DENTAL X-RAY

BELRAY

MODEL 096

OPERATOR'S INSTRUCTIONS

CE 0197

⚠WARNING:

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

Belmont®

Table of Contents

Intended Use of the Product

This product is an active device intended to emit ionizing radiation for the exclusive use for diagnoses of dentistry, and must be operated or handled by the qualified personnel only.
Such qualified personnel should instruct and/or assist the patient to approach to and leave from the product.
Patients should not be allowed to operate or handle the product.
It is always recommended that both operator and patient use the proper protective means for radiographying.

[1] INTRODUCTION

1. GENERAL

BELRAY 096 is a extraoral source dental radiographic x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with resultant image recorded on intraoral dental x-ray film or image receptor.
This manual provides information for the operation and maintenance procedures and technical specifications for BELRAY 096 dental x-ray. The instructions contained in this book should be thoroughly read and understood before operation.
BELRAY 096 has no user serviceable items. Maintenance and repair should be performed by qualified dealer service personnel.

2. PARTS IDENTIFICATION OF X-RAY SYSTEM "BELRAY 096"

a. Tube housing assembly : 096-H
b. X-ray controls : 096-C
c. Cones : 096-R (regular), 096-L (long)
d. Balance arm : 096-A
e. RK stand : 096-RK

3. COMPLIANCE WITH STANDARD

BELMONT BELRAY 096 x-ray unit complies with the following standard.
EN60601-1 : 1990 including A1:93, A2:95 and A13:96, EN60601-1-3 : 1994, EN60601-2-7 : 1998, EN60601-2-28 : 1993, EN60601-2-32 : 1994

4. CLASSIFICATION

According to EN60601-1, BELMONT BELRAY 096 is classified as follows.

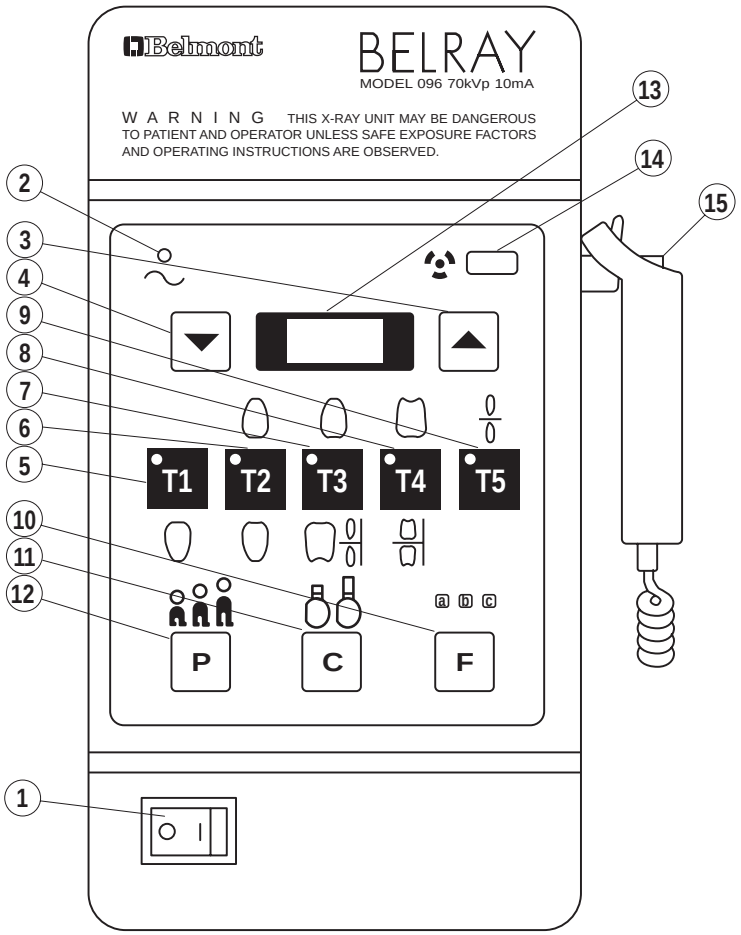
a. Protection against electric shock : Class I Equipment, Type B Applied Parts
b. Protection against ingress of water : Ordinary
c. Mode of operation : Continuous Operation with Intermittent Loading (Duty Cycle = 1 : 60)
d. Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

5. SYMBOL

In this book, on the labels or on the control panel of BELRAY 096, following symbols are used. Confirm the meaning of each symbols.

	Consult written Instructions in Manuals		Protection against electric shock : Type B		ON (POWER)		OFF (POWER)
	Protection Grounding		Separate Collection for Electrical and Electronic Equipment		X-ray Emission		Ready
	Upper Incisor		Upper Cuspid & Pre Molar		Upper Molar		Occlusal
	Lower Incisor		Lower Cuspid & Pre Molar		Lower Molar & Bite Wing		Bite Wing
SN	Serial Number		Patient Child		Patient Normal		Patient Obese
	Regular Cone		Long Cone	EC REP	Authorized Representative in The European Community		Manufacturer
	Non-ionizing Radiation		Date of Manufacture				

[2] LAYOUT OF CONTROL BOX



[3] FUNCTION OF CONTROLS

① Main Power switch

Pushing right side of this switch energizes the x-ray unit.
(Ready lamp and pre-selected lamps for patient size, cone type and film speed illuminates.)
It is recommended to keep this switch OFF when the unit is not in use in order to prevent an accidental exposure.

② Ready Lamp

This lamp lights when the line voltage is within operable range.
When this lamp is not on, exposure can not be made.

③,④ Exposure Time Adjusting Switches

By momentarily pushing ▲ (or ▼) switch, exposure time displayed increases (or decreases) by one step. By keeping the switch depressed more than 2 sec., exposure time displayed increases (or decreases) continuously until the switch is released.

⑤ ~ ⑨ Tooth Selection Switch (T1 ~ T5)

Pushing one of these switches sets the exposure time automatically in combination with following ⑩ ~ ⑫.

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 : Molars of Maxilla, Bitewing Molars
⑨ T5 : Occlusal

⑩ Film Speed Selection Switch

a) Three types of film speed can be selected. Pushing this switch momentarily indicates the film speed number being selected in exposure time display window⑬. Depressing the switch for more than 2 seconds alters the film type being selected.

b) Film speed : Refer to page 1, Layout of control box.
As factory installation, following three kinds of film speeds are registered(a,b,&c), and can be selected by the film speed selection switch, Item 10 on page 1.
a = Film speed No. F.08 (equivalent to ISO speed group "D", or Kodak Ultra-Speed film)
b = Film speed No. F.03 (equivalent to ISO speed group "F/E", or Kodak InSight film)
c = Film speed No. F.02 (equivalent to ISO speed group "F")

TABLE 1 : FILM SPEED and EXPOSURE TIME (REGULAR CONE) (UNIT : SEC.)

Patient Size	SMALL					MEDIUM					LARGE				
Tooth	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5
F. 08	0.08	0.14	0.17	0.22	0.33	0.14	0.22	0.27	0.36	0.54	0.17	0.27	0.33	0.44	0.66
F. 03	0.03	0.06	0.06	0.09	0.13	0.05	0.09	0.10	0.15	0.20	0.06	0.11	0.13	0.18	0.25
F. 02	0.03	0.05	0.06	0.07	0.11	0.05	0.08	0.09	0.12	0.18	0.06	0.10	0.11	0.15	0.22

TABLE 2 : FILM SPEED and EXPOSURE TIME (LONG CONE) (UNIT : SEC.)

Patient Size	SMALL					MEDIUM					LARGE				
Tooth	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5
F. 08	0.18	0.29	0.36	0.47	0.71	0.29	0.47	0.58	0.76	1.15	0.36	0.58	0.71	0.93	1.41
F. 03	0.07	0.12	0.14	0.19	0.27	0.11	0.19	0.22	0.31	0.44	0.14	0.24	0.27	0.38	0.54
F. 02	0.06	0.10	0.12	0.16	0.24	0.10	0.17	0.19	0.25	0.38	0.12	0.20	0.24	0.31	0.47

⑪ Cone Type Selection Switch

The exposure time corresponding to the cone type being used (Standard Regular Cone or Optional Long Cone) can be selected by this switch.

⑫ Patient Size Selection Switch

Pushing this switch alters the selection of patient size (child/adult/obese) and sets the exposure time accordingly.

NOTE : Setting or adjusting the exposure time manually (with ▲ or ▼ switch) supersedes ⑤ ~ ⑫ functions.

⑬ Exposure Time Display Window

Normally the exposure time selected is displayed.
Error Code is displayed when abnormal condition exists or malfunction occurs.

⑭ Exposure Warning Light

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

⑮ Exposure Switch

Deadman Type exposure switch. When making an exposure, depress this switch and keep it depressed until the exposure warning light ⑭ and the audible warning terminate. Failure to keep this switch depressed will result in premature termination of the exposure.

[4] OPERATING PROCEDURES

1. Turn ON the main power switch ①.

2. Confirm that ready lamp ② is illuminated.
   NOTE: The ready lamp will not illuminate unless the incoming line voltage is correct and within the x-ray's operable range.

3. Select the appropriate tooth type(⑤ ~ ⑨), and confirm if the pre-selected conditions (film speed ⑩, cone type ⑪ and patient size ⑫) are suitable for radiographing.

   NOTE: To manually set the exposure time, depress either manual exposure time adjust switch(③ ▲ or ④ ▼) until the desired exposure time is displayed in exposure time display window ⑬. While the unit is in manual mode, other selection switches(⑩~ ⑫) do not affect exposure time. (All the tooth selection lamps are off.)

   To return to the automatic exposure time selection mode, depress any one of tooth selection switches.

4. Set the x-ray head in the position. X-ray head can be rotated 600 degrees horizontally and 300 degree vertically

5. Depress the exposure switch ⑮. When the exposure switch is depressed, the exposure warning lamp ⑭ illuminates and the audible warning sounds. Do not release the exposure switch until the audible warning and the warning lamp terminate. Failure to keep the switch depressed will result in the exposure being terminated prematurely.

6. To continue to radiograph other teeth, just select appropriate tooth selection switch.

   IMPORTANT : To protect x-ray tubehead from heat accumulation, wait for 60 times of exposure time between exposures. [ex. 30 second wait interval for 0.5 sec. exposures]

7. After use turn OFF the main power switch ① in order to prevent accidental exposures.

   NOTE : If the unit is left over 8 minutes without being operated and the main power switch is kept on, figure "1" runs through the exposure time display window. This does not mean that a malfunction of the unit has occurred, but saves energy. The unit returns to normal condition by pressing any one of the switches except the exposure switch.

[5] DIGITAL IMAGING SYSTEM

If electrical instruments such as a digital imaging system is used with BELRAY 096 x-ray, the following points should be confirmed to keep electrical safety.

⚠CAUTION

The use of ACCESSORY equipment not complying with the equivalent safety requirements of BELRAY MODEL 096 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 EN60601-1 and/or EN60601-1 harmonized national standard.

[6] CLEANING AND DISINFECTION

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

⚠WARNING

Before cleaning the unit, turn off the main power switch and breaker on the blanch 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 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 blanch 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 disinfectant is recommended.
Recommended disinfectant : FD333 (Durr Dental GmbH)
Drying : Allow surface to air dry before tuning breaker and main switch back on.

[7] DISPOSAL

1. Disposal of x-ray unit or components
The tube head of this x-ray unit contains the lead for x-ray shield and oil for the insulation. When disposing the x-ray unit or components, appropriately dispose complying with all current applicable regulations and local codes. In EU area, EU directive 2002/96/EC 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 of used film covers and CCD sensor covers appropriately, according to procedures indicated by each manufacturer and all current applicable regulations and local codes.

[8] ERROR CODES

When abnormal condition exists in the unit, or malfunction occurs, error code is displayed in exposure time display window.
Please refer to the table below.

<table>
<tr><th>Error code</th><th>Condition</th><th>Step to be taken</th><th>Possible solution</th></tr>
<tr><td>E.00</td><td>Exposure switch was released before the exposure terminates.</td><td>All the tooth selection switches blink.
Depress one of the switch.</td><td>Release exposure switch after exposure lamp turns off.</td></tr>
<tr><td rowspan="3">E.01</td><td>Exposure switch was depressed within 10 sec. of previous exposure.</td><td rowspan="3">A 10 second delay is built in between each exposure.

Release exposure switch.</td><td>There is to be an "wait" interval of 60 times of exp. time between successive exposures.</td></tr>
<tr><td>Exposure switch was depressed within 3sec. after the main power switch has been turned on.</td><td>Exposure switch should be depressed after the ready lamp comes ON.</td></tr>
<tr><td>E.02</td><td>Line voltage was less than 90% of rated voltage.</td><td rowspan="2">Confirm that ready lamp is on before exposure.
Ask service personel to check the line voltage.</td></tr>
<tr><td>E.03</td><td>Line voltage was more than 110% of rated voltage.</td></tr>
<tr><td>E.04</td><td>Excess current during exposure.</td><td rowspan="9">Turn off the main power switch and wait for a while.
Turn on the main power switch again.</td><td rowspan="9">If same error code is displayed, call service personel.</td></tr>
<tr><td>E.05</td><td>Tube current of the last pulse was less than 7.5mA.</td></tr>
<tr><td>E.06</td><td>Tube current of the last pulse was more than 12.5mA.</td></tr>
<tr><td>E.07</td><td>Tube current during exposure was less than 5mA.</td></tr>
<tr><td>E.08</td><td>Tube current during exposure was more than 15mA.</td></tr>
<tr><td>E.09</td><td>Malfunction of the microcomputer.</td></tr>
<tr><td>E.10</td><td>Exposure switch or exposure circuit had been ON, when main power switch is turned on.</td></tr>
<tr><td>E.11</td><td>Tube current is detected during pre-heating period.</td></tr>
<tr><td>E.12</td><td>Tube current is detected when main power switch is turned on.</td></tr>
</table>

[9] MAINTENANCE

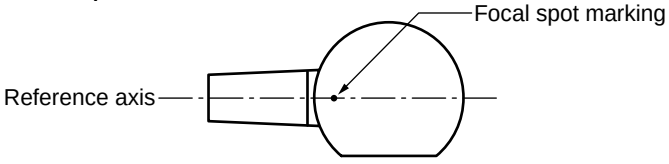
BELRAY 096 X-ray unit requires the following post installation confirmation and periodic maintenance checks to be performed by dealer service personnel, to ensure that the x-ray unit is functioning with the manufacturer's specifications and remains in compliance with the Standard.
It is the responsibility of the owner of the unit to see that these maintenance checks are done once every 6 months and that they are performed by a trained, certified service technician.

The specific instructions to perform these check are located within the Model 096 installation manual.

A. Line voltage confirmation
B. Tube current confirmation
C. Inspection of arm and head movements
D. MECHANICAL SAFETY
    1. The wall plate, if used, should be checked to confirm its secure attachment to the wall.
    2. The arm mounting bracket should be checked to confirm its secure attachment to the wall mounting plate or, to the wall. The arm mounting bracket must be level horizontally and vertically.
    3. Check to insure the horizontal arm is not raising up and out of the arm mounting bracket. This should be observed routinely by treatment room personnel.

[10] TECHNICAL DATA

1. Nominal focal spot value ..... 0.8 mm (IEC60336)
2. Rated peak tube potential..... 70 kV(peek)
3. Rated tube current ..... 10 mA
4. Maximum rated peak tube potential ..... 70 kV(peek)
5. Electrical ratings
   a) Rated Line Voltage..... 230 V
   b) Min Line Voltage ..... 207 V
   c) Max Line Voltage ..... 253 V
   d) Rated Line Power ..... 1.3 kVA
   e) Rated Line Current ..... 5.6 A
   f) Max Line Current ..... 6.2 A
   (Internal Resistance ..... 1.20Ω max.)
   g) Range of Line Ragulation ..... 0 ~ 3 %
6. Power line frequency ..... 50/60 Hz
7. Exposure time ..... 0.02 ~ 3 sec.
   (ON and OFF are zero crossed.)
8. Timer accuracy..... ±1 pulse (1/50sec. for 50Hz,1/60sec. for 60Hz)
9. Inherent filtratio ..... 1.3 mmAl Equivalent
10. Added filtratio ..... 0.8 mmAl
11. Minimum filtration permanently in useful bea ..... 2.1 mmAl Equivalent at 70 kV(peek)
12. Nominal roentgen output
    a. Distal end of regular cone ..... 1.30 R/sec. + 30 %, - 40 %
    b. Distal end of long cone ..... 0.58 R/sec. + 30 %, - 40 %
13. Source to skin distance
    a. Regular cone..... 204 mm
    b. Long cone..... 305 mm (OPTION)
14. Leakage technique factor ..... 70 kV(peek) / 0.16 mA
    0.16 mA is maximum rated continuous current for 10 mA with a duty cycle 1: 60
15. Duty cycle ..... 1: 60 (0.5 sec. exposure with 30 sec. interval)
16. Source to the base of cone distance ..... 81 mm
17. Reference current time product..... 30 mAs (70kV(peek), 10mA, 3sec.)
    Maximum earth leakage current ..... 0.5 mA
19. Field size ..... Round 58 mm
20. Tolerance of the focal spot marking..... ±1 mm
21. Tolerance of target angle..... 1°
22. Measurement base of technique factors



    a. Peak tube potential ..... Peak tube potential of conducting half cycle
    b. Tube current ..... Average of tube current during one cycle of line frequency
    c. Exposure time..... Impulese of power line frequency
23. Environmental condition for storage.....-20 ~ 70℃, 10 ~ 90%, 500 ~ 1060hPa
24. Environmental condition for operation.....10 ~ 40℃, 30 ~ 75%, 700 ~ 1060hPa
25. Movable range of head.....Horizontal 0 ~ 600°
    Vertical 0 ~ 300°
26. Service Life.....10 Years

[11] ELECTROMAGNETIC COMPATIBILITY(EMC)

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

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

Guidance and manufacture's declaration – electromagnetic emissions		
The BELRAY 096 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the BELRAY 096 x-ray should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BELRAY 096 x-ray uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BELRAY 096 x-ray is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The BELRAY 096 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the BELRAY 096 x-ray should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic file. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25cycle <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25cycle <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BELRAY model 096 x-ray requires continued operation during power mains interruptions, it is recommended that the BELRAY model 096 x-ray be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to applications of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity			
The BELRAY 096 x-ray is intended for use in the electromagnetic environment specified below. The customer or the user of the BELRAY 096 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 BELRAY 096 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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BELRAY 096 x-ray is used exceeds the applicable RF compliance level above, the BELRAY 096 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 BELRAY 096 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 BELRAY 096 x-ray

The BELRAY 096 x-ray is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BELRAY 096 x-ray can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BELRAY 096 x-ray as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

EC REP

Takara Belmont (UK) Ltd.
Belmont House
One St.Andrews Way,Bow,
London E3 3PA U.K.
Tel: (44)20 7515 0333
Fax:(44)20 7987 3596

Belmont

TAKARA BELMONT CORPORATION
1-1, 2-Chome, Higashi-shinsaibashi,Chuo-ku,Osaka,Japan
TEL. : (06) 6213-5945 FAX. : (06) 6212-3680

Book No. 1A048AB0
Printed in Japan 2011-09 MA