK2, CK) | Make sure the pole is securely attached to the mounting plate. | Yearly | | |
| 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). | |
| 8. Horizontal arm (WK, FK1/FK2) | 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, take counter measure that prevent the retaining bolt become loose. | |
| 9. Head | Confirm the head can be smoothly positioned. | Daily (before use) | Adjust the brake screws by referring to installation instructions. | |
| 10. Vertical movement of balance arm | Confirm the balance arm moves smoothly without making noise. | Daily (before use) | Adjust the tension of the balance arm by referring to installation instructions. If the balance arm makes noise, apply grease. | |
| 11. Swing angle of balance arm (FM) | Confirm the balance arm swings between two long legs. | Daily (before use) | Check the stopper screws and mounting screws of pole bushing. | |
| 12. Caster (FM) | Confirm all casters move smoothly and lock function works fine by two lock casters. | Daily (before use) | Clean up the casters or replace them. | |
| 13. Sliding post (RK) | Confirm the post slides smoothly. | Daily (before use) | Check the rollers of sliding post. | |
| 14. Swing arm (CK, RK) | Confirm the joints of the swing arms are connected firmly and stopper and friction are adequate. | Daily (before use) | Check the keys, stopper ring, stopper screws and brake screw of swing arm, and change them as necessary. | |

[12] TECHNICAL DATA

| 1. X-ray tube | - Toshiba D-046 (Stationary Anode) | | | | | | |
|---|--|--|--|--|--|--|--|
| a. Nominal focal spot value | - 0.4 | | | | | | |
| b. Target Material | - Tungsten | | | | | | |
| c. Target angle | - 12.5 deg | | | | | | |
| 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 | | | | | | | |
| 4. Rated tube current | - 3 mA / 6 mA selectable | | | | | | |
| 5. Maximum rated peak tube potential | - 70 kV | | | | | | |
| 6. Rated line voltage | | | | | | | |
| 7. Line voltage range | - 207 VAC ~ 253 VAC | | | | | | |
| 8. Range of line voltage regulation | $-0 \sim 3$ % (Apparent resistance 1.02 ohm) | | | | | | |
| 9. Rated line current | | | | | | | |
| 10. Maximum line current | - 7 A at 70 kV, 6 mA | | | | | | |
| 11. Exposure time | $-0.01 \sim 2.0 \text{ sec.}$ | | | | | | |
| 12. Inherent filtration | | | | | | | |
| 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 | <u>*</u> | | | | | | |
| • | the next page. | | | | | | |
| 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 | - 203 mm 58 mm dia., circular | | | | | | |
| b. Long cone (option) | - 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 | | | | | | | |
| 21. Maximum deviation of tube potential, tube current | and exposure time | | | | | | |
| a. Below 0.1 sec. setting | $\pm 10 \text{ kV}, \pm 2 \text{ mA}, \pm 5 \text{ msec}.$ | | | | | | |
| b. 0.1 sec. setting & up | $\pm 5 \text{ kV}, \pm 1 \text{ mA}, \pm 10 \text{ msec}.$ | | | | | | |
| 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 | | | | | | | |
| 27. Dose area product | | | | | | | |
| - | x 26.4 [cm ²] (for regular and long cone) | | | | | | |
| | Estimated air kerma displayed [mGy] | | | | | | |
| | x 12.8 [cm ²] (for rectangular collimator) | | | | | | |
| 28. Service life | - 10 years | | | | | | |

Nominal Radiation Output Table

| | | | | | | | Nomin | al Rad | iation (| Output | | | | | | |
|--------|--------|---------|----------|---------|---------|---------|-------|--------|-----------------------------|---------|------|------|--------|---------|------|------|
| Exp. | | W | ithout l | Rectang | gular C | ollimat | or | | with Rectangular Collimator | | | | | | | |
| Time | | 60 | kV | | | 70 | kV | | | 60 | kV | | | 70 | kV | |
| [sec.] | Regula | ır Cone | Long | Cone | Regula | r Cone | Long | Cone | Regula | ar Cone | Long | Cone | Regula | ır 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 : $[mGy] \pm 50\%$

[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 manufacture's declaration - electromagnetic emissions | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|
| | | tromagnetic environment specified below. The customer or | | | | | | | | |
| the user of the PHOT-X IIs 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 505 x-ray uses RF energy only for its | | | | | | | | |
| CISPR 11 | Group 1 | internal function. Therefore, its RF emissions are very | | | | | | | | |
| | Group 1 | low and are not likely to cause any interference in nearby | | | | | | | | |
| | | electronic equipment. | | | | | | | | |
| RF emissions | Class A | The PHOT-X IIs 505 x-ray is suitable for use in all | | | | | | | | |
| CISPR 11 | Class A | establishments other than domestic and those directly | | | | | | | | |
| Harmonic emissions | Class A | 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 | 1 | | | | | | | | | |

| 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 | ±6 kV contact | ±6 kV contact | Floors should be wood, concrete or | | | | | |
| discharge (ESD) | ±8 kV air | ±8 kV air | ceramic file. If floors 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 _T | <5% U _T | Mains power quality should be | | | | | |
| interruptions and | $(>95\%$ dip in $U_{\rm T})$ | (>95% 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 | $40\%~U_{\mathrm{T}}$ | $40\%~U_{\mathrm{T}}$ | user of the PHOT-X IIs 505 x-ray | | | | | |
| input lines | $(60\% \text{ dip in } U_{\text{T}})$ | $(60\% \text{ dip in } U_{\text{T}})$ | requires continued operation during | | | | | |
| IEC 61000-4-11 | for 5 cycle | for 5 cycle | power mains interruptions, it is | | | | | |
| | $ 70\% \ U_{\scriptscriptstyle m T} $ | $70\%~U_{\mathrm{T}}$ | recommended that the PHOT-X IIs | | | | | |
| | $(30\% \text{ dip in } U_{\text{T}})$ | $(30\% \text{ dip in } U_{\text{T}})$ | 505 x-ray be powered from an | | | | | |
| | for 25cycle | for 25cycle | uninterruptible power supply or a | | | | | |
| | <5% U _T | <5% U _T | 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 $U_{\rm T}$ is the a.c. | 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-X IIs 505 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the PHOT-X IIs 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 505 x-ray, including cables,than the recommended separation distance calculated from the equation applications to the Frequency of the transmitter. |
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz outside ISM bands ^a | 3 Vrms | 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. |
| | | | 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-X IIs 505 x-ray is used exceeds the applicable RF compliance level above, the PHOT-X IIs 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 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 505 x-ray

The PHOT-X II 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-X IIs 505 x-ray can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PHOT-X IIs 505 x-ray as recommended below, according to the maximum output power of the communications equipment.

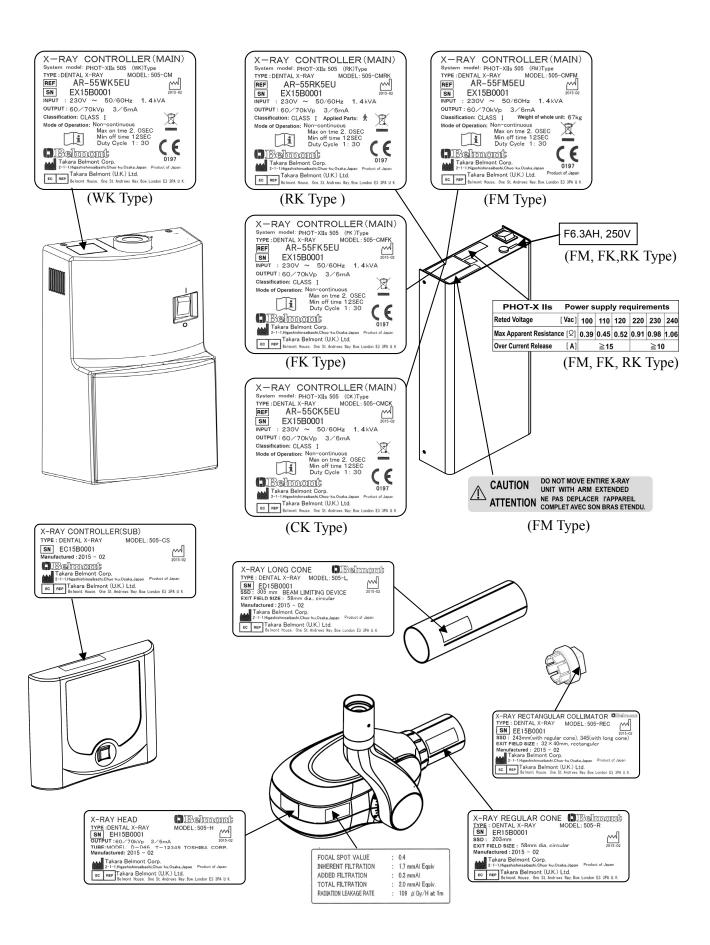
| D-4-1 | Separation distance according to frequency of transmitter m | | | |
|---------------------------|---|--|---|--|
| Rated maximum output | | | | |
| power of transmitter W | 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ | |
| 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 | |

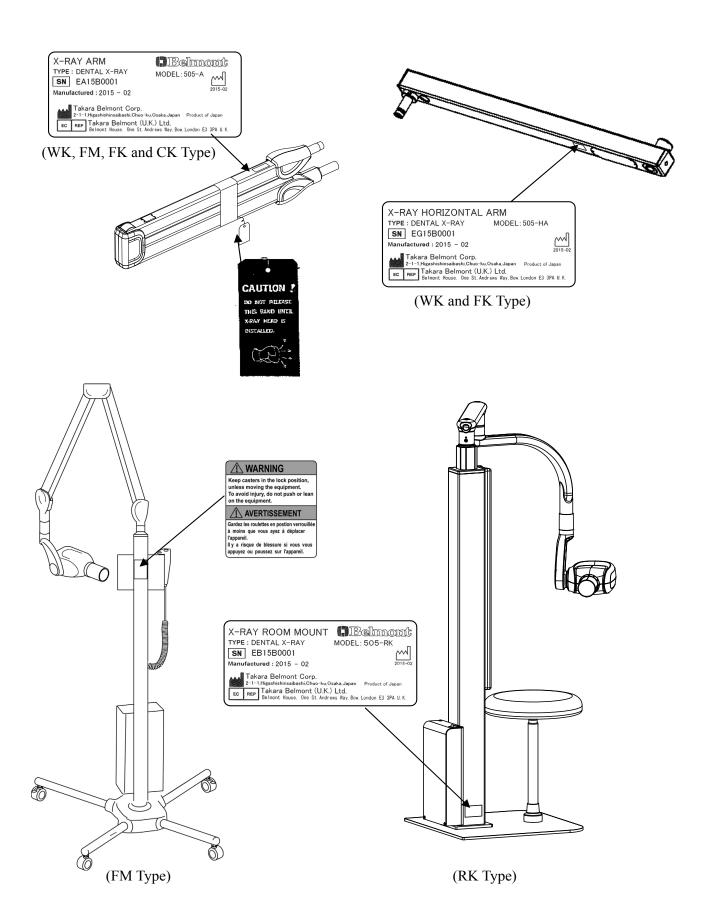
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

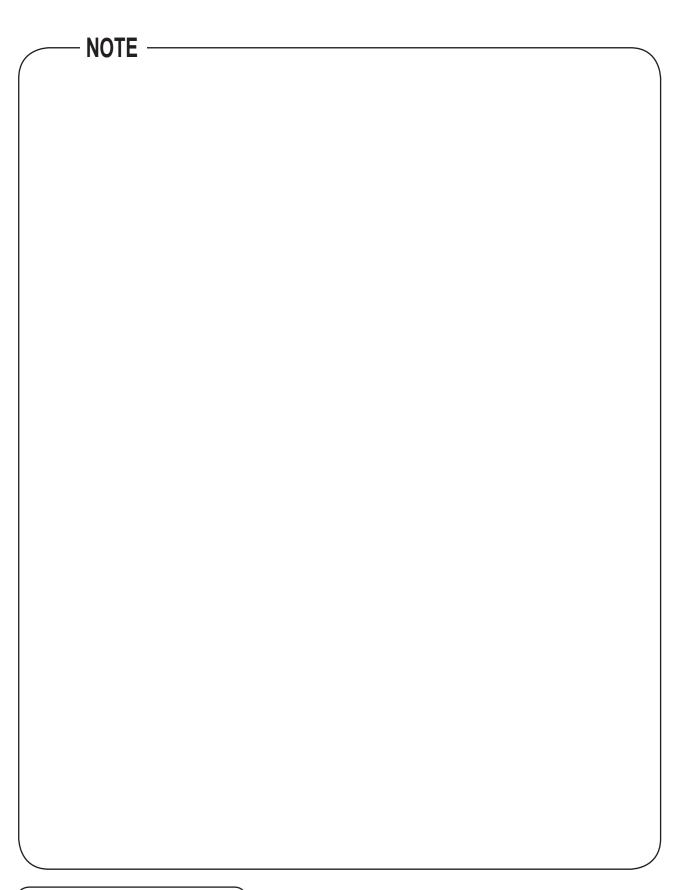
NOTE 1 At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.

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

[14 | LABEL LOCATION









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