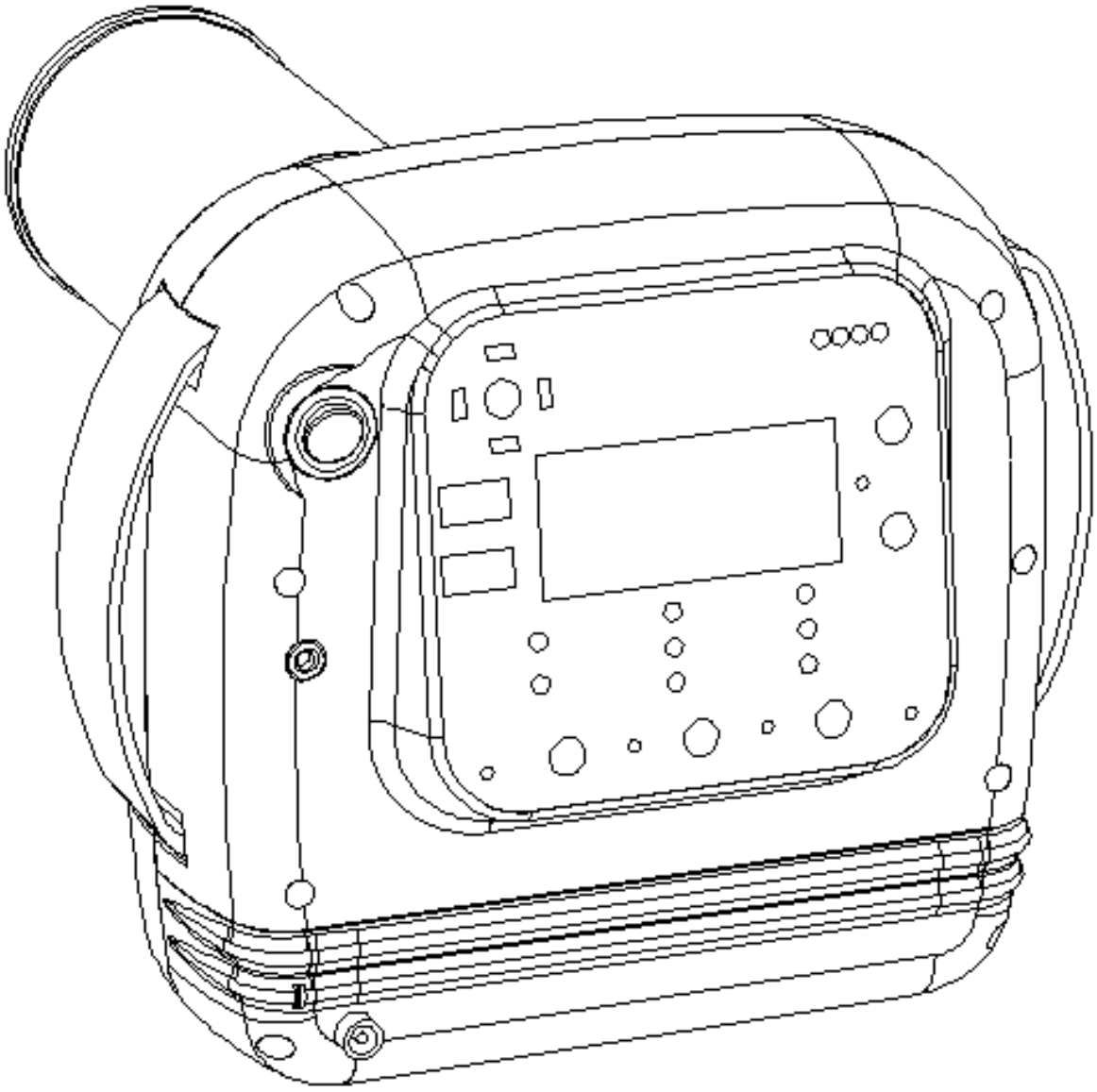
XR - 01

PORTABLE X-RAY SYSTEM



TRAINING MANUAL

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Introduction

There are many beneficial uses of ionizing radiation; however, of equal importance we note that there are potential risks associated with its use. Radiation safety training is an important part of any radiation safety program. Receiving appropriate training ensures users are following proper safety practices to minimize risks and maintaining a safe work environment.

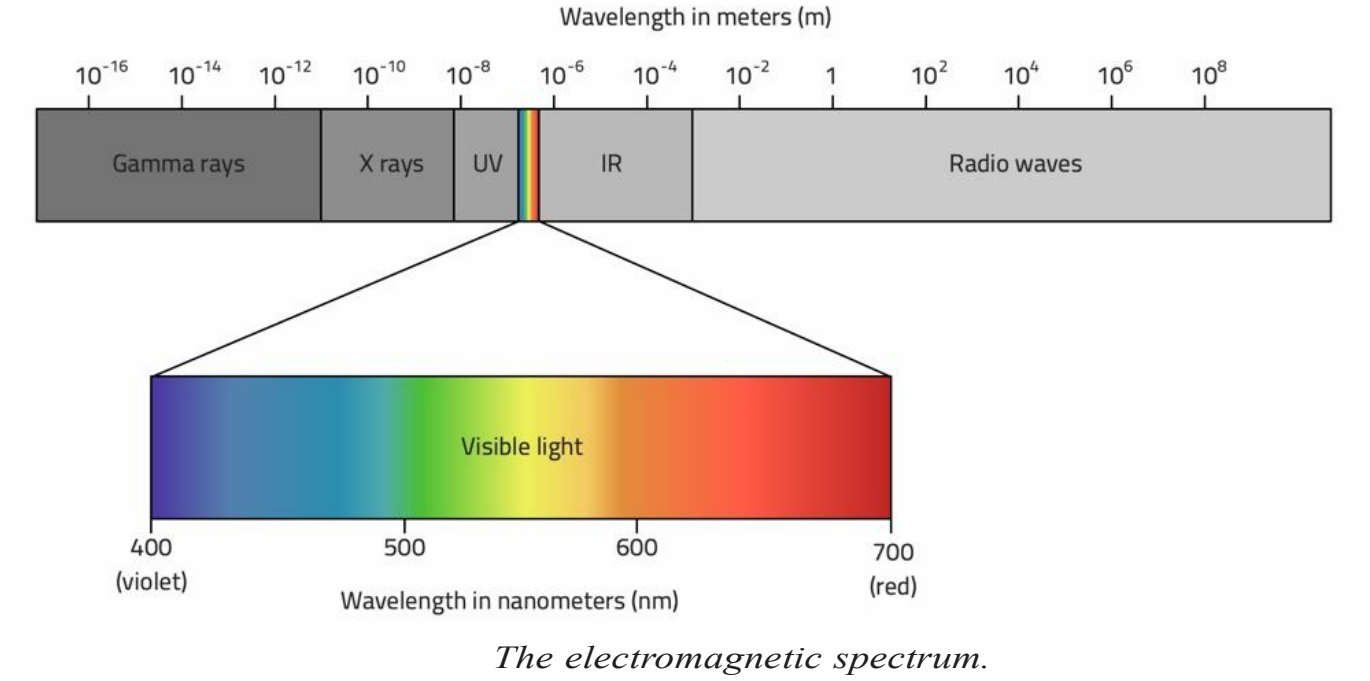
In this training manual, we discuss basic X-ray safety in addition to specific safety information about operating the XR-01. XR-01 is a portable, compact, handheld X-ray system meant for dental radiology that is certified by the FDA and CE which is consider as completely safe when used as intended. All operators must read the User's Manual of XR-01 before use it.

This unit is only to be operated by authorized personnel. **DO NOT** operate the XR-01 in any manner other than that specified herein, and in the User's Manual. Anyone else other than trained and certified personnel to operate the XR-01 is prohibited.

Background

What are X-rays?

X rays are a form of ionizing radiation and are a part of the electromagnetic spectrum. X rays are the same as the light from the sun, except that their energy is much higher. As X rays travel through and interact with various materials, human tissue for instance, they transfer energy to the atoms of that material. This process of energy transfer can result in atomic ionization. X rays can penetrate certain materials, but they can be blocked or shielded with high-density materials.

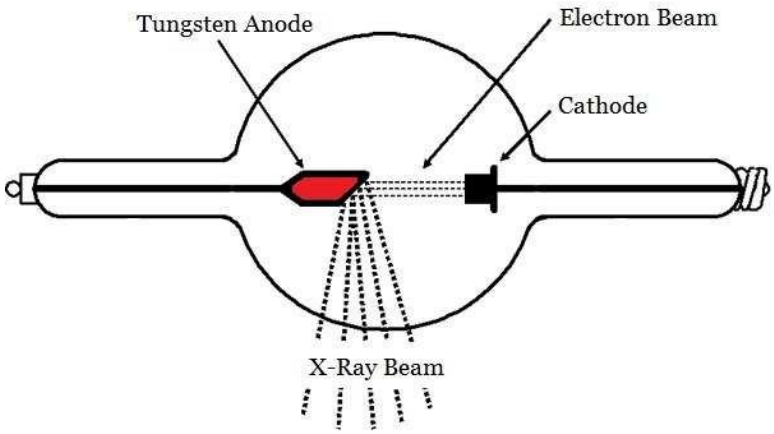


The electromagnetic spectrum.

When living systems are exposed to ionizing radiation there is a risk for biological damage to occur. Exposure to X rays in the workplace, however, is highly regulated and current safety standards are very effective at keeping risks at minimum.

How did X-ray Generated

X type of vacuum tube specifically designed for that function. As power is applied to the tube, X-rays are emitted in a prescribe fashion from a shielded housing.



Generally, the three parameters that are usually adjusted by the X-ray technician (tube potential (kVp), tube current (mA), and time (sec) establish the characteristics of the X-ray beam emanating from the tube. The tube potential determines the energy range of X rays and the tube current establishes the rate at which X rays are emitted.

All X-ray tubes have some form of filtration, whether it be inherent to the design or added afterward to adjust the usefulness of the X-ray beam. The X-ray housing will have additional shielding to minimize “leakage radiation” that can cause unwanted exposure to the technician.

Primary and Scatter Radiation

Once X rays leave the tube housing, they are categorized as primary or secondary radiation. Secondary radiation is further characterized into scatter radiation and leakage radiation.

Primary radiation
This type of radiation describes the useful beam of radiation that is produced in the tube and exits the filtration window as designed. This is the radiation which is fundamental in producing the radiograph. Continued exposure to the primary beam can result in a significant hazard.

Scatter radiation
This refers to the radiation that is scattered after the primary beam interacts with the patient. The patient is therefore the major source of scatter radiation. Even though the primary beam is much more intense than scatter radiation, it is this scatter that is of primary concern when protecting the safety of the worker.

As stated above, leakage radiation refers to radiation from the X-ray tube that penetrates the device housing. Leakage is usually quite small relative to the primary beam and scatter.

Interactions with Matter

The interaction of X rays with matter is a random process. As tissue is exposed, the X rays may interact with the atoms of the material through which they pass. A small percentage of the X rays will pass through matter without interacting.

Biological Effects of Radiation

While X rays are an important part of the diagnostic process, it is important to be aware that there is potential for biological damage to occur when exposed to ionizing radiation. Efforts should be made to evaluate the benefit and potential risk in order to avoid unnecessary radiation exposure. The benefits of medical/dental evaluation using X-ray technology are obvious, but the biological effects of ionizing radiation must be weighed against the benefits. These effects are commonly grouped into two categories:

Non-stochastic Effects (deterministic effects)

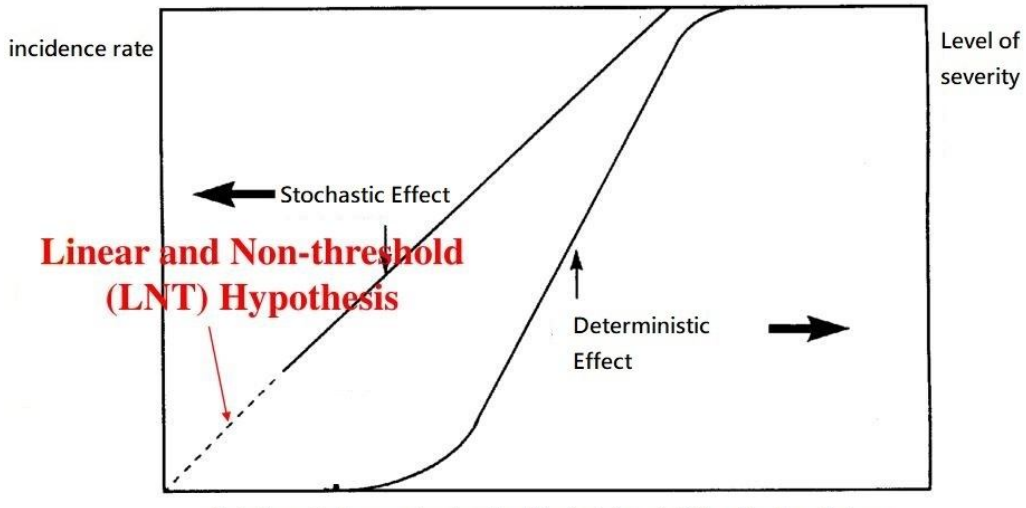
Non-stochastic effects related to those that are non-random and are directly related to the radiation dose received. For these effects to occur, a threshold dose must be met. Once the threshold has been exceeded, the severity of biological damage (e.g., skin burns, hair loss, reddening of the skin, cataracts) increases with the dose received. These effects are seen only after exposure to large doses of radiation (> 1,000 mSv), much larger than doses received when undergoing dental imaging.

Stochastic Effects (probabilistic effects)

Stochastic effects are randomly occurring and the severity of biological damage (e.g., cancer, birth defects) is independent of the dose received. Since it is based on probability, the chance of occurrence increases with radiation exposure. Stochastic effects are of typical concerned when speaking of exposure to diagnostic X rays; radiation dose is very small; therefore, the only real potential outcome is the random chance of cancer.

Linear No-Threshold Risk Model

Because the random chance of cancer is so small, science must use a small set of existing data to predict cancer probability. Currently, the prediction is based on what's called a "linear, no-threshold model" and is intended to convey that cancer risk is thought to be proportional (linear) to dose, with zero dose resulting in zero risk (no-threshold). This model is conservative and follows the philosophy that it is better that risk be overestimated rather than underestimated.



Relations between stochastic effect, deterministic effect and dose

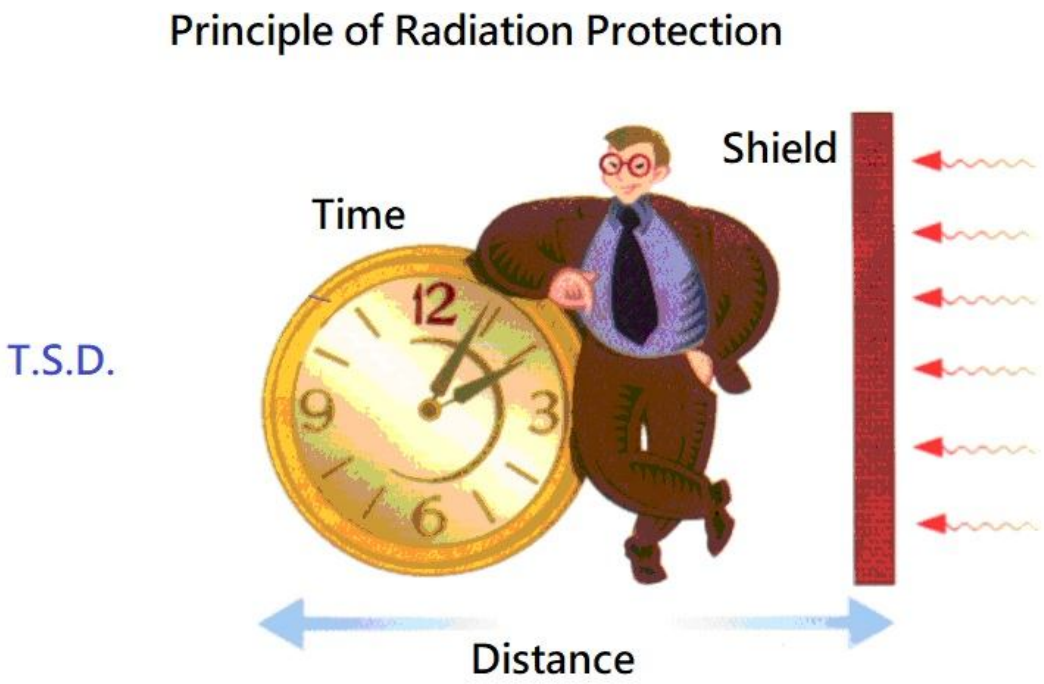
Basic X-ray Safety

Safety Rules to Minimize Radiation Dose

ALARA. ALARA (As Low As Reasonably Achievable) is a safety principle that ensures radiation exposure levels are kept as low as practical, far below the exposure limits set by the regulatory agencies. It is a regulatory requirement and it is mandated that all radiation safety programs follow the ALARA principle.

In order to maintain ALARA, it is important to remember that radiation protection consists of time, distance, and shielding (TSD):

- **Time** : Minimize exposure time
- **Distance** : Maximize distance (between you and the source)
- **Shielding** : use appropriate radiation shielding



The most effective shielding for X rays is lead or concrete. Patients should be shielded to protect their thyroid and reproductive organs, and the X-ray technician should wear a leaded apron. Our handheld X-ray systems come equipped with a leaded-plastic backscatter shield which is very effective. With this shield, leaded aprons may not be required by your regulator, but it's always a safe bet to wear the apron anyway.

Pregnancy, owing to the fetus is undergoing rapid cell reproduction, it is important to reduce radiation exposure during pregnancy. As the X-ray operator, if you are, or become, pregnant, you should notify your employer immediately. It is your responsibility to declare your pregnancy. For the safety of your patients, you should question the patient regarding the possibility of them being pregnant. If the patient is, or may be, pregnant, they should be advised by your radiation safety officer prior to exposure.

Medical Procedure Doses

Dental imaging procedures contribute to a Much lower patient than other imaging studies. The table to the right presents typical patient Doses associated with various medical imaging procedures.

Procedure	Dose (mSv)
X-ray (single exposure)	
Hand/Foot	0.005
Dental	0.005
Chest	0.02
Abdomen	0.60
Pelvis	0.70
Mammogram (2 views)	0.70
CT(multiple exposures)	
Head	2
Chest	7
Full Body	10

**Data source: NRC

Worker Radiation Dose Limits

Occupational dose limits are set by regulatory agencies to limit cancer risk as well as the other potential biological effects of radiation. Annual occupational dose limits, as established in U.S. federal law (10 CFR 20) are provided below, however some locally established dose limits may be more protective. Check with your local regulator for dose limits that apply specifically to you.

Type of Limit	Occupational Dose Limit
Total effective dose equivalent	50 mSv
Lens of the eye	150 mSv
Skin	500 mSv
Hands and feet	500 mSv
Embryo/fetus	5 mSv (over the length of pregnancy)

**from 10CFR20.1202 and 10CFR20.1208

XR-01 Safety

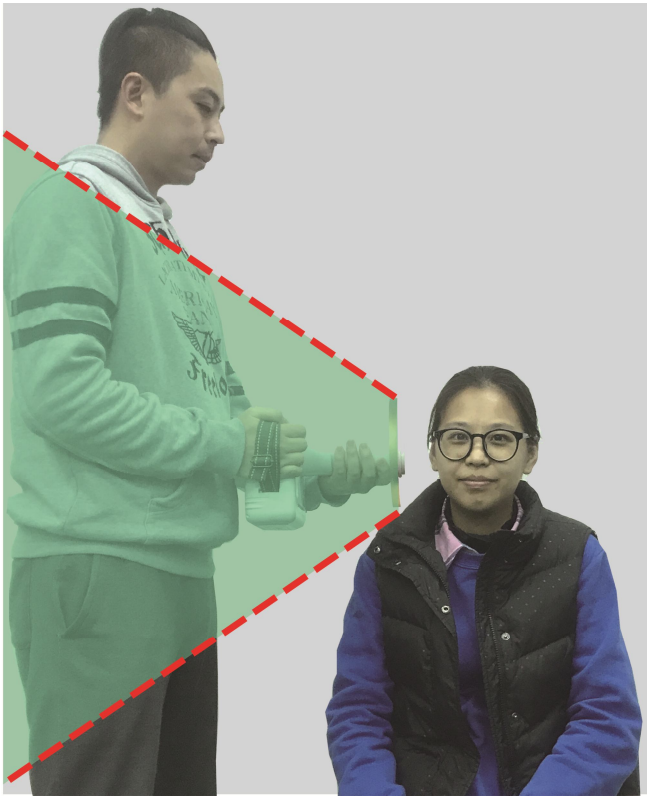
Backscatter Shield

The XR-01 has a circular, lead infused plastic disc (0.35 mm lead-equivalent) surrounding the X-ray beam emission port. The purpose of this "backscatter shield" is to absorb radiation scattered from the patient's jaw so that it doesn't reach the operator. The backscatter shield should never be removed, as this shield is very effective at reducing radiation scatter in the direction of the operator. As seen by the figure, the shield, in relation to the patient's head, provides a safety zone in which the operator should remain during exposures.

(Please Note: This photo was taken in a studio. In the clinical setting, the patient and technician should be wearing leaded protection.)

The backscatter shield provides a safety zone fo

Additionally, the emission port should be held close to the patient to maximize the backscatter protection zone. As the cone and shield move farther from the cheek, the angle defining the backscatter protection zone decreases.



Dosimetry

XR-01 has been shown to be a very safe portable X-ray system when used as intended. The occupational dose from leakage radiation at 1 cm from the case is less than 0.05 mSv to the fingers for an entire work year. And, as long as the operator remains within the safety zone (provided by the backscatter shield), their dose to the whole body is less than 0.20 mSv. These dose estimates assume that the operator makes 7,200 dental X-rays each year; the unit is very safe. For reference, the regu- latory dose limits are 500 mSv to the fingers and 50 mSv to the whole body.

Accidental Exposure Prevention

Accidental exposures are easy to prevent if the operator remains aware of the direction in which the emission port is pointing and the on/off status of the XR-01. As a general rule, whether on or off, the operator should NEVER point the XR-01 emission port at anyone, except the area of the patient about to be radiographed. Exposure occurs only when the activation button is pressed. The operator should remain vigilant and keep their finger off the activation button until ready for the intended exposure.

As the operator, it is important to be aware of your surroundings in order to maintain ALARA. Always ensure that you are within the backscatter protection zone, and that all unnecessary persons are out of the room prior to initiating an exposure.

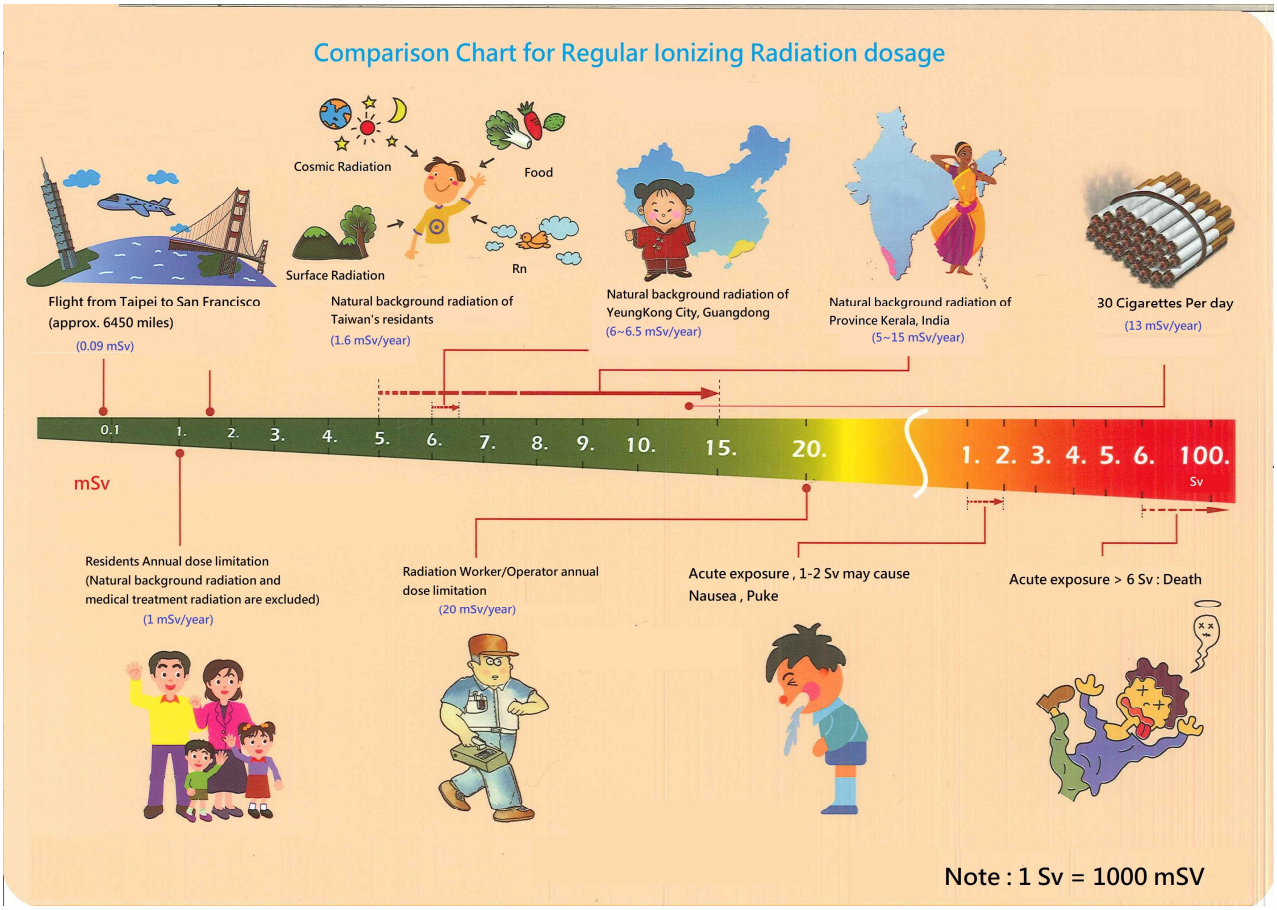
When taking an image, operator will hear a steady tone during the exposure; this sound will end when the selected time has passed. As a safety feature, the expo- sure will stop when the activation button is released, even if the selected time cycle is not complete.

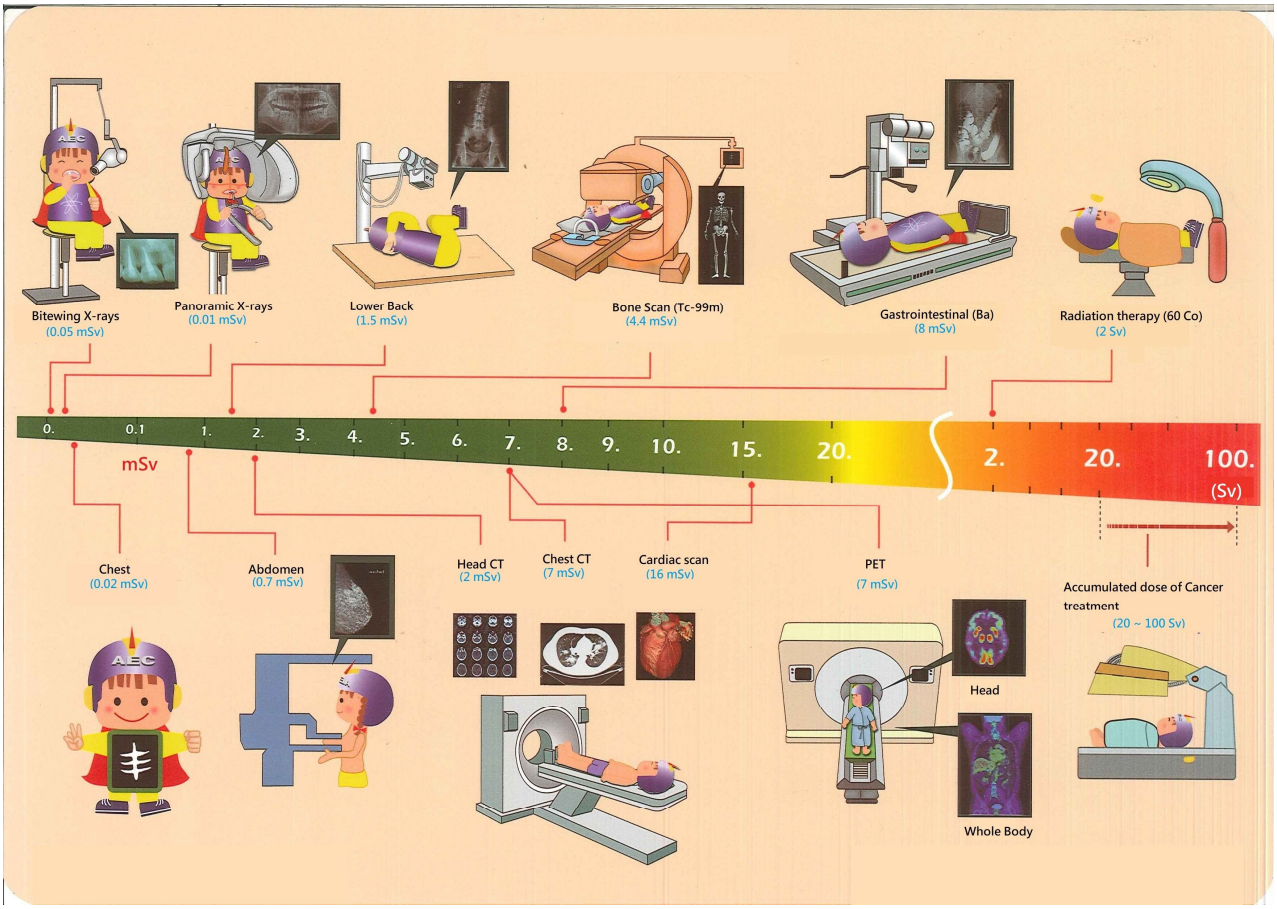
Exposure Time

There is only one variable of exposure on the XR-01 that can be changed for a given radiograph, exposure time. The XR-01 has exposure factors of mA and kV that are fixed and cannot be changed by the operator. The exposure time is changed based on patient age (adult or child), image receptor (film or digital or PSP), and the location of teeth being imaged. The operator makes selections of age, receptor, and position on the XR-01, and in turn the XR-01 provides a suggested range of ex- posure time in increments of 0.01 seconds. For example, a selection of adult, digital (sensor), molar results in suggested time option of 0.40 seconds (see chart below). See the User's Manual for more details on selecting the exposure time. (refer to user's manual, P33)

Item	Part		Exposure Time
Phosphor Plate	Adult	Anterior	0.27 sec
		Posterior	0.32 sec
		Bite Wings	0.34 sec
	Child	Anterior	0.15 sec
		Posterior	0.26 sec
		Bite Wings	0.27 sec
Digital Sensor	Adult	Anterior	0.20 sec
		Posterior	0.27 sec
		Bite Wings	0.29 sec
	Child	Anterior	0.15 sec
		Posterior	0.22 sec
		Bite Wings	0.24 sec

There is a direct correlation between exposure time and dose. If exposure time is increased, patient dose increases. There is certainly a trade-off between image quality and patient dose. It is important to practice ALARA by keeping dose as low as possible while maintaining adequate image quality for diagnosis. Exposure to the operator and the patient should be limited and having to repeat images should be avoided.


Comparison Chart for Regular Ionizing Radiation dosage
Cosmic Radiation
Food
Surface Radiation
Rn
Flight from Taipei to San Francisco (approx. 6450 miles)
(0.09 mSv)
Natural background radiation of Taiwan's residants
(1.6 mSv/year)
Natural background radiation of YeungKong City, Guangdong
(6~6.5 mSv/year)
Natural background radiation of Province Kerala, India
(5~15 mSv/year)
30 Cigarettes Per day
(13 mSv/year)
0.1 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 15. 20.
1. 2. 3. 4. 5. 6. 100.
mSv
Sv
Residents Annual dose limitation (Natural background radiation and medical treatment radiation are excluded)
(1 mSv/year)
Radiation Worker/Operator annual dose limitation
(20 mSv/year)
Acute exposure , 1-2 Sv may cause Nausea , Puke
Acute exposure > 6 Sv : Death
Note : 1 Sv = 1000 mSV


Bitewing X-rays
(0.05 mSv)
Panoramic X-rays
(0.01 mSv)
Lower Back
(1.5 mSv)
Bone Scan (Tc-99m)
(4.4 mSv)
Gastrointestinal (Ba)
(8 mSv)
Radiation therapy (60 Co)
(2 Sv)
0. 0.1 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 15. 20.
2. 20. 100.
mSv
(Sv)
Chest
(0.02 mSv)
Abdomen
(0.7 mSv)
Head CT
(2 mSv)
Chest CT
(7 mSv)
Cardiac scan
(16 mSv)
PET
(7 mSv)
Accumulated dose of Cancer treatment
(20 ~ 100 Sv)
Head
Whole Body