Equipment Packet: X-Ray Systems

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Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of x-rays systems.

Part I: External From the Packet:

1. **An Introduction to X-Rays:** PowerPoint

Part II: Included in this Packet:

1. Operation and Use of X-Ray Systems

Featured in this Section:

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

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Brief Overview of X-Rays

User Care of Medical Equipment – First line maintenance for end users

Chapter 4.22 X-Ray Machines

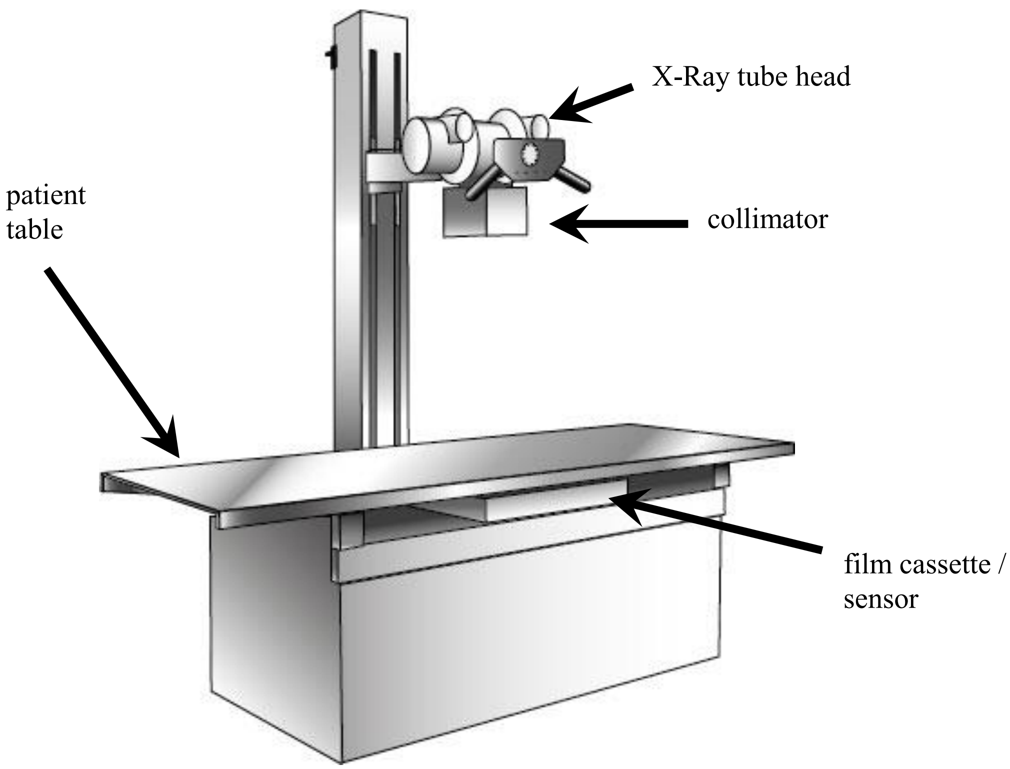
Function

X-Ray machines are used for imaging bones and hard tissues and diagnosing fractures, joint defects, choked lungs etc. Sometimes contrast agents are also used to highlight any defects in the abdomen under X-rays.

How it works

X-rays are high energy electromagnetic waves. The transformer produces a high voltage that directs electrons onto a target in the machine head. X-rays are produced by the target and are directed into beams by a collimator towards the human body. Soft body tissue absorbs less X-rays, i.e., passes more of the radiation, whereas bone and other solids prevent most of the X-rays from going through. A photographic film or electronic sensor displays how much X ray has passed through, forming an image of the interior of the body. Bone appears nearly white, because few X-rays strike the corresponding part of the film, leaving it largely unexposed; soft tissue allows much more radiation to pass through, darkening the film in those places.

Users must ensure proper radiation safety protocols and supervision are in place. See Chapter 9 for suitable references and further information.



(control panel and transformer not shown)

Strengthening Specialised Clinical Services in the Pacific. User Care of Medical Equipment: A first line maintenance guide for end users. (2015).

Radiographic, Fluoroscopic System

UMDNS	GMDN
16885 Radiographic/Fluoroscopic Systems, General-Purpose	37645 Stationary basic diagnostic x-raysystem, digital

Other common names:
General-Purpose Radiographic/Fluoroscopic Systems; Radiographic/Fluoroscopic Units, General-Purpose; Tables, Radiographic/Fluoroscopic; Direct-Controlled Radiographic/Fluoroscopic Systems; Remote-Controlled Radiographic/Fluoroscopic Systems

Health problem addressed

This technology is effective in arthrography, bronchography, gastrointestinal and biliary tree studies, hysterosalpingography, intravenous and retrograde pyelography, myelography, and sialography. Other applications include locating ingested foreign materials; localizing lesions for needle aspiration or biopsy; highlighting congenital anatomic abnormalities; diagnosing congestive heart failure; and evaluating chest pain.

Product description

These devices consist of a combination of a patient support unit (usually a table base and a movable tabletop), an under-table x-ray tube and holder, x-ray generators, a power-assisted spot-film device, an image intensifier, radiation shields, a Bucky film tray, an overhead x-ray tube and ceiling support for follow-up radiography, and a control panel.

Principles of operation

Most R/F systems allow spot filming of the image to produce an x-ray film for later detailed study by the radiologist and for film archiving. For routine radiography and follow-up x-ray scans after studies that use contrast media (e.g., gastrointestinal studies), most systems include an under-table Bucky tray for use with an overhead x-ray tube.

Operating steps

Patients are positioned on the x-ray table and a catheter inserted (procedure-dependent). The x-ray scanner will be used to produce fluoroscopic images. Depending on the procedure, a dye or contrast substance may be injected into the patient via an IV line in order to better visualize the organs or structures being studied. After the procedure is complete the IV line will be removed.

Reported problems

Typical problems include mechanical issues; unexpected failures of safety features; overexposure or unexpected exposure to radiation; breakage or weakening of mechanical supports; overheating in drive motors; table misalignments; inadequate radiation shielding; and noncompliance with regulatory codes.

Use and maintenance

User(s): Radiologic technician

Maintenance: Medical staff; technician; biomedical or clinical engineer

Training: Initial training by manufacturer and manuals

Environment of use

Settings of use: Hospitals; private practices; clinics; stand-alone imaging centers

Requirements: Radiation shielding (room, mobile, or overhead); stable power source

Product specifications

Approx. dimensions (mm): Configurable

Approx. weight (kg): Configurable

Consumables: NA

Price range (USD): 415,000 - 1,150,000

Typical product life time (years): 10

Shelf life (consumables): NA

Types and variations

Over- or under-table x-ray tube; C-arm; remote control; direct control

WHO. "Radiographic, Fluoroscopic System." From the publication: Core Medical Equipment. Geneva, Switzerland, 2011.

X-ray

X-radiation (composed of **X-rays**) is a form of electromagnetic radiation. X-rays have a wavelength in the range of 10 to 0.01 nanometers, corresponding to frequencies in the range 30 petahertz to 30 exahertz (3×10^{16} Hz to 3×10^{19} Hz) and energies in the range 120 eV to 120 keV. They are shorter in wavelength than UV rays. In many languages, X-radiation is called **Röntgen radiation**, after Wilhelm Conrad Röntgen, who is generally credited as their discoverer, and who had named them X-rays to signify an unknown type of radiation.[3] :1-2

Hand mit Ringen (Hand with Rings): print of Wilhelm Röntgen's first "medical" X-ray, of his wife's hand, taken on December 22, 1895 and presented to Professor Ludwig Zehnder of the Physik Institut, University of Freiburg, on 1 January 1896[1] [2]

X-rays from about 0.12 to 12 keV (10 to 0.10 nm wavelength), are classified as "soft" X-rays, and from about 12 to 120 keV (0.10 to 0.010 nm wavelength) as "hard" X-rays, due to their penetrating abilities.

Hard X-rays can penetrate solid objects, and their largest use is to take images of the inside of objects in diagnostic radiography and crystallography. As a result, the term *X-ray* is metonymically used to refer to a radiographic image produced using this method, in addition to the method itself. By contrast, soft X-rays can hardly be said to penetrate matter at all; for instance, the attenuation length of 600 eV (~ 2 nm) x-rays in water is less than 1 micrometer[4] X-rays are a form of ionizing radiation, and exposure to them can be a health hazard.

The distinction between X-rays and gamma rays has changed in recent decades. Originally, the electromagnetic radiation emitted by X-ray tubes had a longer wavelength than the radiation emitted by radioactive nuclei (gamma rays).[5] So older literature distinguished between X- and gamma radiation on the basis of wavelength, with radiation shorter than some arbitrary wavelength, such as 10^{-11} m, defined as gamma rays.[6] However, as shorter wavelength continuous spectrum "X-ray" sources such as linear accelerators and longer wavelength "gamma ray" emitters were discovered, the wavelength bands largely overlapped. The two types of radiation are now usually distinguished by their origin: X-rays are emitted by electrons outside the nucleus, while gamma rays are emitted by the nucleus.[5] [7] [8] [9]

Units of measure and exposure

The measure of X-rays ionizing ability is called the exposure:

- The coulomb per kilogram (C/kg) is the SI unit of ionizing radiation exposure, and it is the amount of radiation required to create one coulomb of charge of each polarity in one kilogram of matter.
- The roentgen (R) is an obsolete traditional unit of exposure, which represented the amount of radiation required to create one electrostatic unit of charge of each polarity in one cubic centimeter of dry air. 1.00 roentgen = 2.58×10^{-4} C/kg

However, the effect of ionizing radiation on matter (especially living tissue) is more closely related to the amount of energy deposited into them rather than the charge generated. This measure of energy absorbed is called the absorbed dose:

- The gray (Gy), which has units of (Joules/kilogram), is the SI unit of absorbed dose, and it is the amount of radiation required to deposit one joule of energy in one kilogram of any kind of matter.

- The rad is the (obsolete) corresponding traditional unit, equal to 10 millijoules of energy deposited per kilogram. 100 rad = 1.00 gray.

The equivalent dose is the measure of the biological effect of radiation on human tissue. For X-rays it is equal to the absorbed dose.

- The sievert (Sv) is the SI unit of equivalent dose, which for X-rays is numerically equal to the gray (Gy).
- The Roentgen equivalent man (rem) is the traditional unit of equivalent dose. For X-rays it is equal to the rad or 10 millijoules of energy deposited per kilogram. 1.00 Sv = 100 rem.

Medical X-rays are a significant source of *manmade* radiation exposure, accounting for 58% in the United States in 1987, but since most radiation exposure is natural (82%), medical X-rays only account for 10% of *total* American radiation exposure.[10]

Reported dosage due to dental X-rays seems to vary significantly. Depending on the source, a typical dental X-ray of a human results in an exposure of perhaps, 3,[11] 40,[12] 300,[13] or as many as 900[14] mrems (30 to 9,000 μSv).

Medical physics

X-ray K-series spectral line wavelengths (nm) for some common target materials.[15]

Target	$K\beta_1$	$K\beta_2$	$K\alpha_1$	$K\alpha_2$
Fe	0.17566	0.17442	0.193604	0.193998
Co	0.162079	0.160891	0.178897	0.179285
Ni	0.15001	0.14886	0.165791	0.166175
Cu	0.139222	0.138109	0.154056	0.154439
Zr	0.070173	0.068993	0.078593	0.079015
Mo	0.063229	0.062099	0.070930	0.071359

X-rays are generated by an X-ray tube, a vacuum tube that uses a high voltage to accelerate the electrons released by a hot cathode to a high velocity. The high velocity electrons collide with a metal target, the anode, creating the X-rays.[16] In medical X-ray tubes the target is usually tungsten or a more crack-resistant alloy of rhenium (5%) and tungsten (95%), but sometimes molybdenum for more specialized applications, such as when soft X-rays are needed as in mammography. In crystallography, a copper target is most common, with cobalt often being used when fluorescence from iron content in the sample might otherwise present a problem.

The maximum energy of the produced X-ray photon is limited by the energy of the incident electron, which is equal to the voltage on the tube, so an 80 kV tube cannot create X-rays with an energy greater than 80 keV. When the electrons hit the target, X-rays are created by two different atomic processes:

1. X-ray fluorescence: If the electron has enough energy it can knock an orbital electron out of the inner electron shell of a metal atom, and as a result electrons from higher energy levels then fill up the vacancy and X-ray photons are emitted. This process produces an emission spectrum of X-ray frequencies, sometimes referred to as the spectral lines. The spectral lines generated depend on the target (anode) element used and thus are called characteristic lines. Usually these are transitions from upper shells into K shell (called K lines), into L shell (called L lines) and so on.
2. *Bremsstrahlung*: This is radiation given off by the electrons as they are scattered by the strong electric field near the high-Z (proton number) nuclei. These X-rays have a continuous spectrum. The intensity of the X-rays increases linearly with decreasing frequency, from zero at the energy of the incident electrons, the voltage on the X-ray tube.

So the resulting output of a tube consists of a continuous bremsstrahlung spectrum falling off to zero at the tube voltage, plus several spikes at the characteristic lines. The voltages used in diagnostic X-ray tubes, and thus the highest energies of the X-rays, range from roughly 20 to 150 kV.[17]

In medical diagnostic applications, the low energy (soft) X-rays are unwanted, since they are totally absorbed by the body, increasing the dose. Hence, a thin metal sheet, often of aluminum, called an X-ray filter) is usually placed over the window of the X-ray tube, filtering out the low energy components in the spectrum. This is called *hardening* the beam.

Both of these X-ray production processes are very inefficient, with a production efficiency of only about one percent, and hence, to produce a usable flux of X-rays, a high percentage of the electric power inputted is released as waste heat. The designers must design the X-ray tube to dissipate this excess heat.

Radiographs obtained using X-rays can be used to identify a wide spectrum of pathologies. Due to their short wavelengths, in medical applications X-rays act more like particles than waves. This is in strong contrast to the application of X-rays in crystallography, X-ray crystallography, where their wave-like nature is more important.

To make an X-ray image of human or animal bones, short X-ray pulses illuminate the body or limb, with radiographic film placed behind it. Any bones that are present absorb most of the X-ray photons by photoelectric processes. This is because bones have a higher electron density than soft tissues. [Note that bones contain a high percentage of calcium (20 electrons per atom), potassium (19 electrons per atom) magnesium (12 electrons per atom), and phosphorus (15 electrons per atom). The X-rays that pass through the flesh leave a latent image in the photographic film. When the film is developed, the parts of the image corresponding to higher X-ray exposure are dark, leaving a white shadow of bones on the film.

To generate an image of the cardiovascular system, including the arteries and veins (angiography) an initial image is taken of the anatomical region of interest. A second image is then taken of the same region after iodinated contrast material has been injected into the blood vessels within this area. These two images are then digitally subtracted, leaving an image of only the iodinated contrast outlining the blood vessels. The radiologist or surgeon then compares the image obtained to normal anatomical images to determine if there is any damage or blockage of the vessel.

A specialized source of X-rays which is becoming widely used in research is synchrotron radiation, which is generated by particle accelerators. Its unique features are X-ray outputs many orders of magnitude greater than those of X-ray tubes, wide X-ray spectra, excellent collimation, and linear polarization.[18]

Detectors

Photographic plate

The detection of X-rays is based on various methods. The most commonly known methods are photographic plates, photographic film in cassettes, and rare earth screens. Regardless of what is "catching" the image, they are all categorized as "Image Receptors" (IR).

Before the advent of the digital computer and before the invention of digital imaging, photographic plates were used to produce most radiographic images. The images were produced right on the glass plates. Photographic film largely replaced these plates, and it was used in X-ray laboratories to produce medical images. In more recent years, computerized and digital radiography has been replacing photographic film in medical and dental applications, though film technology remains in widespread use in industrial radiography processes (e.g. to inspect welded seams). Photographic plates are mostly things of history, and their replacement, the "intensifying screen", is also fading into history. The metal silver (formerly necessary to the radiographic & photographic industries) is a non-renewable resource. Thus it is beneficial that this is now being replaced by digital (DR) and computed (CR) technology. Where photographic films required wet processing facilities, these new technologies do not. The digital archiving of images utilizing these new technologies also saves storage space.

Since photographic plates are sensitive to X-rays, they provide a means of recording the image, but they also required much X-ray exposure (to the patient), hence intensifying screens were devised. They allow a lower dose to the patient, because the screens take the X-ray information and intensify it so that it can be recorded on film positioned next to the intensifying screen.

The part of the patient to be X-rayed is placed between the X-ray source and the image receptor to produce a shadow of the internal structure of that particular part of the body. X-rays are partially blocked ("attenuated") by dense tissues such as bone, and pass more easily through soft tissues. Areas where the X-rays strike darken when developed, causing bones to appear lighter than the surrounding soft tissue.

Contrast compounds containing barium or iodine, which are radiopaque, can be ingested in the gastrointestinal tract (barium) or injected in the artery or veins to highlight these vessels. The contrast compounds have high atomic numbered elements in them that (like bone) essentially block the X-rays and hence the once hollow organ or vessel can be more readily seen. In the pursuit of a non-toxic contrast material, many types of high atomic number elements were evaluated. For example, the first time the forefathers used contrast it was chalk, and was used on a cadaver's vessels. Unfortunately, some elements chosen proved to be harmful – for example, thorium was once used as a contrast medium (Thorotrast) – which turned out to be toxic in some cases (causing injury and occasionally death from the effects of thorium poisoning). Modern contrast material has improved, and while there is no way to determine who may have a sensitivity to the contrast, the incidence of "allergic-type reactions" are low. (The risk is comparable to that associated with penicillin.)

Photostimulable phosphors (PSPs)

An increasingly common method is the use of photostimulated luminescence (PSL), pioneered by Fuji in the 1980s. In modern hospitals a photostimulable phosphor plate (PSP plate) is used in place of the photographic plate. After the plate is X-rayed, excited electrons in the phosphor material remain "trapped" in "colour centres" in the crystal lattice until stimulated by a laser beam passed over the plate surface. The light given off during laser stimulation is collected by a photomultiplier tube and the resulting signal is converted into a digital image by computer technology, which gives this process its common name, computed radiography (also referred to as **digital radiography**). The PSP plate can be reused, and existing X-ray equipment requires no modification to use them.

Geiger counter

Initially, most common detection methods were based on the ionization of gases, as in the Geiger-Müller counter: a sealed volume, usually a cylinder, with a mica, polymer or thin metal window contains a gas, a cylindrical cathode and a wire anode; a high voltage is applied between the cathode and the anode. When an X-ray photon enters the cylinder, it ionizes the gas and forms ions and electrons. Electrons accelerate toward the anode, in the process causing further ionization along their trajectory. This process, known as a Townsend avalanche, is detected as a sudden current, called a "count" or "event".

In order to gain energy spectrum information, a diffracting crystal may be used to first separate the different photons. The method is called wavelength dispersive X-ray spectroscopy (WDX or WDS). Position-sensitive detectors are often used in conjunction with dispersive elements. Other detection equipment that is inherently energy-resolving may be used, such as the aforementioned proportional counters. In either case, use of suitable pulse-processing (MCA) equipment allows digital spectra to be created for later analysis.

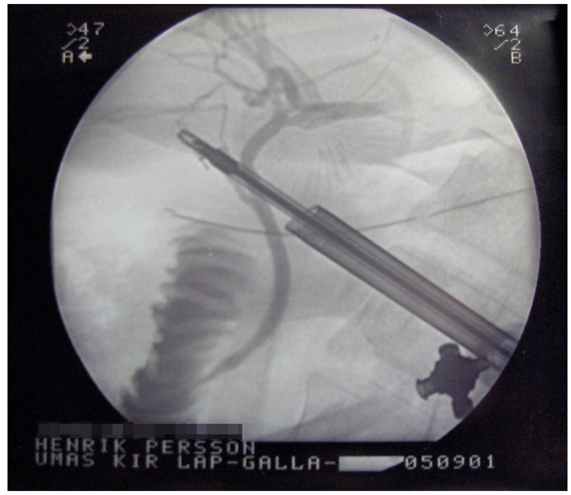
For many applications, counters are not sealed but are constantly fed with purified gas, thus reducing problems of contamination or gas aging. These are called "flow counters".

Scintillators

Some materials such as sodium iodide (NaI) can "convert" an X-ray photon to a visible photon; an electronic detector can be built by adding a photomultiplier. These detectors are called "scintillators", filmscreens or "scintillation counters". The main advantage of using these is that an adequate image can be obtained while subjecting the patient to a much lower dose of X-rays.

Image intensification

X-rays are also used in "real-time" procedures such as angiography or contrast studies of the hollow organs (e.g. barium enema of the small or large intestine) using fluoroscopy acquired using an X-ray image intensifier. Angioplasty, medical interventions of the arterial system, rely heavily on X-ray-sensitive contrast to identify potentially treatable lesions.



X-ray during cholecystectomy

Direct semiconductor detectors

Since the 1970s, new semiconductor detectors have been developed (silicon or germanium doped with lithium, Si(Li) or Ge(Li)). X-ray photons are converted to electron-hole pairs in the semiconductor and are collected to detect the X-rays. When the temperature is low enough (the detector is cooled by Peltier effect or even cooler liquid nitrogen), it is possible to directly determine the X-ray energy spectrum; this method is called energy dispersive X-ray spectroscopy (EDX or EDS); it is often used in small X-ray fluorescence spectrometers. These detectors are sometimes called "solid state detectors". Detectors based on cadmium telluride (CdTe) and its alloy with zinc, cadmium zinc telluride, have an increased sensitivity, which allows lower doses of X-rays to be used.

Practical application in medical imaging started in the 1990s. Currently amorphous selenium is used in commercial large area flat panel X-ray detectors for mammography and chest radiography. Current research and development is focused around pixel detectors, such as CERN's energy resolving Medipix detector.

Note: A standard semiconductor diode, such as a 1N4007, will produce a small amount of current when placed in an X-ray beam. A test device once used by Medical Imaging Service personnel was a small project box that contained several diodes of this type in series, which could be connected to an oscilloscope as a quick diagnostic.

Silicon drift detectors (SDDs), produced by conventional semiconductor fabrication, now provide a cost-effective and high resolving power radiation measurement. Unlike conventional X-ray detectors, such as Si(Li)s, they do not need to be cooled with liquid nitrogen.

Scintillator plus semiconductor detectors (indirect detection)

With the advent of large semiconductor array detectors it has become possible to design detector systems using a scintillator screen to convert from X-rays to visible light which is then converted to electrical signals in an array detector. Indirect Flat Panel Detectors (FPDs) are in widespread use today in medical, dental, veterinary and industrial applications.

The array technology is a variant on the amorphous silicon TFT arrays used in many flat panel displays, like the ones in computer laptops. The array consists of a sheet of glass covered with a thin layer of silicon that is in an amorphous or disordered state. At a microscopic scale, the silicon has been imprinted with millions of transistors arranged in a highly ordered array, like the grid on a sheet of graph paper. Each of these thin film transistors (TFTs) is attached to a light-absorbing photodiode making up an individual pixel (picture element). Photons striking the photodiode are converted into two carriers of electrical charge, called electron-hole pairs. Since the number of charge carriers produced will vary with the intensity of incoming light photons, an electrical pattern is created that can be swiftly converted to a voltage and then a digital signal, which is interpreted by a computer to produce a digital image. Although silicon has outstanding electronic properties, it is not a particularly good absorber of X-ray photons. For this reason, X-rays first impinge upon scintillators made from e.g. gadolinium oxysulfide or caesium iodide. The scintillator absorbs the X-rays and converts them into visible light photons that then pass onto the photodiode array.

Visibility to the human eye

While generally considered invisible to the human eye, in special circumstances X-rays can be visible.[19] Brandes, in an experiment a short time after Röntgen's landmark 1895 paper, reported after dark adaptation and placing his eye close to an X-ray tube, seeing a faint "blue-gray" glow which seemed to originate within the eye itself.[20] Upon hearing this, Röntgen reviewed his record books and found he too had seen the effect. When placing an X-ray tube on the opposite side of a wooden door Röntgen had noted the same blue glow, seeming to emanate from the eye itself, but thought his observations to be spurious because he only saw the effect when he used one type of tube. Later he realized that the tube which had created the effect was the only one powerful enough to make the glow plainly visible and the experiment was thereafter readily repeatable. The knowledge that X-rays are actually faintly visible to the dark-adapted naked eye has largely been forgotten today; this is probably due to the desire not to repeat what would now be seen as a recklessly dangerous and potentially harmful experiment with ionizing radiation. It is not known what exact mechanism in the eye produces the visibility: it could be due to conventional detection (excitation of rhodopsin molecules in the retina), direct excitation of retinal nerve cells, or secondary detection via, for instance, X-ray induction of phosphorescence in the eyeball with conventional retinal detection of the secondarily produced visible light.

Though X-rays are otherwise invisible it is possible to see the ionization of the air molecules if the intensity of the X-ray beam is high enough. The beamline from the wiggler at the ID11 [21] at ESRF is one example of such high intensity.[22]

Medical uses

X-ray image of the paranasal sinuses, lateral projection

Since Röntgen's discovery that X-rays can identify bone structures, X-rays have been developed for their use in medical imaging. Radiology is a specialized field of medicine. Radiologists employ radiography and other techniques for diagnostic imaging. This is probably the most common use of X-ray technology.

X-rays are especially useful in the detection of pathology of the skeletal system, but are also useful for detecting some disease processes in soft tissue. Some notable examples are the very common chest X-ray, which can be used to identify lung diseases such as pneumonia, lung cancer or pulmonary edema, and the abdominal X-ray, which can detect intestinal obstruction, free air (from visceral perforations) and free fluid (in ascites). X-rays may also be used to detect pathology such as gallstones (which are rarely radiopaque) or kidney stones which are often (but not always) visible. Traditional plain X-rays are less useful in the imaging of soft tissues such as the brain or muscle. Imaging alternatives for soft tissues are computed axial tomography (CAT or CT scanning)[23] , magnetic resonance imaging (MRI) or ultrasound. The latter two do not subject the individual to ionizing radiation. In addition to plain X-rays and CT scans, physicians use fluoroscopy as an X-ray test methodology. This method often uses administration of a medical contrast material (intravenously, orally or via enema). Examples include cardiac catheterization (to examine for coronary artery blockages) and Barium swallow (to examine for esophageal disorders.

Head CT scan (transverse plane) slice – a modern application of X-rays

Since 2005, X-rays are listed as a carcinogen by the U.S. government.[24] . The use of X-rays as a treatment is known as radiotherapy and is largely used for the management (including palliation) of cancer; it requires higher radiation energies than for imaging alone.

Risks of Medical Diagnostic X-rays

X-rays are a relatively safe method of investigation and the radiation exposure is relatively low, depending upon the study. Experimental and epidemiological data, however, do not support the proposition that there is a threshold dose of radiation below which there is no increased risk of cancer.[25] Diagnostic X-rays account for 14% of the total annual radiation exposure from man-made and natural sources worldwide.[26] It is estimated that the additional radiation will increase a person's cumulative risk of getting cancer by age 75 by 0.6-1.8%.[27] The amount of absorbed radiation depends upon the type of X-ray test and the body part involved.[28] CT and fluoroscopy entail higher doses of radiation than do plain X-rays.

To place the increased risk in perspective, a plain chest X-ray or dental X-ray will expose a person to the same amount from background radiation that we are exposed to (depending upon location) everyday over 10 days.[29] Each such X-ray would add less than 1 per 1,000,000 to the lifetime cancer risk. An abdominal or chest CT would be the equivalent to 2–3 years of background radiation, increasing the lifetime cancer risk between 1 per 10,000 and 1 per 1,000.[29] These numbers are very small compared to the roughly 40% chance of developing any cancer during our lifetime.[30]

The risk of radiation is greater to unborn babies, so in pregnant patients, the benefits of the investigation (X-ray) should be balanced with the potential hazards to the unborn fetus.[31] [32] In the US, there are an estimated 62,000,000 CT scans performed annually, including more than 4,000,000 on children.[28] Avoiding unnecessary X-rays (especially CT scans) will reduce radiation dose and any associated cancer risk.[33]

Shielding against X-Rays

Lead is the most common shield against X-rays because of its high density (11340 kg/m^3), stopping power, ease of installation and low cost. The maximum range of a high-energy photon such as an X-ray in matter is infinite; at every point in the matter traversed by the photon, there is a probability of interaction. Thus there is a very small probability of no interaction over very large distances. The shielding of photon beam is therefore exponential (with an attenuation length being close to the radiation length of the material); doubling the thickness of shielding will square the shielding effect.

The following table shows the recommended thickness of lead shielding in function of X-ray energy, from the Recommendations by the Second International Congress of Radiology.[34]

X-Rays generated by peak voltages not exceeding	Minimum thickness of Lead
75 kV	1.0 mm
100 kV	1.5 mm
125 kV	2.0 mm
150 kV	2.5 mm
175 kV	3.0 mm
200 kV	4.0 mm
225 kV	5.0 mm
300 kV	9.0 mm
400 kV	15.0 mm
500 kV	22.0 mm
600 kV	34.0 mm
900 kV	51.0 mm

References

- NASA [53] Goddard Space Flight centre introduction to X-rays.

External links

- An Example of a Radiograph [54]
- A Photograph of an X-ray Machine [55]
- X-ray Safety [56]
- An X-ray tube demonstration (Animation) [57]
- 1896 Article: "On a New Kind of Rays" [58]
- "Digital X-Ray Technologies Project" [59]
- A video of a medical X-ray procedure example [60]
- What is Radiology? [61] a simple tutorial
- 50,000 X-ray, MRI, and CT pictures [62] MedPix medical image database
- Index of Early Bremsstrahlung Articles [63]

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Radiation Dose Management

Radiation Dose Management

An indicator of the radiation exposure required to generate a CR or DR image is provided on many systems. This indicator can be called the **Sensitivity Index** (SI), the **Log Median** (LgM), the **Exposure Index** (EI) or similar parameter and can be used to gauge the adequacy of an exposure. Note that these parameters are generally referenced to exposures generated under specific conditions, e.g. X-ray energy, beam filtration etc., and therefore can be regarded only as a crude indicator of patient dose.

Dose-Area Product (DAP) - see the discussion below - records can be used to review exposure trends over time in the clinical environment[12]. One of the aims here is to reduce the phenomenon of **Exposure Creep**, where exposures slowly increase over time in the pursuit of images of excellent quality, for example. Another aim here can be to review exposure measurements relative to Diagnostic Reference Levels (DRLs).

Retake analysis can also be combined with such exposure reviews so that, for instance, a team of X-ray personnel can work collectively to improve performance. Reasons for retake radiographs can be catalogued into radiographic exposure errors, including those resulting from patient movement, when too long an exposure is used, for example, and radiographic positioning errors[13].

Skin Injury

There has been considerable interest in recent years in reducing fluoroscopic doses following numerous reports of epilation and skin injuries to patients from prolonged interventional procedures[14]. Regulatory agencies throughout the world have responded to ICRP deliberations[15] and have issued recommendations to the effect that the person responsible for the apparatus:

- Needs to establish standard operating procedures and clinical protocols.
- Should know typical radiation dose rates for the specific fluoroscopic system.
- Must assess the impact of each procedure's protocol on the potential for radiation injury to patients.
- Must modify the protocol to limit the dose.
- Should enlist a qualified health physicist to provide assistance in developing and optimising dose minimisation techniques.
- Should give consideration to rotating the tube and the image intensifier through 180° during prolonged neuroradiological procedures.
- Should give consideration to carrying out those cardiology procedures where multiple stenting is necessary over a period of weeks to fractionate the radiation dose.
- Should give due consideration when purchasing new equipment to features offered by the manufacturer that may aid in reducing the patient dose.

Skin injury has been found to be sensitive to factors such as previous high dose exposure, medication, connective tissue disease and diabetes mellitus. A review of hair and skin effects is given in Balter *et al.* (2010)[16]. Single-site skin doses in interventional radiology above 2 Gy, for example, have been found to cause erythema and epilation and higher doses to cause permanent skin damage.

Mechanisms of patient dose reduction which have been developed include:

- **Pulsed Fluoroscopy**: this is a feature which uses short pulses of radiation of variable duration and frequency (Fig. 3.1). Such pulsing can be generated by switching the mA in the HV generator or by controlling the electron beam of the XRT, as in the Grid-Controlled XRT. Following each exposure pulse, the image is stored in image memory and displayed continuously until the next pulse to give a contiguous visual effect. Dose rate reductions of the order of 90% are achievable using this approach although a stroboscopic artefact may result when imaging fast moving objects such as the heart.

- **Additional Filtration**: the addition of a thin Cu filter (0.1 - 0.3 mm) at the output of the X-ray tube can generate substantial dose reductions without a detrimental impact on image quality. A refinement to this approach is the Region of Interest (ROI) filter which provides little filtration to the central region of the field of view and substantial filtration in peripheral regions - the rationale being that high image quality is required in the centre of the field and noisier image data of lower contrast is tolerable outside of this region for providing general anatomical information only. This latter mechanism has also been referred to as the X-ray fovea.

- **Collimation**: Since the use of conventional rectangular collimators used with XII-based fluoroscopy systems (which generate circular images) results in unused exposure, some modern systems use circular collimators. These typically have the capability of automatically responding to changes in source-to-image distance and in the electronic zoom selection used in the XII. A complex collimator assembly, based on adjustable multileaf absorbers, results and can include robotic control. Another feature in this regard is referred to as radiation-free collimator positioning and involves storing an image in computer memory, stopping the exposure and adjusting the collimator controls so that the computer generates a graphics display of the collimated region.

- **Digital Image Storage**: the fact that images are stored in computer memory (see the following chapter) allows the possibility of using features such as **Last-Image-Hold** (LIH), where the most recently acquired image is displayed continuously without irradiating the patient, **Reference Imaging**, where a previously acquired image is displayed on a second video monitor for comparison purposes, **Image Browsing**, where multiple images acquired previously can be displayed, and **Fluoroscopic Loop**, where an imaging sequence can be continuously replayed for closer inspection.

Automatic Brightness Control (ABC) can be used in conjunction with exposure pulse control and additional filtration to generate what is called **Automatic Dose Rate Control** (ADRC)[17]. Here, different filters can be selected automatically for insertion into the X-ray beam depending on the particular exposure factors encountered when screening commences. For example, some ADRC systems can generate the selection of:

- a kilovoltage which remains constant during the imaging sequence,
- an mA pulse height and width which maintains image brightness, and
- the automatic insertion of Cu filters of different thicknesses,

depending of the thickness and composition of the body part being examined. Such systems can be used with four selectable copper filters, for instance, of thickness 0.2, 0.3, 0.6 and 0.9 mm depending on patient thickness. Since absorbed doses are greater for larger patient thicknesses, because higher exposure factors are required to acquire images of adequate brightness, a filter thickness is chosen that hardens the X-ray beam appropriately and reduces patient dose. This is referred to as **Spectral Filtering**. The ADRC system can cause the HV generator to select a constant kV, depending on the Cu filter thickness, and vary the mA pulse height depending on the anatomy. For example, it may select 60 kV with a 0.9 mm Cu filter for a thin body part, such as the foot, and 80 kV with a 0.3 Cu filter for a body part greater than 20 cm thick, with the mA adjusted for each exposure by the generation of pulses of the necessary intensity.

Most fluoroscopy systems also feature an audible alert which sounds after a 'beam-on' time of five minutes. The accumulated exposure time is generally displayed in real-time on the image display, along with the kV and mA - and dose rate readings when a Dose-Area Product meter (see below) is installed.

Staff Dose

Three sources of exposure arise for staff when operating radiography and fluoroscopy equipment: the primary beam used to expose the patient, leakage radiation from the XRT and scattered radiation from the patient. Lead aprons can be worn and distance exploited to minimise the impact of leakage and scattered radiation in instances where staff are required to remain in an X-ray room or operating theatre during exposures. Note however that lead aprons only attenuate X-rays by ~90-95%, depending on their lead equivalence. These aprons are generally made from lead-impregnated vinyl, are equivalent to 0.25-0.5 mm of lead and weigh about 5 kg. Lighter aprons with similar attenuation can be made from composites, such as tungsten and tin, and may be of value to staff during long interventional procedures. Aprons of 0.5 mm lead equivalence should be used by staff who remain in close proximity to the patient during exposures. The safer style is the wrap-around apron, in comparison to backless designs. From a practical perspective, lead aprons should always be stored vertically on racks since folding them can introduce cracks which reduce their effectiveness. In addition, they should be radiographed at least annually to check for any such signs of wear and tear.

In addition, the number of staff in the immediate vicinity of the patient can be kept to a minimum and warnings given when an exposure is impending. Ideally, staff should be behind a shielded operator's console area during an exposure. The design of X-ray rooms is such that, in general, adequate shielding and distance ensures that doses to any person in the room, behind the console or, indeed, external to the room can be optimised.

In some interventional cases, the interventionist may find it necessary to have their hands in the primary beam for parts of the procedure. Such repeated exposure over a number of years may potentially lead eventually to radiation dermatitis of the hands. Dose optimisation in such circumstances can be achieved by arranging the imaging system so that the hands are kept on the beam exit side of the patient. For example, if the XRT is positioned under the patient then the hands manipulating the catheter should be on top of the patient.

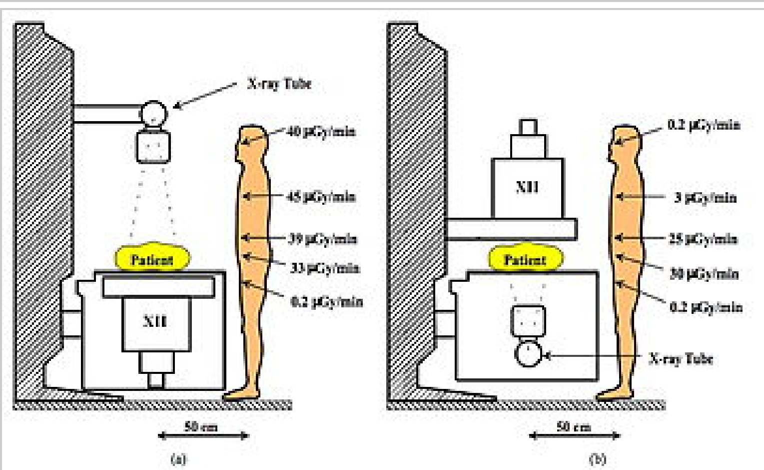

Fig. 4.15: Typical occupational skin absorbed dose rates near fixed fluoroscopic equipment in the absence of protective aprons and drapes: (a) over-couch and (b) under-couch X-ray tube.

Wikipedia. Basic Physics of Digital Radiography/ The Image Receptor. Wikibooks. Downloaded 6/25/2014. Retrieved from: https:// en.wikibooks.org/wiki/ Basic_Physics_of_Digita l_Radiography/ The_Image_Receptor

It should also be noted that the use of over-couch XRTs in fluoroscopy can lead to significantly greater staff doses than systems which use under-couch XRTs - see Figure 4.15. Increased radiation scattered from the patient and the lack of shielding provided by the structure of the patient table are the cause. An increased incidence of lens injuries has been found, for instance, in radiologists who have used over-couch systems without protective screens[18]. Note, however, that this over-couch argument may not always be valid when inverted C-arms are used to assist with hand surgery[19].

The elevated dose rates to the trunk and head of the staff member can be noted in panel (a) of the figure. Radiation dose to the legs of interventionists can also be significant even with the use of under-couch XRTs -

and with C-arm systems[20][21].

The use of C-arm and similar arrangements in cardiac catheterisation laboratories, operating theatres and angiography suites can introduce additional hazards - see Figure 4.16. These arise because of the ergonomics associated with the use of lead shielding devices - which are intended for the minimisation of scatter and leakage at the interventionist's position. It is therefore quite possible for their thyroid and eye lens, for instance, to receive substantial doses. Thyroid shields and lead spectacles can be worn and adjustable lead glass shields used for dose optimisation purposes in these circumstances[22][23]. Shielding equivalent to 0.25 mm of lead is generally required with glasses also having side protection. In addition, interventionists can wear a second dosemeter at the level of their neck to monitor the dose to their thyroid and eyes. Note that radiation-associated posterior lens changes have been observed in the eyes of cardiac Cath Lab staff - both medical and clinical, most not wearing lead glasses - with an incidence significantly greater than an unexposed control group[24] and that a study of cataract incidence has been launched for a large sample of interventional cardiologists[25].

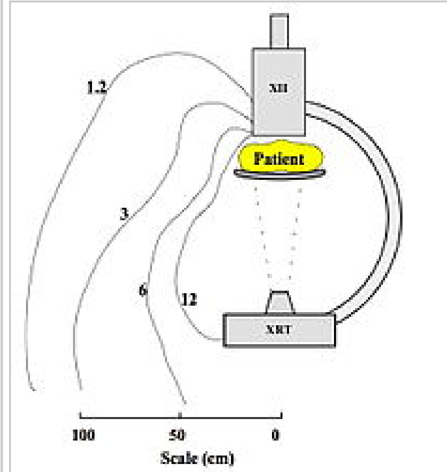

Fig. 4.16: Typical isodose curves (in µGy/min) for a mobile C-arm fluoroscopy system.

The location of the interventionist during the procedure has a large influence on their hand dose[26]. A ring dosemeter on the finger proximal to the XRT can be used to monitor such doses. Lead gloves are not generally worn for ergonomic reasons and also because the additional attenuation generated when shielded hands are in the beam will increase the automatically controlled exposure factors. Note that particular additional optimisation techniques can be required in specialities such as urology[27] and endovascular surgery[28].

Targeted education for all users of specialised X-ray apparatus has been identified as a key optimisation strategy[29] and has been implemented successfully in, for example, computed tomography[30].

Patient Dose

Good imaging geometry should be used to optimise patient protection in radiography, fluoroscopy and fluorography. In most situations the image receptor should therefore be moved to the maximum distance from the XRT and the patient placed as close to the image receptor as possible. In other words, the patient should ideally be moved to the image receptor and not the other way around. Some fluoroscopy systems can do this automatically so as to maintain a narrow air gap between the patient and image receptor before exposures.

Effective doses to patients from fluoroscopy procedures are considerably higher, as might be expected, than in General Radiography - see the table below. The higher doses result from both fluoroscopy-screening exposures and multiple fluorography exposures. Notice that strongly attenuating parts of the body which contain a number of radio-sensitivite organs, such as the abdomen, generate the larger doses in the table.

Mean Effective Doses from Fluoroscopy Procedures[31][32]

Procedure	Effective Dose (mSv)
Cerebral Arteriography	2.5
Nephrostomy	5.5
Barium Meal	8.2
Renal Arteriorography	10.3
Barium Enema	11.7
Biliary Stent Placement	12.5
Enteroclysis	14.0

More recent and extensive data is provided in Mettler *et al.* (2008)[33]. Note that specific patient shielding can be of benefit to patient dose in different types of X-ray examinations, e.g. thyroid protection in cerebral angiography[34].

It can be noted from the table that all doses are higher than that of the average annual background dose (2.4 mSv). From this perspective, the dose from a Cerebral Arteriogram is equivalent to about 1 year of background exposure - its so-called Background Equivalent Radiation Time (**BERT**). Note however that considerable variations can exist in patient dosimetric survey data, by a factor of 10 or more, due to patient anatomical differences and the quality of the imaging technology, for example. Note also that variations by a factor of over 100 occur in background exposure in different parts of the world. It is apparent that the BERT is therefore only a very approximate indicator of relative dose.

The higher doses in the above table, and higher still in extended interventional procedures, have prompted the use of dosimetry equipment to routinely monitor parameters such as the Dose-Area Product (DAP) and the Peak Skin Dose. DAP (also called the Kerma-Area Product) is a measure of the total energy exiting an XRT and is generally measured (in Gy cm^2) at a location in the beam close to the collimators. The parameter has the advantage that it is independent of source-to-skin distance, as was described previously, and can be used to estimate stochastic risk from a procedure. The Peak Skin Dose is a useful indicator of the likelihood of deterministic effects. Such measurements can be also be used to establish a dose scale to assist interventional staff in radiation dose management[35].

Implementation of dose monitoring is critical for dose optimization in digital radiography. Staff guidelines as previously developed for film/screen radiography, should include appropriate collimation, source-to-image distance (SID), focal spot size and patient positioning. This information can also enable effective doses to be subsequently estimated, in situations where DAP meters, for instance, are not available. The use of image quality indicators for different examinations is an additional step in assisting clinical management of the balance between dose and image quality[36].

Results of a comprehensive catalogue of dose surveys from 1980-2007 are summarised in Figure 4.17. It can be seen that effective dose in General Radiography vary by a factor of >1,000, in the range 0.001 to 3 mSv, depending on the area of anatomy irradiated. Radiography/fluoroscopy procedures, as used for barium studies, can be seen to generate higher doses (4-8 mSv) as do CT studies (2-16 mSv). Interventional radiology is seen to generate still higher doses (5-70 mSv). CT and interventional exposures can therefore be considered at relatively high dose examinations and therefore require greater attention from a dose management perspective. However, it should be appreciated that these values contain large uncertainties, which can range by factors of 5-10 or more. Furthermore, the average figures are themselves age- and sex-averaged and are also subject to a variation of ±40% when referred to an individual patient, depending on variables which include the patient's weight, orientation, X-ray exposure factors and imaging technology used. It is therefore apparent that they should be considered as indicative values only which should never be used as a substitute for the dose to an individual patient from a particular examination. Their use here is solely to provide a comparison for dose management purposes.

On a final point, note that patient dosimetry in general radiography, fluoroscopy, mammography and computed tomography is reviewed in Huda et al. (2008)[37].

Modality	Examination	Average Effective Dose (mSv)
General Radiography	Extremities	0.001
	Knee	0.005
	Shoulder	0.01
	Chest (PA)	0.02
	Chest (PA + Lateral)	0.1
	Skull	0.1
	Cervical Spine	0.2
	Mammography	0.4
	Pelvis	0.6
	Abdomen	0.7
	Hip	0.7
	Thoracic Spine	1
	Lumbar Spine	1.5
	Intravenous Urography	3
DEXA	without CT	0.001
	with CT	0.04
Fluoroscopy	ERCP	4
	Small Bowel series	5
	Upper GI series	6
	Ba Enema	8
Computed Tomography	Head	2
	Neck	3
	Calcium Scoring	3
	Pelvis	6
	Spine	6
	Chest	7
	Abdomen	8
	Virtual Colonoscopy	10
	CTPA	15
	Three-Phase Liver	15
	Coronary Angiography	16
Interventional Radiology	Head/Neck Angiography	5
	Thoracic Angiography	5
	Coronary Angiography	7
	Abdominal Angiography	12
	CTPA, Stent or RF Ablation	15
	Pelvic Vein Embolization	60
	TIPS Placement	70
Dental Radiography	Intra-oral Radiography	0.005
	Panoramic Radiography	0.01
	Dental CT	0.2

Fig. 4.17: Adult effective doses from various X-ray procedures (adapted from ref. #31).

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7. X-ray diagnostic equipment

The production and use of X-rays

When a stream of electrons is accelerated by an electrical potential to a very high speed and then decelerated and absorbed by hitting a target material, X-rays are produced. Thus the main requirements for producing X-rays are:

- a source of electrons,
- a source of electrical potential,
- an appropriate target material.

X-rays are invisible. Because of their high energy and short wavelength they can penetrate almost all materials, but are absorbed to a different extent by different tissues. In the human body, absorption is high for bones, and low for muscles and other soft tissues. These differences in absorption can be shown on a photographic film as differences in density: the result is a radiograph. Thus, radiographic examination consists of irradiating a part of the patient with a uniform beam of X-rays and recording the emerging rays on a double emulsion film sandwiched between a pair of fluorescent screens. The screens convert the X-rays into light, which in turn exposes the X-ray film. The screens and the film are enclosed in a cassette for protection from daylight. After the exposure, the film must be processed, manually or automatically, in a darkroom by means of developer and fixer solutions.

X-ray examinations should be ordered only by physicians or experienced clinical health workers. "Routine" examinations are seldom indicated. A few of the more common indications and examinations that can be performed with diagnostic X-ray equipment are listed below (this is not a complete list).

- *Skeleton:* for fractures, and bone and joint diseases, e.g., arthritis, tumours.
- *Head:* for trauma and infections, e.g., sinusitis.
- *Chest:* for tuberculosis, pneumonia and other respiratory infections, heart disease, tumours, pleural diseases, and trauma.
- *Abdomen:* for trauma, intestinal obstruction, calculi, contrast urography, cholecystography, and problems in pregnancy, if ultrasound is not available.
- *Soft tissues:* for foreign bodies and calcifications, e.g., parasites.

Examinations with contrast media are recommended only when an experienced physician is available to carry out and interpret such examinations, and to treat the possible complications of contrast injections.

Components of the X-ray system

The components of an X-ray diagnostic system are:
- the X-ray tube, X-ray generator, tube stand (support), examination table (patient support), and control unit;
- accessories such as cassettes, intensifying screens, and film;
- darkroom equipment and other supplies for processing the exposed film;
- radiation protection devices.

X-ray tube

X-rays are produced in an X-ray tube. In all X-ray tubes, the source of electrons is a heated filament made of tungsten wire, the cathode. The area that is bombarded by the electrons is called the focal spot, and it is part of a metal body called the anode. The high voltage between the cathode and the anode sets the electrons in motion.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

The anode and the cathode are sealed into a glass envelope, the tube, in a vacuum. This glass X-ray tube is enclosed in a casing made of aluminium, and lined with thin sheets of lead to prevent leakage of radiation. The tube is fixed in the casing at its anode end. The metal case protects the tube from mechanical shock, and also protects the users from radiation and electrical risks. The amount of protection has to be in accordance with international standards. The X-ray beam leaves the housing through a plastic-covered aperture called the tube port, or window.

X-ray generator

The purpose of an X-ray generator is to provide the high voltage that is applied to the X-ray tube for the production of X-rays. There are several types. One older type of generator, in common use in small X-ray departments, is the single-phase generator. In large hospitals, with a very good mains power supply, a more powerful three-phase generator may be installed. Recent developments indicate that, in the future, most X-ray generators will be frequency-converter, multipulse generators. These generators use a direct current (DC) source and convert the DC to alternating current (AC) with a higher frequency than the mains. These generators are much smaller, lighter and less expensive than conventional generators, and produce a high quality X-ray beam.

Usually, an X-ray generator has a number of fuses to safeguard the various circuits and their components. The fuses may be of different ratings and types, according to their use. They are usually mounted in the control unit, except in larger generators.

Tube stand (tube support, tube column)

The function of the tube stand is to support the X-ray tube so that it can be used with the X-ray beam in a horizontal or vertical position, or at an angle.

There are six basic kinds of tube support:

- integrated with the control unit and the transformer (e.g., a standard ward unit, or mobile unit, for use in hospitals);
- a column mounted on floor rails alone;
- a column mounted on floor rails, but also with a ceiling rail;
- a fixed column with a tube rotating around a central axis (e.g., a "C-arm", or a modified "C-arm" type, as used in the WHO Basic Radiological System);
- a column forming an integral part of the X-ray table;
- a carriage suspended from the ceiling, moving on rails.

With all these tube supports, except the "C-arm" or modified "C-arm", a separate vertical cassette holder, or chest stand, is needed for upright chest radiography.

Chest stand

The chest stand is a holder for cassettes that is used to examine patients in the erect position, for chest or other radiography. It must hold the size of cassette used for chest examinations, and be adjustable in height, strong and rigid. It may incorporate an anti-scatter grid (either fixed or movable) and should be able to hold cassettes either in front of the grid or behind it. With some types it is also possible to orient the cassette at an angle to the vertical.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

Grid (anti-scatter grid)

When an X-ray beam passes through a patient, some of the X-rays continue in a straight line (the direct beam) and other X-rays are scattered in different directions. If the scattered X-rays reach the film, they will distort and spoil the image. The grid is a metal screen that absorbs almost all the scattered X-rays, i.e., those that did not pass through the patient in a straight line from the anode of the tube. The grid is properly called an "anti-scatter grid" or a "secondary radiation grid". The grid may be stationary or it may be incorporated in a "bucky" mechanism, which makes the grid move during the exposure and blurs out the image of grid lines.

All grids are delicate and very expensive: they are easily damaged, and are useless if bent. If not part of the equipment, they should be supplied either coated in plastic (for protection), or as an integral part of a cassette. Once damaged they cannot be repaired, but with proper care they will have a long life.

Examination (X-ray) table (patient support)

The examination table is used for X-ray examinations when the patient is lying down. It must be rigid, with a top permeable to X-rays, approximately 2.0 m × 0.65 m in size, and approximately 0.7 m from the floor. It must be able to support a patient weighing 110 kg without appreciable distortion. It should be impervious to fluids, resistant to scratching, and easy to clean. It may incorporate a "bucky" with a grid (see above). It may be fixed or mobile; if mobile, it must have good brakes.

Control unit

The control unit includes the meters, or digital indicators, that provide information on the state of the electricity supply, the chosen values of kV and mA · s (or mA and time), and the exposure switch. Often, the control unit is located outside the X-ray room. For busy X-ray rooms, this is recommended. If the control unit is located inside the X-ray room, a radio-opaque protection screen, large enough to protect a standing operator, should be an integral part of the control unit, or should surround it. There should be a lead glass window so that the patient can be watched during the examination.

Cassettes, intensifying screens, and films

Cassettes are the light-proof, rigid containers that enclose the X-ray film, to protect it from light. Within the cassette are two intensifying screens that fluoresce and produce visible light when irradiated by X-rays. The film is placed between the two intensifying screens, inside the cassette. The cassettes must be strong, rigid, and durable. They must provide firm pressure so that there is good contact between the film and the screens, but must be easy to open in the dark.

Darkroom equipment and supplies

A darkroom for the manual processing of X-ray films should have a master processing tank filled with water, in which two smaller tanks are supported to hold chemicals (developer and fixer). Running water is desirable, but alternatively the water can be changed frequently. If the workload is large enough, for example more than 15–20 patients per day, an automatic film processor may be needed. There must be a "dry" workbench, a film marker, safelights, and a thermometer. If manual processing is used, film-hangers and a timer-clock are also needed. If powdered chemicals are to be used, two auxiliary buckets for mixing, and mixing rods, will be required. Note, however, that powdered chemicals must never be mixed inside the darkroom.

Radiation protection devices

The essential radiation protection devices include a shielded control booth, outside the X-ray room, or a protective screen (large enough to protect a standing operator), with a lead equivalence of at least 0.5 mm, and with a lead glass window. There must also be leaded protective aprons, and leaded gloves, with lead equivalence of at least 0.25 mm, plus leaded rubber or leaded plastic strips with a lead equivalence of at least 0.5 mm, for use as gonadal shields.

Maintenance and repair in the X-ray department

X-ray equipment is complex and expensive: although minor maintenance can be done by hospital staff, routine servicing and repairs after a breakdown usually require trained personnel. Nevertheless, a regular routine of cleaning and checking will help to maintain efficiency and often provides early warning of developing faults.

Installation

Because X-ray equipment produces ionizing radiation and uses a high-voltage electric current, there are strict international and, usually, local rules governing all aspects of any X-ray department. These include specifications for room size, electricity supply, radiation exposure, and many other important details.

X-ray equipment should be installed only by trained X-ray engineers; even the transfer of used equipment from one site to another should be done only by trained staff. It may seem expensive, but incorrect installation may result in even more expenditure, and may be hazardous to hospital staff and patients.

Warranties and service contracts

The warranty given with all equipment must be carefully checked.

Service contracts should be part of the initial purchasing agreement. It is recommended that there be two routine, scheduled maintenance visits every year (at 6-month intervals) for at least 5 years from the date of installation. The first visit (at 6 months) should be without charge to the purchaser.

A written schedule of the maintenance required should be provided by the manufacturers, and each item should be completed, dated, and signed by the service engineer during each visit.

Log books

Log books are essential for proper maintenance. Quality control will be successful only if careful records are kept.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

The front page should contain telephone numbers (and fax numbers, if available) of service personnel and suppliers or manufacturers for all the equipment, including films, chemicals, and accessories.

Every item, large and small, in the X-ray department should have a written record in the log book providing:

- the make, model number, and name of the equipment;
- specifications for the generator, tubes, and all other items, including accessories;
- date of installation (and by whom); total cost of the equipment and the installation (shown separately);
- address of supplier, manufacturer's agent, and local service engineer;
- a list of the technical service manuals provided;
- details of any variation or modification from the standard equipment.

Thereafter every service visit, fault, repair, change, spare parts supplied and their warranty, and any other event should be recorded and dated.

Similar records should be kept when items such as lead aprons are routinely tested, and concerning any other similar departmental maintenance (for example, the regular cleaning of intensifying screens, cassettes, etc.).

Tools for the X-ray department

Mechanic's tools:

- standard and cross-head screwdrivers, with insulated handles,
- coarse and fine insulated pliers,
- shift spanners and sockets (matched to the equipment),
- oil can, with light machine oil.

Quality assurance equipment:

- step wedge and spinning top,
- densitometer and sensitometer, if funds permit.

Spares:

- fuses for the main switches and electricity supply boxes,
- fuses for the X-ray room and darkroom lights and sockets,
- 15 and 25 watt bulbs for the darkroom,
- 40, 60, and 100 watt bulbs for the X-ray room, or fluorescent tubes and starters as appropriate,
- replacement tubes or bulbs for the X-ray film illuminators (viewing boxes).

Do not keep a spare X-ray tube at the hospital; it will deteriorate even when not used and the warranty will become invalid.

Daily maintenance schedule

X-ray room

Clean the floor, sweep, and wash or polish, if necessary.

Clean the X-ray table and controls. **Do not** use water on the X-ray equipment: use a dry cloth, adding spirits if marks must be removed.[1]

[1] It is very important to remove traces of contrast material and plaster from the table top (they may show on radiographs) and to clean off blood or other contaminants, but water cannot be used where there are electrical connections.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

If the X-ray table is on wheels, move it away from the other equipment. It can then be cleaned with soap and water if necessary, provided there are no electrical connections.

Darkroom

Manual processing

Remove any films that have been left in the washing tank overnight. Wipe clean around the edges of the main tank. Make sure the washing water is clean and flows freely, and is at the correct level. Top up the developer and fixer from stock bottles.

Each morning and again each afternoon, measure the temperature of the developer, and adjust the processing time accordingly.

Replace all film hangers on their hooks. If any have been in the water overnight, wipe each one before hanging it above the dry bench.

If there is a separate film drier, remove all films and hangers. Check to make sure that no film has fallen to the bottom of the drier (remove any other material that may be there!).

If there are film carriers for wet films, empty the bottom tray, and clean the tray and the rack.

Automatic processor

Turn the electric power switch on and check the temperature after 10 minutes. Turn on the water and check the water pressure.

Check the levels of the developer and the fixer in the storage tanks. Some of the large automatic processors also have a washing agent; check this as well.

When the first films are processed, watch the indicators of chemical flow (usually near the delivery end of the processor) and check that the films are properly processed, washed, and dried. If there are clean, dry, but discarded films from previous work, feed one or two of them through the processor at the start of each day. This will ensure that the rollers are working well. Do no not use any bent, stiff, or distorted film.

Film testing

In busy departments it is important to run a test strip through the processor every day at the same time, for example at 10:00. Strip films can be purchased ready to use: alternatively, they can be manufactured in the darkroom. The best method is to expose areas of the film to a constant light source from a sensitometer and then develop the film. The test strip can also be made with an X-ray machine, but a generator of reproducible output must be used. In the latter case, to make a strip film, put a standard film in a 24 cm × 30 cm cassette (or larger). Position the cassette on the X-ray table, closing the collimator, or light beam, to the film size. Cover a strip 3 cm × 24 cm at one end of the cassette with a leaded rubber sheet. Put the step wedge on the other part of the cassette. Give the exposure normally used for a postero-anterior view of an adult wrist. Take the film out of the cassette in the darkroom, cut the film into strips so that each strip has a part of the covered section and also includes each step of the step wedge. Regardless of the method used to obtain the test strips, take one strip and feed it through the processor; it may be necessary to fasten the strip to a large-size discarded film to ensure that it moves through the processor smoothly. Store the other strips in a light-proof box

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

in the darkroom. Repeat the processing of one strip of film every day at the same time. Compare the processed strip films against a viewing box; they should be identical if the processor is working properly. The covered section of the film should be quite clear, proving that the film was not fogged before the X-ray exposure. If there is a densitometer, read the values for density, at each step, on both films. This is more accurate than visual comparison. On a daily basis, it is only necessary to read three steps; the base and fog (lightest), and those corresponding approximately to optical densities 1.0 and 2.0. It is important to record the results, and useful to plot the results and to indicate on a graph the tolerances accepted.

Dry bench

Every morning wipe the dry bench with a clean cloth, remove any dust and pieces of film or paper. Dispose of any film wrapping paper, empty film boxes, name-marking strips, request forms, etc. Leave the dry bench clear of all unwanted items.

Remove from the darkroom any white coats, plates, cups, books, or other items that should not be in the darkroom at any time! Put them in their proper place.

Mobile X-ray unit or ward unit

Remove any dirt or dried liquids that may have splashed on to the mobile X-ray unit (e.g., in the operating room or emergency room) but **do not** use water. Use a dry cloth, adding spirit if necessary, but make sure that no liquid runs into the gaps around the control knobs or the edges of the meters.

If the unit is battery-powered, check the battery meter, or other indicator, on the control unit to make sure that the batteries are fully charged.

If the electrical connecting plug, or socket, gets hot after an exposure has been made, or during battery recharging, make sure the wires connecting the cable to the plug are not loose. Only do this when the plug is **not** in the socket.

Recharge the unit every night by connecting it to the power outlet; leave it connected during the day also, when not in use.

Office

File any returned X-ray films. If there are written reports, file them with the films, or send them to the records department as required. Complete the register with details of any late examinations from the previous day or night. Make up envelopes, and file any films taken the previous day that have not yet been properly organized. File the request form with the films.

Weekly maintenance schedule

On the first working day of each week, the following items should be checked.

X-ray room

Check that the equipment for use in case of fire is in the correct place. There should be:

– one fire extinguisher for electrical fires (water must not be used).
– sand in a bucket, or in sand bags.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

Replace any supplies that have been used, e.g., cotton wool, sterile dressings, bandages. Check the contents of the emergency drug cupboard. Check that there are sufficient contrast drugs (for urography and cholecystography) and the necessary sterile syringes, needles, and skin cleaner. If the department undertakes fluoroscopy, check the supply of barium and all other items for gastrointestinal studies (enema tubing, cups/mugs, etc.). Order the replacement stores, as necessary, from the central store or pharmacy.

Instructions for cardiopulmonary resuscitation and for dealing with reactions to contrast drugs should be fixed on the wall of the X-ray room — always

Darkroom

Manual processing

In addition to the daily tasks (page 126), check the film boxes and add new boxes of films from the store, if necessary.

Automatic processor

Lift the lid of the processing compartment, and lift out the developing racks. Wash the racks in clean water. Wipe and replace them. Be careful not to spill chemicals on the floor or elsewhere; damage may result.

Lift out the fixer racks. Wash them in clean water. Wipe and replace them.

Wipe up any liquid (water or chemicals) that has been spilt on the floor or the outside of the processor.

Monthly maintenance schedule

On the first working day of each month, the following maintenance should be carried out.

X-ray room

Perform the daily and weekly tasks, as applicable.

If the tube column runs on rails, clean the rails and the wheels of the column. Remove all dirt, fluff, etc.

Darkroom

Manual processing

The processing chemicals must be changed at least each month. Whenever the chemicals are changed, the tanks must be thoroughly cleaned.

Switch off any heating or cooling system and stop the running water. Empty all the tanks. Wash and scrub all the tanks, including the master tank, with a brush and running water. Mix new developer and fixer solutions. Use different rods for

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

mixing the developer and the fixer. The developer is an alkaline solution, while fixer is acid. Do not allow even a few drops of the chemicals to get into the wrong tank or container.

Refill the chemical tanks with the new solutions: the developer must always be in the same developing tank, and the fixer in the same fixer tank as before. Never interchange tanks. Refill the master tank with water.

Automatic processor

Turn off the water and the electricity supply. Clean the racks as on the weekly schedule. Clean the developer and fixer tanks (using separate brushes for each tank). Refill with fresh chemicals following the manufacturer's instructions. Turn on the processor and the water supply.

Silver recovery

With either manual or automatic processing, collect fixer or silver, according to the manufacturer's or recovery company's instructions. If the fixer is to be transported to a central depot, it should be put into airtight containers.

Office

Add up the monthly totals of all entries in the patient register. For example, the total number of patients radiographed, the number of adults, the number of children, the number of chest radiographs, skeletal radiographs, etc., during the preceding month. Also, determine the total number of examinations.

Calculate the total number of X-ray films of each size used during the preceding month and check the stock of unused film, film envelopes, and chemicals. Order stocks as necessary.

Six-month maintenance schedule

Every six months, in addition to all previous routine maintenance, the following maintenance should be carried out.

X-ray room

Check all the moving parts on the equipment, particularly the brakes on the tube column and on the mobile patient support. If the brakes are mechanical, clean where possible. If the brakes are electric, and not working properly, request service. Do not continue to use equipment with poorly functioning brakes, since patients or staff may be hurt. Check all floor rails, wheels on examination table, etc., and clean as necessary.

Collimator alignment

Check the collimator alignment. If the collimator does not have a light beam, centre the tube on the middle of a 24 × 30 cm cassette, accurately placed in, or on, the cassette holder. Set the diaphragm for one size smaller (for example 18 × 24 cm). Make an exposure equal to that for a postero-anterior view of an adult hand. Develop the film and examine it on a viewing box. The square defined by the collimator should be clear cut and exactly the same distance inside the edge of the film all around. If the alignment is not exact, check to see if the tube casing has rotated, or if the collimator is loose. Tighten screws if necessary. (See below for tube rotation.)

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

Repeat the procedure with a horizontal X-ray beam in the position used for a chest radiograph of an erect patient.

If there is a light-beam collimator, choose the same size cassette, 24 × 30 cm. Centre the cassette exactly in, or on, the cassette holder, centre the tube on the cassette, and narrow the illuminated area by about 2 cm all around the inside of the edges of the cassette. Then expose and process the film as above. Take another cassette of the same size and repeat the procedure with a horizontal X-ray beam, and with the cassette holder in the position used for a chest radiograph of an erect patient.

Incorrect collimation

Misalignment will be shown by the exposed area being closer to one edge of the film than the other. There are two common causes. The tube housing may have rotated, or the collimator may be loose. Most tubes are held in place by two circular bands, which can be loosened or tightened by screws. Collimators are fastened to an X-ray tube on a base plate, often with four screws. These can become loose. Alignment of either the tube or the collimator can be more difficult than it sounds. Repeated check films may be necessary, particularly when there is no light beam collimator.

If the alignment is only slightly out, it is probably better to check that the screws are tight and then make no adjustment. If the alignment is badly out and cannot be corrected easily, notify the service engineer.

X-ray room and X-ray generator

Check the generator output. If there is a step-wedge, use it to make exposures at 55, 90, and 120 kV, with a constant mA·s, but varying mA and time. For each value of mA·s, the densities should be similar at each level on films developed in the same way, in the same chemicals, at the same time.

If there is no step-wedge, use any partially radiation-translucent object, for example, several ball point pens with metal covers. Expose the film, using different exposure factors, and process as described above. Visual comparison will show any marked discrepancies.

Check the timer. This can be done by using a metal spinning-top that has a small hole in the disc. The top is placed on a 24 × 30 cm cassette and centred under the X-ray tube. The cassette is shielded with leaded rubber so that only 1/4 of it is exposed. Twist the top so that it is spinning quite fast, and make an exposure at 55 kV, 100 mA, 0.1 sec. Repeat this procedure on each quarter of the film. The images should all show the same number of dots. For a single-phase X-ray unit, if the line frequency is 60 Hz, there should be 12 dots for each exposure. The number will vary with the design of the X-ray generator, but should be the same for each exposure with the same machine.

This is a very simple test, and not very accurate for complex 3-phase units. However, it does give a reasonable guide, and if there are discrepancies the service engineer should be notified. It cannot be used for frequency-converter multipulse generators, but these should remain accurate.

Darkroom

All the intensifying screens should be cleaned at least every 6 months. If the department is busy, clean them every 3 months.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

First, clean and dry your hands. Then, in the darkroom, using the safe-light without any white lights, open all cassettes, remove the films and replace them in lightproof film boxes, with the matching sizes of unused films. Put the lids on the boxes. Turn on the white light, or take the cassettes into the X-ray room, open them and dust the inside carefully with a light, soft brush. Then carefully clean the screens, using warm clean water, cotton wool, and good quality soap or washing solution. (Do not use the sort of detergent recommended for washing clothes or saucepans.) Do not use too much water; use a damp pad of cotton wool with a very small amount of soap. Remove any soap residue, using another cotton wool pad. Dry with yet another cotton wool pad. Then leave the cassette open in a dust-free, darkened room (e.g., the darkroom) for several hours.

Never let water or soap flow over the edges of the screens. This will damage both the screen and the felt pad underneath it.

Check the screen–film contact. This can be done without any special equipment by carefully checking the definition of the lungs (especially the small blood vessels in the lungs) on a good quality chest radiograph. All areas should be equally well defined. Smaller cassettes can be checked by looking at the clarity and definition of any image, comparing the centre with the edges.

A standard, commercially available, thin metal grid that has been precisely perforated with small, well-defined holes is a better way to check screen–film contact. This is placed in front of a cassette, and the film is exposed, using an exposure equal to that for a postero-anterior view of an adult hand. The small holes should all be well defined on the processed film and the overall density should be the same. If it is impossible to obtain such a thin metal grid, a wire mesh screen could be used instead.

Uneven definition, or uneven density, can be due to poor contact between the screens and the film. Underneath the back screen, there are felt pads and these may be worn or flattened by long use. Alternatively, the cassette may be damaged and warped, or not fastening properly.

Inspect the cassette first. Check that the hinges are intact and that the cassette opens and closes smoothly. Check that the edges are exactly aligned. Check that the locks for the cassette are all working properly. If there are spring pressure straps, check that they are symmetrical and engaging properly.

If the cassette is satisfactory, the lack of pressure is probably due to the felt pads inside the cassette, behind the back screen. Alternatively, the screens themselves may be loose.

Screens must be fastened by double-sided adhesive tape. Ordinary adhesive tape or glue will damage the screen. When replacing the screens or pads, fasten the front screen (which will be clearly marked "front screen") by first putting double-sided tape all around the inside of the front of the cassette. The front of the cassette is the smooth, sunken side, without any outside attachments. Put the front screen into the well of the cassette, with the emulsion side upwards. Put the back screen on top of it, with the fronts of the screen surfaces in contact. Fasten the adhesive tape all around the border of the back of the screen and put similar double-sided adhesive tape around the inside border of the cassette. Put the new felt pad (plastic pads are not satisfactory) exactly in position on the back of the cassette and close the cassette. Fasten, and leave closed for 24 hours without film.

Care of screens

It is important to know the following:

- Screens deteriorate when exposed to light. Keep cassettes closed.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

- Screens deteriorate with normal use over 3–5 years.
- Screens are easily scratched. Never touch the surface of the screen with your fingers, and always keep the screens clean.
- Liquid, especially chemicals and sweat, damages screens. Keep cassettes away from the processing tanks. Dry your hands before opening a cassette.
- To allow easy identification when screen marks appear on films, the back screen of each cassette should be marked by writing a small number in one corner, inside. Screen damage will show as a similar "shadow" on the same part of the finished films, for many different patients.
- All screens in a department should be replaced at the same time (because the X-ray exposure needed to produce the same quality of radiograph changes as the screens deteriorate).

Lead aprons and gloves

Each item should be numbered when new and recorded in the log book.

Every 6 months, each item of protective lead clothing must be tested for defects. Check by looking for cracks, tears, blisters, or other signs of wear. If there is a small tear, secure the edges with strong adhesive strapping. Then put the damaged area over a cassette and give a normal postero-anterior wrist exposure. Process the film, and look for a black line, which would indicate incomplete protection. Any damaged item that fails this test should be discarded (after a replacement has been acquired).

If fluoroscopy is available, each item can be tested using the fluoroscope; cracks will be seen immediately. This is a good way to test double-layered items, such as gloves; these should be rotated while being tested in this way.

Some types of lead apron have an outer plastic cover and the leaded rubber is not visible. These must be carefully palpated for irregularities and tested in the same way by X-raying any doubtful areas. Some lead gloves have removable leather covers, which must be taken off the inner glove before examination for damage.

Twelve-month maintenance schedule

X-ray room

Turn off the generator at the mains switch.

Visually check all the cables for cracks or irregularities, especially where a cable is bent. Check the cable–socket connections; make sure they are not loose or corroded.

Check the X-ray tube and the transformer (the other end of the cables from the X-ray tube) for signs of oil leakage.

Check the earthing cables (connected to the table, the tube stand rails, etc.) for looseness, damaged insulation, or any sign of wear.

These checks should, of course, be routinely made by the service engineer every 6 months, but it is also a good idea for the X-ray staff to make these visual checks at least every 12 months.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

Be careful with X-ray equipment. It can be dangerous.

Do not open the side or other panels on any part of the equipment. Only a service engineer will be able to correct any fault inside. If someone with authority insists on opening the panels, turn off the mains switch on the wall first.

Before sending for the service engineer

If the films have varied in density—too light or too dark, or inconsistent

- Are the chemicals too old? Do they need changing?
- Have you checked the temperature of the chemicals, and are you developing the films accordingly?
- Are the films developed using a timing-clock? And for the correct time for each temperature?
- Are you using a different make of film?
- Are the screens in the cassettes of different speeds? (If so, label the outside of the cassette "Fast", "Slow" or "Medium".)
- Are the screens inserted in the cassette the correct way round? The front screen should be on the side which will be nearest to the patient.
- Are the screens fixed properly? The film must lie between the screens.
- If there is an automatic processor, is the unit running smoothly? Are the chemicals fresh? Is the temperature correct?

If the films are "grey" or fogged where they should be clear

- Is the bulb in the darkroom safelight more than 25 watts?
- Is the safelight filter damaged? Has it got too hot and changed colour? Are there any cracks, especially at the edges?
- Is the safelight too close to the dry bench in the darkroom?
- Are the films fresh? (Check the date on the box.)
- Have the films in the box been exposed to X-rays? Has the box of films, or a cassette, been in the X-ray room while patients were being radiographed?
- Is the temperature of the chemicals too high? Is the fixer too old?
- Is light leaking into the darkroom? (Stay in the darkroom with the door closed for 10 minutes and look around.)

If there are marks on all the films

Marks in the same place on films of the same size.

- Look at the outside of the front of the cassette. Is anything stuck to it? Have any liquids left a residue on it? (For example, barium, intravenous contrast medium, or iodine.)
- Open the cassette in the darkroom, take out the film and put it into a film box. Close the box. Turn on the white light. Check the screens, front and back, for

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

marks, scratches, or stains. Clean the screen if possible. If the mark cannot be removed, carefully draw a circle around it with a pencil or ball-point pen. This will show on the film, but the doctors will know that it is a film fault and not something wrong with the patient. Replace the screens as soon as possible.

- If there are no marks on the cassette or screens, and the film fault is a "dark" mark on the films after processing, check the box in which the unexposed films were delivered, or are kept. A small hole or crack in the box may allow light to mark the film. This is unlikely, but if there is no other explanation it should be considered.

If the mark on the film changes its position it is nearly always due to a small loose piece of paper inside the cassette.

Whenever faults appear on film and the cause is not found, keep the films to show to the service engineer.

General rules

- There is no reason for anyone other than a trained X-ray service engineer to open the side or other panels of any item of X-ray equipment. If you are tempted to open any part of the X-ray equipment, resist. If required to open the equipment, turn off the mains electricity supply first—switch off both the switch on the control panel and the mains switch on the wall of the X-ray room.
- All moving parts of X-ray equipment should move smoothly, not stiffly or jerkily. Never force any item that does not move properly. When there is a problem with movement, check to see if there is any dirt or other obvious cause. Never force control knobs to turn. If a knob will not move easily, turn off the generator, wait 5 minutes, turn it on again and try once more. If unsuccessful, turn off the mains switch and send for the service engineer.
- The rotating anode tube makes a humming noise when it is turned on and is working. After an exposure the tube will go on running, gradually slowing down after a few minutes. If it stops suddenly, or if it makes a strange noise, or if the noise increases or sounds "rough", stop using the tube, and send for the service engineer. If the tube does not start rotating you cannot make an exposure at all. Send for the service engineer and warn him or her in advance that a new tube may be necessary.
- If any meter or light on the X-ray equipment does not work normally, contact the service engineer, tell him or her what is happening, and ask for advice. It may, or may not, be serious. Try not to use the equipment until you have consulted the service engineer.
- Water (or almost any liquid other than oil) and electricity must not be mixed. Keep water and other liquids well away from X-ray equipment.
- If any fuse blows and it can be easily replaced, use exactly the same type of fuse to replace it. Turn off the mains switch first. **Never** use a stronger fuse than the original one. If the same fuse blows soon after it has been replaced or repaired, or if other fuses blow quite soon after the first one, turn off the unit and send for the service engineer.
- Any unusual heat, smell of burning, smoke, or sparking is an indication to **turn off** the mains switch at once. Do not turn it on again until the service engineer is available.
- In case of **fire**, turn off the mains switch at once. Do not try to see what is burning or where the fault is. Do **not** turn the switch on again.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

2. Diagrams and Schematics of X-Ray Systems

Featured in this Section:

Dilmen, N. “Medical X-Ray Imaging ALPo2.” *Wikimedia Commons*, November 12, 2011. Retrieved from: https://commons.wikimedia.org/wiki/File:Medical_X-Ray_imaging_ALP02_nevit.jpg

McClelland, I. R. “Appendix E: X-Ray Equipment Operation.” From the Publication: *X-Ray Equipment Maintenance and Repairs Workbook for Radiographers & Radiological Technologists*, (WHO: 2004).

WHO. “Stationary Basic Diagnostic X-Ray System, Digital.” From the publication: “WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

WHO. “Stationary Basic Diagnostic X-Ray System, Analogue.” From the publication: “WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Figure 1: X-Ray Tube and Housing

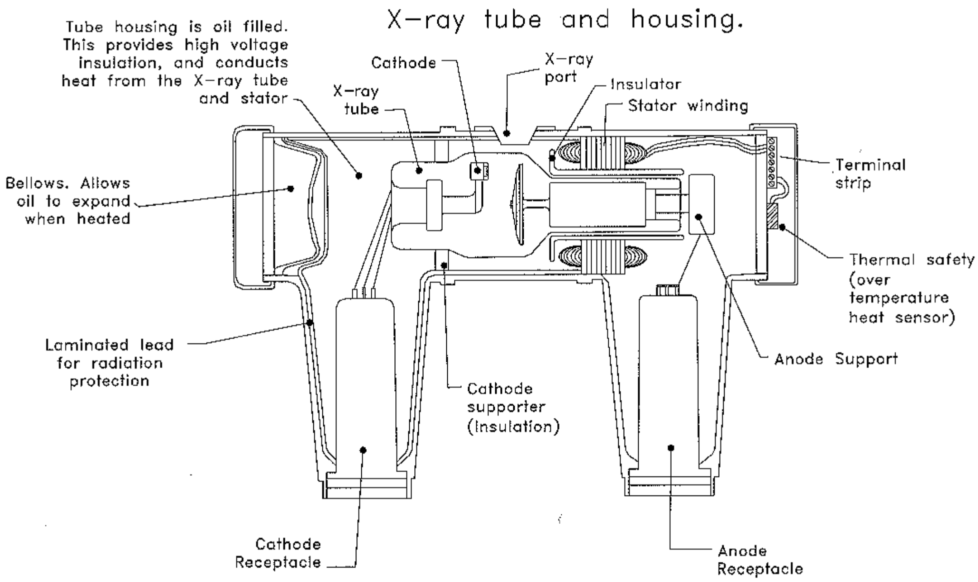

Fig E–9. The X-ray tube and housing

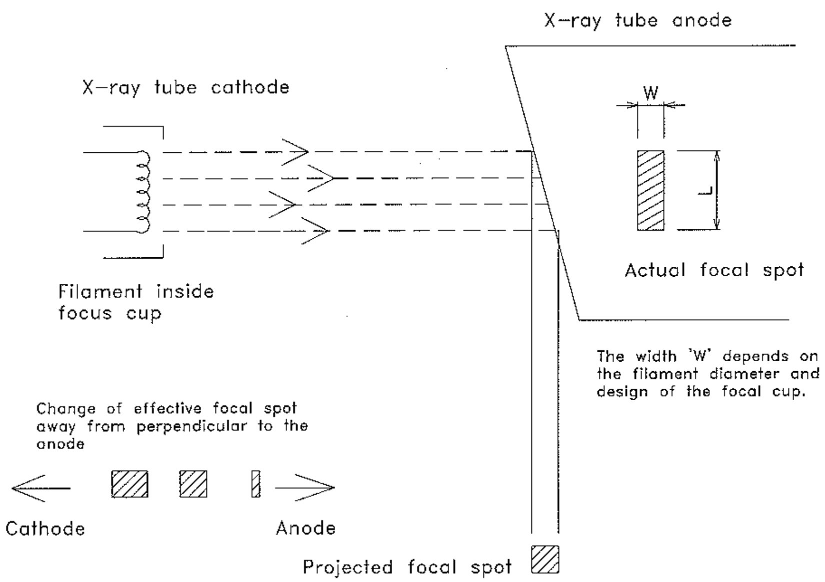

Fig E–10. Formation of the focal spot

e. *Anode angle*

The wider the anode angle, the greater will be the film coverage at a specific distance. However, to maintain the same focal spot size, the length 'L' of the electron beam must be reduced. This results in a smaller area to dissipate the immediate heat, so the maximum output of the tube has to be reduced. See Fig E–10.

A common angle for an over-table tube is 12º. An under-table tube in a fluoroscopy table may have an angle of 16º. With a 12º angle, radiation may cover a 35 x 35 cm film at a FFD of 100 cm, while a 16º angle

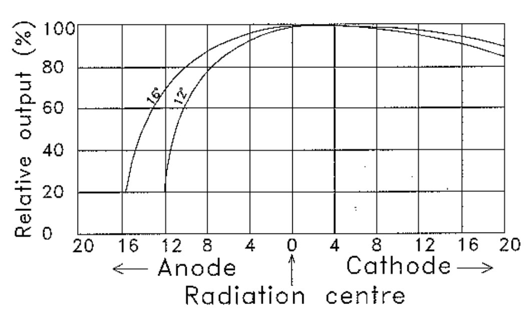

Fig E–11. Relative radiation output for two anode angles

Figure 2: Example of an X-Ray

Dilmen, N. "Medical X-Ray Imaging ALPo2." Wikimedia Commons, November 12, 2011. Retrieved from: https://commons.wikimedia.org/wiki/File:Medical_X-Ray_imaging_ALP02_nevit.jpg

Figure 3: WHO Specification Analog Diagnostic X-Ray

MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	X-Ray Imaging System
3	Specific type or variation (optional)	fixed, analogue
4	GMDN name	Stationary basic diagnostic x-ray system, analogue
5	GMDN code	37644
6	GMDN category	12 Diagnostic and therapeutic radiation devices
7	UMDNS name	Radiographic/Fluoroscopic Systems, General-Purpose
8	UMDNS code	16885
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Basic radiologic system (BRS); General radiographic x-ray equipment; Radiographic unit, chest; Radiographic unit, general-purpose; Paediatric radiographic unit; Radiographic unit, skeletal
11	Alternative code/s (optional)	MS 17153; MS 34239; MS 10822; MS 13271; MS 36119; MS 16557
12	Keywords (optional)	imaging, radiology, film
13	GMDN/UMDNS definition (optional)	An assembly of devices that comprise a general-purpose stationary diagnostic x-ray system used in a variety of routine planar x-ray imaging applications. It is typically an x-ray film based system that use analogue or analogue-to-digital techniques for image capture and display. The stationary design requires it to be installed and used in a fixed location within a building or in a transportation van (mobile imaging facility). This system consists of modular configurations that can be upgraded by the addition of hardware/software components or accessories. This generic device group does not cover systems with fluoroscopic or tomographic capabilities.
PURPOSE OF USE		
14	Clinical or other purpose	An assembly of devices that comprise a general-purpose stationary diagnostic x-ray system used in a variety of routine planar x-ray imaging applications.
15	Level of use (if relevant)	Health post, health centre, district hospital, provincial hospital, specialized hospital, radiology practice
16	Clinical department/ward(if relevant)	Radiology department, Orthopaedics, Emergency room
17	Overview of functional requirements	1. Provides X-ray film images of all body parts except for brain. 2. X ray generator and cassette holder can be moved to image body part of interest. 3. X-ray generator, bucky and patient table movable to enable comfortable and precise imaging. 4. Separate control console (behind protective screens). 5. Fluoroscopic capacity is not required.
TECHNICAL CHARACTERISTICS		

WHO. "Stationary Basic Diagnostic X-Ray System, Analogue." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/

18	Detailed requirements	1. Must have a digital display of mAs and kV, and an electronic timer. 2. kV range at least 50 kV to 150 kV, digitally displayed. 3. mA range at least 0 to 600 mA. 4. Exposure time range at least 1 ms to 5 s. 5. Automatic exposure control facility required. 6. Tube power rating at least 60 kW. 7. Resolution to be better than 5 line pairs / mm. 8. Must have a rotating anode with focal spot size less than 1mm. 9. Heat storage capacity of the anode at least 350,000 HU. 10. Adjustable multileaf collimator, rotatable ±90 deg with patient centering light.
19	Displayed parameters	N/A
20	User adjustable settings	N/A
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	1. Patient table to have motorized tilt from at least +90 deg to -15 deg. 2. All cables on the patient table unit should be concealed. 3. Patient table longitudinal and lateral movements to be at least 160 cm and 20 cm respectively. 4. Patient table vertical movement to include the range 60 cm to 120 cm from ground. 5. X-ray head longitudinal, vertical and lateral patient movement to be at least 100 cm, 30 cm and 20 cm respectively. 6. Source to image distance should at least include the range 90 cm to 125 cm. 7. The tube head must be fully counterbalanced for safe and easy movement. 8. Maximum possible patient weight to be at least 150 kg. 9. Dust cover for control unit to be supplied. 10. Protection against insect and rodent ingress to be incorporated.
22	Mobility, portability(if relevant)	
23	Raw Materials(if relevant)	
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	1. Power input to be ******** fitted with ******* compatible mains plug, if single phase. 2. Power input to be ******* fitted with secure connection to supply, if three phase. 3. Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. 4. Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines. 5. Mains cable to be at least 3m length.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	1. To be supplied with two adult size protective lead aprons. 2. Supplier to specify full range of grids available. 3. Radiation hazard warning signs to be supplied with unit.
26	Sterilization process for accessories (if relevant)	N/A
27	Consumables / reagents (if relevant)	N/A
28	Spare parts (if relevant)	N/A
29	Other components (if rele	N/A
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A

WHO. "Stationary Basic Diagnostic X-Ray System, Analogue." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	1. Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. 2. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover. Supplier to clearly state supply current requirements of unit.
36	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation.
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
38	User care(if relevant)	Unit layout to enable easy cleaning and sterilization of all surfaces.
WARRANTY AND MAINTENANCE		
39	Warranty	1 year
40	Maintenance tasks	Preventive/periodic maintenance requirements to be listed.
41	Type of service contract	N/A
42	Spare parts availability post-warranty	N/A
43	Software / Hardware upgrade availability	N/A
DOCUMENTATION		
44	Documentation requirements	1. User, technical and maintenance manuals to be supplied in (***** language). 2. List to be provided of equipment and procedures required for local calibration and routine maintenance. 3. List to be provided of important spares and accessories, with their part numbers and cost. 4. Certificate of calibration and inspection to be provided. 5. Contact details of manufacturer, supplier and local service agent to be provided.
DECOMMISSIONING		
45	Estimated Life Span	5 years
SAFETY AND STANDARDS		
46	Risk Classification	Class C (GHTF Rule 10 (ii)); Class II (USA); Class II b (EU and Australia); Class II (Japan and Canada)
47	Regulatory Approval / Certification	FDA approval (USA); CE mark (EU)

WHO. "Stationary Basic Diagnostic X-Ray System, Analogue." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60336:2005 (X-ray tube assemblies for medical diagnosis - Characteristics of focal spots) IEC 60522:1999 (Determination of the permanent filtration of X-ray tube assemblies) IEC 60526:1978 (High-voltage cable plug and socket connections for medical X-ray equipment) IEC 60601-1-3:2013 (Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment) IEC 60601-2-8:2010 (Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV) IEC 60601-2-28:2010 (Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis) IEC 60601-2-43:2010 (Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures) IEC 60601-2-54:2009 (Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy) IEC 60613:2010 (Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis) IEC 60627:2013 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids) IEC 61262-1:1994 (Part 1: Determination of the entrance field size) IEC 61262-2:1994 (Part 2: Determination of the conversion factor) IEC 61262-3:1994 (Part 3: Determination of the luminance distribution and luminance non-uniformity) IEC 61262-4:1994 (Part 4: Determination of the image distortion) IEC 61262-5:1994 (Part 5: Determination of the detective quantum efficiency) IEC 61262-6:1994 (Part 6: Determination of the contrast ratio and veiling glare index) IEC 61262-7:1995 (Part 7: Determination of the modulation transfer function) IEC 61267:2005 (Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics) IEC 61676:2009 (Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology) (IEC 62463:2010 Radiation protection instrumentation - X-ray systems for the screening of persons for security and the carrying of illicit items)
49	Reginal / Local Standards	**US standards** NEMA XR7-1995 (R2000) High-Voltage X-Ray Cable Assemblies and Receptacles **EU standards** EN 60522:1999 Determination of the permanent filtration of X-ray tube assemblies EN 60601-2-8:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV EN 60601-2-28:1993 Medical electrical equipment - Part 2: Particular requirements for the safety of X ray source assemblies and X-ray tube assemblies for medical diagnosis EN 60601-2-28:2010 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis EN 60601-2-43:2010 Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures EN 60601-2-54:2009 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy EN 61676:2002 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology EN 62220-1:2004 Medical electrical equipment - Characteristics of digital X- ray imaging devices - Part 1: Determination of the detective quantum efficiency **Japan standards** JIS Z 4751-2-28:2008 (Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis) JIS Z 4751-2-54:2012 (Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy)

50	Regulations	**US regulations** 21 CFR part 820 21CFR part 892.1680 Stationary x-ray system **EU regulations** Council Directive 93/42/EEC Directive 93/68/EEC (CE Marking) Directive 98/79/EC Directive 2001/104/EC Directive 2007/47/EC **Japan regulations** MHLW Ordinance No.169 37644010 Stationary analogue general-purpose diagnostic X-ray system 37644020 Stationary analogue general-purpose integral diagnostic X-ray system

Figure 4: WHO Specification Digital Diagnostic X-Ray

	MEDICAL DEVICE SPECIFICATION	
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	X-ray system
3	Specific type or variation (optional)	stationary, digital
4	GMDN name	Stationary basic diagnostic x-ray system, digital
5	GMDN code	37645
6	GMDN category	12 Diagnostic and therapeutic radiation devices
7	UMDNS name	Radiographic/Fluoroscopic Systems, General-Purpose
8	UMDNS code	16-885
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Basic radiologic system (BRS); Digital radiography; Electronically recorded digital radiography; General radiographic x-ray equipment; Radiographic unit, chest; Radiographic unit, general-purpose; Paediatric radiographic unit; Radiographic unit, skeletal
11	Alternative code/s (optional)	MS 17153; MS 34281; MS 34283; MS 34239; MS 10822; MS 13271; MS 36119; MS 16557
12	Keywords (optional)	imaging, radiology
13	GMDN/UMDNS definition (optional)	An assembly of devices that comprise general-purpose stationary diagnostic x-ray system used in a variety of routine planar x-ray imaging applications. It uses digital techniques for image capture, display and manipulation. The stationary design requires it to be installed and used in a fixed location within a building or in a transportation van (a mobile imaging van). This system consists of modular configurations that can be upgraded by the addition of hardware/software components. This GMDN code does not cover systems with fluoroscopic or tomographic capabilities.
PURPOSE OF USE		
14	Clinical or other purpose	Designed for use in the laboratory for temperatures over a wide or particular range
15	Level of use (if relevant)	Health center, district hospital, provincial hospital, specialized hospital
16	Clinical department/ward(if relevant)	
17	Overview of functional requirements	Provides X-ray film images of all parts of the body X ray generator and image intensifier can be moved to image required body part Control unit to be separate for operation from behind protective screens DICOM compatible image storage and transfer required Fluoroscopic capacity is not required
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	Must have a digital display of mAs and kV, and an electronic timer. kV range at least 50kV to 150kV, digitally displayed mA range at least 0 to 600 mA Exposure time range at least 1 ms to 5 s Automatic exposure control facility required Tube power rating at least 60 kW Resolution to be better than 5 line pairs / mm Must have a rotating anode with focal spot size less than 1mm. Heat storage capacity of the anode at least 350,000 HU Adjustable multileaf collimator, rotatable ±90 deg with patient centering light Alphanumeric annotation of images required Image display to be contrast- and brightness- adjustable, at least 18 inches diagonal size Image to be displayed immediately after exposure The system should be capable of storing at least 3000 images, with capacity for removable media storage
19	Displayed parameters	
20	User adjustable settings	

WHO. "Stationary Basic Diagnostic X-Ray System, Digital." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	Patient table to have motorized tilt from + 90 deg to - 15 deg at least All cables on the patient table unit should be concealed in the system Patient table longitudinal and lateral movements to be at least 160 cm and 20 cm respectively Patient table vertical movement to include the range 60 cm to 120 cm from ground X-ray generator longitudinal, vertical and lateral movement to be at least 100 cm, 30 cm and 20 cm respectively Source to image distance should at least include the range 90 cm to 125 cm The tube head must be fully counterbalanced for safe and easy movement Maximum possible patient weight to be at least 150 kg Dust cover for control unit to be supplied Protection against insect and rodent ingress to be incorporated
22	Mobility, portability(if relevant)	
23	Raw Materials(if relevant)	
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Power input to be ************* fitted with ********** compatible mains plug, if single phase Power input to be ************* fitted with secure connection to supply, if three phase Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Electrical protection by resettable overcurrent breakers, fitted in both live and neutral lines Mains cable to be at least 3m length, if single phase
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	To be supplied with two adult size protective lead aprons Radiation hazard warning signs to be supplied with unit
26	Sterilization process for accessories (if relevant)	
27	Consumables / reagents (if relevant)	
28	Spare parts (if relevant)	
29	Other components (if relevant)	
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	Supplier to perform installation, safety and operation checks before handover.Supplier to clearly state supply current requirements of unit
36	Requirements for commissioning (if relevant)	
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided
38	User care(if relevant)	Unit layout to enable easy cleaning and sterilization of all surfaces
WARRANTY AND MAINTENANCE		
39	Warranty	
40	Maintenance tasks	Advanced maintenance tasks required shall be documented
41	Type of service contract	Local clinical staff to affirm completion of installation
42	Spare parts availability post-warranty	
43	Software / Hardware upgrade availability	
DOCUMENTATION		

WHO. "Stationary Basic Diagnostic X-Ray System, Digital." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

44	Documentation requirements	User, technical and maintenance manuals to be supplied in ************** language. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
45	Estimated Life Span	5 to 10 years
SAFETY AND STANDARDS		
46	Risk Classification	Class C (GHTF Rule 10(ii));Class II (USA); Class II (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	Must be FDA, CE or UL approved product.
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60336:2005 (X-ray tube assemblies for medical diagnosis - Characteristics of focal spots) IEC 60522:1999 (Determination of the permanent filtration of X-ray tube assemblies) IEC 60526:1978 (High-voltage cable plug and socket connections for medical X-ray equipment) IEC 60601-1-3:2013 (Part 1-3: General requirements for basic safety and essential performance - Collateral Standard:Radiation protection in diagnostic X-ray equipment) IEC 60601-2-8:2010 (Part 2-8: Particular requirements for basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV) IEC 60601-2-28:2010 (Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis) IEC 60601-2-43:2010 (Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures) IEC 60601-2-54:2009 (Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy) IEC 60613:2010 (Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis) IEC 60627:2013 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids) IEC 61262-1:1994 (Part 1: Determination of the entrance field size) IEC 61262-2:1994 (Part 2: Determination of the conversion factor) IEC 61262-3:1994 (Part 3: Determination of the luminance distribution and luminance non-uniformity) IEC 61262-4:1994 (Part 4: Determination of the image distortion) IEC 61262-5:1994 (Part 5: Determination of the detective quantum efficiency) IEC 61262-6:1994 (Part 6: Determination of the contrast ratio and veiling glare index) IEC 61262-7:1995 (Part 7: Determination of the modulation transfer function) IEC 61267:2005 (Medical diagnostic X-ray equipment - Radiation conditions for use in the determination of characteristics) IEC 61676:2009 (Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology) IEC 62463:2010 Radiation protection instrumentation - X-ray systems for the screening of persons for security and the carrying of illicit items)
49	Reginal / Local Standards	JIS Z 4751-2-28:2008 (Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis) JIS Z 4751-2-54:2012 (Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy) NEMA XR7-1995 (R2000) High-Voltage X-Ray Cable Assemblies and Receptacles
50	Regulations	**US regulations** 21 CFR part 820 21CFR part 892.1680 Stationary x-ray system **JP regulations** MHLW Ordinance No.169 37645010 Stationary digital general-purpose diagnostic X-ray system 37645020 Stationary digital general-purpose integral diagnostic X-ray system

WHO. “Stationary Basic Diagnostic X-Ray System, Digital.” From the publication: “WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

3. Preventative Maintenance of X-Ray Systems

Featured in this Section:

Engineering World Health. “Preventative Maintenance Schedule for X-Ray Viewer. *EWH*. 2012.

McClelland, I. R. “Appendix E: X-Ray Equipment Operation.” From the Publication: *X-Ray Equipment Maintenance and Repairs Workbook for Radiographers & Radiological Technologists*, (WHO: 2004).

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

X-Ray Preventative Maintenance Checklist

User Care Checklist – X-Ray Machines

Daily	
Cleaning	✓ Clean dust from the unit with a dry cloth ✓ Remove any tape, paper or foreign body from equipment
Visual checks	✓ Check all parts are present and connected ✓ Check cables are not twisted and remove from service if any damage is visible
Function checks	✓ Switch on power and check all indicators function

Weekly	
Cleaning	✓ Clean all dust and dirt from the X-Ray machine and room
Visual checks	✓ If any plug, cable or socket is damaged, refer to biomedical technician ✓ Check all knobs, switches and wheels operate properly ✓ Check lead aprons for any defects ✓ Check table, cassette holder and grids for smooth movement
Function check	✓ If machine has not been in use, wear lead apron and check whether exposure indicator lights on switch operation ✓ Check collimator bulb, replace with correct type if needed

Every six months
Biomedical Technician check required

Strengthening Specialised Clinical Services in the Pacific. User Care of Medical Equipment: A first line maintenance guide for end users. (2015).

Preventative Maintenance for X-Ray Viewers

Preventative Maintenance for X-ray viewer (Illuminator, Radiographic View Box)

- Inspect exterior of equipment for damage or missing hardware.
- Inspect the power cord, strain relief and plug/s for any signs of damage.
- Turn unit off, open user accessible covers and inspect unit for damage.
- Clean unit interior components and exterior with vacuum or compressed air.
- Inspect interior for signs of corrosion or missing hardware. Repair as required.
- Inspect electrical components for signs of excessive heat or deterioration.
- Inspect/adjust film holders and film activated switches as required.
- Verify adequate minimum illumination in all banks.
- Verify correct operation of safety interlocks.
- Verify correct operation of all buttons, controls, displays and/or indicators.

Engineering World Health. “Preventative Maintenance Schedule for X-Ray Viewer. EWH. 2012.

Safety and Fault Detection in X-Ray Systems

these will prevent operation unless the control is switched 'off' then 'on' again. In such a case, considerable caution is required, and any warning signals or codes should be investigated first.

While recent systems may display a fault code, or message, older controls may indicate a fault symbol, or just light up the same indicator used for X-ray tube overload. However, inside the control there are often many indicator LED indicators provided to indicate sequence operation or fault indication. Table E–7 indicates some of the safety interlocks and fault detection requirements that may exist.

Table E–7. Typical safety interlocks and fault detection requirements

On power up and system check.	Interlock test for operation of X-ray tube high-tension selection switch and stator connection relays. Has X-ray tube housing over temperature switch operated? On inverter systems, have the bank of inverter power supply capacitors charged up to the correct voltage?
Before preparation is permitted.	Has a valid technique been selected? Are the exposure factors within the safe operating area of both the X-ray tube and the generator? Entrance door safety switch not activated.
During preparation.	Is the current through the X-ray tube filament transformer above a minimum level? (If below, can indicate open filament connection). Is the filament current inside the maximum limit? Is the current flowing in both the 'start' and 'run' stator windings of the X-ray tube the correct value? Look for illegal voltage on generator transformer primary winding. (In case of an SCR contactor fault in conventional systems). Energize a warning light. 'Do not enter'.
At end of preparation.	Interlock for preparation timers. (Older systems may depend only on the stator control; later systems include a timer for minimum filament heating time.)
On exposure request with peripheral equipment, eg Bucky.	Hand switch exposure request is sent to the required Bucky. The Bucky must move the grid and trigger an interlock to indicate the Bucky is ready for an exposure. This interlock relays the exposure request back to the X-ray control.
To commence actual exposure.	On conventional systems, the expose signal places the timer into operation. The timer waits for a synchronization pulse derived from the mains supply voltage, and at the correct phase interval operates the SCR contactor. With a mechanical contactor, the time for the contactor to operate requires a compensation adjustment. With an inverter system, the signal to the timer and the inverter may occur at the same time. Mains voltage synchronization is not required.
During exposure.	The mA is measured. If mA is higher than a preset detection limit, stop the exposure. With high-frequency systems, if kV is excessive, or, after a short measurement time too low, stop the exposure. Some inverter systems measure the transformer primary current, and if too high stop the exposure.
At the end of a radiographic exposure.	A time-up signal may be sent to peripheral equipment. If in high-speed mode, the X-ray tube starter will now produce a brake cycle. A filament cool-down timer will operate, so a fluoroscopic exposure cannot be made until this timer has finished.

McClelland, I. R. "Appendix E: X-Ray Equipment Operation." From the Publication: X-Ray Equipment Maintenance and Repairs Workbook for Radiographers & Radiological Technologists, (WHO: 2004).

4. Troubleshooting and Repair of X-Ray Systems

Featured in this Section:

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Troubleshooting – X-Ray Machines

	Fault	Possible Cause	Solution
1.	X-Ray unit does not switch on.	Mains power not connected	Check the machine is plugged into the mains socket and that all switches are on. Replace fuse with correct voltage and current if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
2.	X-Ray machine not exposing, even when power is on.	Safety interlock is on Exposure switch cable problem Internal error	Check safety locks, all switches Check for any loose connection Refer to biomedical technician
3.	Poor X-Ray image quality	X-Ray tube problem	Check X-ray film cassette is correct type and is undamaged Refer to biomedical technician / medical physicist
4.	The table does not move.	Table motor or cable problem. Safety switch or fuse problem Control circuit problem	Check all cable connections Check relevant fuse or switch Refer to biomedical technician
5.	Electrical shocks	Wiring fault	Refer to biomedical technician immediately

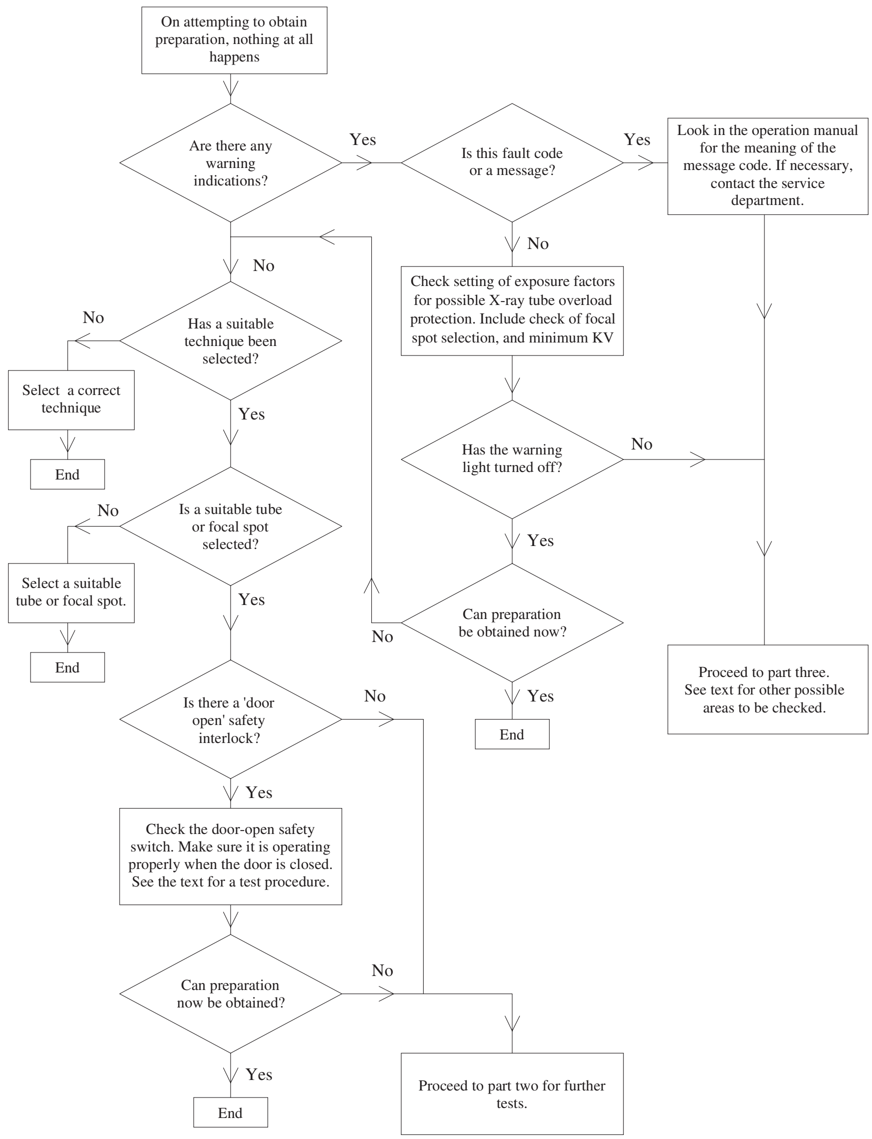

Fig 6–1. Unable to obtain preparation, part one

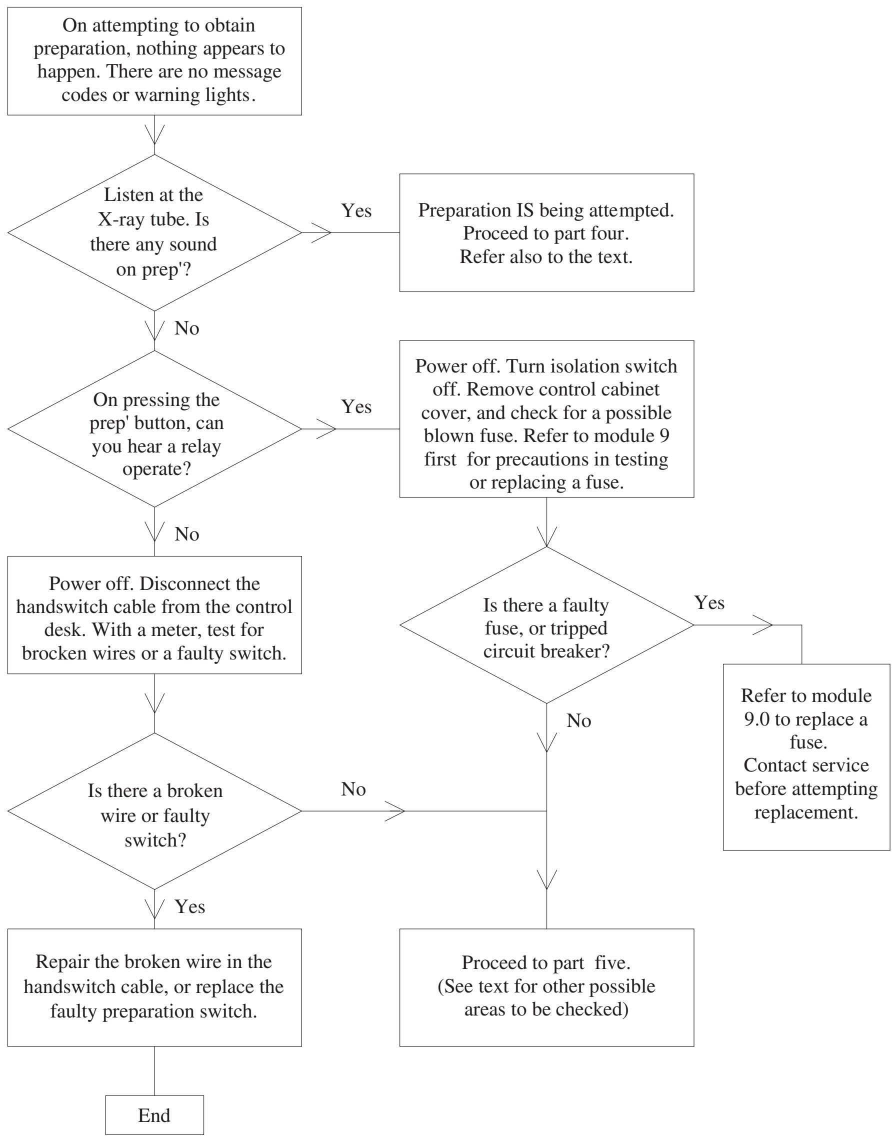

Fig 6–2. Unable to obtain preparation, part two

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

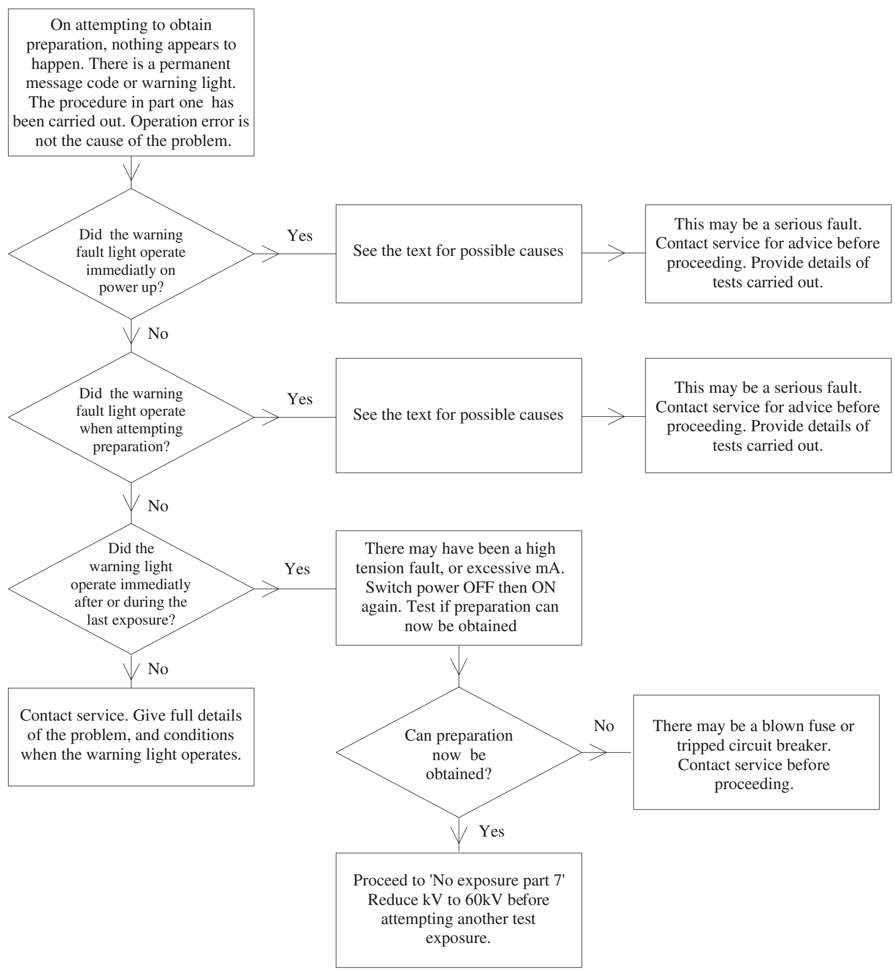

Fig 6–3. Unable to obtain preparation, part three

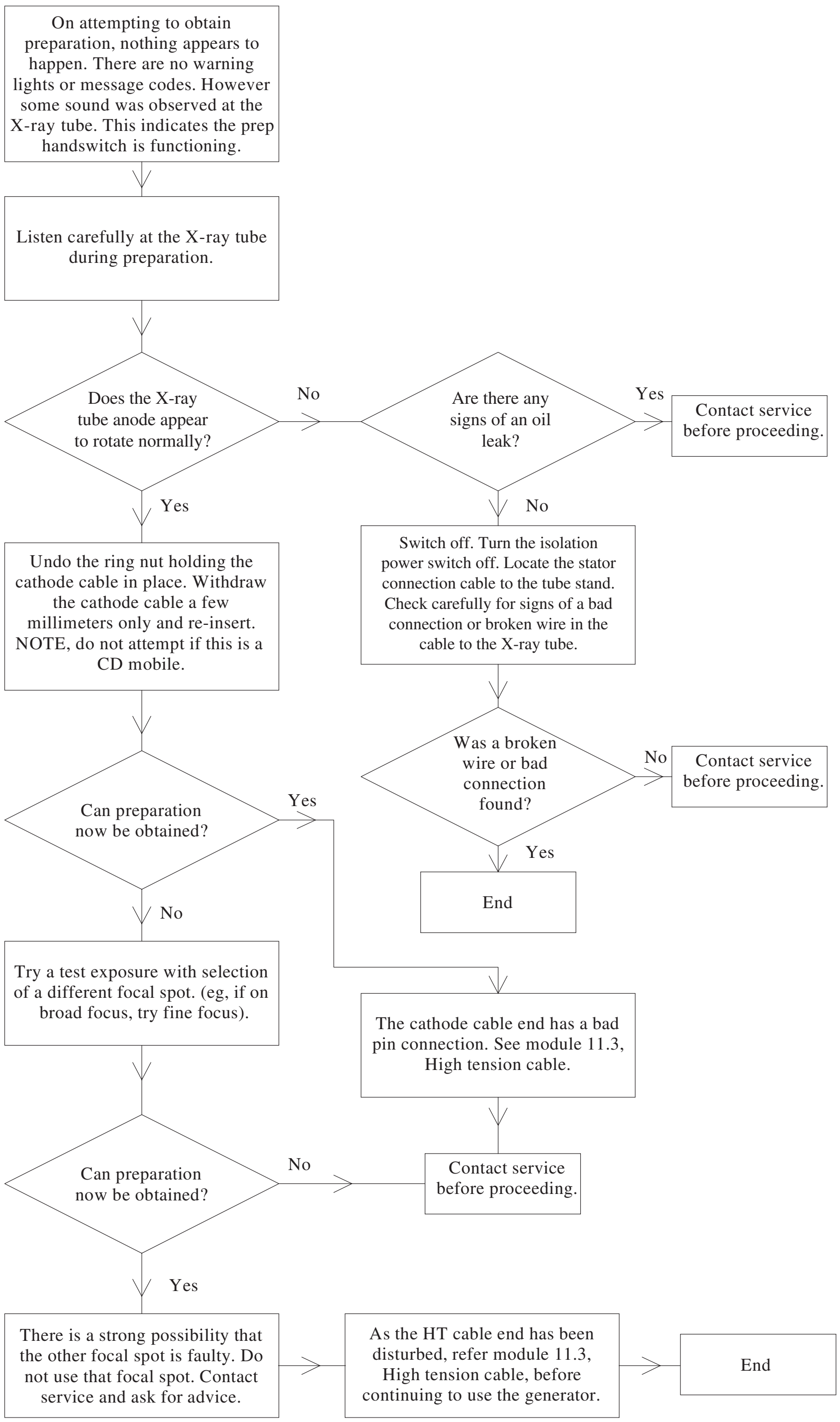

Fig 6–4. Unable to obtain preparation, part four

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

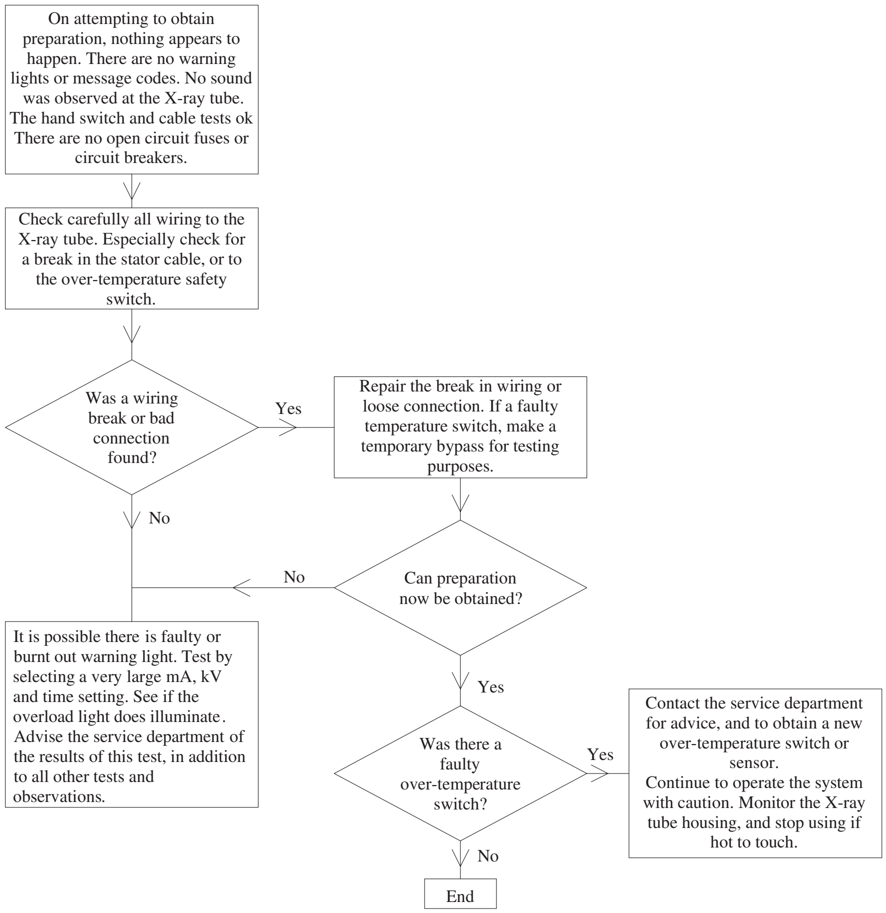

Fig 6–5. Unable to obtain preparation, part five

Part 5. Other tests

Refer first to the flow chart, Fig 6–5 page 79, 'Unable to obtain preparation, part five'.

There remain two possibilities to be checked.

- The wiring to the X-ray tube stator or the housing over-temperature switch is broken or has a bad connection. This could occur where it enters the X-ray tube, or where the cable has received a lot of flexing or twisting. See **module 7.1 page 104**.
- There may be an internal fault or problem in the generator, but the warning light is also faulty or burnt out. Test the light by setting very high exposure factors, which would normally cause a tube overload condition. If no warning light illuminates, then the globe or control circuit is faulty.
- Include the results of all tests, when requesting help from the service department.

Section 2: No radiograph exposure

This section assumes you are able to obtain preparation, the control has indicated preparation is completed, and is ready for an exposure. On attempting to obtain an exposure, nothing happens. Or else, the control appears to expose, but the film is blank or very light. Each part has an associated flow chart. Refer to these flow charts before reading the text.

Part 6. Operation tests

Refer first to the flow chart, Fig 6–6 page 83, 'No exposure, part six'.

The control has indicated it is ready for an exposure. On attempting to obtain an exposure, nothing appears to happen. There is no sound from the Bucky. The exposure light does not operate.

WHO. "X-Ray Diagnostic Equipment." Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

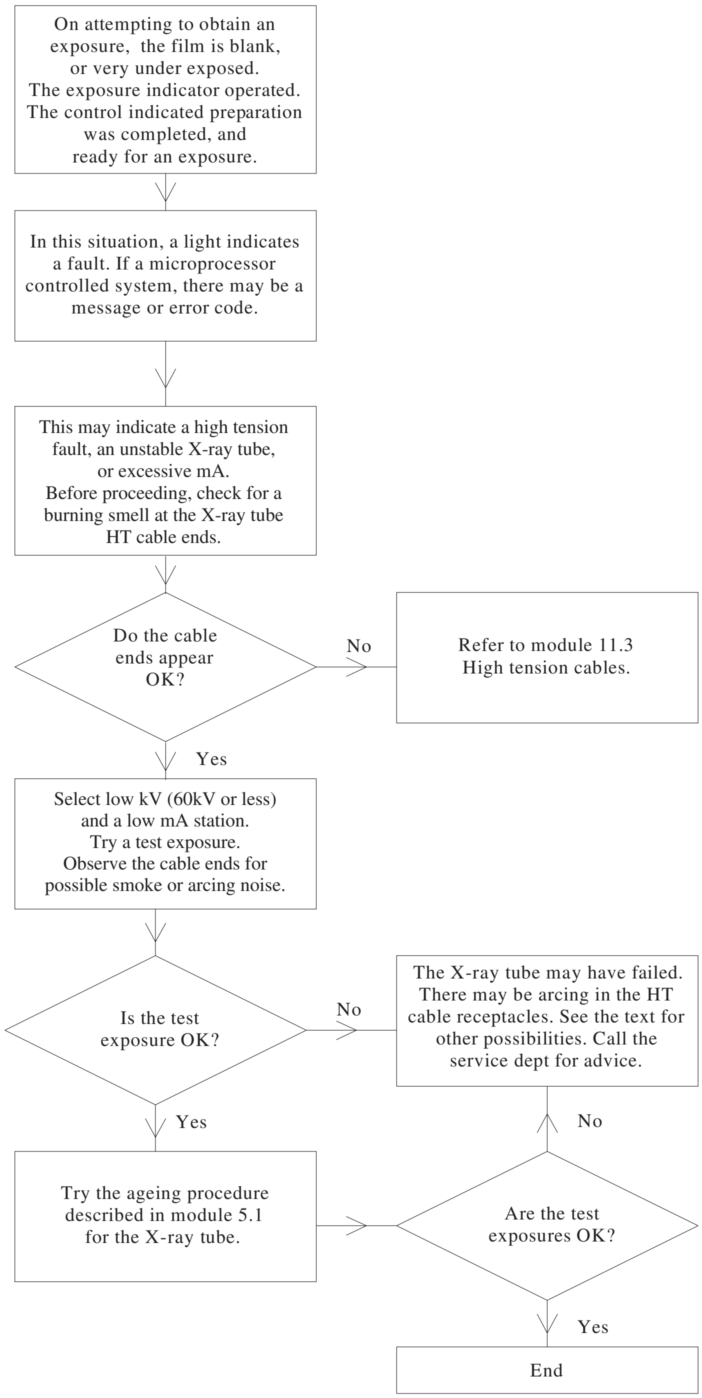

Fig 6–8. No exposure, part eight

5. Resources for More Information about X-Ray Systems

Featured in this Section:

WHO. "Routine Maintenance Models." From the publication: *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996).

WHO. "Fault Diagnosis and Repair Modules." From the publication: *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996).

Resources for More Information:

Internal Resources at library.ewh.org: For more information about maintenance and repair of x-ray systems, please see these resources in the BMET Library!

1. WHO. "Routine Maintenance Models." From the publication: *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996).

2. WHO. "Fault Diagnosis and Repair Modules." From the publication: *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996).

X-Ray Bibliography:

Engineering World Health. "Preventative Maintenance Schedule for X-Ray Viewer. *EWH*. 2012.

Dilmen, N. "Medical X-Ray Imaging ALPo2." *Wikimedia Commons*, November 12, 2011. Retrieved from: https://commons.wikimedia.org/wiki/File:Medical_X-Ray_imaging_ALP02_nevit.jpg

McClelland, I. R. "Appendix E: X-Ray Equipment Operation." From the Publication: *X-Ray Equipment Maintenance and Repairs Workbook for Radiographers & Radiological Technologists*, (WHO: 2004).

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

WHO. "Radiographic, Fluoroscopic System." From the publication: *Core Medical Equipment*. Geneva, Switzerland, 2011.

WHO. "Stationary Basic Diagnostic X-Ray System, Digital." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

WHO. "Stationary Basic Diagnostic X-Ray System, Analogue." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

WHO. "X-Ray Diagnostic Equipment." *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996), p. 121-134.

Wikipedia. " X-Ray." *Wikipedia*, pp. 1-17. Retrieved from: https://en.wikipedia.org/wiki/X-ray

Wikipedia. *Basic Physics of Digital Radiography/The Image Receptor*. Wikibooks. Downloaded 6/25/2014. Retrieved from: https://en.wikibooks.org/wiki/Basic_Physics_of_Digital_Radiography/The_Image_Receptor