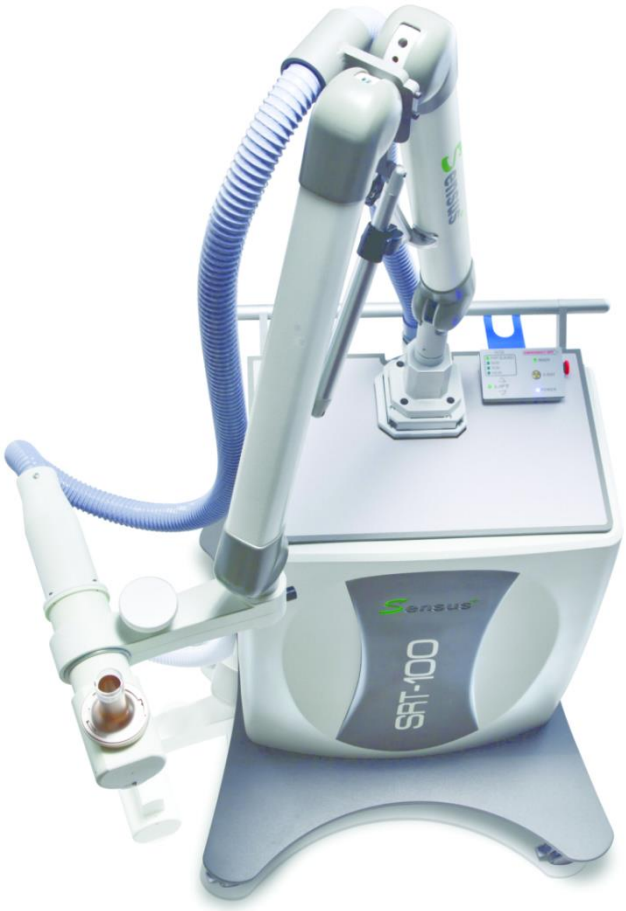
Sensus Healthcare

SRT-100™ Keloid Clinical Handbook



Introduction

When an injury occurs to the body, scar tissue forms to hold the wound tissues together. As the scar matures, the normal repair process takes place where new skin develops and scar tissue is broken down. It is during this maturation phase of healing that problem scars such as Keloids can develop. Keloids are an extreme overgrowth of scar tissue that present as raised, reddish, shiny, smooth skin growths.

Doctors do not understand exactly why keloids form in certain people or situations and not in others. Changes in the cellular signals that control growth and proliferation may be related to the process of keloid formation, but these changes have not yet been characterized scientifically.

Keloids are equally common in women and men, although at least in times past more women developed them because of a greater degree of earlobe and body piercing. Keloids are less common in children and the elderly. Although people with darker skin are more likely to develop them, keloids can occur in people of all skin types. In some cases, the tendency to form keloids seems to run in families.

The decision about when to treat a keloid depends on the symptoms associated with its development and its anatomical location. A chronically itching and irritated keloid can be quite distracting. Keloids in cosmetically sensitive areas that cause disfigurement or embarrassment are obvious candidates for treatment. It is unclear whether early treatment is important. What is clear is that larger keloids are more difficult to treat.

The main problem associated with surgery for heavy scars is recurrence. However, this can be controlled by superficial radiation therapy. Radiation therapy has been employed successfully in the treatment of keloids since the early 20th century. In most series, external kilovoltage beam radiation is directed at the surgical bed within 24 to 72 hours after re-excision of the keloid.

The technique for the treatment of keloids is relatively straightforward. The re-excision incision, plus a 1cm margin, is treated. All suture sites should be included. Superficial 50kV to 100kV x-rays can be used. Doses of 13Gy, 16Gy, and 18 Gy in 1, 2, and 3 fractions respectively are adequate if treatment is begun within 72 hours of excision.

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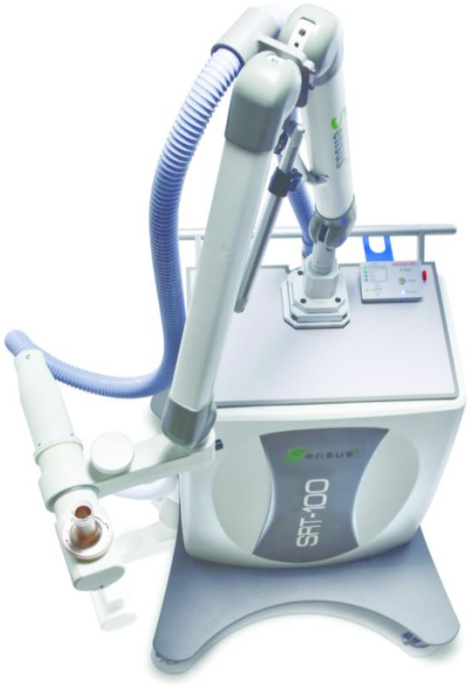
Radiation Physics



What is “Radiation”?

Radiation comes from the root word “radiate.” Radiate is defined as “to proceed in a direct line from or toward a center.”

Radiation is energy that is radiated in the form of waves or particles. Radiation can be thought of as the transmission of energy through space. The two major forms of radiation are:

- Electromagnetic (EM) radiation
- Particulate radiation

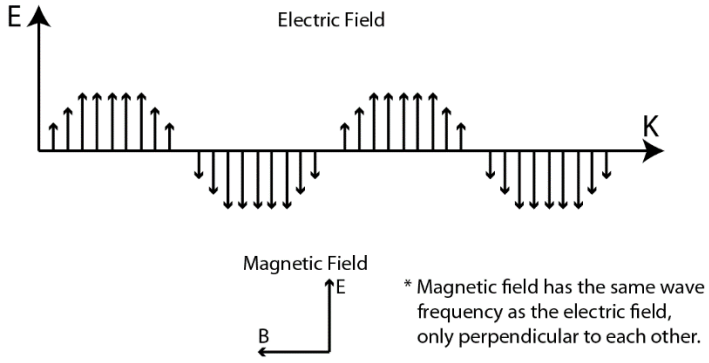
Both forms can interact with matter, and transfer their energy to the matter.

Electromagnetic Radiation

Visible light, radio waves, and UV-rays are all forms of radiation propagated as waves. These are all examples of a more general classification of radiation known as electromagnetic. Electromagnetic (EM) waves transport energy and momentum from one source to a receiver. As the frequency of the EM wave increases, so does the photon’s energy. Also, as frequency increases, wavelength decreases. Electromagnetic radiation has no mass, and moves through space at the speed of light (3.0 x 108 meters per second). An electromagnetic wave is characterized by its intensity and the frequency of the time variation of the electric and magnetic fields.

Electromagnetic radiation can be described by two models:

- Wave Model
- Photon Model



EM Radiation: Wave Model

The distance between maxima of the EM fields is the wavelength (λ). The frequency (v) of the wave is given by:

$$v = c / \lambda$$

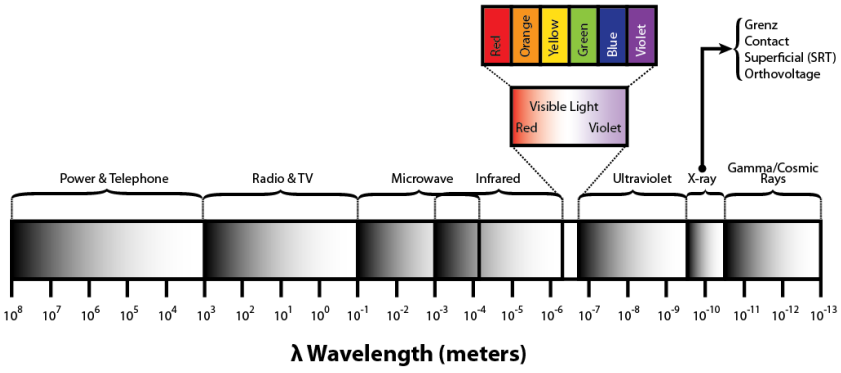
EM Radiation: Photon Model

Electromagnetic radiation can also be described as discrete packets of energy called photons. The energy (E) is related to the wavelength (λ) in the wave model through Planck's constant (h) and the speed of light (c).

$$E = h c / \lambda$$

Electromagnetic Spectrum

Electromagnetic spectrum is defined as the entire range of frequencies or wavelengths of electromagnetic radiation, from gamma rays to radio waves, including visible light. Electromagnetic spectrum comprises electromagnetic waves. Electromagnetic waves constitute similar kind of disturbances repeating at certain wavelengths.



Electromagnetic Spectrum

There are a number of different types of waves that constitute the electromagnetic spectrum. Radio waves are used for radio and television broadcasts, mobile phones, and government and non-government services like aeronautical beacons. The FM stations require 200 KHz of frequencies for a maximum of hundred stations. The 25 KHz frequency range is known as guard bands which are used to minimize interference. Televisions require 5 MHz separation. Micro waves are used in telephone satellites which are used to transmit the human voice in microwave code. It has a very short wavelength that, it is easily absorbed by water. The microwave radiation generates molecular rotation and torsion which produces heat. For this purpose, it is used in microwave ovens. It is also used in electron spectroscopy. Infrared waves form the lower end of the visible spectrum, with a frequency ranging from 10^10 - 10^14 Hertz. They generate heat formed by the vibration of molecules and are used in infrared detectors, television remote controls, etc.

Visible light is the narrow band of electromagnetic spectrum which is detected by the human eye. It has the frequency of 10^14 Hertz and wavelength of 10^ (-6) m. Visible light waves are produced by the ionization of electrons, and retina of the eyes can sense only this range of wavelength. When white light is passed through a prism it splits to form seven different colors, a process known as dispersion. Ultraviolet rays have a very high energy with frequency ranging from 10^14 - 10^16 Hertz. These rays are highly carcinogenic due to ionizing radiation, but they do have some therapeutic features. The sun is the source of UV rays; therefore, sunburns and damage to the eyes can occur with long exposure.

X-rays are penetrating rays formed when fast-moving high energy electrons are stopped by a metal; the frequency range is from 10^16 - 10^19 Hertz and wavelength of 10^ (-8) to 10^ (-10) m. X-rays are used to determine molecular structures and are commonly used in the medical field as they can penetrate through flesh. They can be produced in parcels of energy called photons, just like light. X-rays are produced as the result of changes in the positions of the electrons orbiting the nucleus, as the electrons shift to different energy levels. X-rays were first observed and documented in 1895 by Wilhelm Conrad Roentgen, a German scientist who found them by accident when experimenting with vacuum tubes. Treatment of diseases with X-rays began within months of Roentgen's discovery, and within four years, X-rays were being used successfully for the treatment of skin cancers.

Particulate Radiation

Particle radiation is a stream of atomic or subatomic particles that may be charged positively (e.g. alpha particles), or negatively (e.g. beta particles), or not at all (e.g. neutrons). Alpha particles and beta particles are considered directly ionizing because they carry a charge and can, therefore, interact directly with atomic electrons through coulombic forces (i.e. like charges repel each other; opposite charges attract each other).The neutron is an indirectly ionizing particle. It is indirectly ionizing because it does not carry an electrical charge. Ionization is caused by charged particles, which are produced during collisions with atomic nuclei.

Ionizing and Non-Ionizing Radiation

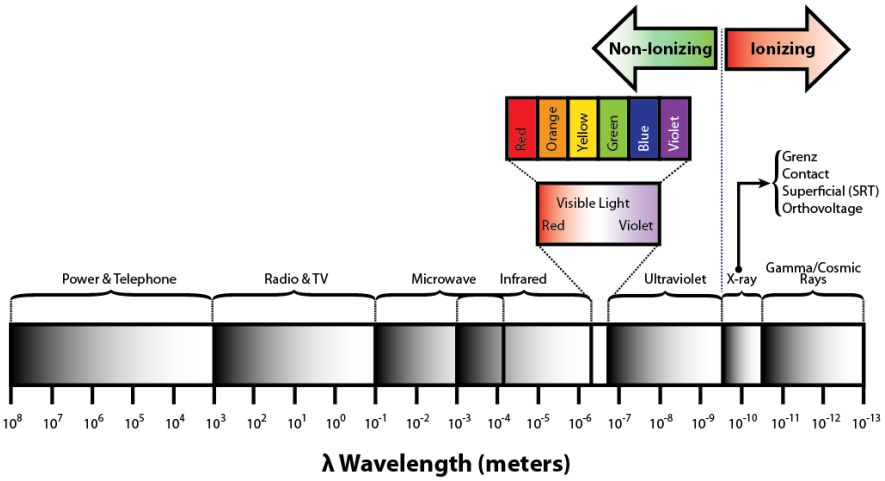
Radiation is categorized as either ionizing or non-ionizing. From the standpoint of radiation protection, this categorization denotes the level of danger posed to humans.

Ionizing Radiation

Ionizing is the process of removing electrons from atoms, leaving two electrically charged particles (an electron and a positively charged ion) behind. The negatively charged electrons and positively charged ions created by ionizing radiation may cause damage in living tissue. Basically, a particle is ionizing if its energy is higher than the ionization energy of a typical substance, and interacts with electrons significantly. Photons (electromagnetic) and particles with energies above about 10 electron volts (eV) are ionizing. Not all electromagnetic radiation (EMR) is ionizing. Only the high-frequency portion of the electromagnetic spectrum, which includes X-rays and gamma rays, is ionizing. Alpha particles, beta particles, cosmic rays, gamma rays, and X-ray radiation all carry energy high enough to ionize atoms. In addition, free neutrons are also ionizing, since their interactions with matter are inevitably more energetic than this threshold.

Non-ionizing Radiation

Non-ionizing radiation is the term given to radiation in the part of the electromagnetic spectrum where there is insufficient energy to cause ionization. It includes electric and magnetic fields, radio waves, microwaves, infrared, ultraviolet, and visible radiation. Longer wave lengths/lower frequency waves (electric and radio waves) have less energy than shorter wave length/higher frequency waves (X-ray and gamma rays). Non-ionizing radiation is harmful to organisms only in proportion to the thermal energy deposited, and is conventionally considered harmless at low powers which do not produce significant temperature rise.



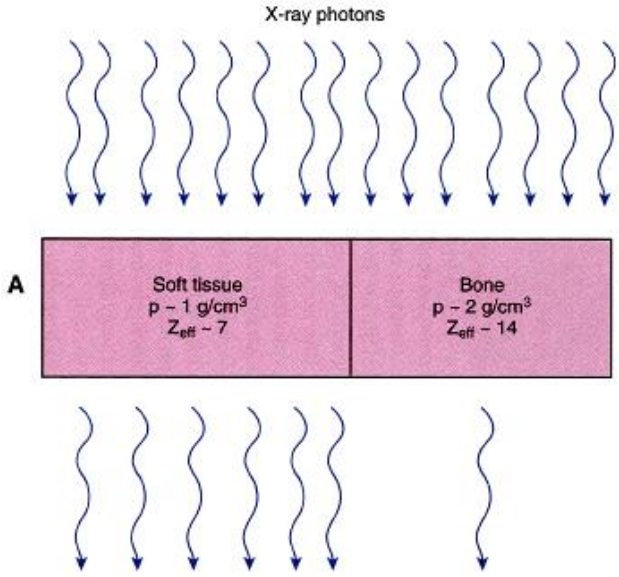
Ionizing vs. Non-Ionizing Radiation

Interactions of Radiation and Matter

Understanding how radiation interacts with matter leads to an understanding of why different types of radiation have greater penetrating power and how to protect against each type of radiation. To develop a means to estimate radiation dose (i.e., the energy absorbed by tissue), one needs to understand the processes by which radiation interacts with tissue.

Photon (X-ray) Radiation

Photon beams interact with the matter through which they pass and consequently, the beam intensity (the number of photons per area) is attenuated. The degree to which photon beams are attenuated, and the degree to which each interaction type contribute to the tissue dose, can be calculated using the incident energy. There are a variety of types of interactions for photons; however, the main interaction that occurs with Superficial Radiation Therapy energies is photoelectric absorption.



The likelihood of a photon interaction in bone is several times greater at energies typical of Superficial Therapy procedures, but the differences decrease at higher energies typical of ortho-voltage therapies.

Particle Interactions

Particles, unlike photons, have mass, and some have charge. Hence, the processes that govern what happens to particles differ from those that govern what happens to photons. Understanding particle interactions in matter (e.g., tissue) is the last major requirement to understanding the phenomenon that contribute to radiation dose.

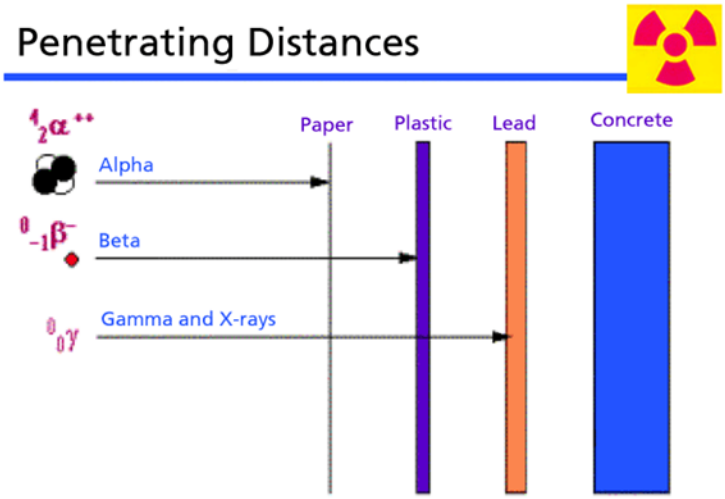
Particles (except for neutrons) are charged and cause atomic ionization or excitation as they move through matter as a result of coulomb forces (repulsion of like electric charges). The electrons released by photon interactions will eventually stop because each coulomb interaction results in a transfer of energy to atomic electrons of the material irradiated. The processes that slow down the incident particles are of importance to the theory of radiation dosimetry because those processes impart energy to the material irradiated.

Beta Particles

Beta particles can travel several hundred times the distance of alpha particles in air, penetrate skin and tissue, and require a few millimeters of aluminum to stop them. Thus, beta particles can be both an external and internal hazard.

Gamma Rays

Gamma rays are the most penetrating type of radiation and can travel many meters in air and many centimeters in tissue. Because gamma rays can travel through the body, they are sometimes referred to simply as “penetrating radiation”. Like beta particles, gamma rays constitute both an internal and external hazard.



Alpha Particles

Alpha particles are relatively heavy (~7300x that of electron) and have 2 units of charge; therefore, they have much shorter range, because each Coloumb interaction is greater. The

typical range of alpha particles in tissue is 40 μm. This explains why alpha particles are normally only a hazard of “internal emitters.”

Neutrons

The processes for slowing of neutrons in matter is the reverse of that of charged particles.

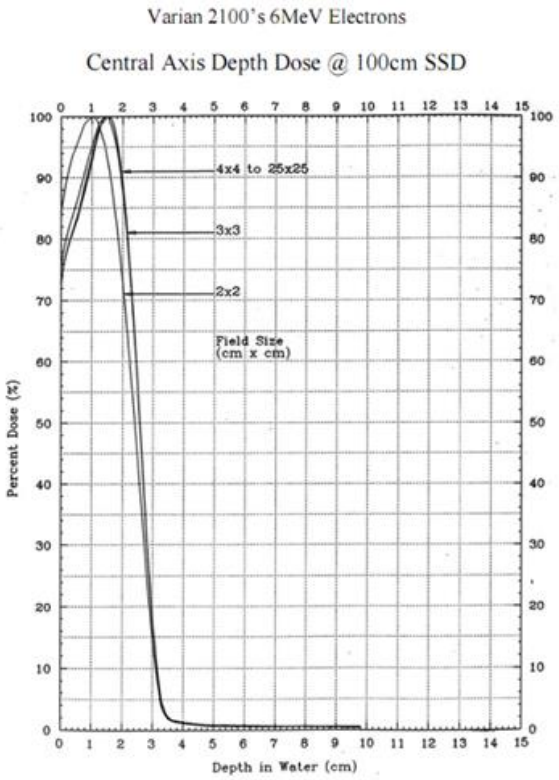
Because neutrons are of neutral charge, there is no Coulomb interaction. Neutrons are primarily slowed as a result of ‘collisions’ and scattering from nuclei and are eventually absorbed in by the nuclei in neutron-capture reactions. In elastic scattering (this is where the kinetic energy is conserved through the collision), the maximum energy (Qmax) that a particle of mass M and energy E can transfer to a free particle of mass m is Qmax = 4mM/(M+m)2 Since neutrons and protons have near equal mass, large energy transfers are possible in proton rich material, e.g., water or tissue. Less energy is transferred (per collision) to 12C or heavier atoms (because their mass m is larger).

Electrons

The lowest stable electron beam used for very superficial lesions is around 6MeV, which only deposits 85% of its energy at the surface with large field sizes. The graph below shows that electron surface dose is field size dependent, and as the file size shrinks, so does the surface dose. The average field size for a very superficial skin lesion is from the 3x3 to 1.5x1.5 (80% skin lesions are head and neck); this lowers the surface dose even more to 77% and 73% respectively. To raise the surface dose, bolus material is applied. The bolus must be of a certain thickness to raises the desired therapeutic dose to the surface. Changing field sizes without changing the thickness of the bolus can lead to some lesions being under-dosed at the surface.

It is also important to note that at the depth of the dermis, high significant dose is being deposited.

Electron beams are produced in the MeV range, which means the beams have to travel to a depth in tissue before the maximum energy is achieved. This lack of saturation at the surface renders less than 100% of the dose to where the lesion lies, but this can be remedied by placing bolus material (which acts as a tissue equivalent) over the patient’s skin. As already mentioned, however, bolus thickness must be adjusted according to field size, making it difficult to provide correct dosage to very superficial lesions that are only a couple of millimeters thick.



Electron suface dose. Note the change in surface dose with different field sizes

Electrons lose energy constantly as they pass through a medium, and their rate of energy loss and amount of scattering is dependent on their energy. For lower energy electrons, lateral scattering happens shortly after entering the tissue. This leads to a relatively rapid loss of energy, with a significant 'peak' of energy loss at Zmax relative to the surface dose. Higher energy electron beams tend to undergo minimal scattering near the surface and continue onwards, losing their energy over a greater distance. This leads to a significantly broader region of dose distribution, and Zmax is not significantly greater than the surface dose. The final outcome of these interactions is that high energy electrons have a high surface dose relative to low energy electrons.

Comparing Interactions of Photon and Electron Beams

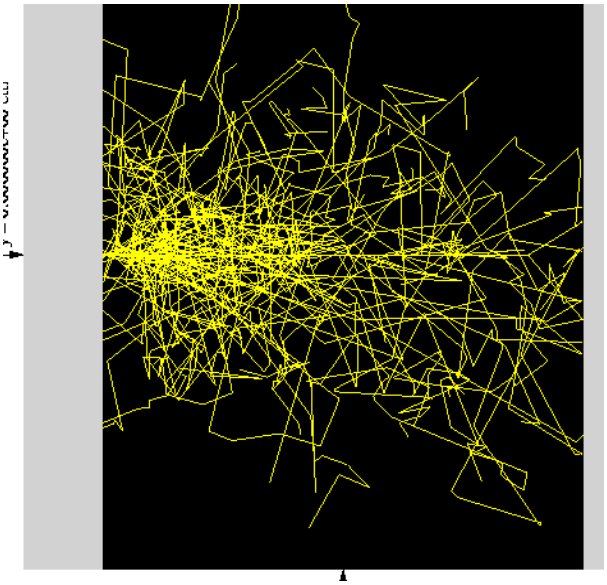
Photons

- Not charged
- Zero rest mass
- V = C (speed of light)
- No Coulomb force
- Random and rare interactions
- Infinite range (in theory)

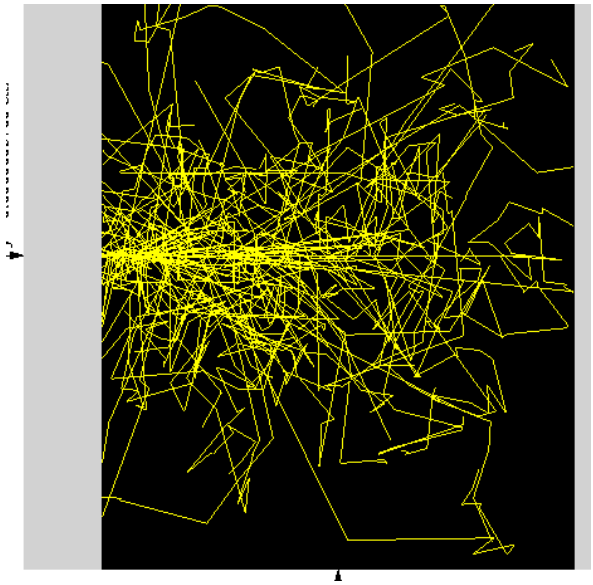
Electrons

- Charged
- Finite mass
- V < C
- Coulomb force
- Continous interactions
- Finite range

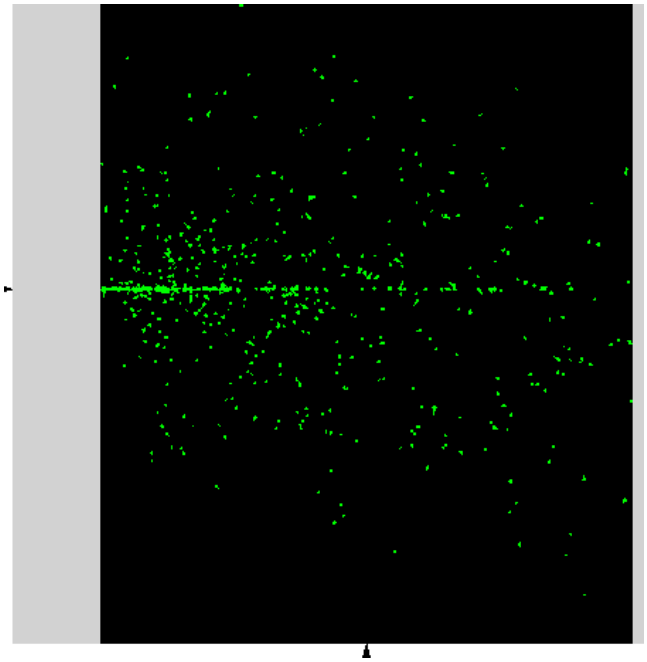
Interactions are random on a micro-scale but result in a predictable average ionization.



1st 100 photons



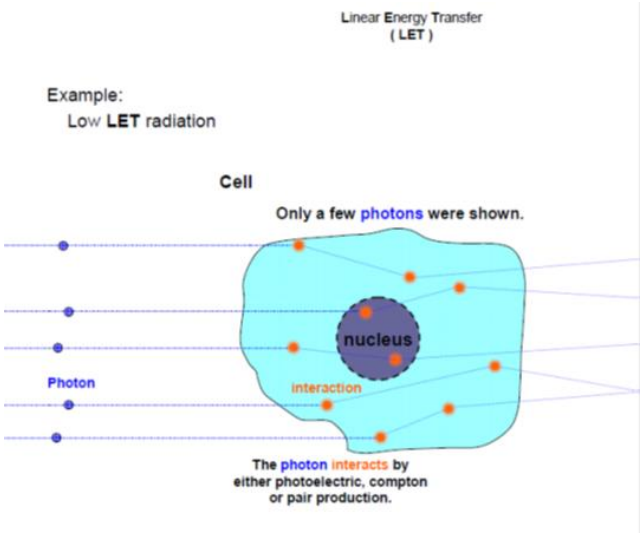
2nd 100 photons



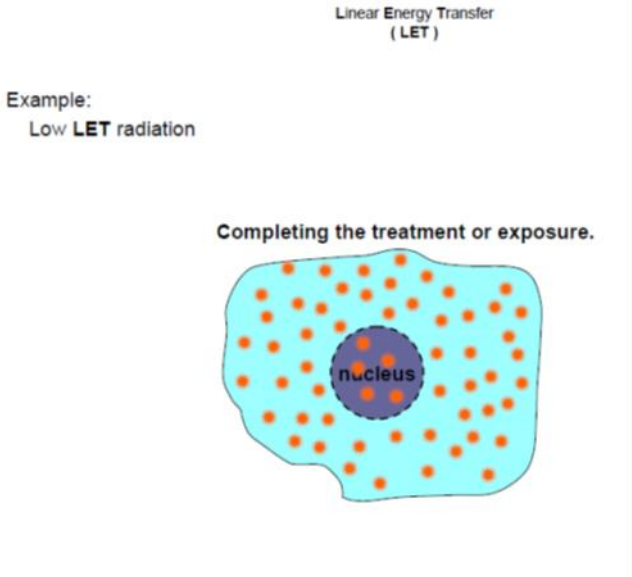
Electrons produced
(Note the under-ionization pattern)

Superficial Radiation Modalities

Superficial kilovoltage modalities deposit energy in a more uniform distribution than electron beams. This is accomplished because of the forms of waves that first interact with the tissue. With low Linear Energy Transfer (LET) radiation, the interactions produced are relatively far apart from each other. Therefore, they will be spread throughout the cell, making for a more uniform dose distribution throughout the cell.



During Superficial Radiotherapy treatment fractions, an accumulation of ionizations take place across the cell, evenly distributing the energy and not leaving areas of under-ionization present. The areas of under-ionization in electron beam therapy are the reason why dosages are much higher than the range of Superficial.

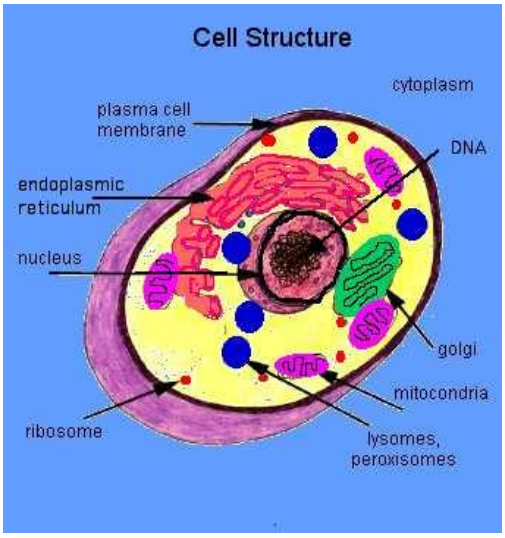


Chapter 2: Radiobiology

Radiobiology, the branch of science concerned with the action of ionizing radiation on biological tissues and living organisms, is a combination of two disciplines: radiation physics and biology. Ionization of the tissue and excitation of orbital electrons results in the disposition of energy in tissues. This produces ions and radicals within the cell (mostly from water molecules). When these radicals and ions interact with other cell materials, damage can result. Certain levels of cellular damage can be repaired by the cell, while further levels can result in cell death. This chapter deals with the interactions of X-rays—the energy used when delivering treatment with the SRT-100™ superficial radiotherapy unit.

Within a year after Roentgen's discovery of X-rays in 1895, scientists learned that exposure to ionizing radiation could lead to biological damage. Since that time, a tremendous amount of research has been performed attempting to interpret the reactions which take place from the moment that radiation enters a living cell until some permanent damage is produced. From beginning to end, these initial reactions are probably completed in a millionth of a second, making them very difficult to study. For this reason, it is still not known which of the many chemical or biochemical reactions brought about by ionizing radiation are responsible for initiating biological damage.

Since the primary site of radiation damage is in the cell, the logical place to start a study of the biological effects of radiation is with the structure of this basic unit of all living material. Cells are the building blocks of which man and his living environment are composed; they are the fundamental unit of which all living organisms are made. Although there is no such thing as a typical cell, all cells have several features in common. Most cells are composed of protoplasm: a mixture of carbohydrates, lipids, proteins, nucleic acids, inorganic salts, gases, and between 70 and 80% water. Cells can be subdivided into three major parts: the cell membrane, the cytoplasm, and the nucleus.



Cell Membrane

The cell membrane is only a millionth of a centimeter thick, and is a living functional part of the cell. It helps to regulate the concentration of water, salts, and organic matter which form the interior environment of the cell. In red blood cells and nerve cells, the membrane distinguishes between sodium and potassium ions even though these ions are alike in size and electrical charge. The membrane actively transports potassium ions into the cell and opposes the entrance of sodium ions. The membrane is thus capable of "active transport." In addition, all food entering the cell and all waste products or secretions leaving it must pass through this membrane.

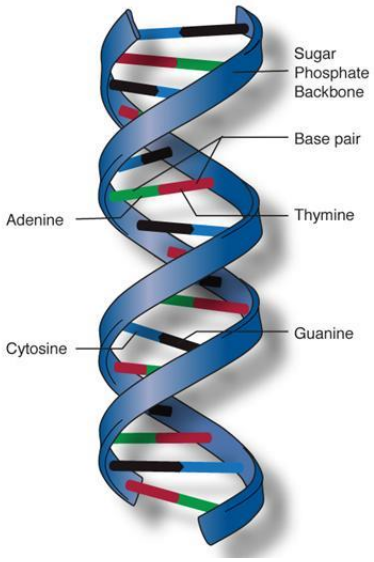
Cytoplasm

The cytoplasm is a jelly-like substance in which the nucleus is suspended; it is encased within the cell membrane. This material is an aqueous solution of soluble proteins and salts which constitutes the interior environment of the cell. Many small functional units called organelles are contained in the cytoplasm. Principal among these is the mitochondria, which are the "power plants" of both plant and animal cells. It is here that oxygen is used for the oxidation of essential foodstuffs and the formation of carbon dioxide. The metabolic energy released is captured in the chemical bonds of a special energy-storing molecule known as ATP (adenosine triphosphate). This molecule supplies the energy for all the activities of the cell, including reproduction. The lysosomes contain the digestive enzymes that break down large molecules, such as those of fats, proteins, and nucleic acids, into smaller constituents that can be oxidized by the oxidative enzymes of the mitochondria. The lysosomal membrane isolates the digestive enzymes from the rest of the cytoplasm. Rupture of the membrane and release of the enzymes leads to the dissolution of the cell.

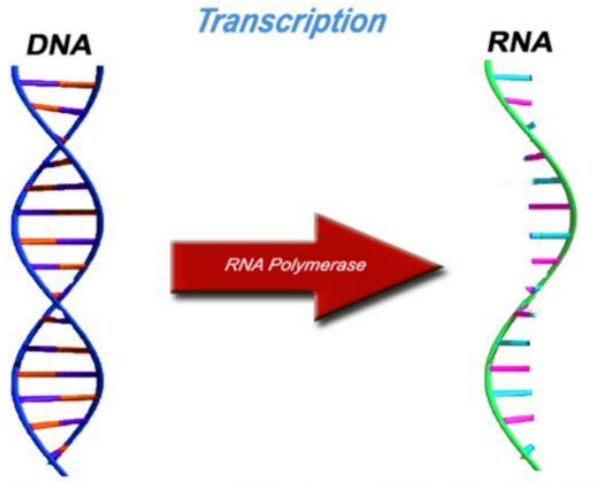
Nucleus

Each cell contains a small, usually oval, body known as the nucleus. In some cells this has a relatively fixed position and is found near the center; in others it may move around freely and be found almost anywhere in the cell. The nucleus is an important center of control of the cell, directing cellular activity and containing the hereditary factors (genes) responsible for the traits of the animal or plant. The membrane surrounding the nucleus and separating it from the adjacent cytoplasm is called the nuclear membrane. It is a double membrane with annuli, or holes, in the outer layer, open to the cytoplasm. This suggests that the cytoplasm of the cell is in direct communication with the protoplasm of the cell nucleus (the nucleoplasm). The function of this nuclear membrane is to regulate the constant flow of materials into and out of the nucleus. The nucleoli are spherical bodies which are found within the cell nucleus. These cell constituents are packed with tiny granules similar to the ribosomes of the cytoplasm. The nucleoli are rich in RNA and appear to be active centers of protein and RNA synthesis.

DNA (Deoxyribonucleic Acid) is the most important material making up the chromosomes and serves as the master blueprint for the cell. It determines what types of RNA are produced which, in turn, determine the types of protein that are produced. It is generally assumed to take the form of a twisted ladder or double helix.

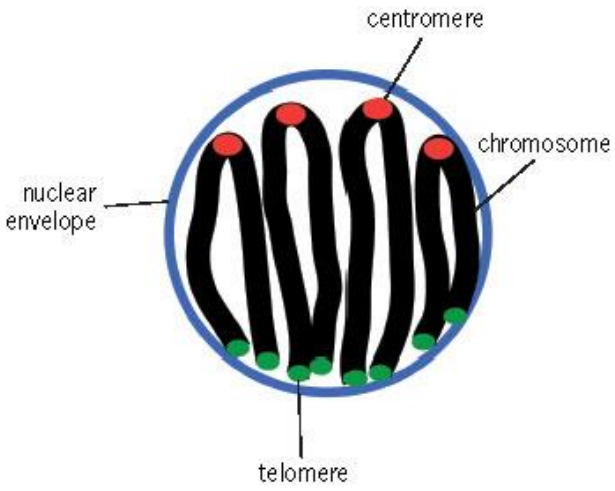


The sides of the ladder are strands of alternating sugar and phosphate groups. Branching off from each sugar group is one of four nitrogenous bases: cytosine, thymine, adenine and guanine. The rungs of the ladder consist of two nitrogenous bases, one from each strand, linked by hydrogen bonds. Cytosine is always paired with guanine and thymine is always paired with adenine. A section of DNA that codes for one protein is referred to as a gene, although the “message” from several genes can be carried by single piece of RNA.



Using an enzyme known as RNA polymerase genetic information in DNA is converted, or "transcribed", into RNA

Chromosomes consist of highly convoluted supercoils of DNA and associated protein. Each chromosome possesses a single centromere, a short specialized section of the chromosome that serves as a type of attachment point. The centromere must be present for the appropriate movement of the chromosomes during cell division. To ensure its survival, each new cell must possess the entire required DNA (a complete chromosome complement).



Effects of Radiation on Cells

A great deal of work has been performed on examining the effects of radiation on various organelles. It has been established that it takes about 3,000 to 5,000 cGy of absorbed dose to rupture a human cell membrane. This major injury to the cell allows the extracellular fluids to enter into the cell. Inversely, it also allows leakage out of ions and nutrients which the cell brought inside. Membrane rupture may result in the death of a cell; in this case, death would be compared to drowning. Large doses below 3,000 rad increase the permeability of the cell membrane and some leakage occurs.

Radiation effects on cytoplasm are negligible compared to observed effects on structures which are suspended within it. The first involve the mitochondria. It requires a few thousand rad to disrupt their function. This results in the immediate interruption of the cell's food supply (ATP). If the cell has a large reserve of ATP it can repair the damage to the mitochondria and then continue to produce ATP. The greater the radiation dose received, the longer the repair time will be. If the stored food supply is not adequate to nourish the cell during repair, then the cell will die from starvation.

Another organelle within the cytoplasm that is affected by radiation is the lysosome. The lysosome will rupture at dose levels between 500 and 1,000 rad. When this occurs, the enzymes are released within the cell and begin digesting structures of the cell. This cell death can be compared with suicide. At much larger doses the digestive enzymes are rendered inactive.

The most radiologically sensitive part of the cell is the nucleus. Because there is a wide band of sensitivity for cell nuclei, quantifying a dose range is difficult. The major effect of radiation on the cell nucleus is the inhibition of DNA replication. This means that the cell is unable to prepare for division. Before a cell divides, it produces a complete duplicate set of chromosomes which carry all the information needed to reproduce the organism. With damaged DNA, duplicate chromosomes cannot be manufactured. If this process is delayed long enough, the cell dies and the death of the cell can be compared to death in childbirth. At lower doses, DNA production is delayed only a short time. As the dose is increased, the delay period gets longer until death occurs.

Law of Bergonie and Tribondeau

As early as 1906 an attempt was made to correlate the differences in sensitivity of various cells with differences in cellular physiology. These differences in sensitivity are stated in the Law of Bergonie and Tribondeau: "*The radiosensitivity of a tissue is directly proportional to its reproductive capacity and inversely proportional to its degree of differentiation*." In other words, cells most active in reproducing themselves and cells not fully mature will be most harmed by radiation. This law is considered to be a rule of thumb, with some cells and tissues showing exceptions.

Since the time that the Law of Bergonie and Tribondeau was formulated, it is generally accepted that cells tend to be radiosensitive if they are:

- Cells that have a *high division rate*
- Cells that have a *high metabolic rate*
- Cells that are of a *non-specialized type*
- Cells that are *well nourished*

Even though all subsequent biological effects can be traced back to the interaction of radiation with atoms, there are two mechanisms by which radiation ultimately affects cells. These two mechanisms are commonly called *direct effects* and *indirect effects*.

Direct Effects

In direct action, radiation interacts directly with the critical target in the cell. The atoms of the target itself may be ionized or excited, leading to the chain of physical and chemical events that eventually produce the biological damage. Direct action is the dominant process in the interaction of high LET particles with biological material. Alpha particles and beta particles are considered directly ionizing because they carry a charge and can, therefore, interact directly with atomic electrons through coulombic forces (i.e. like charges repel each other; opposite charges attract each other).

Indirect Effect

In indirect action, the radiation interacts with other molecules and atoms (mainly water, since about 80% of a cell is composed of water) within the cell to produce free radicals, which can, through diffusion in the cell, damage the critical target within the cell. In interactions of radiation with water, short-lived yet extremely reactive free radicals such as H2O+ (water ions) and OH (hydroxyl radicals) are produced. These free radicals can break the chemical bonds and produce chemical changes that lead to biological damage; they are highly reactive molecules because they have an unpaired valence electron. About two thirds of the biological damage by low LET radiation, such as X-rays, is due to indirect action.

The steps involved in producing biological damage by the indirect action of X-rays are:

Step 1: Primary photon interaction (photoelectric effect, Compton Effect and pair production) produces a high energy electron.

Step 2: The high energy electron moving through tissue produces free radicals in water.

Step 3: The free radicals may produce changes in DNA from breakage of chemical bonds.

Step 4: The changes in chemical bonds result in biological effects.

Step 1 is in the realm of physics; Step 2 is in chemistry; Steps 3 and 4 are in radiobiology.

Linear Energy Transfer (LET)

For use in radiobiology and radiation protection, the physical quantity that is useful for defining the quality of an ionizing radiation beam is the linear energy transfer (LET). The LET focuses attention on the linear rate of energy absorption by the absorbing medium as the charged particle traverses the medium.

In contrast to the stopping power, which has a typical unit of MeV/cm, the unit usually used for the LET is keV/μm. The energy average is obtained by dividing the particle track into equal energy increments and averaging the length of track over which these energy increments are deposited. Typical LET values for commonly used radiations are:

- 250 kVp X-rays: 2 keV/μm.
- Cobalt-60 g rays: 0.3 keV/μm
- 3 MeV X-rays: 0.3 keV/μm.
- 1 MeV electrons: 0.25 keV/μm

X-rays are considered low LET (sparsely ionizing) radiations, while energetic neutrons, protons and heavy charged particles are high LET (densely ionizing) radiations. The demarcation value between low and high LET is at approximately 10 keV/μm.

The cell proliferation cycle is defined by two well defined time periods:

- Mitosis (*M*), where division takes place
- The period of DNA synthesis (*S*)

The *M* and *S* portions of the cell cycle are separated by two periods (gaps)—G1 and G2—when, respectively, DNA has not yet been synthesized or has been synthesized but other metabolic processes are taking place. The time between successive divisions (mitoses) is called the *cell cycle time*. For mammalian cells growing in culture, the *S* phase is usually in the range of 6–8 h, the *M* phase less than an hour, G2 is in the range of 2-4 h, and G1 is 1-8 h, making the total cell cycle between 10-20 hours. In contrast, the cell cycle for stem cells in certain tissues is up to about 10 days. In general, cells are most radiosensitive in the *M* and G2 phases, and most resistant in the late *S* phase.

The cell cycle time of malignant cells is shorter than that of some normal tissue cells, but during regeneration after injury, normal cells can proliferate faster. Cell death of non-proliferating (static) cells is defined as the loss of a specific function, while for stem cells and other cells capable of many divisions it is defined as the loss of reproductive integrity (reproductive death). A surviving cell that maintains its reproductive integrity and proliferates almost indefinitely is said to be clonogenic.

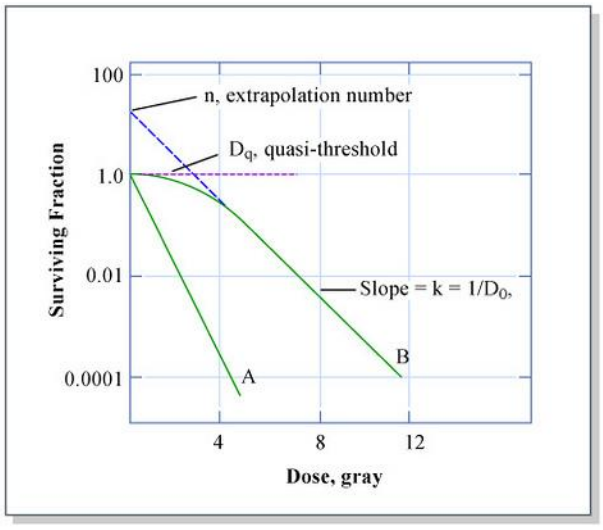
Classification of Radiation Damage

Radiation damage to mammalian cells is divided into three categories:

- *Lethal damage*, which is irreversible, irreparable and leads to cell death.
- *Sublethal damage*, which can be repaired in hours unless additional sublethal damage is added that eventually leads to lethal damage.
- *Potentially lethal damage*, which can be manipulated by repair when cells are allowed to remain in a non-dividing state.

Cell Survival Curve

A cell survival curve describes the relationship between the surviving fraction of cells [i.e. the fraction of irradiated cells that maintain their reproductive integrity (clonogenic cells)] and the absorbed dose. Cell survival as a function of radiation dose is graphically represented by plotting the surviving fraction on a logarithmic scale on the ordinate against dose on a linear scale on the abscissa.



The type of radiation influences the shape of the cell survival curve. Densely ionizing radiations exhibit a cell survival curve that is almost an exponential function of dose, shown by an almost straight line on the log–linear plot. For sparsely ionizing radiation, however, the curves show an initial slope followed by a shoulder region and then become nearly straight at higher doses. Factors that make cells less radiosensitive are: removal of

oxygen to create a hypoxic state, the addition of chemical radical scavengers, the use of low dose rates or fractionated irradiation, and cells synchronized in the late S phase of the cell cycle.

Several mathematical methods of varying degrees of complexity have been developed to define the shape of cell survival curves, all based on the concept of the random nature of energy deposition by radiation. The linear quadratic model is now most often used to describe the cell survival curve, assuming that there are two components to cell kill by radiation:

$$S(D) = e^{-aD-bD2}$$

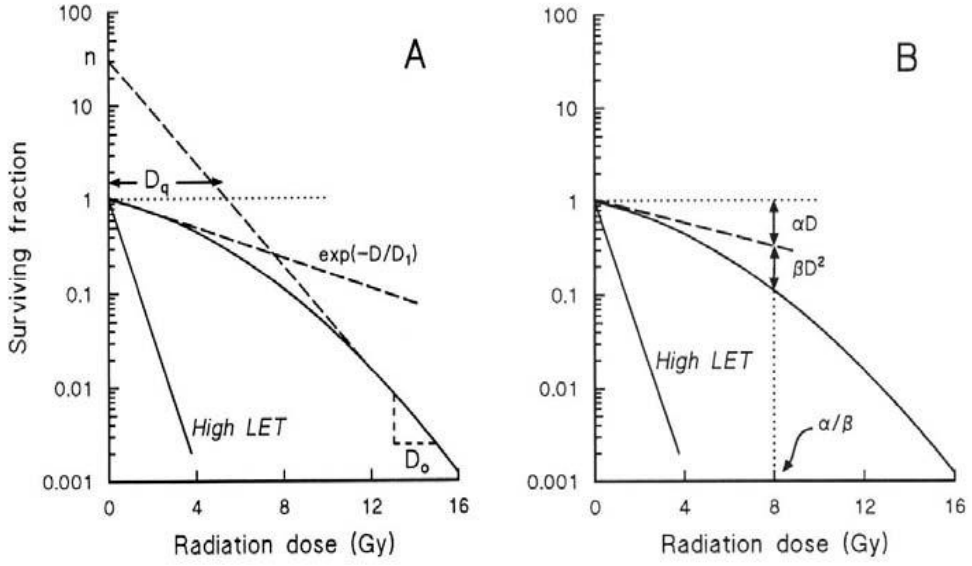
Where: ***S*** **(*D*)** is the fraction of cells surviving a dose *D*;

a is a constant describing the initial slope of the cell survival curve;

b is a smaller constant describing the quadratic component of cell killing.

The ratio *a/b* gives the dose at which the linear and quadratic components of cell killing are equal [8 Gy in the example shown in figure below (b)].

The ratio a/b gives the dose at which the linear and quadratic components of cell killing are equal [8 Gy in the example shown in figure below (b)].



Typical cell survival curves for high LET (densely ionizing) radiation and low LET (sparsely ionizing) radiation. (a) The earlier multitarget single hit model; (b) the current linear quadratic model.

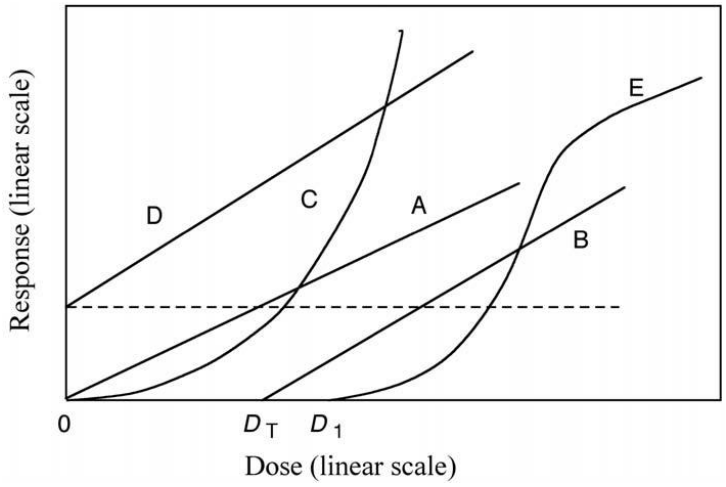
A plot of a biological effect observed (e.g. tumor induction or tissue response) against the dose given is called a *dose response curve*. Generally, as dose increases, so does the effect.

Three types of dose response relationships are known:

- Linear
- Linear quadratic
- Sigmoid

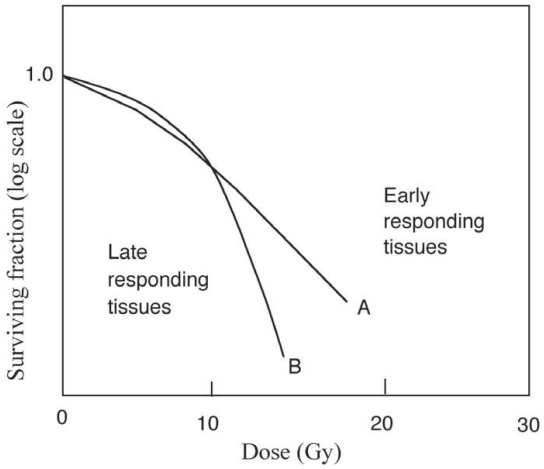
Dose response curves may or may not have a threshold. A threshold dose is the largest dose for a particular effect studied below which no effect will be observed. Various dose response curves are shown in figure below with:

- A linear relationship with no threshold
- A linear relationship with a threshold
- A linear quadratic relationship with no threshold



Typical dose response curves for cancer induction (curves A, B, C and D) and for tissue response (curve E). Curve A represents a linear relationship with no threshold; curve B represents a linear relationship with threshold DT ; curve C represents a linear quadratic relationship with no threshold (assumed for stochastic effects, for example carcinogenesis); curve D represents a linear relationship with no threshold (the area below the dashed line represents the natural incidence of the effect, for example carcinogenesis); and curve E represents a sigmoid relationship with threshold D1, as is common for deterministic effects in tissues, for example tumor control or treatment morbidity. The curves are diagrammatic only and are separated for clarity (in practice the dashed line would be lower).

The response of different tissues or organs to radiation varies markedly, depending primarily on two factors: the inherent sensitivity of the individual cells and the kinetics of the population. There is a clear distinction in radiation response between tissues that are early responding (skin, mucosa and intestinal epithelium) and those that are late responding (spinal cord), as shown schematically in the figure below for the surviving fraction against the dose.

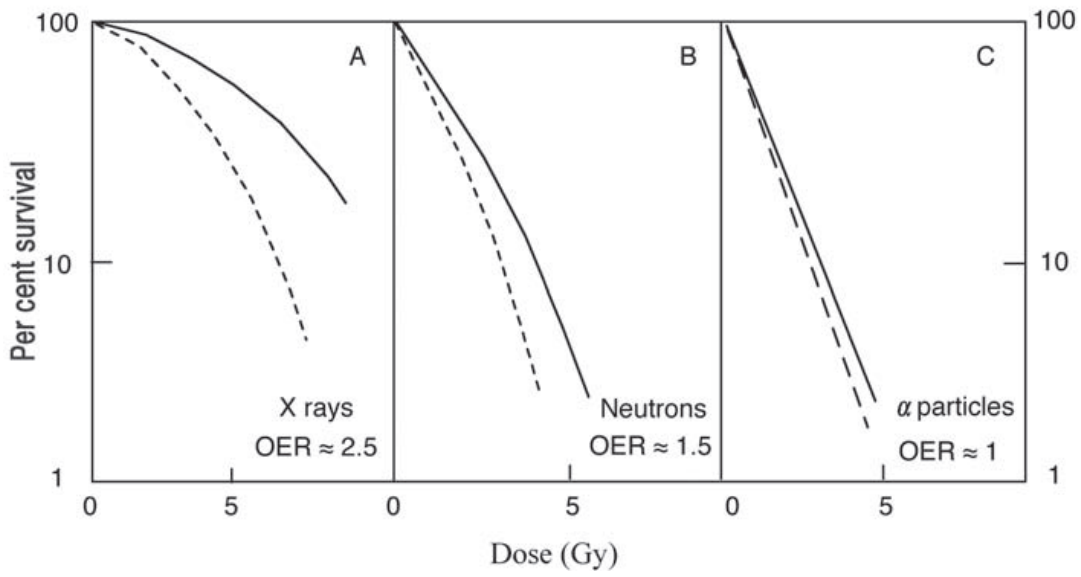


Hypothetical target cell survival curves for (curve A) early responding tissues and (curve B) late responding tissues.

The cell survival curves for late responding tissues are more curved than those for early responding tissues. For early effects, the ratio *a/b* is large and *a* dominates at low doses. For late effects, *a/b* is small and *b* has an influence at doses lower than for early responding tissues. The *a* and *b* components of mammalian cell killing are equal at approximately *a/b* = 10 Gy and *a/b* = 3 Gy for early and late effects, respectively.

Oxygen Enhancement Ratio (OER)

The presence or absence of molecular oxygen within a cell influences the biological effect of ionizing radiation: the larger the cell oxygenation above anoxia, the larger is the biological effect of ionizing radiation. Especially for low LET radiations, the larger the cell oxygenation above anoxia, the larger the biological effect until saturation of the effect of oxygen occurs. As shown in the figure below, the effect is quite dramatic for low LET (sparsely ionizing) radiations, while for high LET (densely ionizing) radiations it is much less pronounced. The ratio of doses without and with oxygen (hypoxic versus well oxygenated cells) to produce the same biological effect is called the *oxygen enhancement ratio* (OER).

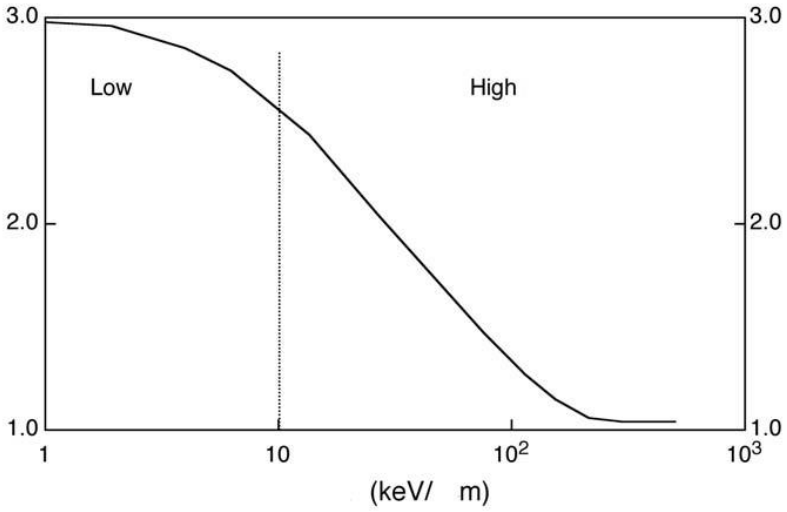


Typical cell surviving fractions for X- rays, neutrons and α particles: dashed curves are for well oxygenated cells, solid curves for hypoxic cells.

$$\text{OER} = \frac{\text{Dose to produce a given effect without oxygen}}{\text{Dose to produce the same effect with oxygen}}$$

The OER for X-rays and electrons is about three (3) at high doses and falls to about two (2) for doses of 1–2 Gy. The OER decreases as the LET increases and approaches OER = 1 at about LET = 150 keV/mm, as shown in the figure below. Cells at the periphery of tumor cords growing around blood vessels become chronically hypoxic because of the consumption of most of the oxygen near the blood vessel. The transient closing of blood vessels can also make the whole tumor cord hypoxic for a few minutes at a time.

Reoxygenation—the process by which cells that are hypoxic become oxygenated after irradiation, through the killing and removal of oxic radiosensitive cells from the tumor—can occur.



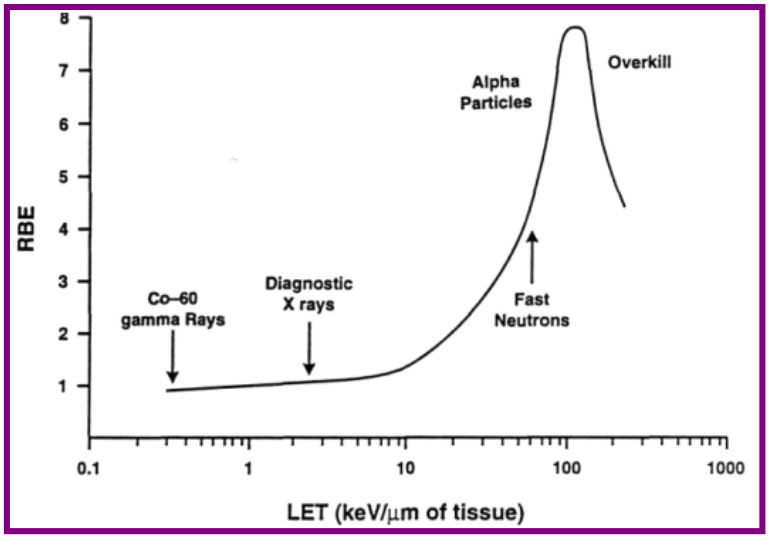
OER plotted against LET. The vertical dashed line separates the low LET region, where LET < 10 keV/mm, from the high LET region, where LET > 10 keV/mm.

Relative Biological Effectiveness (RBE)

As the LET of radiation increases, the ability of the radiation to produce biological damage also increases. The relative biological effectiveness (RBE) compares the dose of test radiation to the dose of standard radiation to produce the same biological effect. The standard radiation has been taken as 250 kVp X-rays for historical reasons, but is now recommended to be Cobalt 60 gamma rays. The RBE is defined by the following ratio:

$$RBE = \frac{\text{Dose from standard radiation to produce a given biological effect}}{\text{Dose from test radiation to produce the same biological effect}}$$

The RBE varies not only with the type of radiation but also with the type of cell or tissue, biologic effect under investigation, dose, dose rate and fractionation. In general, the RBE increases with the LET to reach a maximum RBE of 3-8 (depending on the level of cell death) at LET ^{a} 200 keV/m, and then decreases because of energy overkill, as shown in the figure below.



RBE against LET. The vertical dashed line separates the low LET region, where RBE » 1, from the high LET region, where the RBE first rises with the LET, reaches a peak of about 8 for LET » 200 keV/mm, and then drops with a further increase in the LET.

There are four stages in action of indirect ionizing radiation on biological structures:

- Physical
- Physical-chemical
- Chemical
- Biological

Physical

The transfer of kinetic energy from ionizing radiation to atoms or molecules leads to excitation and ionization of these atoms or molecules.

Physical-Chemical

The placement of absorbed energy from ionizing radiation into molecules and between them. The formation of free radicals takes place.

Chemical

The reactions between free radicals and intact molecules take place. Formation of molecules with abnormal structure and function realize.

Biological

The formation of injures on all levels – from cellular structures to organism and population. Development of processes of biological damage and reparative processes occur on biological stage. As discussed previously, the two mechanisms by which radiation affects cells are through *direct effects* and *indirect effects*.

Effects of Oxygen on Free Radical Formation

The presence of dissolved oxygen can modify the reaction by enabling the creation of other free radical species with greater stability and longer lifetimes.

- $H0+O_2 = HO_2$ (hydroperoxy free radical)
- $R0+O_2 = RO_2$ (organic peroxy free radical)

The transfer of the free radical to a biological molecule can be sufficiently damaging to cause bond breakage or inactivation of key functions. In addition, the organic peroxy free radical can transfer the radical from molecule to molecule causing damage at each encounter. Thus, a cumulative effect can occur, greater than a single ionization or broken bond. Free radicals readily recombine to electronic and orbital neutrality. However, when many exist, as in high radiation fluence, orbital neutrality can be achieved by hydrogen radical dimerization (H_2) and the formation of toxic hydrogen peroxide (H_2O_2). The radical can also be transferred to an organic molecule in the cell.

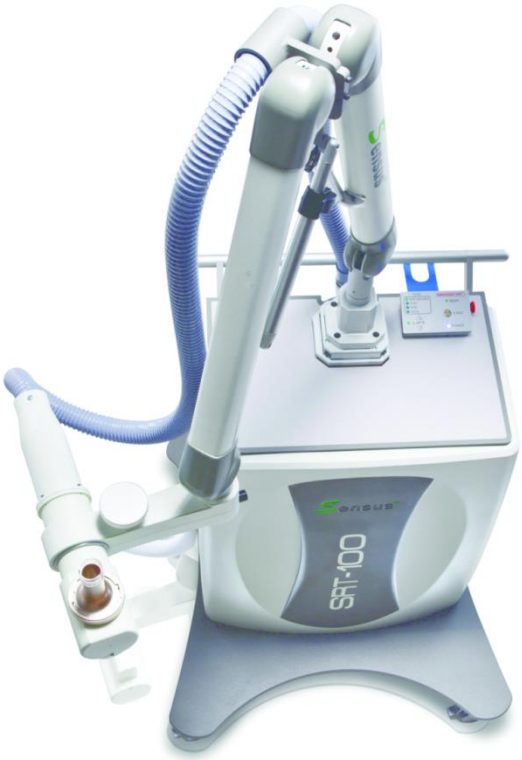
The lifetimes of simple free radicals (H0 or OH0) are very short, with a typical lifetime of less than 0.1 second. While generally highly reactive, they do not exist long enough to migrate from the site of formation to the cell nucleus. However, the oxygen-derived species such as hydroperoxy free radical does not readily recombine into neutral forms. These more stable forms have a lifetime long enough to migrate to the nucleus, where serious damage can occur.

Radiation-Induced Membrane Damage

Biological membranes serve as highly specific mediators between the cell, organelles, and the environment. Radiation changes within the lipid bilayers of the membrane may alter ionic pumps. This may be due to changes in the viscosity of intracellular fluids associated with disruptions in the ratio of bound to unbound water. Such changes would result in an impairment of the ability of the cell to maintain metabolic equilibrium and could be very damaging, even if the shift in equilibrium were quite small.

Alterations in the proteins that form part of a membrane's structure can cause changes in its permeability to various molecules, i.e. electrolytes. In the case of nerve cells, this would affect their ability to conduct electrical impulses. In the case of lysosomes, the unregulated release of its catabolic enzymes into the cell could be disastrous. Ionizing radiation has been suggested as playing a role in plasma membrane damage, which may be an important factor in cell death. New fractionation schemes, outlined in Chapter 8, have been arranged to keep the total dose low so minimal (and no long term) damage is accumulated to the cell membrane.

Chapter 3:
Principles of Radiation Safety



Within a decade of the discovery of X-rays in 1895 and radioactivity in 1896, scientists had developed uses for radiation, primarily in the area of medical diagnosis and treatment. This scientific endeavor has continued to the present, resulting in the current use of radiation for the improvement of human life. The research, development, and use of radiation necessarily results in the researchers and users of this technology being exposed to radiation in the course of their work. Although early scientists were unaware of the potential dangers of occupational radiation exposure, it wasn't long before the scientific and medical communities realized that occupational radiation exposure needed to be controlled for the safety of radiation workers.

In the 1920s, the first formal recommendations for radiation protection were promulgated by the International X-ray and Radium Protection Commission (established by the Second International

Congress of Radiology in 1928) and the United States Advisory Committee on X-ray and Radium protection. These recommendations were based on the concept of a "Tolerance Dose." This concept was intended to set limits that prevented the occurrence of clinically observable radiation effects (like reddening of the skin). The recommended "Tolerance Dose" was gradually reduced in subsequent decades in recognition of the growing use of radiation and the growing realization that chronic effects such as cancer or genetic abnormalities may also be induced by radiation.

By the mid-1950s, with the realization of the potential expansion of the radiation industry and the number of workers that may be exposed, the "Tolerance Dose" levels were reduced again, and the concept of maintaining exposures as low as practical was adopted. This formed the guiding principles of the radiation-protection system still in use today by the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP), the international and national scientific committees charged with development of radiation-protection recommendations. These guiding principles are those of *justification, dose limitation,* and *optimization of dose at levels that are as low as reasonably achievable* (the ALARA principle).

Justification of the use of a source of radiation or radioactivity is accomplished through regulatory reviews, licensing processes, political will (such as national security uses), etc. The principles of the system that are directly applicable to a radiation-safety program protecting workers are those of *dose limitation* and the *ALARA* philosophy. Since the inception of the current system for radiation-safety standards in the mid-1950s, the *dose limitation* principle has been included to meet "the need to apply individual dose limits to ensure that the procedures of justification and ALARA do not result in individuals or groups of individuals exceeding levels of acceptable risk" (NCRP 1993).Therefore, the dose limits represent an acceptable level of potential occupational risk and do not represent a level that will necessarily be unsafe if they are exceeded. Similarly, optimization of actual dose levels through the inclusion of the *ALARA* principle has been to meet "the need to ensure that the total societal detriment from such justifiable activities or practices is maintained ALARA, economic and social factors being taken into account" (NCRP 1993).

X-ray Radiation Safety

X-ray Radiation Safety training is mandatory for radiation workers to comply with State Regulatory requirements and policies. Individuals requiring this training include Physicians, PAs, Nurses, Technical Support Staff, Technicians, Medical Assistants, and medical students.

The goal of the Radiation Safety Program is to provide guidance for the safe use of radiation- producing equipment in clinical areas and for the safety of all personnel involved.

Prohibited Use of X-ray Equipment

It is unlawful to operate any X-ray equipment unless it is operated in compliance with all local, state, and federal regulations.

The use of X-ray radiation on humans is strictly regulated and is only permitted with authorization from a licensed practitioner for healing arts purposes.

Individuals must not be exposed to X-ray radiation for training or demonstration purposes.

Occupational Exposure

Occupational exposure is the radiation exposure potentially received working with and around X-ray systems.

Local, state, and federal regulations limit the amount of radiation dose allowed for occupational radiation workers, members of the public, and the fetus of a declared pregnant radiation worker.

Occupational Dose Limits

All personnel who work with any form of radiation are considered radiation workers and are subject to occupational dose limits. These limits do not include background radiation or radiation received for personal medical reasons.

Maximum Permissible Dose – Adults

Whole Body – **Head, Neck, Torso, Upper arms & legs**	***50.0 mSv***
Lens of the Eye	***150.0 mSv***
Extremities, Skin, and Internal Organs	***500.0 mSv***

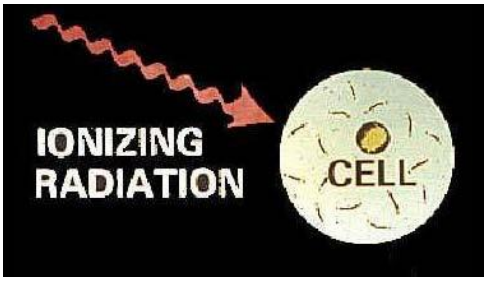
Doses received within these limits are not expected to cause adverse health effects, even if the maximum is received each year for a total of fifty years.

Prenatal Radiation Exposure

A “Declared Pregnant” radiation worker is a woman who has voluntarily chosen to declare her pregnancy *in writing* to the Radiation Safety Officer. The maximum permissible dose limit to an embryo/fetus of a declared pregnant radiation worker is 5.0 mSv for the entire pregnancy.

Why is Radiation Harmful?

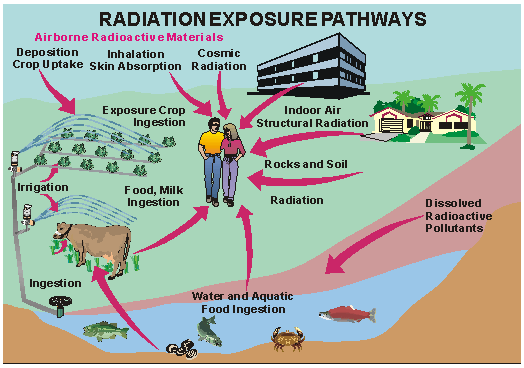
Radiation can cause changes in human cells and tissues by interfering with the way a cell functions.



Radiation Exposure

Current radiation safety practices are focused on keeping occupational exposure to radiation as low as reasonably achievable. However, the radiation exposure received while working with X-ray equipment is only a fraction of a person's total radiation exposure.

Radiation is everywhere, and exposure to ionizing radiation can come from many sources. Typically, the greatest source of radiation exposure comes from nature itself. This is called background radiation.



Sources of Background Radiation

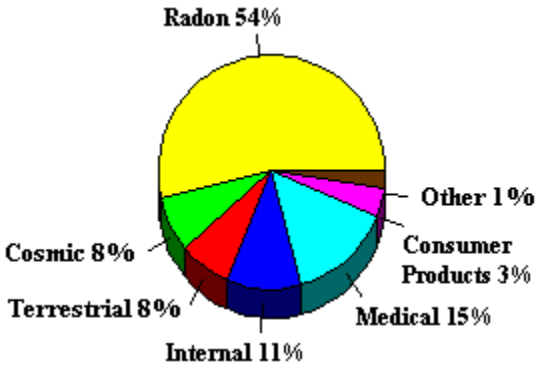
Natural = 3.0 mSv

- Radon – basements and water supplies
- Cosmic – outer space
- Terrestrial – soil, rocks and plants

Human-produced = .60 mSv

- Medical and dental X-rays
  - 200 million medical X-rays performed each year
- Nuclear medicine and cancer therapy
  - 15 million cancer therapy treatments each year
- Consumer products
  - TV's, smoke detectors, tobacco products, natural gas, etc.

The average person receives 3.60 mSv per year



ALARA

ALARA stands for as low as reasonably achievable. Regulations require that employers and staff make "every reasonable effort to maintain radiation exposure as far below the maximum allowable permissible dose limits as practical taking into consideration the purpose for which sources of radiation are used."

The radiation exposure for occupational workers is far less than the annual radiation exposure limits because personnel follow ALARA guidelines. The basic guidelines are:

- Minimize **time** near radiation sources.
- Maximize **distance** from radiation sources.
- Use **shielding** devices when applicable.

Time

Radiation dose is directly proportional to the time an individual is exposed to a source of ionizing radiation.

Distance

The more distance between the body and a radiation source, the less exposure received. This is called the inverse square law.

Shielding

The application of shielding (such as a lead apron) provides a barrier between the body and the source of radiation.

Patient Radiation Exposure

Patient radiation exposure must also be ALARA; this includes:

- Using appropriate applicator with the primary radiation beam.
- Understanding the controls of the equipment to administer the prescribed patient dose.

Dosimetry Badges

Dosimetry badges are intended to measure your external occupational radiation exposure received while working at a clinic. A new badge is issued each quarter. An individual's dosimetry history is available from the RSO by written request.

Dosimetry Badge Guidelines

When issued a dosimetry badge, follow the guidelines below. An individual's badge is his/her own responsibility, and all readings are permanently recorded in the dosimetry history.

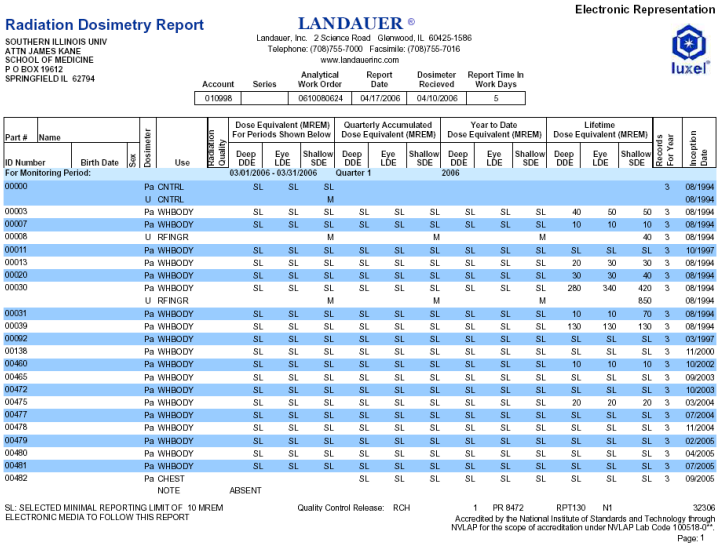
- Wear only the badge assigned to you.
- Do not wear your badge while participating in personal medical /dental procedures.
- Never intentionally expose your badge or anyone else's badge to radiation.
- Never take your badge home. Store your badge in the designated area.
- If your badge is lost or damaged, call the RSO immediately for a replacement.

Wearing Your Dosimeter

- Always make sure your dosimeter is worn on the collar external to your clothing.
- Wearing your dosimeter incorrectly can result in false dose measurements.

Dosimetry Reports

On dosimeter reports (such as the one below from Landauer), individuals are identified by their participant number (found on the back of the dosimeter). Dosimeter reports are sent to the site/ department each quarter. If you are unable to locate any report, contact the RSO.



Electronic Representation

Radiation Dosimetry Report

SOUTHERN ILLINOIS UNIV
ATTN JAMES KANE
SCHOOL OF MEDICINE
P O BOX 19612
SPRINGFIELD IL 62794

LANDAUER ®
Landauer, Inc. 2 Science Road Glenwood, IL 60425-1586
Telephone: (708)755-7000 Facsimile: (708)755-7016
www.landauerinc.com

luxel®

Account	Series	Analytical Work Order	Report Date	Dosimeter Recieved	Report Time In Work Days
010998		0610080624	04/17/2006	04/10/2006	5

Part # / Name / ID Number	Birth Date	Sex	Dosimeter	Use	Radiation Quality	Dose Equivalent (MREM) For Periods Shown Below: Deep DDE	Eye LDE	Shallow SDE	Quarterly Accumulated Dose Equivalent (MREM): Deep DDE	Eye LDE	Shallow SDE	Year to Date Dose Equivalent (MREM): Deep DDE	Eye LDE	Shallow SDE	Lifetime Dose Equivalent (MREM): Deep DDE	Eye LDE	Shallow SDE	Records For Year	Inception Date
For Monitoring Period:				03/01/2006 - 03/31/2006		Quarter 1						2006							
00000			Pa	CNTRL		SL	SL	SL										3	08/1994
			U	CNTRL				M											08/1994
00003			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	40	50	50	3	08/1994
00007			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	10	10	10	3	08/1994
00008			U	RFINGR				M			M			M			40	3	08/1994
00011			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	10/1997
00013			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	20	30	30	3	08/1994
00020			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	30	30	40	3	08/1994
00030			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	280	340	420	3	08/1994
			U	RFINGR				M			M			M			850		08/1994
00031			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	10	10	70	3	08/1994
00039			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	130	130	130	3	08/1994
00092			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	03/1997
00138			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	11/2000
00460			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	10	10	10	3	10/2002
00465			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	09/2003
00472			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	10/2003
00475			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	20	20	20	3	03/2004
00477			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	07/2004
00478			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	11/2004
00479			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	02/2005
00480			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	04/2005
00481			Pa	WHBODY		SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	SL	3	07/2005
00482			Pa	CHEST					SL	SL	SL	SL	SL	SL	SL	SL	SL	3	09/2005
				NOTE	ABSENT														

SL: SELECTED MINIMAL REPORTING LIMIT OF 10 MREM
ELECTRONIC MEDIA TO FOLLOW THIS REPORT

Quality Control Release: RCH 1 PR 8472 RPT130 N1 32306

Accredited by the National Institute of Standards and Technology through NVLAP for the scope of accreditation under NVLAP Lab Code 100518-0**.

Page: 1

"SL" - Selected Minimum Reporting Limit

Whole body doses equivalent to less than 0.10 mSv (10 mrem) will be noted as "SL" for minimal on the dosimeter report. For ring dosimeters, "M" indicates less than 0.30 mSv (30mrem).

ALARA Action Levels

If any dose equivalent exceeds a pre-established ALARA action level, the RSO should contact the participant and his/her supervisor to determine if future exposure can be reduced.

What Do “Deep,” “Eye,” and “Shallow” Indicate on Dosimeter Reports?

- Deep: Dose equivalents in the “Deep” column heading mean penetrating radiation dose to internal organs.
- Eye: Dose equivalents in the “Eye” column heading indicate dose to the lens of the eye.
- Shallow: Dose equivalents in the “Shallow” column heading means dose to the skin for whole body dosimeters.

Shielding for Patients Receiving Superficial Radiation Therapy

Protective apparel can reduce exposure to the thyroid, extremities, and eyes. Lead aprons, thyroid shields, and lead lined glasses should be available to ALL patients involved with receiving Superficial Radiation Therapy, when appropriate.

- Lead aprons cover about 75%-80% of a person’s active bone marrow
- The use of thyroid shields, leaded safety glasses, and lead aprons are strongly recommended during Superficial Radiation Therapy for the patient, as appropriate.

Holding Patients

- No occupational radiation worker should ever hold a patient during a Superficial Radiation Therapy procedure.
- An individual (patient’s family member, etc.) who volunteers to hold a patient, if needed, should wear 0.25 mm lead equivalent protective apparel (i.e. apron, glasses) for exposure to scatter radiation.
- An individual holding a patient should never be in alignment with the primary beam.
- Pregnant women should not hold patients during a Superficial Radiation Therapy procedure.

Caution Signs

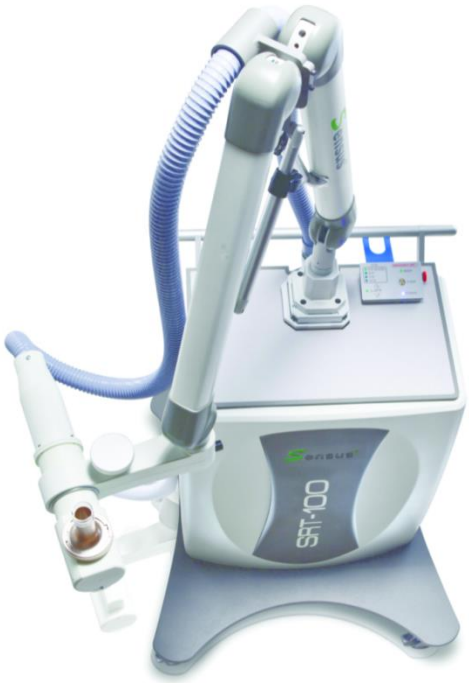
Highly visible signs assure unnecessary exposure to staff and patients, and should be posted wherever applicable.

Unsafe and Emergency Conditions

If an unsafe condition arises with a Superficial Radiation Therapy unit:

- Report any unusual or unsafe conditions involving sources of radiation to the Radiation Safety Officer.
- If an emergency occurs:
  - Turn power OFF to the Superficial Radiation Therapy Unit.
  - Remove patient from the room.
  - Notify your Supervisor and contact the RSO.

Chapter 4:
Principles of X-ray Production



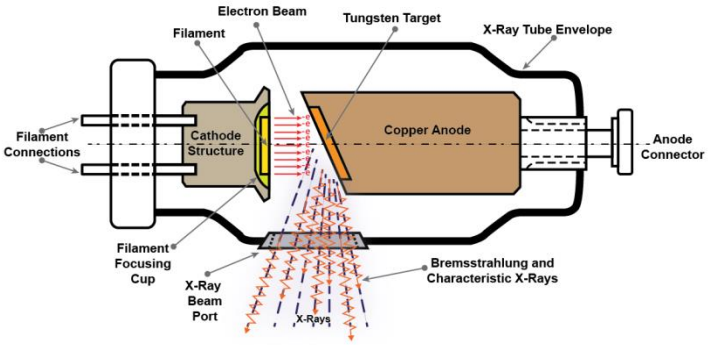
How Are Superficial Radiation Therapy X-rays Produced?

X-rays are created by taking energy from electrons and converting it into photons with appropriate energies. This energy conversion takes place within the system's X-ray tube.

X-ray Tube

The quantity (exposure) and quality (spectrum) of the X-ray radiation produced can be controlled by adjusting the electrical quantities (kV, mA) applied to the tube. An X-ray tube is an energy converter. It receives electrical energy and converts it into two other forms: X-radiation and heat. The heat is an undesirable byproduct. X-ray tubes are designed and constructed to maximize X-ray production and to dissipate heat as rapidly as possible. The X-ray tube is a relatively simple electrical device typically containing two principle elements: a cathode and an anode. As the electrical current flows through the tube from cathode to anode, the electrons undergo an energy loss, which results in the generation of X-radiation. A cross-sectional view of a typical X-ray tube is shown below.

Cathode



Outline of an X-Ray Tube

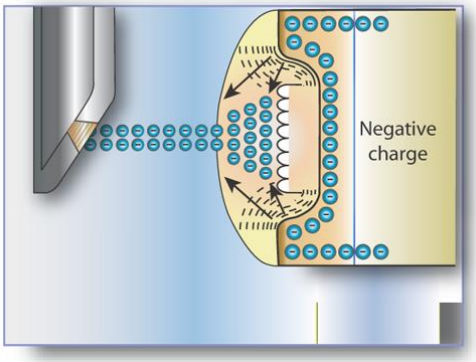
The purpose of the cathode is to:

- Serve as the source of electrons for the X-ray tube.
- Direct their flow toward the anode.

The typical cathode consists of a small coil of wire (a filament) recessed within a cup-shaped region, as shown above. Tungsten is used in construction of the cathode filament because of its high melting point (3370° C) and a vapor pressure that prevents the wire from vaporizing at the high temperatures imposed. In a process known as thermionic emission, thermal energy (or heat) is used to expel the electrons from the cathode. The filament of the cathode is heated in the same way as a light bulb filament by passing a current through it. This heating current is not the same as the current flowing through the X-ray tube (the mA) that produces the X-radiation.

Filament

The filament sits in a separate metallic focusing cup. Because of the tendency for particles of equal charge to repel each other, it would be possible for the electron beam to spread as it crossed the tube and bombard an undesirably large target area on the anode. By maintaining the focusing cup at the same negative potential as is the heated filament, the repulsive charge from the focusing cup tends to direct the electrons toward a relatively small area on the target.

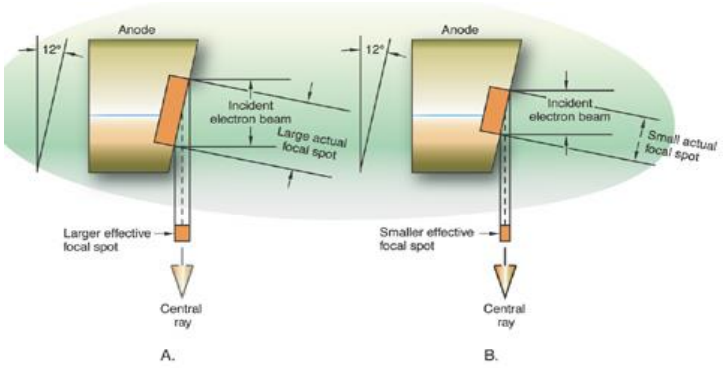


Anode

The anode consists of a target material placed on the surface of a larger cylinder. It is estimated that more than 99% of the energy in the electron beam is converted to heat energy at the time of its interaction with the target. The ability of the target material to withstand high temperatures and the speed with which heat can be dissipated by the anode are therefore of great importance. If the atomic number of the target material is sufficiently high, it will favorably influence the efficiency of production of X-rays. Because tungsten satisfies these requirements, it has long served as a target material of choice. Tungsten has:

- A high melting point (3370° C)
- A high atomic number (74)
- A low tendency to vaporize
- Good heat conductivity

Tungsten is embedded in the end of a copper cylinder. Despite the high melting point of tungsten, a copper cylinder is still needed to dissipate the great amount of heat generated during an exposure. Copper is a better conductor of heat and has a relatively high melting point (1070° C). The tungsten block sits on the end of the copper cylinder with the surface of the tungsten plate at a predetermined angle (usually from 15 to 22.5 degrees).



Focal Spot

The size of the tungsten plate exceeds the size of the electron beam. This is necessary to avoid the electron beam striking the surface of the cylinder and causing melting of the copper, since it has a relatively lower melting point.

The area of the surface of the target that is bombarded by electrons during an exposure is called the focal spot. When viewed perpendicularly to the surface of the target, the size of the focal spot is referred to as the "projected focal spot" or "effective focal spot". The actual focal spot tends to be rectangular in shape while the projected focal spot is more nearly square in shape. In addition to a different shape of the projected versus the actual focal spot, there is also an important difference in area.

The size of the electron beam is determined by the:

- Size of the cathode filament
- Structure of the focusing cup
- Position of the filament within the focusing cup

The anode and cathode are contained in an airtight enclosure, or envelope. The primary functions of the envelope are to provide support and electrical insulation for the anode and cathode assemblies and to maintain a vacuum in the tube.

X-ray Tube Housing

The X-ray tube housing provides support for the envelope, within which a vacuum is maintained. The vacuum permits independent control of both the number of electrons that constitutes an electron beam, and the speed of flow of the electrons. The vacuum eliminates the possibility of collisions between molecules of air and accelerated electrons. In addition, removal of air prevents deterioration of the filament by oxidation.

The tube housing provides:

- A mechanical support for the tube.
- Electrical insulation for high voltage cables that feed into the tube.
- Radiation shielding.

Heat is produced in the focal spot area by the bombarding electrons from the cathode. Since only a small fraction of the electronic energy is converted in X-radiation, circulation of water is needed to dissipate the heat created.

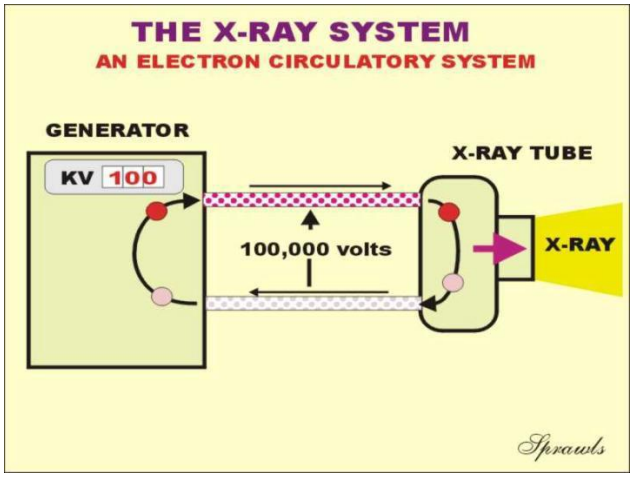
Electrical Circuit

The energy used by the X-ray tube to produce X-radiation is supplied by an electrical circuit, as illustrated below. The circuit connects the tube to the source of electrical energy, often referred to as the generator. The generator receives the electrical energy from the electrical power system and converts it into the appropriate form to apply to the X-ray tube. The generator also provides the ability to adjust certain electrical quantities that control the X-ray production process.

The three principle electrical quantities are:

- kV (the voltage or electrical potential applied to the tube)
- mA (the electrical current that flows through the tube)
- Treatment Time (duration of the treatment time, generally in increments, not seconds, due to incorporation of tube current ramp-up time)

The circuit is actually a circulatory system for electrons; they pick up energy as they pass through the generator and transfer their energy to the X-ray tube anode.



Chapter 5:
Classifications of X-rays

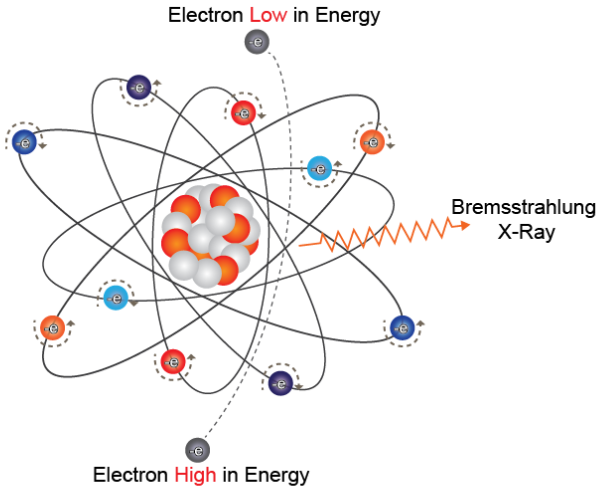
Electrons traveling from the filament (cathode) to the target (anode) convert a small percentage (1%) of their kinetic energy into X-ray photons by the formation of **bremsstrahlung** and **characteristic** radiation.

Bremsstrahlung Interactions

Bremsstrahlung interactions, the primary source of X-ray photons from an X-ray tube, are produced by the sudden stopping, breaking, or slowing of high-speed electrons at the target.

When the electrons from the filament strike the tungsten target, X-ray photons are created if they either hit a target nucleus directly (which is rare), or their path takes them close to the nucleus. If a high-speed electron hits the nucleus of a target atom, all its kinetic energy is transformed into a single X-ray photon. (Total absorption has occurred). Thus, the energy of the resultant photon (keV) is numerically equal to the energy of the electron. This in turn is equal to the kilovoltage applied across the X-ray tube at the instant of its passage. This happens rarely.

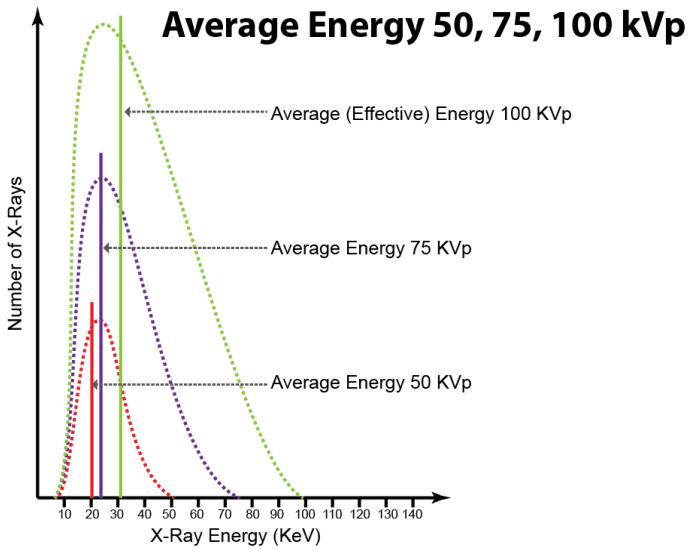
Most high-speed electrons have near or wide misses with the nuclei. In these interactions, a negatively-charged high-speed electron is attracted to the positively-charged nucleus and loses some of its velocity. This deceleration causes the electron to lose some kinetic energy, which is given off in the form of a photon. The closer the high-speed electron approaches the nuclei, the greater the electrostatic attraction on the electron, the braking effect, and the greater the energy of the resulting Bremsstrahlung photon.



Bremsstrahlung X-Rays

Bremsstrahlung interactions generate X-ray photons with a continuous spectrum of energy. The energy of an X-ray beam may be described by identifying the peak operating voltage (in kVp). The SRT-100™ Superficial Radiation Therapy unit operates at peak voltages of 50, 70, and 100 kVp. The spectrum of energies can be explained by the fluctuating voltage across the tube. The reasons for these continuous spectrums are:

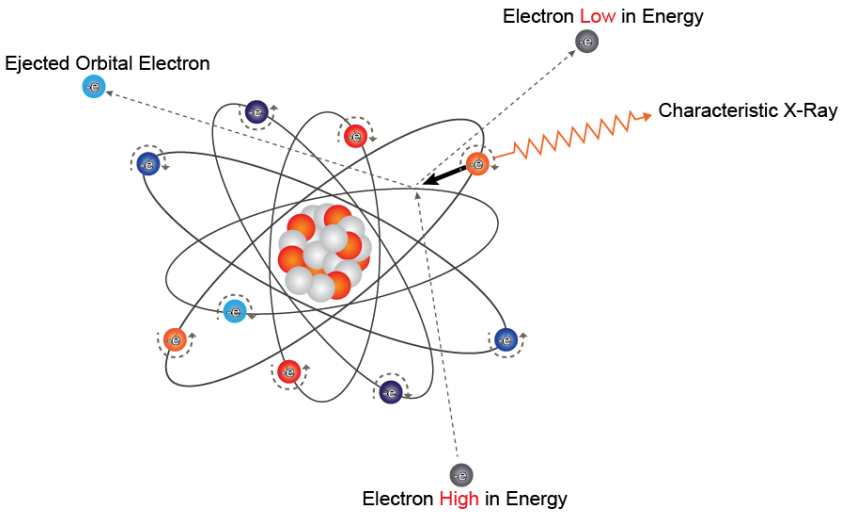
- The continuously varying voltage difference between the target and the filament, which is characteristic of half wave rectification, causes the electrons striking the target to have varying levels of kinetic energy.
- Depth of generation of photons in the target.
- Most electrons participate in many interactions before all their kinetic energy is expended. Therefore, an electron carries differing amounts of energy at the time of each interaction with a tungsten atom that results in the generation of an X-ray photon.
- The bombarding electrons pass at varying distances around tungsten nuclei and are thus deflected to varying extents. As a result, they give up varying amounts of energy in the form of Bremsstrahlung photons.



Characteristic Radiation

Characteristic radiation occurs when an electron from the filament displaces an electron from an inner-shell of the tungsten target atom, thereby ionizing the atom. When this happens, another electron in an outer-shell of the tungsten atom is quickly attracted into the void in the deficient inner-shell. When the displaced electron is replaced by the outer-shell electron, a photon is emitted with an energy equivalent to the difference in the two orbital binding energies.

Characteristic radiation from the K-shell occurs only above 70 kVp with a tungsten target and occurs as discrete increments compared with Bremsstrahlung radiation. The energies of characteristic photons are a function of the energy levels of various electron orbital levels and therefore are characteristic of the target atoms. Characteristic radiation has a higher intensity, but is only a minor source of radiation from an X-ray tube.



Characteristic X-Rays

Chapter 6: Controlling Factors for X-rays

The X-ray beam emitted from an X-ray tube may be modified to suit the needs of the application by altering the beam treatment time (timer), exposure rate (mA), beam energy (kV and filtration), beam shape (applicator and surface cutout), and target-to-patient distance (long or short applicator/cone).

Treatment Time

This factor affects the changes in the X-ray spectrum that result when the exposure time is increased, while the tube current (mA) and voltage (kVp) remain constant. When the treatment time is doubled, the number of photons generated is doubled, but the range intensity of photon energies is unchanged. Therefore, changing the time simply controls the “quantity” of the treatment.

The amount of radiation that a patient receives is determined in cGy. Treatment times are derived automatically when dose in cGy is dialed up on the SRT-100™.

Tube Current (mA)

This illustrates the changes in the spectrum of photons that result from increasing tube current (mA) while maintaining constant tube voltage (kVp) and exposure time. As the mA setting is increased, more power is applied to the filament, which heats up and releases more electrons that collide with the target to produce X-rays. A linear relationship exists between mA and radiation output. The SRT-100 has set mA for all three therapeutic energies.

Tube Voltage (kVp)

Increasing kVp increases the potential difference between the cathode and anode, thereby increasing the energy of each electron when it strikes the target. The greater the potential difference, the faster the electrons travel from the cathode to the anode. This results in an increased efficiency of conversion of electron energy into X-ray photons, and thus an increase in:

- The number of photons generated.
- Their mean energy.
- Their maximal energy.

The increased number of high-energy photons produced per unit time by use of higher kVp results from the greater efficiency in the production of Bremsstrahlung photons that occurs when increased numbers of higher-energy electrons interact with the target. The ability of X-ray photons to penetrate matter depends on their energy. High-energy X-ray photons have a greater probability of penetrating deeper in matter, whereas relatively low energy photons have a greater probability of being absorbed at a shallower depth.

The SRT-100™ has three set therapeutic kVp energies – 50 kV, 70 kV, and 100 kV.

Half Value Layer

A useful way to characterize the penetrating quality of an X-ray beam is by its half value layer (HVL). The HVL is the thickness of an absorber, such as aluminum, required to reduce the number of X-ray photons passing through it by one half. As the average energy of X-ray beam increases, so does its HVL. The term “quality” refers to the mean energy of an X-ray beam. Half value layer measures the intensity of a beam.

Filtration

An X-ray beam consists of a spectrum of X-ray photons of different energies, but only photons with sufficient energy to penetrate to a certain therapeutic depth are useful for Superficial Radiation Therapy. Photons that are of low energy (long wavelength) can’t contribute to a patient’s therapeutic depth, only to surface acute reactions. Consequently, to reduce acute reactions to the patient’s skin surface, the less-penetrating photons should be removed. This can be accomplished by placing an aluminum filter in the path of the beam. The aluminum removes many of the lower-energy photons, with lesser effect on the higher energy photons that are able to penetrate to the appropriate therapeutic depth.

The SRT-100™ has automatic filtration placement. Upon selection of the appropriate therapeutic energy, the filter automatically positions itself and registers on the control console.

Inherent Filtration

In determination of the amount of filtration required for a particular X-ray machine, kVp and inherent filtration of the tube and its housing must be considered. Inherent filtration consists of the materials that X-ray photons encounter as they travel from the focal spot of the target to form the usable beam outside the tube enclosure. These materials include the glass wall of the X-ray tube, the insulation that surrounds the tube, and the barrier material that prevents the air from escaping through the X-ray port.

Total Filtration

The total filtration of the beam includes the inherent filtration (composed of part of the X-ray tube and tube housing) and the added filtration (thin sheets of a metal inserted in the X-ray beam).

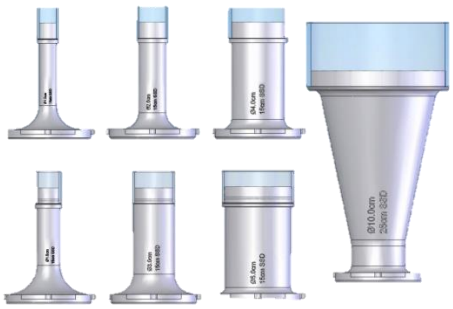
Total filtration = inherent filtration plus external filtration (aluminum disks).

Applicators

An applicator is a metallic barrier with an aperture in the middle used to reduce the size and shape of the X-ray beam, and therefore the volume of irradiated tissue within the patient. Typically, round applicators are built as open-ended aiming cylinders which attach to the X-ray tube aperture.

Many of the absorbed photons generate scattered radiation within the exposed tissues by a process called Compton scattering. These scattered photons travel in all directions. The detrimental effect of scattered radiation can be minimized by using the correct applicator to fit the appropriate margin around the lesion being treated.

The SRT-100™ has applicators available in the following sizes: 1.0 cm, 1.5 cm, 2.0 cm, 2.5 cm, 3.0 cm, 4.0 cm, 5.0 cm, 7.3 cm, 10 cm, 12.7 cm, and 18x8 cm.



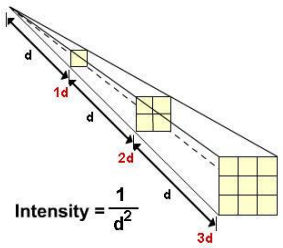
Connected to the end of each applicator is a clear polycarbonate replaceable safety contact shield, which provides:

- Treated area visibility
- Margin clearance
- Clinical safety

The contact shields (also known as applicator tips) must maintain contact with the patient's skin surface in order for the correct therapeutic treatment dose to be administered. If contact is not maintained during treatment, dose may fall below an acceptable therapeutic dose due to the inverse square law.

Inverse Square Law

The intensity of an X-ray beam at a given point (number of photons per cross-sectional area per unit exposure time) depends on the distance of the measuring device from the focal spot. For a given beam, the intensity is inversely proportional to the square of the distance from the source. The reason for this decrease in intensity is that the X-ray beam spreads out as it moves from the source of X-rays.

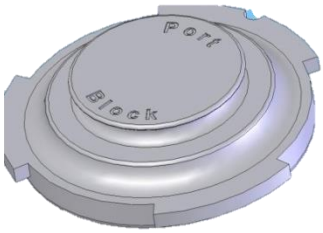


Inverse Square Law

As the above diagram depicts, *I* is intensity and *D* is distance. Therefore, if a dose of 100 centigray (cGy) is measured at a distance of 2 m, a dose of 400 cGy will be found at 1 m, and 25 cGy at 4 m. Therefore, changing the treatment distance between the treatment applicator and the patient's skin distance would affect the beam intensity. Be careful when setting a patient up for treatment by assuring the applicator and skin are in constant contact across the treatment volume.

X-ray Port Block

The SRT-100™ system initiates an automatic Warm-Up when the unit is turned on; this extends the life of the X-ray tube and the efficiency of the output of therapeutic energy. In order for the automatic Warm-Up procedure to take place, the X-ray Port Block, which blocks the X-ray beam, must be in place to minimize any scatter in the room.



SRT-100™ Port Block

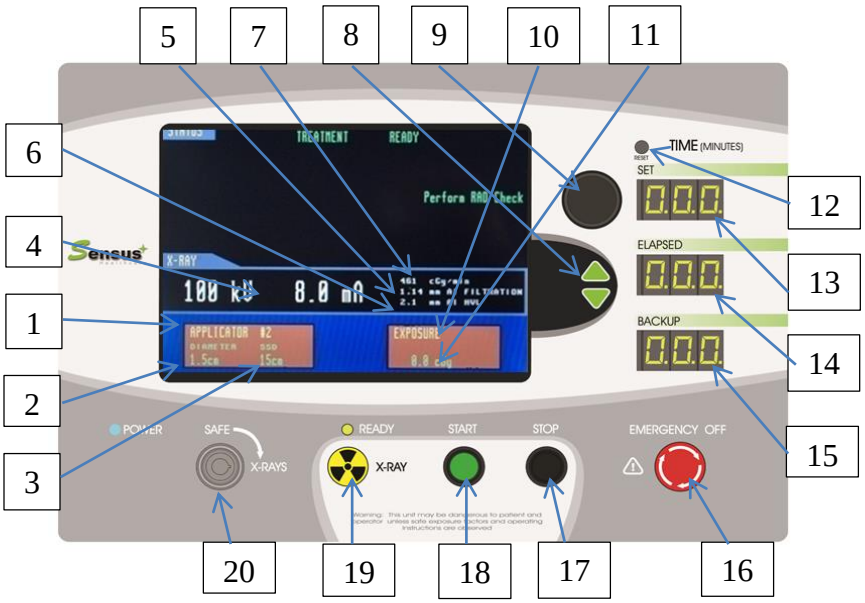
RAD Check™

The SRT-100 is equipped with a patented Physics Daily Constancy Check ("RAD Check") feature. The RAD Check is a pre-treatment X-ray output verification which ensures accurate X-ray dose delivery to the patient. The constancy check is performed daily (per state regulations) and is logged in a quality assurance binder.

SRT-100™ RAD Check Applicator

Operating Console

One of the many technical advantages found on the SRT-100™ is the ability to easily enter the dose in cGy by just turning a dial. This step alone does away with calculations and dial adjustment necessary with less modern systems.



The SRT-100™ console displays:

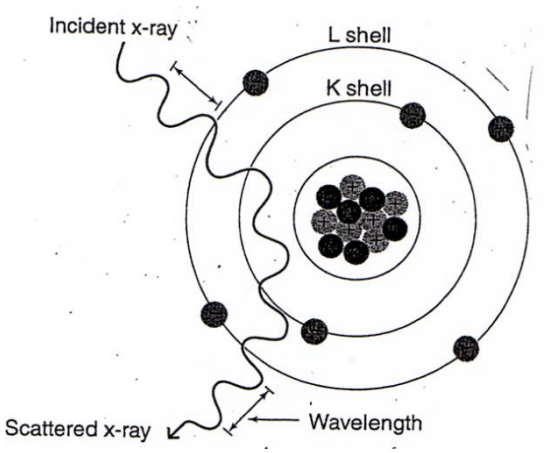
1. Applicator # in use
2. Diameter of applicator
3. Treatment SSD
4. Selected therapeutic energy (kV and mA)
5. Total filtration
6. HVL
7. cGy per minute
8. UP and DOWN arrows to select therapeutic energy
9. Knob to dial up treatment time
10. cGy is illustrated as treatment time is dialed in
11. Real-time cGy being delivered during treatment
12. Reset Button (pushed after delivery of dose and documentation in treatment log)
13. Set treatment time
14. Elapsing of treatment time during actual treatment
15. Backup timer so treatment time will terminate appropriately
16. Emergency OFF
17. STOP Button
18. START Button
19. X-ray illuminated light (activated when X-rays are being produced)
20. X-ray activation key (turn the key from SAFE to X-RAYS, then push START button)

Chapter 7:
Interactions of X-rays with Matter

The intensity of an X-ray beam is reduced by interaction with the matter it encounters. This attenuation results from interactions of individual photons in the beam with atoms at the patient's skin surface. The X-ray photons are absorbed and scattered upon the interaction at the skin surface. In scattering, photons are ejected out of the primary beam as a result of interactions with the orbital electrons of absorber atoms. In the case of Superficial Radiation Therapy, three mechanisms exist where these interactions take place: Coherent scattering, Compton scattering, and photoelectric absorption.

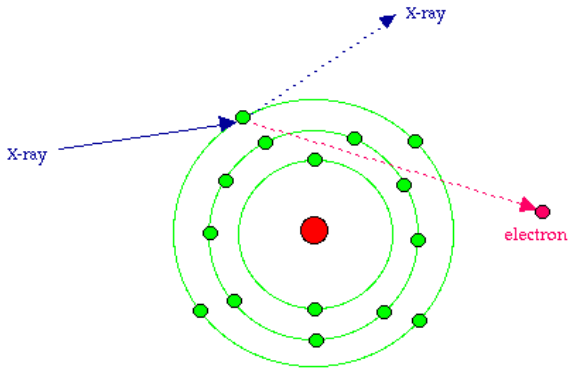
Coherent Scattering

Coherent Scattering (also known as *classical scattering* and *Thompson Scattering*) may occur when a low-energy incident photon passes near an outer electron of an atom (which has a low binding energy). The incident photon interacts with the electron in the outer-shell by causing it to vibrate momentarily at the same frequency as the incoming photon. The incident photon then ceases to exist. The vibration causes the electron to radiate energy in the form of another X-ray photon with the same frequency and energy as in the incident photon. In effect, the direction of the incident X-ray photon is altered. This interaction accounts for low percentage of the total number of interactions.



Compton Scattering

Compton scattering occurs when a photon interacts with an outer orbital electron, which receives kinetic energy and recoils from the point of impact. The incident photon is then deflected by its interaction and is scattered from the site of the collision. The energy of the scattered photon equals the energy of the incident photon minus the kinetic energy gained by the recoil electron plus its bonding energy. As with photoelectric absorption, Compton scattering results in the loss of an electron and ionization of the absorbing atom.



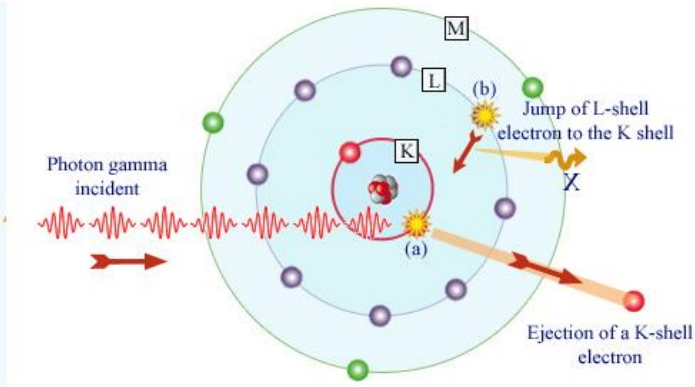
Scattered photons travel in all directions. The higher the energy of the incident photon, however, the greater the probability that the angle of scatter of the secondary photon will be small and its direction will be forward.

The probability of Compton scattering is directly proportional to the electron density. The number of electrons in bone is greater than in water; therefore, the probability of Compton scattering is correspondingly greater in bone than in tissue. The importance of photoelectric absorption and Compton scattering in Superficial Radiation Therapy relates to differences in the way photons are absorbed by various anatomic structures, since the number of photoelectric and Compton interactions are greater in hard tissues than in soft tissues.

Photoelectric Absorption

Photoelectric absorption occurs when an incident photon collides with an inner-shell electron in an atom of the absorbing medium resulting in total absorption and the incident photon ceases to exist. The electron is ejected from its shell, resulting in ionization and becomes a recoil electron (photoelectron). The kinetic energy imparted to the recoil electron is equal to the energy of the incident photon minus that used to overcome the binding energy of the electron. In the case of atoms with low atomic numbers (e.g. those in most biologic energy of the incident photon), most Photoelectric interactions occur in the K shell because the density of the electron cloud is greater in this region and a higher probability of interaction exists.

An atom that has participated in photoelectric interaction is ionized. This electron deficiency (usually in the K shell) is instantly filled, usually by an L- or M- shell electron, with the release of characteristic radiation. Whatever the orbit of the replacement electron, the characteristic photons generated is of such low-energy that they are absorbed within the patient.



The recoil electrons ejected during photoelectric absorptions travel only a short distance in the absorber before they give up their energy. As a consequence, all the energy of incident photons that undergo photoelectric interaction is deposited in the patient. This is beneficial in producing evenly spaced ionizations throughout the cancer cells.

The frequency of photoelectric interaction varies directly with the third power of the atomic number of the absorber. For example, because the effective atomic number of compact bone (Z = 7,4), the probability that a photon will be absorbed by a photoelectric interaction in bone is approximately 6.5 times greater than in an equal distance of water.

Secondary Electrons

In both photoelectric absorption and Compton scattering, electrons are ejected from their orbits in the absorbing material after interaction with X-ray photons. These secondary electrons give up their energy in the absorber by either of two processes: collisional interaction with other electrons, resulting in ionization or excitation of the affected atom, and irradiative interactions. Secondary electrons eventually dissipate all their energy, mostly as heat by collisional interaction, and come to rest.

Beam Attenuation

The reduction of beam intensity is predictable because it depends on physical characteristics of the beam and absorber. A monochromatic beam of photons, a beam in which all the photons have the same energy, provides a good example. When just the primary (not scattered) photons are considered, a constant fraction of the beam is attenuated as the beam moves through each unit thickness of an absorber. Therefore, 1.5 cm of water may reduce beam intensity by 50%, the next 1.5 cm by another 50% (to 25% of the original intensity), and so on. This HVL is a measure of beam energy describing the amount of an absorber that reduces the beam intensity by half; in the preceding example, the HVL is 1.5 cm. The absorption of the beam depends primarily on the thickness and mass of the absorber and the energy of the beam**.**

The Mean Energy

The spectrum of photon energies (as illustrated by the kVp setting) in an X-ray beam is wide. In such a heterogeneous beam the probability of absorption of individual photons depends on their energy. Low-energy photons are much more likely than high-energy photons to be absorbed. As a consequence the superficial layers of an absorber tend to remove the low energy photons and transmit the higher energy photons. Therefore as an X-ray beam passes through matter, the intensity of the beam decreases but the mean energy of the resultant beam increases. In contrast to the absorption of a monochromatic beam, an X-ray beam is absorbed less and less by each succeeding unit of absorber thickness. For example, the first .5 cm of water might absorb about 50% of the photons in an X-ray beam with a mean energy of 35 kVp. The mean energy of the remnant beam might increase 20% as a result of the loss of lower energy photons. The next .5 cm of water removes only about 30 of the photons as the average energy of the beam increases another 10%. If the water test object is thick enough, the mean energy of the remnant beam approaches the peak voltage applied across the tube and absorption becomes similar to that of a monochromatic beam.

K-edge Absorption

As the energy of the beam increases, so does the transmission of the beam through the absorber. When the energy of the incident photon is raised to the binding energy of the k-shell electrons of the absorber, however, the probability of photoelectric absorption increases sharply and the number of transmitted photons is greatly decreased. This is called k-edge absorption. (The probability that a photon will interact with an orbital electron is greatest when the energy of the photon equals the binding energy of the electron; it decreases as the photon energy increases.)

Photons with energy less than the binding energy of K shell electrons interact photoelectrically only with electrons in the L shell, and in shells even farther from the nucleus.

Chapter 8:
The Normal Wound Healing Process

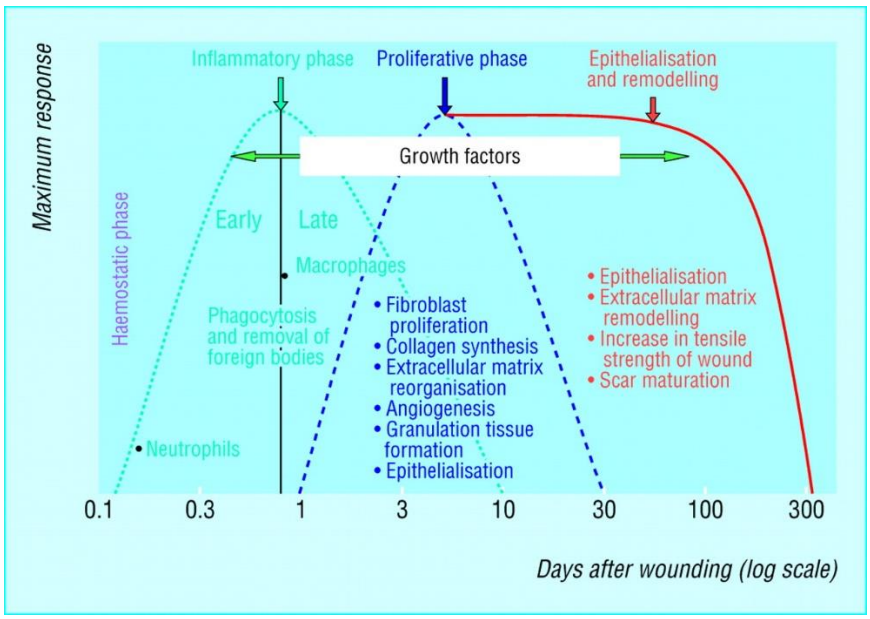
The Normal Wound Healing Process

In order to discuss keloid treatment, a review of the pertinent aspects of wound healing is essential. The process can be categorized in three distinct phases that have very different objectives. These include the inflammatory phase, the proliferative phase, and the maturation phase. The three phases of wound healing form an overlapping continuum.

The inflammatory phase (lasting up to 10 days) begins with the injury, and is marked by cellular and vascular response. Initially there is a brief 5–10-minute period of vasoconstriction followed by active vasodilatation. Vasoactive amines and kinins are released into the wound. Cells migrate into the wound, including neutrophils, monocytes, fibroblasts, and endothelial cells. The venules become dilated and the lymphatics become clogged. The wound develops redness, heat, swelling, and pain. The cellular response helps remove clot, debris, and bacteria from the wound.

The proliferative phase (lasting 1–30 days) follows the inflammatory phase. Fibroblasts that have migrated into the wound begin to produce glycosaminoglycans, which eventually form fibrillar collagen. There is an increased rate of collagen production for the next 3–6 weeks. Collagen accumulates in the wound until the rate of collagen production equals its rate of degradation. Wound tensile strength increases rapidly during the proliferative (fibroblastic) phase. The tensile strength is a measurement of the wound strength per unit area. There is a rapid increase with the peak ultimately occurring at around 60–80 days post injury, when the wound tensile strength achieves 70–80% of normal skin and then plateaus, never quite reaching normal skin strength.

The maturation or remodeling phase (7 days on- ward) is a time of increased collagen production and degradation. Collagen fibers reassemble into a more organized pattern. Intermolecular cross-linking of collagen matures the scar, causing it to be less raised and indurated. This phase lasts 9–12 months or longer in an adult and still longer in a child. The maturation process is dynamic and depends on many variables, such as age, genetics, type of wound, wound location, and the amount of inflammation.



Wounds close by primary, secondary, or tertiary healing. Primary healing (first intention) is the closing of a wound directly by suturing, grafting, or using a flap. The original scar is red and raised during maximal collagen synthesis, but then flattens and lightens in color over time.

Secondary healing (secondary intention) occurs when the wound heals openly and spontaneously with a pro-longed inflammatory phase without being closed by suture. Wound closure depends on epithelialization and contraction. Epithelialization includes the sequence of mobilization, migration, mitosis, and cellular differentiation. Epithelial cells mobilize, migrate as they lose contact inhibition, and flow to cover the wound until they meet cells from the opposite side. As the cells migrate, they in- crease in number by mitosis. Once the wound is covered with cells, cellular differentiation occurs, restoring normal basal to surface layers. Epithelialization proceeds at approximately 1 mm/day. Contraction of the wound is probably provided by myofibroblasts and is an active normal process that decreases the size of the wound. Contracture is a result of the healing process and is due to contraction of a scar.

Tertiary healing (third intention) is delayed primary wound healing after several days. This occurs when the process of secondary intention is intentionally interrupted and the wound is mechanically closed. This usually occurs after granulation tissue has formed.

Chapter 9: Keloids: The Abnormal Wound Healing Process

In the normal maturation phase, the nodularity and redness of the wound soften and flatten due to on-going simultaneous collagen synthesis and degradation and the connective tissue elements regress after the third week. In keloids, the collagen synthesis is approximately 20 times as great as that in normal unscarred skin and three times as great as in hypertrophic scars. Abergel and colleagues showed that not only is collagen production high in hypertrophic scars and keloids, but the ratio of type I to type III collagen is also high. Friedman and colleagues postulated that, in keloids, the down-regulation of type I collagen synthesis is inefficient. This collagen overproduction can be attributed to the stronger proliferating activity of keloid fibroblasts. Aside from high collagen synthesis and proliferation of fibroblasts in keloids, Oliver and colleagues and Babu and colleagues found that keloid-derived fibroblasts show a rate of fibronectin biosynthesis that is as much as four times as high as that of fibroblasts from normal scars and normal dermis.

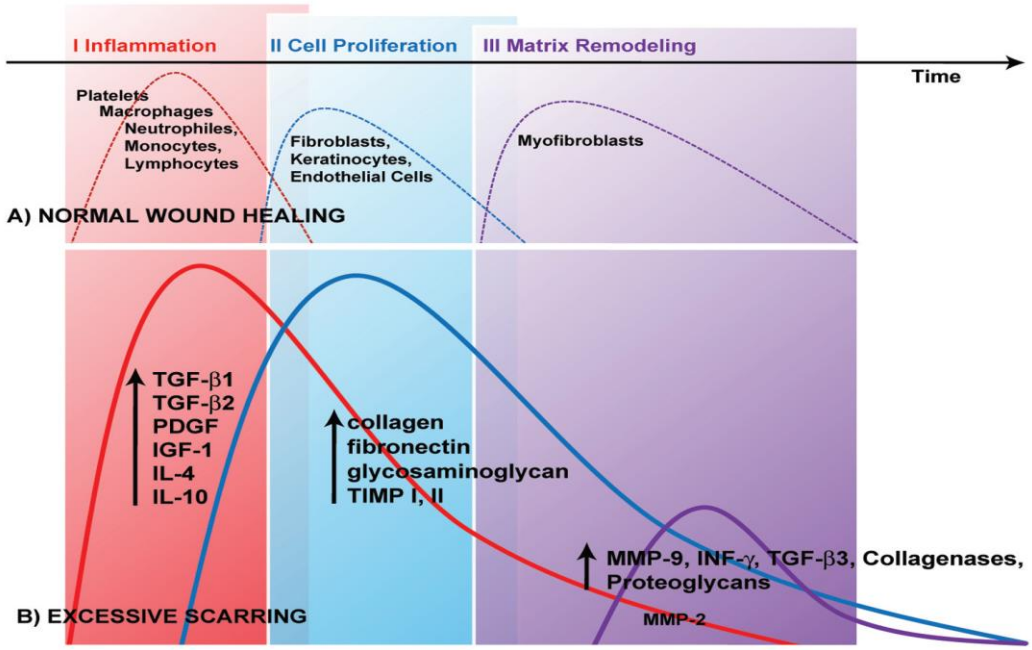
The greater the concentration of melanocytes that exist in an anatomic region, the greater the incidence of keloid formation. This observation is supported by the fact that keloid formation is rare on the palms and soles where melanocytes concentration is minimal. It is also noted that fibroblasts persist longer in keloids than in normal scar tissue. They also show a greater capacity to proliferate and produce high levels of collagen (mainly type I), elastin, fibronectin, and proteoglycan.

It is known that growth factors such as transforming growth factor-B (TGF-b), platelet derived growth factor (PDGF), and insulin-like growth factors (IGF) modulate wound healing. Several studies have associated TGF-b with increased collagen or fibronectin synthesis by keloid fibroblasts. TGF-b strongly promotes the chemotaxis of fibroblasts to the site of inflammation to begin the production of extracellular matrix proteins. The activity of TGF-b is normally turned off when repair is complete; however, dysregulation can occur leading to abnormal fibrosis and keloid formation. IGF-1 increases the expression of types I and III procollagen and the IGF-1 receptor has been shown to be “overexpressed” in keloid fibroblasts.

Furthermore, disturbed apoptosis mechanisms are discussed in the development of hypertrophic scars and keloids. Messadi and colleagues and Luo and colleagues demonstrated a significantly higher rate of apoptosis in normal skin fibroblasts than in keloidal fibroblasts.

Dermal fibroblasts are considered to be key players in scar formation:

- Excess matrix deposition, along with high water content, leads to the abnormal assembly of collagen in keloids.
- Excess matrix deposition results from the high rate of proliferation and metabolic activity of dermal fibroblasts in keloids



Chapter 10:
Keloids:
Epidemiology, Race & Genetics

Keloids are benign dermal fibro proliferative tumors with no malignant potential. The first description of abnormal scar formation in the form of keloids was recorded in the Smith papyrus regarding surgical techniques in Egypt around 1700 BC. The term *keloid*, meaning "crab claw," was first coined by Alibert in 1806, in an attempt to illustrate the way the lesions expand laterally from the original scar into normal tissue.

A keloid is an abnormal proliferation of scar tissue that forms at the site of cutaneous injury (e.g., on the site of a surgical incision or trauma); it does not regress and grows beyond the original margins of the scar. Keloids should not be confused with hypertrophic scars, which are raised scars that do not grow beyond the boundaries of the original wound and may reduce over time.

Epidemiology

Keloids are found only in humans and occur in 5-15% of wounds. They tend to affect both sexes equally, although a higher incidence exists of women presenting with keloids, possibly secondary to the cosmetic implications associated with the disfigurement. The frequency of keloid occurrence in persons with highly pigmented skin is 15 times higher than in persons with less pigmented skin. The average age at onset is 10-30 years. Persons at the extremes of age rarely develop keloids.

Race

Studies have consistently demonstrated that persons of certain races are more susceptible to keloid scar formation. Individuals with darker pigmentation, black persons, and Asian persons are more likely to develop keloids. In a random sampling of black individuals, as many as 16% have reported developing keloid scars, with an incidence rate of 4.5-16% in the black and Hispanic populations. White persons and albinos are least affected. Alhady's 1969 study found that Chinese individuals were more likely to develop keloids than Indian or Malaysian individuals.

Genetics

Some evidence supports a relationship between genetic predisposition and an individual's propensity to form keloid scars. Genetic associations for the development of abnormal scars have been found for HLA-B14, HLA-B21, HLA-BW16, HLA-BW35, HLA-DR5, HLA-DQW3, and blood group A.

Regions of the human genome highly correlated with keloid formation in 2 pedigrees with familial keloids have been recently identified. The regions identified were in 2 separate, unrelated locations on the human genome, underscoring the complex and multivariable pathogenesis of this disease.

Chapter 11: Keloids: Pathophysiology

Pathophysiology

Keloids usually occur during the healing of a deep skin wound. Hypertrophic scars and keloids are both included in the spectrum of fibro proliferative disorders. These abnormal scars result from the loss of the control mechanisms that normally regulate the fine balance of tissue repair and regeneration.

The excessive proliferation of normal tissue healing processes results in both hypertrophic scars and keloids. The production of extracellular matrix proteins, collagen, elastin, and proteoglycans presumably is due to a prolonged inflammatory process in the wound. Hypertrophic scars are raised, erythematous, fibrotic lesions that usually remain confined within the borders of the original wound. These scars occur within months of the initial trauma and have a tendency to remain stable or regress with time.

Keloid formation can occur within a year after injury, and keloids enlarge well beyond the original scar margin. The most frequently involved sites of keloids are areas of the body that are constantly subjected to high skin tension. Wounds on the anterior chest, shoulders, flexor surfaces of the extremities (e.g., deltoid region), and anterior neck and wounds that cross skin tension lines are more susceptible to abnormal scar formation.

The most important risk factor for the development of abnormal scars such as keloids is a wound healing by secondary intention, especially if healing time is greater than 3 weeks. Wounds subjected to a prolonged inflammation, whether due to a foreign body, infection, burn, or inadequate wound closure, are at risk of abnormal scar formation. Areas of chronic inflammation, such as an earring site or a site of repeated trauma, are also more likely to develop keloids. Occasionally, spontaneous keloids occur without a history of trauma.

After the initial insult to the skin and the formation of a wound clot, the balance between granulation tissue degradation and biosynthesis becomes essential to adequate healing. Extensive studies of the biochemical and cellular composition of keloids compared to mature scar tissue demonstrate significant differences. Keloids have an increased blood vessel density, higher mesenchymal cell density, a thickened epidermal layer, and increased mucinous ground substance. The alpha–smooth muscle actin fibroblasts, myofibroblasts important for contractile situations, are few, if present at all.

The collagen fibrils in keloids are more irregular, abnormally thick, and have unidirectional fibers arranged in a highly stressed orientation. Biochemical differences in collagen content in normal hypertrophic scars and keloids have been examined in numerous studies. Collagenase activity, i.e., prolyl hydroxylase, has been found to be 14 times greater in keloids than in both hypertrophic scars and normal scars. Type III collagen, chondroitin 4-sulfate, and glycosaminoglycan content are higher in keloids than in both hypertrophic and normal scars. Collagen cross-linking is greater in normal scars, while keloids have immature cross-links that do not form normal scar stability.

Chapter 12:
Keloids: Histology

Histology

Keloids have a normal epidermal layer; abundant vasculature; increased mesenchymal density, as manifested by a thickened dermis; and increased inflammatory-cell infiltrate when compared with normal scar tissue. The reticular layer of the dermis consists mainly of collagen and fibroblasts, and injury to this layer is thought to contribute to formation of keloids. Collagen bundles in the dermis of normal skin appear relaxed and in an unordered arrangement; collagen bundles are thicker and more abundant in keloids, yielding acellular, and node like structures in the deep dermal region. The most consistent histologic distinguishing characteristic of keloids is the presence of large, broad, closely arranged collagen fibers composed of numerous fibrils. In addition to collagen, proteoglycans are another major extracellular matrix (ECM) component deposited in excess amounts in keloid scars.

In fresh keloids, chemical analysis indicates the presence of a disproportionate increase in the synthesis of collagen, protocollagen, and fibronectin compared with hypertrophic scars and mature keloids, confirming that the anabolic phase in keloids is exaggeratedly accelerated. Under the polarized-light microscope the birefrangent collagen fibers appear yellow-green in color and composed of thick fibers arranged in parallel or irregular bundles. No myofibroblasts are present.

There are four histologic features that are consistently found in keloid specimens that are deemed pathognomonic for their diagnosis. They are 1) the presence of keloidal hyalinized collagen, 2) a tongue like advancing edge underneath normal-appearing epidermis and papillary dermis, 3) horizontal cellular fibrous bands in the upper reticular dermis, and 4) prominent fascia like fibrous bands.

Chapter 13:
Keloids: Pathology

Pathology of Keloid:

When we look at keloids under microscope, we notice that the top levels of skin, what is known as epidermis, is relatively normal and deep parts of the skin, where the keloid tissue resides, is mostly made of excessive amounts of tightly packed collagen fibers randomly oriented in irregular sheets.

Collagen is produced by specialized cells, known as fibroblasts. Collagen is a group of naturally occurring proteins that is abundant in human body and other animals and mammals. Collagen makes up about 25% to 35% of the whole-body protein content. It is made of three separate long chains of amino acids and forms a helix, which put side by side, form very thin fibers, known as collagen fibrils.

Collagen, in the form of elongated fibrils, is mostly found in fibrous tissues such as tendon, ligament and skin, and is also abundant in cornea, cartilage, bone, blood vessels, the gut, and intervertebral disc.
Collagen is found in many parts of human body. So far, 28 types of collagen have been identified and described. The five most common types are: Collagen I; which is mostly found in skin, tendon, vascular ligature, organs, bone (main component of the organic part of bone). Over 90% of the collagen in the body is of type one.

Collagen II is mostly found in cartilage. It is the main component of cartilage tissue. Collagen III is known as reticulate collagen and is commonly found alongside type I collagen. Collagen IV is elemental to the structure of basement membranes which is found is most tissues in the body. Collagen V is mostly found in cell surfaces, hair and placenta.

The Collagen in keloid tissue is mostly Collagen I and III.

Chapter 14:
Keloids:
Pathogenesis & Hypotheses

Pathogenesis of Keloids

The following hypotheses have been proposed for keloid formation and growth.

Altered Growth Factor Milieu

The exuberant scar tissue found in keloids has been attributed to augmented growth factor activity (transforming growth factor-β and platelet-derived growth factor) and alterations in extracellular matrix (fibronectin, hyaluronic acid, and biglycan).

Growth Factor Differences

Transforming growth factor (TGF) -β and platelet-derived growth factor are growth factors normally produced during the proliferative phase of wound healing16 and whose activities are both significantly abnormal in keloids. Keloid fibro- blasts have heightened sensitivity to and dysfunctional regulation of TGF-β .17–19 Areas of enhanced proliferation and collagen deposition within keloid tissue have distinctly elevated levels of TGF-β. Similarly, keloid fibroblasts have four- to five-fold increased levels of platelet-derived growth factor receptor, and the growth-stimulatory effects are synergistic with TGF-β.

Extracellular Matrix Differences

The components of the extracellular matrix regulate growth factor activity. The extracellular matrix of keloids is abnormal, with elevated levels of fibronectin and certain proteoglycans and de- creased levels of hyaluronic acid. Fibronectin and hyaluronic acid are proteins expressed during normal wound healing, and their dysfunctional regulation in keloid contributes to the fibrotic phenotype. Biglycan and Decorin are proteoglycans that bind collagen fibrils and influence collagen architecture. Keloids have aberrant production of these proteoglycans, resulting in disorganized extracellular matrix and collagen architecture.

Three concepts on why the growth factor milieu in keloids is abnormal. Three concepts address why the environment is altered:

Concept 1: Epithelial-mesenchymal interactions likely play a fundamental role in keloid pathogenesis. Studies using keratinocyte-fibroblast in vitro coculture systems have revealed that keloid keratinocytes can induce the keloid phenotype in normal fibroblasts. Furthermore, histologic changes in the epidermis of abnormal scars in vivo correlate with dermal fibroblast activity.

Concept 2: Proliferative pathways active in fetal cells and disabled in the adult possibly re- emerge in the keloid. Unlike normal adult skin fibroblasts, fetal and keloid tissue can survive and proliferate in vitro in a reduced serum environment.

Concept 3: Hypoxia found in keloid tissue could trigger the release of angiogenic growth factors, spurring endothelial proliferation, delayed wound maturation, and increased collagen production by fibroblasts. The hypoxia appears to be caused by endothelial overgrowth partially to fully occluding the microvessel lumens in the keloids.

Collagen Turnover Hypothesis

Abnormal regulation of the collagen equilibrium leads to the characteristic physical appearance of a keloid, the large collagenous mass that distinguishes it from normal scar.

Collagen content in keloids is elevated compared with normal tissue or scar. Light and electron microscopic studies demonstrate that collagen in keloids is disorganized compared with normal skin. The collagen bundles are thicker and wavier, and the keloids contain hallmark “collagen nodules” at the microstructural level. The ratio of type I to type III collagen is increased significantly in keloids compared with normal skin or scar, and this difference results from control at both the pretranscriptional and post transcriptional levels. Collagen is produced mainly by fibroblasts and also by endothelial cells. Keloid fibroblasts have a greater capacity to proliferate because of a lower threshold to enter S phase and produce more collagen in an autonomous fashion. Matrix metalloproteinases and their inhibitors (tissue inhibitors of matrix metalloproteinases) potentially play a major role in keloid formation. Collagen is degraded by collagenase produced in fibroblasts and in inflammatory cells. Enzymes that inhibit or degrade collagenase exert an additional level of collagen regulation. Concentrations of collagenase inhibitors, α-globulins and plasminogenactivatorinhibitor-1,are consistently elevated in both in vitro and in vivo keloid samples, whereas levels of degradative enzymes are frequently decreased. Steroid-treated and irradiated keloids exhibit a decrease in collagenase inhibitors and an increase in apoptosis of fibroblasts, leading to normalization of net collagen levels. Furthermore, matrix metalloproteinase activity differs between keloid and normal fibroblasts, and these differences appear to directly affect phenotype. Because collagen predominates in the phenotypic appearance of keloids, collagen metabolism and particularly modulation of matrix metalloproteinases serve as valuable tar- gets of therapeutic intervention.

Tension Hypothesis

Mechanical tension placed on the healing wound misaligns the orientation of collagen for- mation and results in keloid formation. Mechanical tension drives fibroblast proliferation and collagen synthesis. In vitro and in vivo studies have suggested that stretch and tension not only promote collagen production but also dictate collagen architecture and orientation and affect dermal remodeling. Collagen is oriented perpendicular to the muscle contraction; therefore, incisions perpendicular to the muscle fibers theoretically heal with collagen oriented naturally. Anecdotal evidence suggests that incisions created parallel to skin tension lines rarely form abnormal scars, where as those placed at sites of joint motion frequently do. Keloid and hypertrophic scar formation can also be minimized through the use of absorbable subcuticular suture closure instead of interrupted nonabsorbable suturing, thereby limiting suture trauma to the skin. Furthermore, abnormal scarring rarely develops in elderly patients, whose skin characteristically has poor tension. This hypothesis implies that nonaligned tension forces disrupt scarring into an abnormal pathway. Without objective evidence, there is disagreement regarding whether sites of frequent keloid formation, such as the earlobe and the chest wall, are under tension or not. Indeed, although stretch and tension are important determinants of final scar appearance, they may play a more dominant role in the pathogenesis of hypertrophic scarring than they do in keloid formation. Nonetheless, stretch and tension forces must be carefully considered in all models of skin healing, and future research may reveal more complexity to this hypothesis than the current two-dimensional paradigm.

Genetic Immune Dysfunction

An inherited abnormal immune response to dermal injury may cause keloid formation, as keloids are associated with particular human leukocyte antigen subtypes. Keloids tend to occur in darker skinned individuals, and familial tendencies suggest a polygenic inheritance pattern. However, darker complexion does not correlate directly with a higher rate of keloid formation, as seen in a study of 175 Malaysian keloid patients. A genetic influence is probably directed through an immune phenotype. Studies suggest association of group A blood typeandhumanleukocyteantigenB14, 21, BW35, DR5, and DQW3 in patients with a keloid diatheses.

Patients who develop keloids have a disproportionately high incidence of allergic diathesis and elevated levels of serum immunoglobulin E.

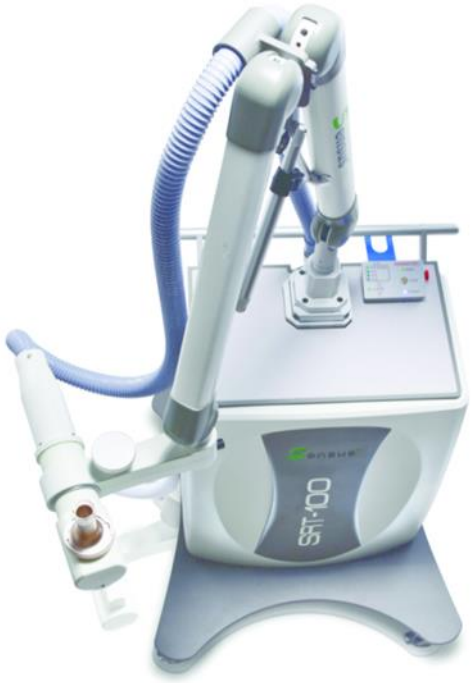
Multiple reports have found trends in patterns of serum complement, immunoglobulin G, and immunoglobulin M levels in patients with keloids, suggesting a systemic immune state genetically predisposed to keloid formation. Keloid formation could be considered an autoimmune connective tissue disease. Circulating non–complement-fixing antifibroblast antibodies could bind to fibroblasts and stimulate proliferation and collagen production, similar to antithyroid antibodies in Hashimoto's thyroiditis. Keloids have been found associated with a number of other genetic connective tissue diseases, including Rubinstein-Taybi syndrome, Ehlers-Danlos syndrome, progeria, osteopoikilosis, scleroderma, and Pachydermoperiostosis.

Clinical evidence also suggests that patients who develop keloids have an inherently hypersensitive cell-mediated immune system. The growth of keloids, characterized by a slow initial phase followed by rapid secondary growth, suggests the occurrence of a local immune reaction. Use of monofilamentous suture material in closure of surgical incisions results in fewer abnormal scars compared with multifilamentous suture, presumably attributable to less local inflammation. Furthermore, actively growing keloid explants, placed into nude mice that lack an immune system, grow initially and then regress despite revascularization. Keloid regression in nude mice supports the theory that a systemic immune response directed their growth before explantation.

Sebum Reaction Hypothesis

Keloids could arise from an immune reaction to sebum. Dermal injury exposes the pilosebaceous unit to systemic circulation, and in individuals who retain T lymphocytes sensitive to sebum, a cell-mediated immune response is initiated. Release of cytokines, in particular interleukins and TGF-β, stimulates mast cell chemotaxis and fibroblast production of collagen. As the keloid expands, further pilosebaceous units on the advancing border are disrupted, and the process propagates. Keloids preferentially occur on anatomical sites with high concentrations of sebaceous glands, such as the chest wall, shoulder, and pubic area, and rarely occur on anatomical sites lacking sebaceous glands, such as the palm and sole. The sebum reaction hypothesis explains why an individual with two otherwise identical incisions could develop one keloid and one normal scar. The sebum reaction hypothesis also explains why only human beings, the only mammals with true sebaceous glands, are affected by keloidal scarring. Patients with keloids demonstrate a positive skin reaction to intradermal sebum antigen and tend to have a greater resultant weal size than patients without a keloid diathesis. Furthermore, keloids can form following immunization with autologous skin, and a sebum vaccine can successfully desensitize patients from keloid recurrence following excision. The success of radiation therapy and steroids in the treatment of keloids, the former reducing sebum production and the latter inhibiting local lymphocyte activity, is consistent with a sebum reaction as the cause. It has been speculated that ablation of the pilosebaceous unit before elective surgical excision may provide prophylaxis against the later formation of keloids.

Chapter 15:
Keloid & Hypertrophic Scars



Keloid and hypertrophic scars

While there was little disagreement about distinctions concerning the gross appearance of keloid and hypertrophic scars, histopathological differences between them are often considered to be insignificant. There are conflicting reports in literature as to whether there are histopathological distinctions between these two scars. These results confirm and extend the reports of histopathological differences between keloid and hypertrophic scars, these are:

1) The first difference was in the epidermal features; the keloid scars demonstrated normal thickness of epidermis in all cases with regular and palliating basal cell organization, and basal cell vacuolar change in most cases. The papillary dermis show scarring in many keloid scars. On the other hand, the epidermis in all hypertrophic scars was flattened, with disarray of basal cells in most cases and vacuolar change in few. These epidermal changes of keloid scars are concordant to other studies in literature, and are suggestive of presence of prior external injury to the dermis locally. This correlates well with the fact that keloid scarring develops from either a deep or a superficial injury. In contrast, some studies report epidermal hyperplasia in keloid, and this could be explained partly, by the phenotypic variations in the study groups.

2) The second difference was the collagen quality and orientation of the scar; all keloid scars in our study demonstrated the presence of large, broad, glassy, eosinophilic focally fragmented and haphazardly arranged collagen complexes referred to as “keloid collagen” in association with variable amounts of myxoid extracellular matrix in most cases. As opposed to hypertrophic scar which showed nodules containing fibrillar collagen of fairly regular thickness arranged parallel to the epidermis, with absence of myxoid extracellular matrix with high density of cells. Similar differentiating findings are reported in other studies. Verhaegen et al. found that compared with normal skin, norm trophic scar, and hypertrophic scar, the bundle distance was significantly larger in keloid scar, which confirms that thicker collagen bundles are present in keloid scar. Abnormally, large collagen bundle complexes associated with variable amounts of "ground substance" mucopolysaccharides have been identified in keloid scar, but are absent from hypertrophic scars. This was explained by the fact that compared to normal dermal fibroblasts keloid; fibroblasts exhibit increased production of collagen and matrix metalloproteinase. Additionally, the keloid collagen occupied full thickness of the reticular dermis in all cases, while remained confined to the upper one third in the hypertrophic scars. This again correlates with the exuberant amount of collagen and extension beyond boundaries of actual wounds in the keloid scar.

3) The third difference was that “keloid collagen” showed positivity for α-SMA expressing myofibroblasts in only one third of keloid scars while the collagen nodules of hypertrophic scars contained no α-SMA expressing myofibroblasts, although they were cellular. There are wide variations in the literature regarding α-SMA expression in scars ranging from completely negative in keloid to 45% keloid cases positive, and the same for hypertrophic scar, 70% positive to most cases in another study.

Possible explanations for this variation between different studies are: (a) Differences in genetic backgrounds of the population studied (b) differences in the criteria used for diagnosing scars, positivity scales used for α-SMA expression; (c) presence of mixed keloid - hypertrophic scars in the sample populations studied (d) interobserver variability.

Histopathological characteristic of hypertrophic scar has the presence of nodules containing a high density of cells and collagen similar in appearance to the nodules described in Dupuytren's contracture. They are cigar-shaped and run parallel to the surface of the skin, are located in the middle or deeper layer of the scar, plus they are oriented along the tension lines of the scar. The absence of such nodules is characteristic of keloid scar. Myofibroblasts are differentiated fibroblasts found in granulation tissue and fibrotic lesions. They differ from normal fibroblasts by their characteristic cytoplasmic bundles of microfilaments, nuclear indentations and cell-to-cell or cell-to-stroma connections. Moreover, a large proportion of myofibroblasts express smooth muscle proteins such as α-SMA and Desmin. It was well accepted that myofibroblasts appear temporarily in granulation tissue during wound healing, but are present permanently in hypertrophic scars and other fibrotic settings.

4) The fourth difference was the presence of horizontal fibrous bands in all keloid scars with an advancing edge underneath the epidermis in 66% of cases, and the total absence of such features in all the hypertrophic scars. Similarly, these features have been reported in other studies. Some authors describe this phenomenon as “pseudopodia-like extensions” into the surrounding tissue.

5) The fifth difference was the presence of small aggregating blood vessels just below the epidermis appearing to grow out or from it, in the keloid scars, while in the hypertrophic scars the blood vessels were oriented vertically around the nodules. Prominent telangiectasia in the papillary dermis has been reported in keloid scars and vertically oriented blood vessels have been reported in the hypertrophic scars. The evidence demonstrates that hypertrophic scars and keloids are hypoxic, undoubtedly due to the microvascular occlusion. Hypoxia may stimulate excessive production of collagen, which forms the bulk of these lesions, from fibroblasts and myofibroblasts.

6) The sixth difference was in the presence of moderate degree of perivascular chronic inflammatory infiltrate in all keloid scars, with mast cells seen in the reticular dermis in 73%, as compared to hypertrophic scars where this feature was seen infrequent in 20-30% of cases. Immunohistochemical investigations have shown a high amount of activated immune-cell infiltrate in the excised keloid scars, consisting of CD3+, CD4+, and CD45R0. Several studies investigated the contribution of lymphocytes and macrophages to keloid scarring by morphologically characterizing inflammatory cell subpopulations in keloid scars. It was found that there was a significantly higher CD4 (+):CD8 (+) (Th: Ts) ratio in keloid tissue, suggesting that an imbalance in these inflammatory cell subpopulations may contribute to keloid scarring mast cells in the middle dermis as they are activated and may be involved in the pathogenesis of keloid scars.

Keloid Facts:

Approximately 700 million people are affected globally (10% of world population)

Ethnic groups with high levels of pigmentation are 5 to 15 times more often to keloid when compare to European Caucasians or of that ethic heritage.

People of African descent and Latin/Indian ethnic heritage have a higher prevalence of 16%

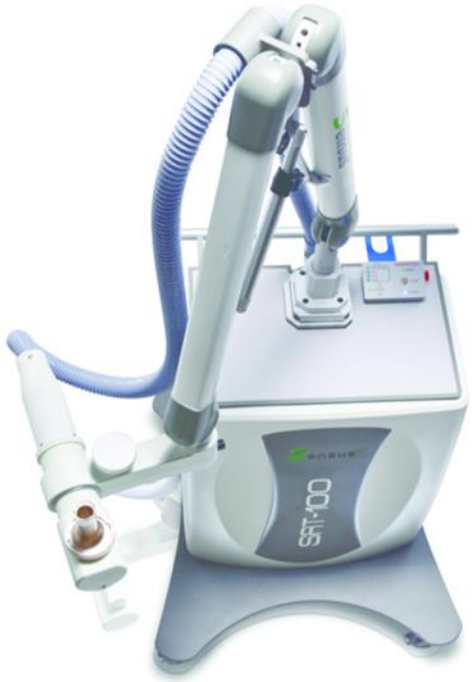
The highest incidence is noted in persons in the twenties

Keloid scarring equally affects both genders

The incidence of keloid and hypertrophic scars combined ranges from 40% to 70% following surgery

The incidence skyrockets to up to 91% following burns'

Chapter 16:
Keloids: Surgery & Superficial Radiation Therapy



Surgical excision of a keloid followed with superficial radiation therapy within 72 hours has a success rate of over 90%.The procedures need to be performed in a timely manner in order to excise the collagen bundles and retard the overgrowth of fibroblasts.

Surgery

The Surgery portion of the procedure is performed in order to excise collagen bungles. If the collagen bundles are not removed, the superficial radiation will not be as effective. The collagen nodule is the structural unit of all in keloids. It is never found in the fully mature scars. Nodules are composed of a marked increase of unidirectional collagen fibrils aligned in a highly stressed orientation. There is also a marked increase in the number of fibroblasts. Few microvessels appear within the nodule; rather, they remain peripheral and encompass the main body of the nodule as a net. There is a heavier concentration of microvessels (3-13 micrometer in diameter) at the terminal ends, many of which are occluded. The occlusion appears due principally to an apparent increase in the number of endothelial cells. The character of the nodule and its relationship with a peripheral semi occluded microvascular network suggests an origin of the hypertrophic scar and keloid to be related to revascularization of a deep wound.

Differential degeneration of the lateral microvessels may account for increases in collagen bundle growth and ultimate size. As degeneration or apoptosis continues the nodules and scar become more avascular and more hypoxic, prompting fibroblast death and release of lysosomal enzymes important for maturation.

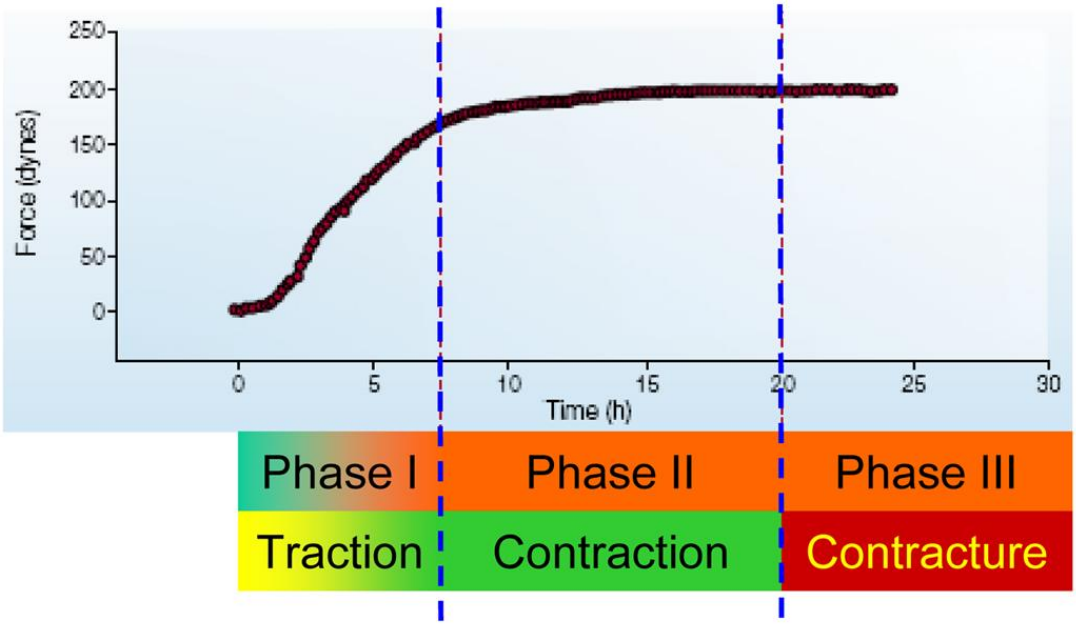
The evidence demonstrates that keloids are hypoxic, undoubtedly due to the microvascular occlusion. Hypoxia may stimulate excessive production of collagen, which forms the bulk of these lesions, from fibroblasts and myofibroblasts. The hypoxic condition of the collagen bundles can cause ionizing radiation to be ineffective. The lack of oxygen in the bundles lowers the production of radicals from radiolysis.

Surgery for Tension Reduction

The recurrence rate can be reduced even further by using particular surgical methods, namely, subcutaneous/fascial tensile reduction sutures, Z-plasties, and local flap transfer. The choice of suture material is important because some sutures trigger more immune reaction than others. Monofilament absorbable synthetic biopolymers produce the least reaction. Minimizing the tension acting on the wound by aligning the incision parallel to natural skin lines (when possible).

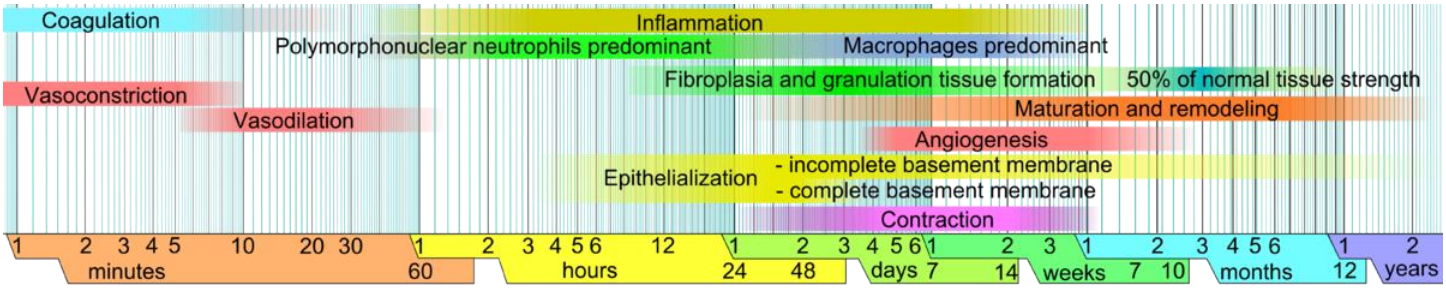
Superficial Radiation Therapy

Fibroblasts are one of the most abundant cell types in connective tissues. In the first phase, when fibroblasts attach to collagen fibrils, spread, and migrate, they exert traction forces to the matrix and cause slow compaction of the collagen lattice. As a result, mechanical stresses start to develop within the lattice, which induce differentiation of fibroblasts into pro-myofibroblasts.



Keloids exhibit abnormal collagen metabolism and an increased abundance of extracellular matrix components. Comparison of fibronectin levels in fibroblasts derived from keloids and normal dermis revealed a relative increase in intracellular and extracellular fibronectin in the keloid-derived cells. While fibronectin was similarly processed, compartmentalized, and degraded by both cell types, fibronectin biosynthesis was found to be accelerated as much as fourfold in keloid fibroblasts due to a corresponding increase in the amount of accumulated fibronectin mRNA. These changes account for the elevated steady-state level of the molecule in keloid fibroblasts and suggest that increased fibronectin in keloid lesions is due to overproduction by the wound-healing fibroblasts.

Superficial Radiation Therapy is administer in order restrict the overgrowth of fibroblasts in the first phase of the healing process. Within 24-48 hours, fibroblasts mainly migrate and proliferate, while later, they are the main cells that lay down the collagen matrix in the wound site. A BED therapeutic dose of 30 restricts the overproduction of fibroblast. This reduction in fibroblast over proliferation balances the healing process with increase of apoptosis. The result should render a normal healing process.



Chapter 17:
Medical Dosimetry

Dosimetry is simply applied physics. The primary goal of radiation dosimetry is a quantitative estimation of the absorption of energy in tissue. To make estimates of radiation dose (i.e., the energy absorbed by tissue), one needs to understand the processes by which radiation interacts with tissue as it those interactions that result in the transfer of energy to the tissue. The term *dose* is used to describe the amount of energy absorbed per unit mass at a site of interest, while *exposure* is a measure of radiation based on its ability to produce ionization in air under standard conditions of temperature and pressure.

Radiation Dose Quantities and Units

Three physical quantities are basic to radiation dosimetry of photon beams:

- Exposure
- Kerma
- Absorbed Dose

The conventional units for these quantities are:

- Roentgen (R) for exposure
  - The amount of ionizing X-ray exposure that would liberate 1 electrostatic unit of negative or positive charge per cm^3 of air
- Rad for kerma and absorbed dose
  - Where 100 erg/g = 1 rad

The International System of Units (SI) uses:

- Coulomb per kilogram (C/kg) for exposure (2.58 x 10-4 C/kg = 1 R)
- Joule per kilogram for kerma and absorbed dose (1 Gy = 1 j/kg)

The special name for the joule per kilogram is the Gray. The SI system has no special name for units of exposure.

Exposure

Exposure is a measure of radiation quantity, the capacity of radiation to ionize air. The roentgen is the traditional unit of radiation exposure measured in air; 1 R is the amount of ionizing radiation (i.e. X- and gamma radiation) that produces 2.08 x 109 ion pairs in 1 cc of air (STP). Roentgen measures the intensity of radiation to which an object is exposed.

No specific SI unit is equivalent to the R (as mentioned above), but in terms of other SI units it is equal to coulombs per kilogram (C/kg); 1 R = 2.58 x 104 C/kg equals 3.88 x 103 R.

The roentgen applies only for X-rays and gamma rays. In recent years the roentgen has been replaced by air kerma, an acronym for kinetic energy released in matter.

Kerma

Kerma (K)—kinetic energy released in medium—is defined as the sum of the initial kinetic energies of the charged particles liberated by indirectly ionizing radiation (photons) in a volume element of a material divided by the mass of the volume element. In other words, Kerma measures the kinetic energy transferred from photons to electrons.

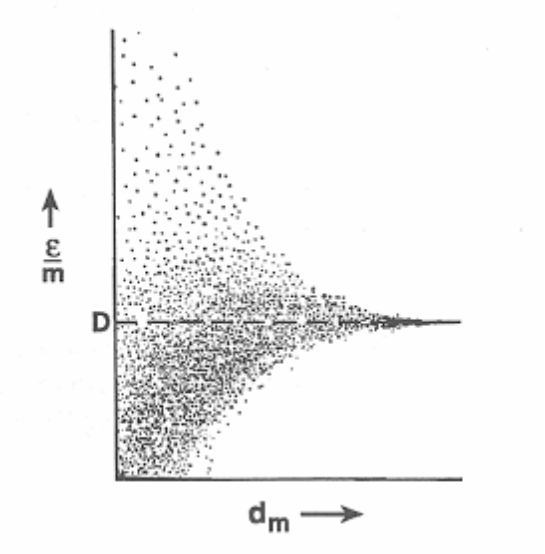
The unit for kerma is joule per kilogram [gray (Gy)], which is the same unit as for absorbed dose. (Kerma is closely related to—but not exactly the same as—absorbed dose.)

Absorbed Dose

Absorbed dose is a measure of the energy absorbed by any type of ionizing radiation per unit mass of any type of matter.

The SI unit is the gray (Gy); as with kerma, 1 Gy equals 1 joule/kg. The traditional unit of absorbed dose is the Rad (radiation absorbed dose), where 1 rad is equivalent to 100 ergs/g of absorber.

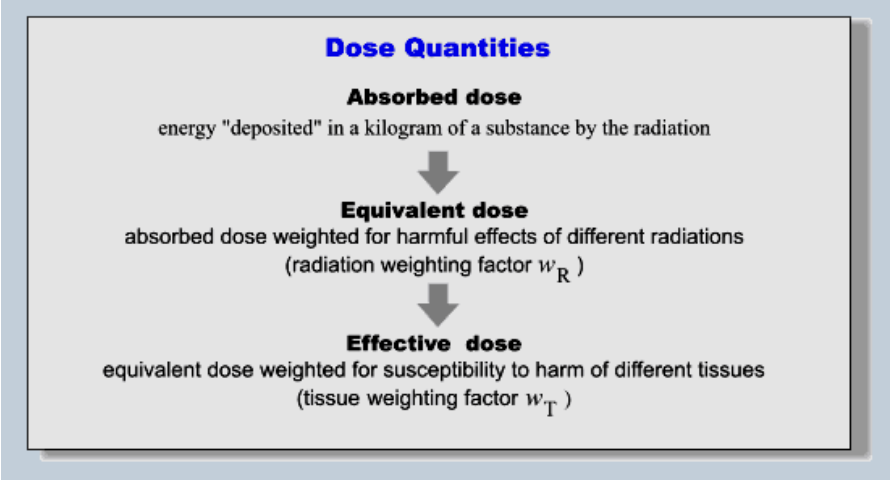
For small volumes, there is statistical variation of the absorbed dose since the likelihood of interaction per unit distance is characterized by a probability. The stochastic (random) variation of absorbed dose as a function of volume is shown here:



When averaged over the mass of an organ, the absorbed dose is probably the most useful measure of radiation dose for epidemiologic studies. Absorbed dose is defined by the energy absorbed per gram and is generally viewed, particularly in epidemiology, as a macroscopic quantity. The damage to living tissues, on a microscopic level, can vary depending on a number of physical and biological parameters.

Equivalent Dose

The equivalent dose (H_T) is used to compare the biologic effects of different types of radiation on a tissue or organ. It is expressed as a sum to allow for the time possibility that the tissue or organ has been exposed to more than one type of radiation. The radiation weighting factor is chosen for the type and energy of the radiation involved. Therefore, high LET radiations (which are more damaging to tissue than low LET radiations) have a correspondingly higher WR. The unit of equivalent dose is the Sievert (Sv). For diagnostic X-ray examinations, 1 Sv equals 1 Gy. The traditional unit of equivalent dose is the rem (roentgen equivalent man). One Sievert equals 100 rems.



Absorbed dose: rad or Gray (1 Gy = 100 rad, for photons)

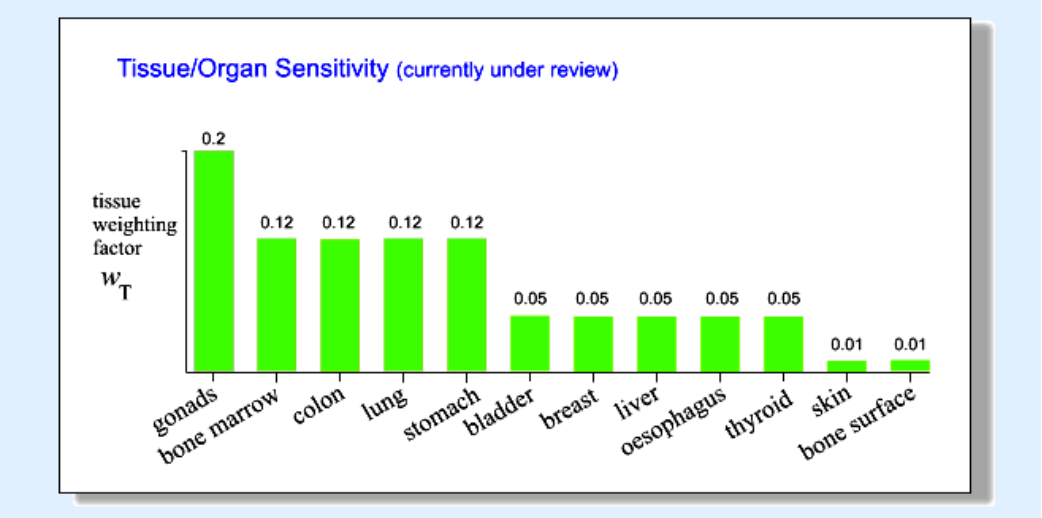
Equivalent dose: rem or Sievert (1 Sv = 100 rem for photons

Effective dose: rem or Sievert (1 Sv = 100 rem for photons)

Effective Dose

Effective Dose a measure of the stochastic effect that a radiation dose to part of the body will have on the whole organism; it is used to estimate the risk in humans, and is a “radiation protection” quantity.

The unit of effective dose is the Sievert (Sv). The tissue weighting factors include gonads, 0. /20; red bone marrow, 0.12; esophagus, 0.5; thyroid, 0.05; thyroid, 0.05; skin, 0.01; and bone surface, 0.01.



ICRP Publication 60		2006 Draft ICRP Report	
Gonads	0.20	Gonads	0.08
Bone marrow	0.12	Bone marrow	0.12
Colon	0.12	Colon	0.12
Lung	0.12	Lung	0.12
Stomach	0.12	Stomach	0.12
Bladder	0.05	Bladder	0.04
Breast	0.05	Breast	0.12
Liver	0.05	Liver	0.04
Oesophagus	0.05	Oesophagus	0.04
Thyroid	0.05	Thyroid	0.04
Skin	0.01	Skin	0.01
Bone surface	0.01	Bone surface	0.01
		Brain	0.01
		Salivary glands	0.01
Remainder	0.05	Remainder	0.12

Radioactivity

The measurement of radioactivity (A) describes the decay rate of a sample of radioactive material. The SI unit is the Becquerel (Bq). 1 Bq equals 1 disintegration/second. The traditional unit is the curie (Ci), which corresponds to the activity of 1 g of radium.

Chapter 18:
BED for Keloids

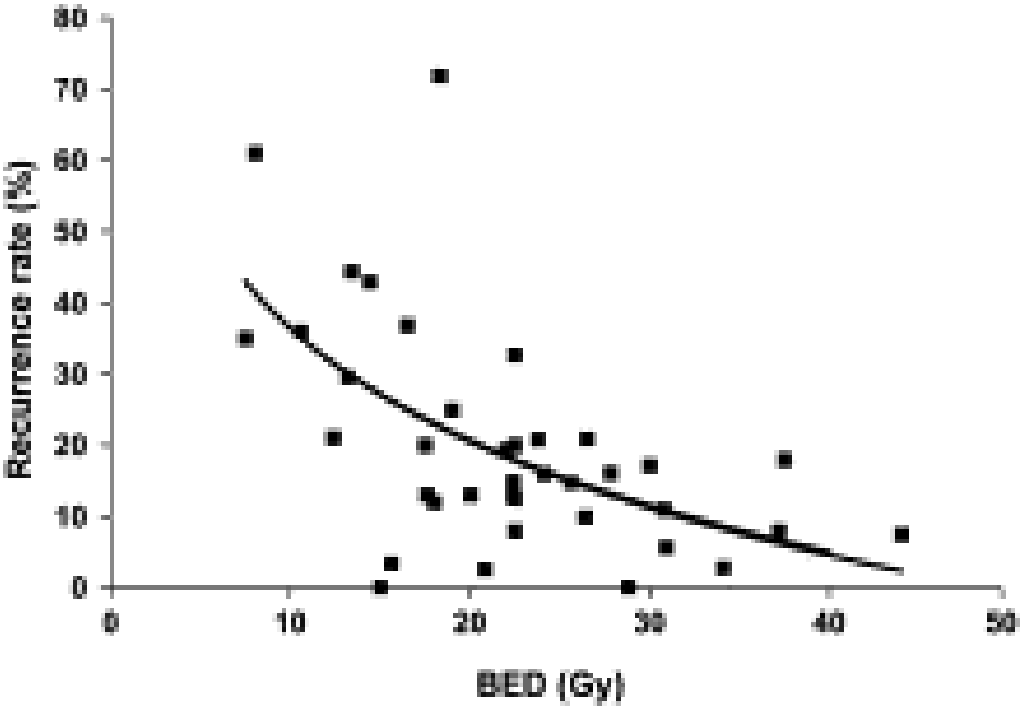
BED

BED is used in practice to have a simple way to compare different fractionation schemes and to assign them a numerical score. For many years the nominal standard dose (NSD) system, developed by Ellis and colleagues, was widely used. It proved useful for assessing modest changes in fractionation schemes, but fell into dispute when extrapolated beyond the data range on which it was based.

The linear-quadratic model is now more widely used and has received greater acceptance. Use of the Linear Quadratic (LQ) model, with appropriate values for the parameters, α and β, emphasizes the difference between early and late responding tissues and the fact that it is never possible to match two different fractionation schemes to equivalent for both.

For maximum efficacy and safety, postoperative superficial radiation therapy for keloids requires 13 to 18 Gy delivered in three different fractionation schemes. Calculation of the biologically effective doses (BEDs) of various radiation schemes for keloid therapy using the linear-quadratic concept revealed that when the BEDs equals or exceeded 30 Gy, the recurrence rate was less than 10%. A BED value of 30 Gy can be obtained with:

- A single-fraction dose of 13 Gy
- Two fractions of 8 Gy,
- Three fractions of 6 Gy,



Keloid recurrence after surgery and radiotherapy as a function of the biologically effective dose (BED). The data points were fitted with a logarithmic function. (Reprinted from Kal HB, Veen RE, Jürgenliemk-Schulz IM. Dose-effect relationships for recurrence of keloid and pterygium after surgery and radiotherapy. *Int J Radiat Oncol Biol Phys*. 2009; 74:245-251, with permission from Elsevier.)

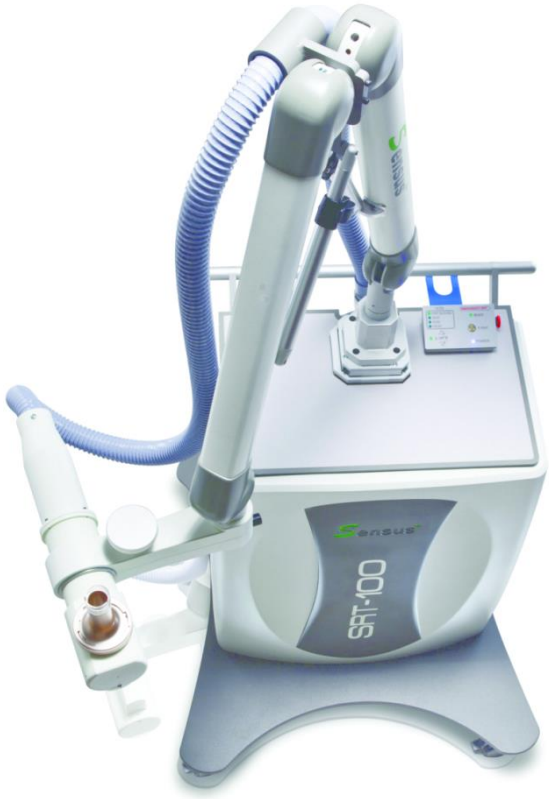
Protocol

Kal and Veen (2005) stated that for successful prevention of recurrence of keloids after surgical excision, a relatively high dose must be applied in a short overall treatment time. The optimal treatment probably is an irradiation scheme resulting in a biologically effective dose (BED) value of at least 30 Gy. The radiation treatment should be administered within 2 days following surgery.

Summary

While there are several options for the treatment of keloids, radiotherapy remains a safe and effective treatment of choice. Surgery-alone combined with other adjuvant approaches exhibit literature reported recurrence rates of 80% on average. Many studies have been published using superficial radiotherapy systems to treat Keloids with superior results. While there are not well established standards for managing the treatment protocol there is a copious amount of literature defining treatment, dose and fractions.

Chapter 19: Keloids: Margins, Energy & Fractionation Guidelines



Keloids Margins

Histological Type	Recurrence risk, Aggressiveness	Margins
Keloid Scars after Excision	**High Risk**	10mm

There are four histologic features that are consistently found in keloid specimens that are deemed pathognomonic for their diagnosis:

- The presence of keloidal hyalinized collagen
- A tongue like advancing edge underneath normal-appearing epidermis and papillary dermis
- Horizontal cellular fibrous bands in the upper reticular dermis
- Prominent fascia like fibrous bands

Energy Selection

Keloid Scars after Excision:

Auricular	70kV
Chest (sternum)	70kV
Shoulders	100kV
Back	100kV
Abdomen	100kV

All other areas of the body, applications consult

The Keloid treatment should be administered within 72 hours after surgery

Keloid Scars after Excision:

BED 30 Fractionation Schemes (post-Surgery):

- A single fraction of 1300 cGy Total Dose
- Two fractions of 800 cGy, 1600 cGy Total Dose (Fractionation used with Feather technique)
- Three fractions of 600 cGy, 1800 cGy total Dose

The Keloid treatment should be administered within 72 hours after surgery

Recurrence and Cosmesis of treatment of Keloids

Author	Patients/Keloid (N)	Type of therapy	Local recurrence	Good Cosmetic results
Malaker K et al	64	Kilovoltage X-rays	**3%**	
Borok *et al*	**393**	Superficial	.5%	**92%**
Guix	169	No Surgery 6x3 Gy Surgery 4x3 Gy	6% 4%	**77** **97**
Speranza	**234**	Orthovoltage	**15%**	**60%**

Chapter 20: Keloids: Clinical Radiation Oncology

Keloid superficial radiation therapy is a clinical treatment modality where ionizing radiation is used to treat patients with post excision keloids. The goal of superficial radiation therapy is to deliver a measured dose of radiation to a defined margin around the excision with minimal damage to surrounding normal tissue. Keloid superficial radiation therapy is generally given in post-surgical 1, 2, 3, or 4 fractionated treatment schemes. Keloid superficial radiation therapy is useful in the treatment of post-surgical excision and can provide long-term local control with preservation of regional function. There are several principles that dictate the prescription of irradiation and therefore the management of keloid patients, with the goal of delivering a precise dose of radiation to a defined excision and margin with as minimal damage as possible to surrounding normal tissues.

Principles of Keloid Superficial Radiation Therapy

- Precise dose to defined excision and treatment margin
- Improvement of quality of life
- Prolongation of life span

Process of Keloid Superficial Radiation therapy

- Keloid staging. Complete evaluation of the full extent of the keloid.
- The knowledge of the biologic behavior of specific lesion types.
- Defining the goal of keloid superficial Radiation Therapy: Curative or limited control treatment.
    - Curative: It is projected that the patient has the probability for long-term success.
    - Limited control: Patient keloid control for an extended period is not projected. However, irradiation of the tumor will improve the patient's quality of life.
- When selecting an appropriate fractionation scheme, clinicians will utilize irradiation in combination with surgery for keloids originating from trauma.
- Determination of the irradiation dose and volume to be treated. This depends upon the anatomic location, excision size, other excision characteristics and normal structures present in the area to be irradiated.
- Evaluation of the patient's general condition.

Clinical Evaluation

- Pathology
- Staging work-up
- Patterns of failure
- Biologic mechanisms
- Microenvironment conditions
    - Oxygen tension (necessary for production of free radicals and the resultant tumor damage)
- “Inherent “cellular radioresistance
    - Repair sublethal and potential lethal damage
- Collegian nodule repopulation

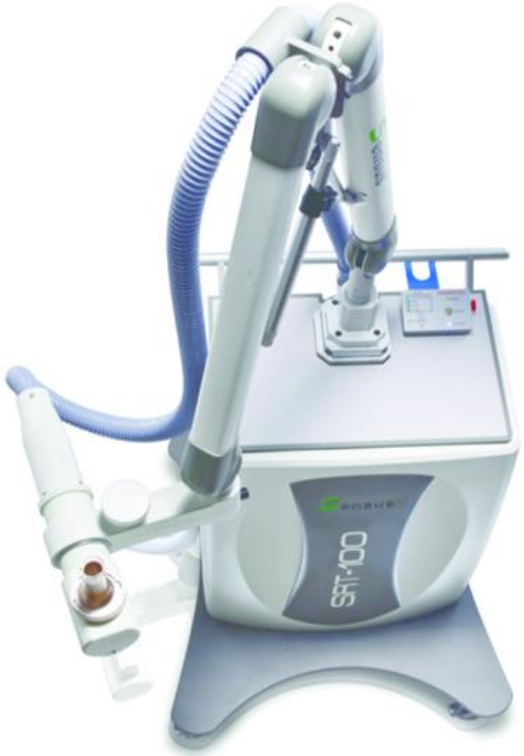
Therapeutic Decision: Goal of Therapy

- Curative: definitive

Periodic Evaluation (During Treatment) and Follow-Up

- Careful assessment of acute and late toxicity

Chapter 21:
Keloids: Patient Selection for Treatment



The main objective in keloid superficial radiation oncology for Keloid excisions is to correct the healing process while maintaining the patient's present and future quality of life. Delivering precisely measured dose of radiation to a defined excision and margin with minimal damage to surrounding tissue is the main goal. The success of eradiating the return of a keloid depends on the radiosensitivity of the excision as well as tolerance of surrounding normal tissue. Normal tissue toxicity factors that should be considered in selecting a kV energy should depend on the size or volume of the area, vascularity, and the underlying and supporting tissues. The tissues of the body have individual variation of absorption and tolerance to ionizing radiation. Area of treatment on the body are a good tool for kV energy selection.

When the soft X-rays from the SRT beam hits a cell that is dividing, the cell will be damaged. As the damaged cells die, healthy cells begin to replace them. Keloid superficial radiation therapy works by optimizing damage to the onset of fibroblast by minimizing its overproduction and setting a balance for a normal healing process. SRT is specifically engineered to deliver 100% of the energy at the skin surface. SRT-100 has 3 therapeutic energies that cover all desired depth of keloids that a Dermatologist would want to treat.

The average outpatient treatment can takes place 1 to 3 times within 72 hours of excision. The number of sessions required will vary based upon location of keloid excision and physicians preference.

During treatment, a lead cutout with a treatment applicator is placed on the skin thru which soft X-rays are delivered for a designated amount of time. Plastic wrap is placed between the lead shield and the patient's skin. The therapy is non-invasive and painless. Upon completion, the lead cutout and applicator are removed.

The patients are able to drive themselves home and immediately return to normal activities. Keloid Superficial radiation therapy skin treatments are localized to the excision and margin that surrounds it; all other areas of the body are protected with treatment devices which are placed prior to treatment. There is no exposure to other areas of your body.

As treatments progress, patients will develop some inflammation which may result in some soreness around the area being treated. Many patients equate the sensation to minor sunburn.
Patient selection for training:

1. Patient's Keloids that have been excised
2. Keloid excision size is not limited to the largest applicator, a feathering technique can be applied for such sized excisions.
3. Optimal keloid excision selection should cover any part of the body
4. Keloid excisions covering upper eye lid, lower eye lid, outer canthus, or inner canthus need purchase of an internal eye shield. Instructions provided by Sensus healthcare

General outline of a patient treatment: the procedure consists of 5 documents which justify the CPT codes used with Keloid superficial radiation therapy. The documents consist of: Eligibility, Simulation, Prescription, Second Calculation, and Management.

a. A day prior to the start of treatment, day of excision, physician will perform a "simulation". Using the information from the excision, the doctor will outline the treatment area with a marking pen and prescribe a dose. Generally this dose is divided from 1-3 equal treatments called "fractions". This method allows for the marginal tissue to recover from targeted hits made by the soft X-rays. A custom shield is cut from a piece of lead to minimize the area exposed by the SRT beam. The Eligibility, simulation, Prescription, and second Calculation documents are completed at this time, post Simulation.

b. The patient will start treatment not less than 24 hours after excision.
c. Complete treated within 72 hours. Total treatment time from setup to end of treatment us usually around 10 to 15 minutes.
d. On 2 and 3 fractionation schemes, an evaluation of the excisions reaction will be documented on the Management form.
e. Upon completion of the fractionation scheme the patient will experience 2 weeks of a continued biological reaction.
f. A six week follow-up is the standard to give time for the excision and margin to be fully irradiated and for marginal tissue respond back to normal.

Chapter 22: Keloids: Clinical Treatment Planning

Tumor Depth

Once the decision has been made to proceed with keloid Superficial Radiation Therapy, several logistical issues need to be addressed prior the beginning of therapy. The first consideration is the penetration depth of the beam needed to adequately treat the keloid excision and margin. The area of treatment and underlying tissue confirms the kV energy selection.

Beam Quality

The heterogeneous beam produced by superficial dermatologic X-ray units consists of X-rays of varying wavelengths. The distribution and proportion of short wavelengths (hard X-rays) versus longer wavelengths (soft X-rays) determines the penetrating effect, or quality, of the radiation. The penetration of superficial quality X-rays is determined by three variables: the voltage (kV), the filtration, and the target skin distance (TSD). The combined effect of these variables has been traditionally expressed as the “half-value layer” (HVL). The half value layer is the thickness of a given material (typically aluminum) that reduces the intensity of the photon beam to 50% of the original exposure (Goldschmidt, 1991). The greater the HVL, the more penetrating the resulting beam.

The range in which most dermatologic X-ray machines operate within is 50 to 100 kV, which relates to an HVL range of 0.4mm Al to 2.0mm Al. As the kilovoltage increases, the potential difference between the cathode and the anode increases, resulting in a higher speed and energy of the electrons aimed at the tungsten target. The increase in kV results in a higher intensity photon beam with greater penetrating power.

Beam quality is also affected by the degree of filtration. An aluminum filter is typically employed to filter out the lower intensity portions of the heterogeneous beam, resulting in an emerging beam of less intensity but of greater average penetration.

Umbra Selection

In a similar fashion, once the beam energy has been selected, the beam width must be considered. The umbra of the treatment field is directly proportional to the *clinical* margins of the excision. Careful clinical inspection by an experienced clinician with proper illumination is the gold standard of margin delineation. Once the clinical lesion border has been identified, it should be delineated and recorded in some fashion. Various marking techniques are available of varying degrees of permanence and visibility. One commonly employed method is to delineate the clinical excision with a gentian violet marker or Castellani paint. A treatment margin is then selected beyond the clinically excision. 10mm margins are common for keloids. Lead shields are typically utilized to limit the beam to a desired treatment area. Because there is an inherent drop-off in the beam along the edges, it is preferable to use a shield diameter smaller or equal to the applicator size to minimize the lateral edge drop-off effect.

If more than one keloid excision is being treated concomitantly or the treatment site is near a previous radiation treatment site, care must be taken to prevent overlap of the treatment fields.

Chapter 23: Keloids: Clinical Treatment Documentation

Proper documentation with the delivery and evaluation of a patient receiving Superficial Radiation Therapy for keloids is essential and state regulated. This is to help assure that no treatment misadministration will occur. The following template of treatment forms is provided to generate proper documentation. The documentation is completed by the treating physician.

The prescriptions are designed for a choice of different three fractionation schemes in the treatment of Keloids. Each treatment fraction, regardless of the scheme, will then be divided into subsets, if a large applicator cone is used (i.e., 10cm diameter or 18cm x 8cm cones). When using a large applicator cone, the dose rate is relatively low due to the greater length of the cone (i.e., distance from the X-ray source to the patient's skin surface). The dose rate lowers per the square of increase in distance, thus increasing the time for delivery. The longer the time to deliver the treatment dose, the greater the chance that a patient would move and change the alignment of the treatment cone with the area being treated. So, the subsets allow a 'mid-course correction' during each treatment. Between subsets, the Physician Assistant (PA) and/or Physician enter the room and verify alignment of the treatment cone and lead cutout with the incision and margin.

It is important to deliver a complete fractionation scheme within 72 hours from which time the surgery was performed. The first fraction should be delivered within 24 hours of surgery.

Upon the Prescription and treatment parameters (Written Directive) being signed by the physician and delegation of authority for the Physician Assistant (PA) to start treatment, no change in treatment time or treatment parameters will take place, unless directed by the Physician.

1. Keloid SRT Patient Eligibility and Treatment Selection
2. Keloid SRT Simulation and Treatment Device Design
3. Keloid SRT Treatment Time Calculation
4. Keloid Superficial Radiotherapy Prescription (Written Directive)
5. Post Evaluation and Management for Keloid Superficial Radiotherapy

Keloid
Patient Eligibility and Treatment Selection

Name: _____ DOB: _____ Field Number: _____

Pathology: _____ Site: _____ Field Names: _____

Patient Eligibility and Treatment Selection

Functional Status (check one):____ 0 (fully active) ____ 1 (ambulatory, light activity) ____ 2 (ambulatory, performs self-care)
____ 3 (limited, performs self-care) ____ 4 (completely disabled)

Relevant Functional Limitation: _____ N/A

Surgery Date: _____ Age of Keloid: _____

Relevant Medical History (check all that apply):

Systemic:
____ History of MRSA infection
____ Congestive Heart Failure
____ Cardiac Disease
____ Pacemaker
____ Pulmonary Disease
____ Requires O2
____ Peripheral Vascular Disease
____ Bleeding Disorder
____ Anticoagulation: _____
____ Immune suppression
____ Diabetes
____ Advanced Dementia
____ Other: _____

Local:
____ Lower Extremity edema
____ Cutaneous Atrophy
____ Poor Local Circulation
____ Poor Tissue Mobility
____ Local Infection
____ Other: _____

Indications for Keloid Superficial Radiation therapy:
____ Needed to improve the functioning of a body part
____ Pain Reduction
____ Medically necessary even if the surgery also improves or changes the appearance of a portion of the body

Indications for not performing Superficial Radiotherapy:
____ Previous Radiation therapy to the area of concern
____ Pacemaker or defibrillator within the treatment area

Physician: _____ Date: _____

Patient Eligibility for Keloid Superficial Radiation Therapy

Keloid Superficial Radiation Therapy can provide a viable option for Keloid control, tissue preservation, and excellent cosmesis in select patients. Keloid Superficial radiation therapy, when used post surgically, is an excellent option for patients.

Patients eligible for Superficial Radiation Therapy of Keloids include all patients who have had the Keloid of concern surgically removed within 24 hours prior to Superficial Radiation Therapy. The surgical removal should include spindle structures in the tissues immediately deep and lateral to the Keloid.

Shields / Treatment Devices Used	Simple / Complex Device
External: ____ Lead Apron Covering, ___Breasts, ___Abdomen, ___Pelvis/Groin	Simple
____ Therapeutic Head Holder	Simple
____ Thyroid	Simple
____ Lead External Eye Shields	Simple
____ Lead Lined Glasses	Simple
____ Molded, Custom, Site-Specific Lead Shield	Complex
Internal: ____ Lead Ear Canal Shield L/R	Complex
____ Lead Intranasal Shield L/R Both	Complex
____ Lead Intraoral / Dental Shield	Complex
____ Silver lined Lead Eye Shield	Complex
__1__ Clear Plastic Wrap used as a border between patient's skin and Lead	

Total Complex Treatment Devices used: ____ *Total Simple Treatment Devices used: ____*

Keloid
SRT Simulation and Treatment Device Design

Name: _____ DOB: _____ Field Number: _____

Site: _____ Field Name: _____

Shielding and Treatment Devices Used: A lead of 0.762 mm thickness is utilized to form a custom shield with a ____ x ____cm opening to encompass the Incision size with a treatment margin. The custom lead shield is adequate to accommodate the appropriate applicator and provide adequate shielding to organs of critical risk and to limit scatter to surrounding normal tissue. Additional shielding (as noted below) may be used to protect sensitive areas such as cavities of the body.

Field Size (applicator): ___1.5cm ___2.0cm ___2.5cm ___3.0cm ___4.0cm ___5.0cm ___10.0 cm____18x8cm

Shields / Treatment Devices Used	Simple / Complex Device
External:	
____ Lead Apron Covering, ___Breasts, ___Abdomen, ___Pelvis/Groin	Simple
____ Therapeutic Head Holder	Simple
____ Thyroid	Simple
____ Lead External Eye Shields	Simple
____ Lead Lined Glasses	Simple
____ Molded, Custom, Site-Specific Lead Shield	Complex
Internal:	
____ Lead Ear Canal Shield L/R	Complex
____ Lead Intranasal Shield L/R Both	Complex
____ Lead Intraoral / Dental Shield	Complex
____ Silver lined Lead Eye Shield	Complex
__1__ Clear Plastic Wrap used as a border between patient's skin and Lead	

Total Complex Treatment Devices used: ____ *Total Simple Treatment Devices used:* ____

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Clinical Photographs: ____ Incision with Margins ____ Incision with Shields ____ Patient positioning

Patient Treatment Position: ____Prone ____ Supine ____ Sitting ____ Lying on Side: R / L

Description of Patient Position if different from above description:

_____
_____
_____

Physician: _____ Date: _____

Patient Simulation

Simulation is the preparation of radiotherapy treatment in which the:

- treatment area is marked,
- lead blocking shape and size is determined,
- applicator cone size is chosen, and
- Patient positioning and applicator cone orientation are decided.

Simulation is the phase in which “patient set-up” parameters are established. Adequate time needs to be allotted for this process. A critical component of the simulation is patient positioning. It is very important to be able to reproduce the position on a treatment-to-treatment basis. The ease at which the patient can achieve reproducible positioning leads to reduced setup error and reduced patient movement during treatment. When simulating, ensure setting up a patient to achieve as much a vertical entry as possible to eliminate angles and possible shifting during treatment.

Margins around the periphery of the incision edge should be wide enough to encompass the area of possible ‘spindle’ formation (10mm is suggested for Keloid incisions). Generally, the physician will mark the outline of the margin on the patient’s skin. After the margin has been achieved, select the treatment cone and lead cutout which best fits the margin. Place the lead on the skin with plastic wrap between the patient’s skin / incision and the lead cutout. Note that sometimes cutouts with a standard circular or elongated opening may not conform to the physician’s needs. In those instances, irregular cutouts can be created. Once the appropriate lead cutout has been chosen and/or created, ensure the applicator cone is encompassed by the lead, i.e. no portion of the cone will directly irradiate skin outside the treatment margin. Photograph and document the patient’s position, this will assist with making consistent setups for each treatment and also with any post treatment assessments.

The SRT Simulation and Treatment Device Design form (found on the next page) can be used to properly document shielding and treatment devices. If a different form is chosen, it should contain the following information:

- Patient name and identification number
- Treatment site (Anatomical location of Keloid)
- Incisions treated should be assigned a number (i.e. 1, 2, 3) with an associated Keloid site name
- Type of shielding used, as well as its relationship to the area being treated
- General description of patient position
- Lead cutout shielding size (maximum length and width)
- Applicator size
- Clinical photograph(s) of setup and confirmation of patient shielding (i.e., lead apron)
- Physician signature and date of simulation

Properly documenting lead cutout, positioning, other treatment devices, and patient shielding with lead apron enables reproducibility and ensures consistent treatment delivery during the short keloid fractionation schemes.

Other parameters to be selected by the physician are the beam energy, total dose, fractional dose, and number of fractions. The treatment time of each fraction and associated subset treatment times are calculated.

Keloid
SRT Treatment Time Calculation

Name: _____ DOB: _____ Field Number: _____

Site: _____ Field Name: _____

Field Size (applicator): _____cm Energy: _____ kV

Selected Fractionation Scheme: _____

Subset Dose per Fractionation: _____ cGy = Subset Treatment Time: _____ Min
Radiation Output Rate: _____ cGy/min

Calculated Subset Treatment Time: _____ Min Console Subset Treatment Time: _____ Min.

Physician: _____ Date: _____

Second Check Calculations

A check of the console's treatment time must be performed with an independent calculation. Calculations must be confirmed using the output sheet that was provided by the physicist after the SRT-100™ was calibrated. The output sheet contains several columns of information: the tube voltage (Energy in kV); SSD (source to skin distance); field size (defined by the applicator); output in cGy/min (used in the second check calculation); and time in min for subset dose delivery (reference to three dose entries of 1300cGy, 800cGy, and 600cGy and the treatment times the subsets yield).

The second check calculation is performed by taking the dose per subset in the fraction divided by the output in cGy/min for a specific energy and applicator used in treatment.

Keloid
Superficial Radiotherapy Prescription

Name: _____ DOB: ____/____/_____ Field Number: _____

Pathology: _____ Field Name: _____

Incision Size____ x ____ mm Treatment Margin: ____ mm

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INSISION AND THE LEAD CUTOUT

Keloid Fractionation Scheme: 1300cGy in 1 Fraction

Energy: 50kV / 70kV / 100 kV Depth**: Surface** Fractions within 72Hr: __1___
BED: __30____

Applicator: ___1.5cm ___2.0cm ___2.5cm ___3.0cm___4.0cm ___5.0cm____7.3cm

___10.0cm____12.7cm____18x8cm

Custom lead Shielding Size: _____X_____

Number of Subsets: __3__ Dose per Subsets 433.33cGy (rounded up): _____cGy

Each Subset's Treatment Time: _____min

Daily Fractionation Dose: _____cGy (3 subsets added together)

Overall Total Dose from selected Fractionation Scheme: _____ cGy (all fractions added together)

Physician: _____ Date: ___/_____/_____

Fx#	DOSES	Treatment Energy	SSD	TX Time (Min)	Dose Per Subset (cGy)	Total Dose (cGy)	Date	Initials (MD)
Fx1	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Subset 3	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Total Dose	Add Together All 3 Dose Subsets	→			(cGy)	/ /	

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid
Superficial Radiotherapy Prescription

Name: _____ DOB: ____/____/_____ Field Number: _____

Pathology: _____ Field Name: _____

Incision Size____ x ____ mm Treatment Margin: ____ mm

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid Fractionation Scheme: 1600cGy in 2 Fractions

Energy: 50kV / 70kV / 100 kV Depth**: Surface** Fractions within 72Hr: __2___ BED: ___30____

Treatment Applicator: ___1.5cm ___2.0cm ___2.5cm ___3.0cm___4.0cm ___5.0cm____7.3cm ___10.0cm____12.7cm____18x8cm

Custom lead Shielding Size: _____X_____

Number of Subsets: __2__ Dose per Subsets 400 cGy (rounded up): _____cGy

Each Subset's Treatment Time: _____min

Daily Fractionation Dose: _____cGy (2 subsets added together)

Overall Total Dose from selected Fractionation Scheme: _____ cGy (all fractions added together)

Physician: _____ Date: ___/_____/_____

Fx #	DOSES	Treatment Energy	SSD	TX Time (Min)	Dose Per Subset (cGy)	Total Dose (cGy)	Date	Initials (MD)
Fx1	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx1	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx1	Total Dose	Add Together 2 Dose Subsets				(cGy)	/ /	
Fx2	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx2	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx2	Total Dose	Subsets added Together				(cGy)	/ /	
	Overall Total Dose	Add Fx 1 and F2 Total Doses together				(cGy)	/ /	

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid
Superficial Radiotherapy Prescription

Name: _____ DOB: ____/____/_____ Field Number: _____

Pathology: _____ Field Name: _____

Incision Size____ x ____ mm Treatment Margin: ____ mm

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid Fractionation Scheme: 1800cGy in 3 Fractions

Energy: 50kV / 70kV / 100 kV Depth**: Surface** Fractions within 72Hr: __3___ BED: ___30____

Treatment Applicator: ___1.5cm ___2.0cm ___2.5cm ___3.0cm___4.0cm ___5.0cm____7.3cm ___10.0cm____12.7cm____18x8cm

Custom lead Shielding Size: _____X_____

Number of Subsets: __2__ Dose per Subsets 300 cGy (rounded up): _____cGy

Each Subsets Treatment Time: _____min

Daily Fractionation Dose: _____cGy (2 subsets added together)

Overall Total Dose from selected Fractionation Scheme: _____ cGy (all fractions added together)

Physician: _____ Date: ___/_____/_____

Fx #	DOSES	Treatment Energy	SSD	TX Time (Min)	Dose Per Subset (cGy)	Total Dose (cGy)	Date	Initials (MD)
Fx1	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Total Dose	Subsets added Together				(cGy)	/ /	
Fx2	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx2	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx2	Total Dose	Subsets added Together				(cGy)	/ /	
Fx3	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx3	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx3	Total Dose	Subsets added Together				(cGy)	/ /	
	Overall Total Dose	Add Fx 1,Fx2,Fx3 Total Doses together				(cGy)	/ /	

Prescription and Fractionation Log

The Keloid Superficial Radiotherapy Prescription and Fractionation Log documents the fractionation scheme and daily treatments. The prescription portion of the form notes:

- Energy (Subject to the tissue thickness and the age of the Keloid)
- Treatment Depth (delivered to the patient Surface)
- Fractions complete within 72 Hours
- The BED Dose (Biological Effective Dose) assigned to the fractionation scheme
- The treatment applicator used during the treatment
- The custom lead shielding size that will be used in contact with the CLEAR PLASTIC WRAP to create a boundary between the lead and the patients incision
- The number of Subsets used in the prescription. Due to the high therapeutic dose that needs to be delivered to eradicate a keloid; the dose given in one fraction is broken up to equal subsets. Always round up your subset to the nearest suggested dose in the prescription outline.
- Dose per subset in cGy (round up from suggested dose)
- Each subsets treatment time
- Daily fractionated dose in cGy (total of all subsets delivered on a single day)
- Overall Total Dose (all fractions added together)

Treatment Prescription must be completed well in advance of first fraction. Advance preparation and completion of this section will minimize the change for errors (i.e., avoid a treatment misadministration).

The following procedure must be followed in order to prepare the treatment time.

1. Select the Keloid Fractionation scheme to be used for patient Incision.

2. Insert the applicator that best fits the custom Lead shield into the SRT-100™ applicator port mount.

3. Leave and close the door to the treatment room; ensure the treatment room is vacant.

4. Turn the key on the control console from SAFE mode to X-RAYS (treatment mode).

5. Select the proper energy (50 kV, 70 kV, or 100 kV).

6. Turn the black knob next to the treatment time clockwise to the general area of the desired dose per fraction. (Pushing the knob in while turning increases the increments, while leaving the knob out will fine tune the dose selection).

Note that dose rate per applicator is set; in other words, when a certain applicator with a specific energy is selected, the treatment time will always be the same for that selection (i.e. kV and mA do not change).

Keloid
(Used with 2 or 3 Fractionation schemes)
Evaluation and Management for Keloid Superficial Radiotherapy

Name: _____ DOB: _____ Field Number: _____

Pathology: _____ Site: _____ Field Name: _____

	Post Treatment	Fractionation valuation
	Date	
Subjective	None	
(√=present)	Redness	
	Pruritus	
	Pain	
	Drainage	
	Fatigue	
	Other	
Objective	Erythema	
(√=present)	Atrophy	
	Scaling	
	Crusting	
	Erosion	
	Ulceration	
	Edema	
	Purpura	
	Tenderness	
	Warmth	
	Drainage	
	Other	
	Cumulative Dose (cGy)	
Plan	Dose Reviewed	
(√=complete)	Dosimetry Reviewed	
	Simulation Reviewed	
	Clinical set-up Reviewed	
	External Shields Reviewed	
	Internal Shields Reviewed	
	Special care	
	Comments	
MD		

Additional Comments_____
_____
_____

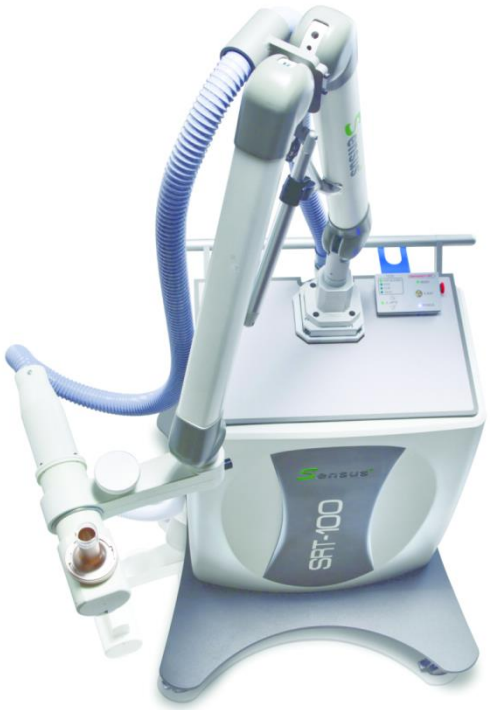
Post-SRT Follow up: _____ Physician: _____

Evaluation and Management for Superficial Radiotherapy

A review of the treatment area should be performed post treatment fractionation. The Evaluation and Management for Keloid Superficial Radiotherapy form assists in reviewing and documenting the treatment site's reaction to treatment up to this point as well as any local or systemic complaints or concerns and the general wellbeing of the patient. Based on this inventory, recommendations or modifications can be made, if necessary.

Upon full treatment completion, treated areas may continue to experience reactions for one to two weeks after the final fraction. In most cases, healing is completed three to four weeks after final treatment.

Chapter 24:
Keloids:
Clinical Applications Definitions



A

Absorbed Dose: The energy imparted to matter by ionizing radiation per unit mass of irradiated material. The unit of radiation absorbed dose is the rad. One rad equals 100 ergs or energy per gram of matter.

Acute Exposure: Radiation exposure of short duration.

Alpha Particle: A charged particle having a mass and charge equal in magnitude to a helium nucleus (a cluster of two protons and two neutrons) that is emitted from the nucleus of an atom.

Anemia: Deficiency of blood as a whole, or deficiency in hemoglobin or in the number of the red blood cells.

Area Monitoring: Routine monitoring of the radiation level or contamination in a particular area, building, room, or piece of equipment. Some laboratories or operations distinguish between routine monitoring and survey activities.

Atom: Smallest unit of an element which is capable of entering into a chemical reaction.

Atomic Mass: The mass of a neutral atom of a nuclide, usually expressed in terms of “atomic mass units”. An “atomic mass unit” is one-twelfth the mass of one neutral atom of 12C; equivalent to 1.6604 x 10 –24 grams. (Symbol: A).

Atomic Number: The number of protons in the nucleus of an atom of a nuclide. The “effective atomic number” is calculated from the composition and atomic numbers of a compound or mixture of atoms with different atomic numbers. An element of this atomic number would interact with photons in the same way as the compound or mixture. (Symbol: Z).

Attenuation: The process by which a beam of radiation is reduced in intensity when passing through some material. It is the combination of absorption and scattering processes and leads to a decrease in flux density of the beam when projected through matter.

Autoradiograph: Record of radiation from radioactive material in an object, made by placing the object in close proximity to a photographic emulsion.

B

Beam: A unidirectional or approximately unidirectional flow of electromagnetic radiation or particles.

Beta Particle: Charged particle emitted from the nucleus of an atom, with a mass and charge equal in magnitude to that of the electron.

Bone Marrow: Soft material which fills the cavity in most bones; it manufactures most of the formed elements of the blood (white and red blood cells).

Bone Seeker: Any compound or ion that migrates into a bone in the body.

Bremsstrahlung: Secondary photon radiation produced by deceleration of charged particles passing through matter.

C

Carcinogenic: Capable of producing cancer.

Chronic Exposure: Radiation exposure of long duration by fractionation or protraction. (See Dose, Fractionation and Dose, Protraction.)

Contamination, Radioactive: Deposition of radioactive material anywhere where it is not desired, particularly where its presence may be harmful. The harm may be in interfering with an experiment or a procedure, or in actually being a source of danger to personnel.

Counter, Geiger-Mueller: Highly sensitive, gas-filled radiation-detecting device. It operates at voltages sufficiently high to produce avalanche ionization.

Counter, Proportional: Gas-filled radiation detection device; the electronic pulse produced is proportional to the number of ions formed in the gas by the primary ionizing particle.

Counter, Scintillation: The combination of phosphor, photomultiplier tube, and associated circuitry for measuring light emissions produced by ionization in the phosphors.

Cumulative Dose (Radiation): The total dose resulting from repeated exposures to radiation.

Curie: The special unit of activity. One curie equals 3.700 x 1010 nuclear disintegrations per second. (Abbreviated Ci.) Several fractions of the curie are in common usage.

D

Decay, Radioactive: Disintegration of the nucleus of an unstable nuclide by spontaneous emission of charged particles and/or photons.

Detector, Radiation: Any device for converting radiant energy to a form more suitable for observation. An instrument used to determine the presence, and sometimes the amount, of radiation.

Dose Equivalent (DE): A quantity frequently used in radiation protection. It expresses all radiation on a common scale for calculating the effective absorbed dose. It is defined as the product of the absorbed dose in Gray or rad and certain modifying factors. (The unit of dose equivalent is the Sievert or rem.)

Dose, Fractionation: A method of administering radiation, in which relatively small doses are given daily or at longer intervals.

Dose, Protraction: A method of administering radiation by delivering it continuously over a relatively long period at a reduced dose rate.

Dose: A general term denoting the quantity of radiation or radiant energy absorbed. For special purposes it must be appropriately qualified. If unqualified, it refers to absorbed dose.

Dosimeter: Instrument to detect and measure accumulated radiation dose. See Film Badge and TLD.

E

Effective half-life = Biological half-life x Radioactive half-life Biological half-life + Radioactive half-life

Elastin: is a protein in connective tissue that is elastic and allows many tissues in the body to resume their shape after stretching or contracting. Elastin helps skin to return to its original position when it is poked or pinched.

Electron Volt: A unit of energy equivalent to the energy gained by an electron in passing through a potential difference of one volt. Larger multiple units of the electron volt are frequently used: keV for one thousand (or kilo) electron volts; MeV for one million (or mega) electron volts. (Abbreviated: eV, 1 eV = 1.6 x 10-12 erg.)

Electron: A stable elementary particle having an electric charge equal to +/- 1.60210 x 10-19 coulomb and a rest mass equal to 9.1091 x 10-31 kg.

Exposure: A measure of the ionization produced in air by x or gamma radiation. It is the sum of the electrical charges on all ions of one sign produced in air when all electrons liberated by photons in a volume of air are completely stopped in air, divided by the mass of the air in the volume. The special unit of radiation exposure is the roentgen (R).

F

Fibrillar Collagens: A family of structurally related collagens that form the characteristic collagen fibril bundles seen in connective tissue.

Film Badge: A pack of photographic film which measures radiation exposure for personnel monitoring. The badge may contain two or three films of differing sensitivity and filters to shield parts of the film from certain types of radiation.

Fissile: A nuclide capable of undergoing fission by interaction with slow neutrons.

Fission, Nuclear: A nuclear transformation characterized by the splitting of a nucleus into at least two other nuclei and the release of a relatively large amount of energy in the form of heat and nuclear radiations.

G

Gamma Ray: Short wavelength electromagnetic radiation (range of energy from 10 keV to 9 MeV) emitted from the nucleus of an atom during radioactive decay.

Gas Amplification: As applied to gas ionization radiation detecting instruments, the ratio of the charge collected to the charge produced by the initial ionizing event.

Geiger Region: In an ionization radiation detector, the operating voltage interval in which the charge collected per ionizing event is essentially independent of the number of primary ions produced in the initial ionizing event.

Geiger Threshold: The lowest voltage applied to a counter tube for which the number of pulse produced in the counter tube is essentially the same, regardless of a limited voltage increase.

Grenz rays: (10–20kv - kilovolts.) These are still used in some centers, particularly in Germany. Contact therapy using 40–50kv and short source to surface distance (SSD). Grenz rays are used for treatment depths of 1–2mm, as they provide very rapid falling depth-doses.

H

Half Value Layer (Half Thickness) (HVL): The thickness of a specified substance which, when introduced into the path of given beam of radiation, reduces the exposure rate by one-half.

Half-Life, Biological: The time required for the body to eliminate one-half of an administered dosage of any substance by regular biological processes of elimination. It is approximately the same for both stable and radioactive isotopes of a particular element.

Half-Life, Effective: Time required for a radioactive element deposited in a human or animal to be diminished by 50 percent as a result of the combined action of radioactive decay and biological elimination.

Half-Life, Radioactive: Time required for a radioactive substance to lose 50 percent of its radioactivity by decay. Each radionuclide has a unique half-life.

I

Interlock: A device, usually electrical and/or mechanical, to prevent activation of a device until a preliminary condition has been met, or to prevent hazardous operations. Its purpose usually is safety.

Ion Pair: Two particles of opposite charge, usually referring to the electron and positively charged atomic or molecular residue resulting from the interaction of ionizing radiation with the orbital electrons of atoms.

Ion: Atomic particle, atom, or chemical radical bearing an electrical charge, either negative or positive.

Ionization Chamber: An instrument designed to measure a quantity of ionizing radiation in terms of the electric charge associated with ions produced within a defined volume.

Ionization: The process by which a neutral atom or molecule acquires a positive or negative charge.

Irradiation: Exposure to radiation.

Isotopes: Nuclides having the same number of protons in their nuclei, and hence the same atomic number, but differing in the number of neutrons, and therefore differing in the mass number. Almost identical chemical properties exist between isotopes of a particular element.

K

Kerma: The sum of the initial kinetic energies of all charged particles liberated by indirectly ionizing particles in a volume, divided by the mass of matter in that volume.

L

Linear Energy Transfer (LET): The amount of energy transferred to matter as radiation interacts with it. Often expressed in units of keV per micron of path length.

M

Maximum Permissible Dose Equivalent (MPD): The greatest dose equivalent that a person or specified body part shall be allowed to receive in a given period of time.

Microcurie: One-millionth of a curie (3.7 x 104 disintegrations per second). Abbreviated µCi.

Millicurie: One-thousandth of a curie (3.7 x 107 disintegrations per second). Abbreviated mCi.

Monitoring: Periodic or continuous determination of the amount of ionizing radiation or radioactive contamination present in an occupied region.

O

Orthovoltage therapy: ('Deep therapy' with 150–300kv.) Most clinical units operate at 200–300kv. The treatment distance is about 50cm SSD. Ninety percent of the dose is delivered within approximately 2cm of the surface.

P

Personnel Monitoring: Monitoring of any part of an individual, his breath or excretions, or any part of his clothing.

Photon: A quantity of electromagnetic energy (E) whose value in joules is the product of its frequency (v) in hertz and Planck's constant (h). The equation is E = hv.

Picocurie: One-millionth of a microcurie (3.7 x 10-2 disintegrations per second or 2.22 disintegrations per minute). Abbreviated pCi.

Proton: Elementary nuclear particle with a positive electric charge equal numerically to the charge of the electron and a mass of 1.007277 mass units.

Q

Quality Factor (QF): The linear-energy-transfer-dependent factor by which absorbed doses are multiplied to obtain (for radiation protection purposes) a quantity that expresses (on a common scale for all ionizing radiations) the effectiveness of the absorbed dose of radiation.

R

Rad: The unit of absorbed dose in rads is equal to 0.01 J/kg in any medium. (See Absorbed Dose.)

Radiation or Ionizing Radiation: Gamma rays and X-rays, alpha and beta particles, neutrons, protons, high-speed electrons and other nuclear particles, but not visible light, sound, radio waves, laser radiation, or microwaves.

Radiation-Producing Machine: Any device capable of producing radiation when the associated control devices are operated or electrical circuits are energized.

Radioactive Material: Any material which emits radiation spontaneously.

Rem: A special unit of radiation dose equivalent. The dose equivalent in rems is numerically equal to the absorbed dose in rads multiplied by the quality factor QF.

Roentgen (R): The unit of radiation exposure. One roentgen equals 2.58 x 10-4 coulomb per kilogram or air. (See Exposure.)

S

Scattering: Change of direction of subatomic particles or photons as a result of a collision or interaction.

Sealed Source: Any radioactive material permanently encapsulated in such a manner that it will not be released under the most severe conditions likely to be encountered in normal use. This encapsulation must meet rigid specifications.

Secondary Electron: An electron ejected from an atom, molecule, or surface as a result of an interaction with a charged particle or photon.

Source Material: Uranium or Thorium, or any combination thereof, in any physical or chemical form except SNM, and ores which contain less than one-twentieth of one percent (0.05%) of Uranium or Thorium.

Special Nuclear Material (SNM): Plutonium or Uranium-235, or material enriched in U-233, U-235, or Plutonium.

Specific Ionization: Number of ion pairs per unit length of path of ionizing radiation in a medium; e.g., per cm of air, or per micrometer of tissue.

Superficial therapy: (50–150kv) with typical filtration, beams with half-value layers (HVLs) in the range of 1–8mm Al. The SSD is normally 10–30cm. Beam characteristics are suitable for treatment of lesions up to 5mm deep, delivering 90% of the dose to the surface.

T

TLD (Thermo luminescent Dosimeter): A crystalline material (e.g., lithium fluoride) which is used to measure accumulated radiation dose. When exposed to radiation at ambient temperatures, electrons migrate to crystal lattice defects. When heated, the crystal releases this energy as light which can be detected by a photomultiplier tube and correlated to the amount of radiation dose received.

Total Ionization: The total electric charge of one sign on the ions produced by radiation in the process of losing its kinetic energy. For a given gas, the total ionization is closely proportional to the initial ionization and is nearly independent of the nature of the ionizing radiation. It is frequently used as a measure of radiation energy.

U

Useful Beam (Radiology): Radiation that passes through the aperture, cone, or other collimating device of the source housing, “Sometimes called the “primary beam”.

V

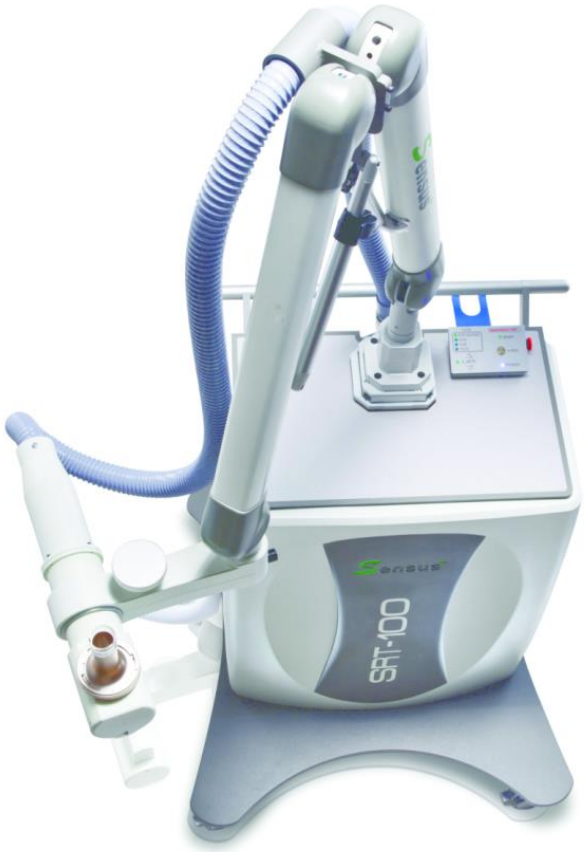
Valence Electron: Electron that is gained, lost, or shared in a chemical reaction.

Vasoactive Amine: A substance containing amino groups, such as histamine or serotonin, which acts on the blood vessels to alter their permeability or to cause vasodilation.

X

X-rays: Penetrating electromagnetic radiation whose wavelengths are shorter than those of visible light and ultraviolet radiation. X-rays are usually produced by bombarding a metallic target with fast electrons in a high vacuum. In nuclear reactions, it is customary to refer to photons originating in the nucleus as gamma rays, and those originating in the extra-nuclear part of the atom as X-rays. These rays are sometimes called roentgen rays after their discoverer, W.C. Roentgen.

Chapter 25:
Keloids:
Clinical Applications Procedures



Chapter 25: Clinical Applications Procedures

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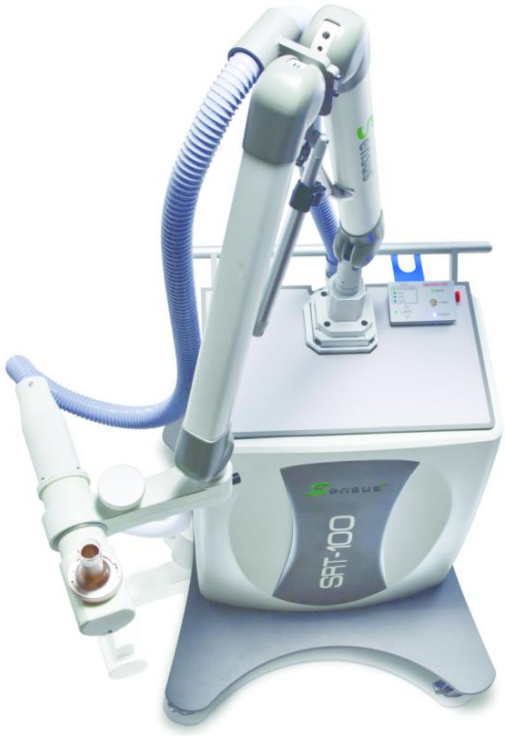


Patient Positioning

There are several factors that must be taken into account when positioning a patient for superficial radiation therapy; these include the patient's ability to lie flat, or on their side, the mobility of the patient's head and neck, and the patient's ability to remain still. Patients with good mobility can lie in the supine position and turn their head either way, allowing access to the lesion. The only blocking required for this type of patient is a pillow under the head and downward pressure from the SRT-100™. It is helpful in these patients to place a pillow under the knees to alleviate any pressure on the lower back and to minimize the chance of movement during the treatment. The more comfortable the patient is, the less they are apt to move during treatment.

Patients with a lesion on the vertex of the scalp, or on the posterior aspect of the scalp, may need to lie in the prone position for adequate treatment to be achieved. This is most easily accomplished with a prone pillow with a face cutout. With the prone pillow on the bed, the patient can use a pushup like motion to lay prone with their face in the cutout area. They can then place their hands either by their side or in front of their face.

Patients confined to a wheelchair require both blocking and immobilization to achieve a reliable and effective means of treatment. These patients usually require immobilization of the neck to stabilize the head, which is best achieved with the use of foam blocks applied to the neck in the same fashion as a c-collar would be in a trauma situation. After the head and neck are stabilized, apply the external eye shields and thyroid shield, then place the lead shield/cutout over the lesion for treatment. The use of an elastic bandage material to anchor the arm of the SRT-100™ is helpful in this setting, since it keeps the SRT-100™ applicator tight against the treatment area, and also helps the patient remember to be still.

Shielding

Lead cutouts are used to define the edge of the treatment field and stop radiation to normal tissue outside the selected margin. The kV energy which is used has very small penumbra regions when it comes to the beam profiles of the treatment applicator. The lead cutouts which help define the borders on the skin are usually smaller in size than the applicator diameter. The lead inside the applicator will actually limit the penumbra because it is not the natural border of the applicator. Again, the lead cutouts should always be smaller or equal to the area of the applicator.

Treating Over a Cavity

Should the lesion exist over a cavity, such as the nasal, ear, or oral cavity, internal shielding needs to be applied? Look at the entry of the beam, does it exit into a cavity or close to it. If it does, take a surgical glove and cut one of the fingers off. Put one of the lead sinkers provided in the starter kit, this will provide a barrier between the lead and the patient. Try and select a sinker that will fit snug into the cavity. For the oral cavity, just take a flat piece of lead and place it into the figure tip. Make sure to align the shield in the direction the beam will exit behind the lesion. The purpose for blocking the cavity is to absorb the remaining low energies that can exit into the cavity, thus bouncing around causing mucosal breakdown.

When any part of the head is treated, external eyes should be shielded. The thyroid gland area should also be protected with a thyroid shield. When the eyelids, internal canthus, and external

canthus are irradiated, internal eye shields should be placed between the eyelid and the properly anesthetized eye. A lead apron should be placed over the patient's pelvis and neck area (thyroid), before such sections of the body are treated. Anytime an area is treated and a cavity is present in the underlining area, fill the cavity with lead to reduce reactions (place lead in a barrier in order to stop the leads contact to the patient's skin).

When treating the head and neck or upper thoracic region, blocking of the thyroid is required. The thyroid shield comes with the starter kit. They have a Velcro closure for use on sitting patients. It is simply placed over the thyroid during the treatment. One can use a larger lead apron if one is treating non facial lesions.

When radiating around the eyelids, internal canthus, or external canthus are irradiated, silver-plated lead internal eye shields (not provided) should be placed between the eyelid and the properly anesthetized eye. Internal eye shields have tabs on the top which can be grasped with a hemostat; a curved hemostat enables a better angle of insertion. Insert the intraocular eye shields using the following procedure: Instill one drop of tetracaine ophthalmic solution into the eye. Ensure that the shield is lubricated with a sterile eye lubricant. Lift up the superior eyelid and place the shield between the upper eyelid and the globe, then slide the shield under the lower eyelid. After the shield is placed, treatment of the lesion on or around the eyelid can commence. Typically, a custom lead shield is used, but in some cases (such as at a medial canthal concave location) a treatment cone of the exact desired port can be used without a shield. The removal of the intraocular shield is the exact opposite of the insertion.

Clinical Setups

Setups in areas which take a little effort to get a flat entry or a consistent margin are referenced as clinical setups. The ears, nose, appendages that have a curvature to their surface often require documentation and photos to help with consistent recreation of applicator contact with the lesion and surrounding margin. These setups tend to have areas of "flash" within the cutout of the lead shield on the surface of the patient. Flash is simply the lack of tissue in the way of the beam, air. In these instances, block down with a separate piece of lead, without violating the margin or lesion. Should the flash simply go off into air in the direction away from the patient's skin, no blocking is needed.

Air Gaps

The human body is not flat, so every setup will have its mounds and valleys. Despite these challenges, it is important to maintain consistency in these irregularities. Although 1 to 2 mm will not push a lesion's dose outside the therapeutic index, 3 to 5mm could have an impact in clearing the backside of the lesion or pushing a section into an acute reaction scenario.

Inverse Square Law

Certain situations, such as lesions with a bulky top, or where a large air gap remains after setup, are subject to the inverse square law and may be more prone to reactions. The inverse square law says that an object that is twice the distance from the source of the radiation will receive a quarter of the radiation. The beam of radiation affects intensity of energy, and not a direct proportion. On an average, 6-8% of dose can be lost for every 1 mm of air gap (depending upon the applicator size with relation to scatter). Inversely, does is gained for every 1 mm of tissue that rises up through the applicator from the set SSD of treatment. The inverse square law is one of the main reasons to select a TDF number of 100 when selecting a fractionation scheme for treatment. This therapeutic number mitigates reactions and assures index compliance, even if there are small irregularities in the setup.

Keloid Starter Kit

The Starter Kit included with the SRT-100™ system comes with items helpful when beginning to treat using Superficial Radiation Therapy.

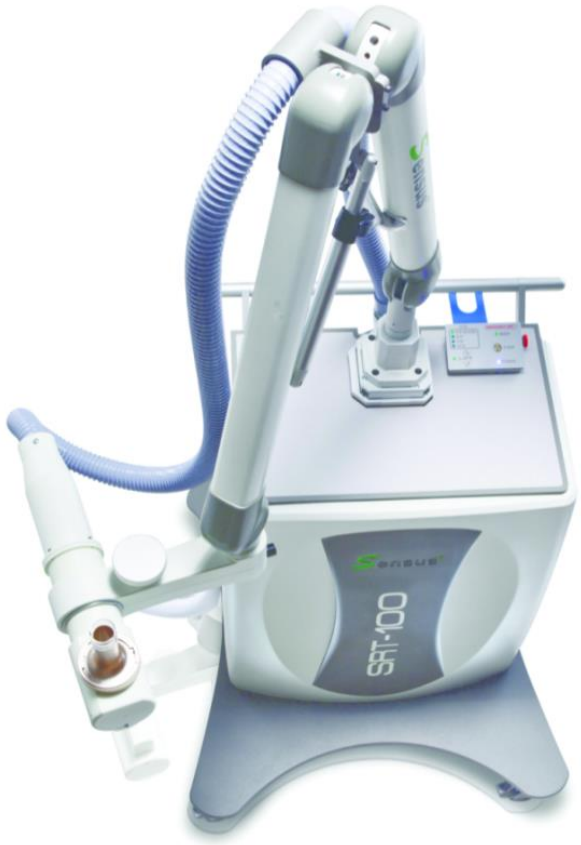
Standard cutout kits: The most important items included in the kit are prefabricated lead foil cutouts (precut to 8cm by 8cm, with circular cuts of 1.0 cm, 1.5 cm, 2.0 cm, 2.5 cm, 3.0 cm, 3.5 cm, 4.0 cm, 4.5 cm, 5.0 cm, plus 4 blanks with no cutouts), along with tools to help make additional lead cutouts.

Keloid cutout kits: The lead foil cutouts are: 18x3 cm, 17x3 cm, 16x3 cm, 15x3 cm, 14x3 cm, 13x3 cm, 12x3 cm, 11x3cm, 10x3 cm, 9x3 cm, 8x3 cm, 7x3 cm, 6x3 cm, 5x3 cm, 4x3 cm, plus 3 blanks with no cutouts.

Additional lead shielding items in the kit include four intra-nasal weights (elongated Barrel weights which will fit snuggly in the nose), and four oval weights for the ear canal (sized to fit snuggly in the ear).

The kit also contains important blocking and radiation protection items, such as lead goggles, a thyroid collar, an X-ray apron, and a coated head and neck support.

P2: Administrative Procedures for Superficial Radiation Therapy



The Sensus Healthcare SRT-100™ program is administratively controlled by several procedures. These procedures include radiation safety, training requirements, operator qualifications, as well as mandatory records, postings, and reporting. These are required by state and federal regulatory codes for ionizing radiation therapy devices with X-ray energies of 100 kV and less.

1. Radiation Safety

General safety procedures for Superficial Radiation Therapy:

- All individuals must wear their assigned dosimeters as required.
- Individuals whose presence during an exam is not required should not stay as an observer unless required as a part of the clinical learning process.
- All individuals shall exit the room while a patient receives a treatment.
- A patient shall not be held by another individual during a treatment.
- Immobilization devices should be used whenever possible to insure accuracy of treatments.
- Patients shall wear externals eye shields or goggles during treatments.
- Patients shall have lead shields placed on the skin to define the treatment area (minimal of .762mm lead thickness).
- Patients shall wear lead aprons (minimal of .25mm lead thickness) over unaffected areas of the body that are close to the treatment site.
- Patients shall wear thyroids shield when treatment areas are in the proximity of the head and neck region (minimal of .25mm lead thickness).
- Only individuals who meet the state-mandated qualifications for an operator of Superficial Radiation Therapy may operate the SRT-100™ unit.

Exposure limits:

- Annual radiation exposure limits for Superficial Radiation Therapy workers are:
  - Whole body effective dose – 50.0 mSv
  - Any individual organ or tissue, other than the lens of the eye – 500.0 mSv
  - Lens of the eye – 150.0 mSv
  - Skin – 500.0 mSv
  - Extremity – 500.0 mSv

2. ALARA

ALARA stands for: “As Low As Reasonably Achievable”; radiation workers are encouraged, empowered, and required to keep their radiation exposures ALARA for themselves as well as that of their co-workers, visitors, and patients (excluding therapeutic radiation doses).

- Methods include time, distance, and shielding.
- Be cognizant of where radiation exposures might be highest and minimize time in those areas.
- Place shielding apron(s) on patients as appropriate.

3. Personnel Radiation Monitoring

General dosimeter requirements:

- Dosimeter shall, at a minimum, be worn by all personnel who may receive greater than 10% of the regulatory annual occupational dose limit.
- Dosimeters are required for individuals involved in the therapeutic treatment procedures of patients.
- Dosimeters used for individuals shall be able to detect photon radiation.
- Dosimeters shall be provided by and applied for through the Radiation Safety Officer.
- The dosimeter is worn at the collar.
- Declared pregnant workers who frequent a restricted area shall be assigned two dosimeters.
    - One dosimeter worn at the collar (labeled “neck” or “collar”)
    - Second dosimeter worn at waist level (labeled “waist” or “chest”)

Care of dosimeters:

- Personal radiation dosimeters are for use by a single individual and shall not be shared, reassigned or discarded.
- Radiation dosimeters do not provide protection from radiation; they only provide an "after the fact" assessment of radiation to which it (and presumably the wearer) was exposed.
- Radiation dosimeters shall be worn at the position appropriate for the work being performed.
- Radiation dosimeters are very sensitive to environmental conditions such as heat, light and moisture. Dosimeters should be used properly, should not be taken home or stored in cars or on windowsills.
- Radiation dosimeters shall be stored in low background areas (e.g., offices) when not being worn.
- Radiation dosimeters are for occupational exposure only and are NOT to be worn during personal medical or dental procedures.

Dosimetry analysis and reports:

- Personal dosimeters must be returned in a timely fashion to the Radiation Safety Officer for analysis.
- Quarterly dosimeter analysis reports are sent by the vendor to the Radiation Safety Officer.
- Quarterly analysis reports shall be placed in the document binder for review.
- Monitored personnel shall be provided copies of individual dosimeter reports upon request.
- Requests must be made to the Radiation Safety Officer. Reports will be provided within 30 days after the request is made or within 30 days after receipt of the data for the last dosimeter, whichever is later.

Dosimeter exchange procedure:

- To prevent unmonitored exposure, before used dosimeters are returned, new dosimeters are picked up.
- All dosimeters shall be picked up in the Radiation Safety Officer during the first 3 working days of each quarterly series.
- All dosimeters shall be returned to the Radiation Safety Officer during the first 10 days of the quarterly series.
- All late returned and non-returned dosimeters require completion of a radiation dosimetry follow-up form.
- The Radiation Safety Officer shall issue the form upon receipt of a report indicating a dosimeter was not returned as required.

Lost, late return, or damaged dosimeters:

- Lost or damaged dosimeters shall be reported immediately to the Radiation Safety Officer.
- Temporary replacement dosimeters will be issued if dosimeters are lost or damaged prior to the return exchange.
- A radiation dosimeter follow-up is required to be completed for all lost, late return and damaged dosimeters.

4. Pregnant Worker Radiation Safety

- Pregnant individuals are not considered declared pregnant workers until they declare the pregnancy in writing to the Radiation Safety Officer.
- The declaration must include:
  - The name of the individual
  - The date of declaration
  - The type of radiation exposed to in the workplace
  - The estimated date of conception
- The radiation dose limit to the fetus/embryo of a declared pregnant worker is 5.0 mSv total effective dose equivalent over the term of the pregnancy.
- The RSO will review the individual's exposure record. If the record indicates that an exposure to the embryo/fetus of greater than 5.0 mSv may occur, the RSO will initiate steps to move the individual to a position of lower radiation exposure and one that the exposure can be maintained less than 5 mSv.
- Pregnant individuals may continue to operate and work around Superficial Radiation Therapy unless deemed otherwise by the RSO.
- Pregnant individuals should review NRC Regulatory Guide 8.13. This guide covers the effects of radiation to the embryo and fetus.

5. Radiation Survey Requirements

- Radiation surveys should be performed at Commissioning and Annual QA.
- Performed to verify shielding adequacy.
- They determine worst-case exposure to any individual outside of treatment room per criteria of mSv or mRem per hour, week, and year.
- They help inform staff of radiation exposure rates during treatment to assist in maintaining radiation exposures ALARA.

6. Operator Requirements

- All operators of the SRT-100™ Superficial Radiation Therapy unit shall be licensed in accordance with state regulations.
- A radiation therapy technologist may utilize the SRT-100™ Superficial Radiation Therapy unit for therapeutic purposes on a patient.
- A radiation therapy technologist must work under the general supervision of a licensed practitioner.
- In order to provide general supervision, the licensed practitioner must be readily available for consulting with and directing the procedures.
- Each department that utilizes the SRT-100™ Superficial Radiation Therapy unit must maintain copies of current licensure for all personnel who operate the unit.
- Before operating any SRT-100™ Superficial Radiation Therapy unit, the operator shall ensure they are familiar with the unit's operating characteristics, as well as the purpose and function of protective devices.
- Any operator who has questions concerning or doubts regarding the operation of a unit shall immediately seek guidance from their RSO or other appropriate individual.
- Operators shall report promptly to their RSO any condition they know or suspect may constitute, lead to or cause a violation of regulations, or unnecessary exposure to radiation.

7. Training Requirements

SRT-100™ Superficial Radiation Therapy Radiation Worker:

- Only individuals who meet the qualifications for an operator of Superficial Radiation Therapy unit may operate in a clinical (human-use) setting.
- Prior to allowing an individual to operate a Superficial Radiation Therapy unit, ensure the individual is licensed in accordance with the state.
- Ensure the individual has obtained SRT-100™ Superficial Radiation Therapy training. Generally this training includes:
    - Radiation
    - Generating X-rays
    - Types of X-rays Produced
    - Controlling X-rays
    - Fundamental Principles of Radiobiology
    - Principles of Radiation Oncology
    - Therapeutic Index
    - Fractionation

- TDF Tables
- Clinical Treatment Planning
- SRT Documentation for Clinical Treatment
- Radiation Safety
- SRT-100™ Operations and Procedures
- Instructions for promptly reporting any condition that may constitute, or lead to, or cause a violation of radiation protection or QA procedures, policies, rules or regulations

Ancillary Radiation Worker

- All employees shall receive general radiation protection training.
- The minimum training shall include:
  - Health protection problems associated with exposure to radiation and procedures to minimize the exposure
  - Instruction to report promptly any condition that they know or suspect may constitute or lead to or cause a violation of radiation protection or QA procedures, policies, rules or regulations.
  - Applicable warning signage
  - The location of the restricted area

Patients

- Departments that perform procedures involving SRT shall maintain informational material on procedures routinely performed.
- Informational material shall be provided upon request or as considered necessary by the prescribing physician

8. Intervals for Quality Assurance & Routine Maintenance of the SRT-100™ Unit

Daily QA:	Each day any patients are being treated. At least three times per week if patients are not being treated.
Monthly QA:	Encompassed by Daily QA. Certain states may require Physicists to review Daily QA records at least once per week/per month.
Annual QA:	Once per calendar year. Interval between Annual QA should be 'reasonably' spaced to accommodate the annual definition (e.g., not less than nine months and not more than fifteen months between performances of Annual QA's). State regulations may dictate a more restrictive interval.
SRT-100™ PM:	Unit Preventive Maintenance should be performed annually.

9. Equipment Logs

- Owners of an SRT-100™ Superficial Radiation Therapy unit should maintain a separate maintenance log, which should include:
  - Unit serial number

    - Incidents and actions
    - Maintenance performed
    - Repair information
- The SRT-100™ Superficial Radiation Therapy system includes a User Manual, which is readily available as a reference to operators.
- SRT-100™ Superficial Radiation Therapy logs and manuals shall be maintained in or accessible from (e.g., computer terminal) the area (e.g., room) where the SRT-100™ is housed.
- SRT-100™ Superficial Radiation Therapy logs and manuals shall be readily available for use by the operator and inspection by the RSO or state inspector.

10. Posting and Signage

- Each site/department where SRT is used shall post in conspicuous locations:
    - State Notice to Employees
    - Location where this manual, applicable audit(s) and applicable inspection report(s) are maintained
    - Location where applicable rules and regulations are maintained
    - Method for contacting the RSO
    - A caution sign on the treatment room door: “CAUTION – RADIATION,” or "CAUTION-This equipment produces radiation when energized," or equivalent.
    - A sign reminding patients to inform the staff prior to having Superficial Radiation Therapy treatment if there is a possibility of pregnancy.

11. Incident and Overexposure Notification Action

ALARA investigations and notifications:

- ALARA investigations shall be performed when individuals exceed 10% and 30% of the applicable regulatory limits for general radiation workers.
- The RSO will provide a written report of the exposure to the individual.
- Request the individual submit an explanation of radiation exposure during the time period in question.
- The RSO will investigate the cause(s) of the exposure and implement corrective action as deemed necessary.
- The RSO will notify the state Department of Radiation Protection within 30 days, or per state requirements.
- The notification shall include:
    - An estimation of the individual's dose
    - The levels of radiation involved
    - The cause of the exposure
    - Any corrective action taken or planned to assure against recurrence
    - Written notification to the individual
        - The written notification shall include nature and extent of the exposure

QA Recordable Incidents

- QA “recordable” incidents are include those that may or may not be reportable to the state:
  - Any problems with the operation of SRT-100™ Superficial Radiation Therapy unit shall be reported immediately to the RSO and documented.
  - Any problems with the operation of SRT-100™ Superficial Radiation Therapy unit that could result (but has not yet resulted) in an overexposure to personnel shall be reported immediately to the RSO (i.e., exposure greater than allow limits).

QA Reportable Incidents

- QA "reportable" incidents are ones, by rule, which require a written report to the state.
- Examples of reportable incidents:
  - Superficial Radiation Therapy to the wrong patient.
  - Superficial Radiation Therapy to the wrong treatment site.
  - Superficial Radiation Therapy dose involving the wrong energy of treatment.
  - Superficial Radiation Therapy treatment consisting of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent of the total prescribed dose.
  - Superficial Radiation therapy treatment consisting of more than three fractions and the calculated total administered dose differs from the total prescribed dose by more than twenty percent of the total prescribed dose.
- The RSO shall investigate the overexposure and submit required reports to the appropriate state department.
- Reportable incidents shall be reported to the appropriate state department by letter within 15 days after the incident occurred. The letter shall include:
  - The name and address of the facility
  - A brief description of the event
  - Why the event occurred
  - The effect on the patient
  - What improvements are need to prevent recurrence
  - Actions taken to prevent recurrence

Other Reportable Incidences

- "Overexposures" to personnel ("overexposure" means greater than the limit(s) allowed by regulatory requirements for personnel) shall be reported by the RSO to:
  - Appropriate state department
  - Immediately by phone if personnel exposures of 250.0 mSv or more to the whole body; 1500.0 mSv or more to the skin, and/or 3,750 mSv or more to an extremity (note: this must be followed by the written report listed below.)
  - Within 24 hours by phone if personnel exposures of 50.0 mSv or more to the whole body, 300.0 mSv or more to the skin, and/or 750.0 mSv or more to an extremity (note: this must be followed by the written report listed below.)
  - Within 30 days, in writing if personnel exposure is greater allowable limits.
- Written reports to the appropriate state department shall include:
  - Extent of the exposure
  - The cause of the exposure
  - Corrective steps take or planned to be taken to prevent recurrence
  - The individual receiving the overexposure.

12. Records

Training

- Training records shall be maintained in a readily accessible file(s).
- Training records shall be current and made available upon request to the inspectors.
- All training records associated with a Superficial Radiation Therapy Radiation Worker shall be maintained for three years after deactivation of the individual.
- Copies of records documenting completion of initial training shall be provided to the Radiation Safety Officer upon application for dosimetry and shall be maintained by the Radiation Safety Officer with the individual's SRT Radiation Worker records.

QA

- QA records shall be maintained in a readily accessible file(s).
- QA records shall be current and made available upon request to the inspectors.
- QA records shall be maintained at least since the last regulatory inspection (though it is recommended to keep records for at least seven years, as storage space allows).

Badge Reports

- Badge Reports shall be maintained in a readily accessible file(s).
- Badge Reports shall be current and made available upon request to the inspectors.
- Badge Reports shall be made available to radiation workers at their request and actively provided for their review at least once per year. It is recommended they be located in a known and easily accessible location.

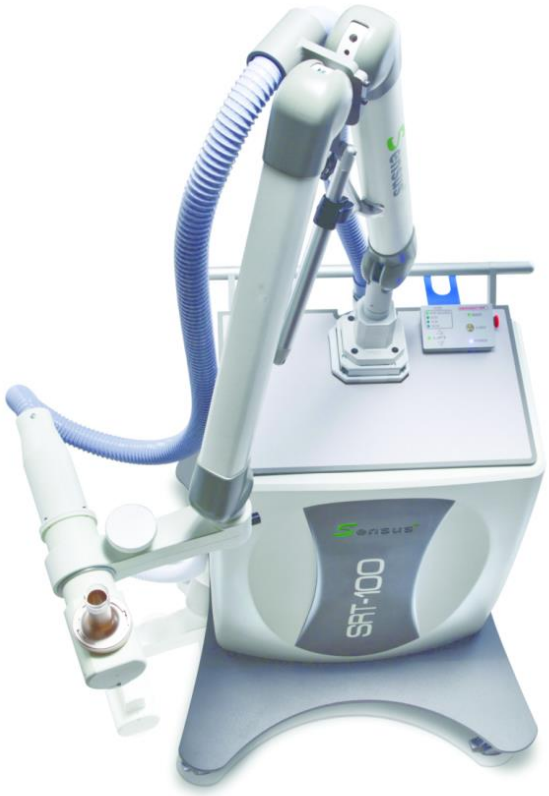
Patient Records

- Patient records to be maintained for at least seven years and maintained per requirements of HIPAA.

Inspection Reports

- All inspection reports should be maintained on site in a file associated with the SRT-100™ unit
- Any inspection with a finding must be posted in a location frequented and easily observable by Radiation Workers. Follow-up and final resolution of findings must also be posted for Radiation Workers to easily observe.

P3: Operating Procedures for Superficial Radiation Therapy



Safety Features

- **Normal X-ray Beam termination**: After the programmed Beam On time is reached during normal treatments the X-ray beam terminates
- **"Stop" beam**: The SRT-100™ has a "Start" and "Stop" button on the Control Console. To stop the X-ray beam before the end of a normal treatment, simply press the Stop button.
- **"Emergency Stop" beam**: If the normal Stop button fails to terminate the X-ray beam, press the Emergency Off button. This will de-energize the treatment unit and control console.
- The unit may have a door interlock. If so, then opening the door during periods of 'X-ray beam ON' will terminate the beam.

Power Up and Down the SRT- 100™

- To turn power on, place the circuit breaker, located at the rear of the Base Unit, to the "ON" Position (1=ON). This circuit breaker applies power to both the Base Unit and the Control Console.
- To turn the power OFF, return the circuit breaker on the Base Unit to the "0" position.

Warm-Up Modes

- The SRT-100™ X-ray tube must be gradually brought up to operating temperature by delivering short intervals of X-ray beam at increasing kilovoltage levels. This is Warm-Up.
- The SRT-100™ unit has two Warm-Up modes: Automatic and Manual.
- Normally, each day before treatments begin, the unit is warmed up using the automatic Warm-Up sequence. The unit will be interlocked and not allow X-ray beam production until a Warm-Up is completed each treatment day.
- Warm-Up also is necessary if the SRT-100™ has been idle for more than eight hours (i.e., has not produced an X-ray beam). However, if the unit has not been powered down and more than eight hours have elapsed since the last Warm-Up, a manual Warm-Up may be completed. This manual Warm-Up requires less time than the automatic Warm-Up and is used to accommodate patient scheduling to avoid the time required for a normal Warm-Up (approximately 6.5 minutes for normal Warm-Up vs. approximately 1.25 minutes for manual Warm-Up).

- Automatic Warm-Up
    - When a Warm-Up is necessary, “Warm-Up” mode is displayed at the top of the LCD screen.
    - Warm-Up mode can only occur if the Port Block applicator is installed on the X-ray port.
    - The Warm-Up cycle will start at 50 kV with X-rays produced for 60 seconds. The unit then automatically increases by 10 kV and runs another 60 seconds. The unit will continue to increment up by 10 kV with 60 second beam-on times until the 100 kV beam is completed. At that point, the Port Block can be removed, and the RAD Check or a normal treatment applicator cone can be installed on the X-ray Port.
- Manual Warm-Up
    - Manual Warm-Up mode is used if Warm-Up is needed, yet a full Warm-Up was completed since the unit has been energized, and a full Warm-Up will conflict with a soon-to-be performed treatment.
    - Enter the Manual Warm-Up mode by pressing the Beam Energy arrow down past 50 kV. “Manual Warm-Up” will appear on the Control Console screen.
    - In Manual Warm-Up mode the beam -on period is only 20 seconds (as opposed to 60 seconds for Automatic Warm-Up mode).
    - Press the Start button to initiate each Warm-Up mode beam on.

Daily Safety Check for Door Interlocks and X-RAY ON Light

- The daily safety checks of the door interlocks and the X-RAY ON light should be done AFTER a Warm-Up is completed. It can be done before or after Rad Check
- To perform a daily interlock and light check:
    1. Press the Clear button, then press the green toggle switch to “Warm-Up” mode.
    2. Press the Start button. When beam is on, look at the X-RAY ON light to verify it is lit.
    3. While the beam is still on, open the treatment door; the beam should stop.
    4. Close the door. Press the Clear button and toggle the green switch back to Warm-Up mode.
    5. Press the Start button and wait for beam on to start. Press the Stop button. Beam should stop.
    6. Press the Clear button and continue with RAD Check mode.

RAD Check

- Prior to patients’ therapy sessions, the operator should perform a RAD check procedure to confirm accurate radiation output of the SRT-100™ system. RAD Check should be performed after the morning Warm-Up
- To perform a RAD check procedure:
    1. Attach RAD check Sensor to applicator mount.
    2. Set time to 0.2 minutes.

3. Press START. Let exposure run to termination.
4. After the exposure, the LCD shows a number indicating the percentage of Baseline reference.

97%-103%:

- If the percentage is between 97% and 103% it is **OK to treat**.
- Please note that the 100% ±3% variation is perfectly normal and that the unit is functioning within an acceptable range.
- Please note that a percentage between 97%-103% does not change dose output!

≤96% or ≥104%

- If the percentage is ≤96% or ≥104% **DO NOT TREAT**.
- Notify management and physics. The unit needs recalibration and/or repair.

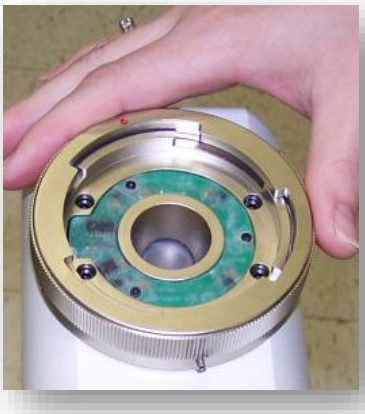
Upon completion of RAD Check, patient treatment can commence.

Treatment Procedure

After the treatment applicator cone size, beam energy, and treatment time is determined the patient and treatment unit can be setup for patient treatment.

- Installation of Applicator Cone
    - An applicator must be installed before exposures are enabled. The applicator must have a clear tip installed on the distal end.
    - The proximal end of the clear tip must be fully seated against the shoulder of the applicator cone to maintain the correct Source to Skin Distance.

- Applicator Installation**:**
    - Rotate the spring-loaded outer collar of the X-ray housing port counterclockwise so that the “slot” in the collar is over the “slot” inside the applicator mount.
    - While holding the rotated collar, place the Applicator Cone into the mount, and seat the applicator “tab” into the “slot” of the inner mount.
    - Slowly release the collar to its normal position. Do not allow it to snap back into place (this may damage the collar spring assembly)
    - If the outer does not fully return to its normal position, the Applicator Cone is not positioned properly in the applicator mount. Rotate the collar again, and reseat the applicator tab into the inner applicator mount.



Applicator Cone Removal

- Rotate the spring-loaded collar counterclockwise to line up the collar with the Applicator Cone tab.
- Lift the Applicator straight out of the X-ray tube port.
- Slowly release the collar to its normal position. Do not allow it to snap back into place.

X-ray Tube Head Positioning

- Prior to positioning the X-ray Tube Assembly for treatment, mount prescribed sized Applicator in the tube port. Ensure that the Applicator tip is clean for contact with the patient.
- Use the Up/Down Lift buttons on the Base Unit control panel to roughly adjust the vertical height for the patient's position and anatomical treatment site.
- Release the Arm Locks as needed and extend the arms to the appropriate position near the patient's treatment site.
- Loosen the X-ray Tube Head assembly Rotation Lock by turning it counterclockwise and rotate the X-ray Tube Head into the appropriate position.
- Use all three of the positioning controls as needed to position the Applicator to be in proper contact and angle with the patient's skin for the prescribed treatment. These controls include the Up/Down Lift buttons, Arm Locks, and Tube Rotation Lock. Applicator Cone positioning is often an iterative process.
- When the desired positioning has been achieved, ensure the two Arm Locks are locked and the Rotation Lock is firmly set.

Input and Verify Treatment Parameters

- Treatment Parameters include:
    1. Beam Energy

2. Treatment Time
3. Applicator Cone size
4. Fractional Dose

- Note that:
  - Treatments are given in fractionated doses, with each fraction generally given each treatment day.
  - A patient will receive several fractions that will deliver an overall total prescribed dose.
  - The total dose, fractional dose, and number of fractions are specified on a patient's prescription chart that a physician fills out.
  - The fractional dose will generally stay consistent throughout the patient's treatment scheme, unless otherwise changed by the physician.

1. Beam Energy (kV setting)

- Move the key switch to the X-RAYS position.
- Use the Up/Down Arrows to select the kV treatment setting. These beam energies are displayed in the X-ray Parameter Field as 50 kV, 70 kV or 100 kV. [It is noted that the SRT-100™ can be configured to have only two or even one energy available. If configured for less than three energies, the disabled kV treatment settings do not display on the LCD.]
- The SRT-100™ automatically selects and displays the mA setting corresponding to the kV value shown in the X-ray Parameter Field.
- The SRT-100™ automatically determines the appropriate filter for the selected kV value and moves it into place in the X-ray Tube Port. When the filter is in place, it is identified by its thickness and material on the display, to the right of the mA indication. These are in mm Al. Until the filter is in place, the Exposure Display and Status Display will indicate STANDBY.
- When the kV is selected, the calibrated values for Half Value Layer (HVL) and Dose Rate (cGy/min) are also displayed to the right of the mA value.
  - NOTE: The HVL and Dose Rate values displayed are based on calibration factors entered into the SRT-100™ by the Medical Physicist during commissioning and routine system calibration.

2. Treatment Time (set in 0.00 minutes)

- Rotate the black Rotary Knob (Exposure Time Control) to display the desired exposure time on the SET display. Pressing the knob inward while turning it moves the display in increments of 0.1 of a minute. Turning the knob without pressing it inward moves the display in increments of 0.01 of a minute. Rotating the knob clockwise increases the setting. Rotating the knob counterclockwise decreases the setting.
- When the SET display indicates the desired setting, the exposure time is selected, and will be in effect for the next exposure.

3. Applicator Cone Size

- The Applicator size is automatically set and displayed when an Applicator is installed in the X-ray Tube Port. Each Applicator has small magnets positioned in special patterns in the Applicator flange; the pattern is sensed by the X-ray Tube Port housing so the unit 'knows' what Applicator is installed.

- As part of the control console parameter setting process, however, verify the intended Applicator was indeed installed.

4. Fractional Dose (cGy for each treatment)
    - The fractional dose will be displayed to the right of the Applicator size on the control console.
    - A fractional dose is a function of the Beam Energy, Treatment Time, and Applicator Size.
    - The displayed fractional dose should be approximately the same as the physician's prescribed fractional dose.

5. Verify:
    - Beam Energy
    - Treatment Time
    - Applicator Cone Size
    - Prescribed Fractional Dose

Confirm READY Mode

- To enable an exposure, the system must be in READY mode, which will be indicated by the following conditions:
    - No Faults or Errors displayed.
    - Status Display indicates TREATMENT and READY.
    - Exposure Display indicates READY.
    - Green Ready Lamp above X-ray Indicator is ON.

Initiate Treatment

- Press and hold the START pushbutton for approximately 1 second until READY on Status Display changes to PREHEAT to begin the X-ray exposure.
- When PREHEAT appears, the system is preparing for the exposure (cooling pump starts, high voltage power supply begins charging, etc.).
- The status changes to X-RAY ON when the system starts emitting X-rays.
- The SRT-100™ will emit a brief tone and then short intermittent tones for the duration of the exposure. The X-ray lamp on the control console will also light up during X-ray production.
- The absorbed radiation dose to the skin surface will be displayed in cGy on the control console as the exposure progresses. This is the calculated dose based on the treatment parameters set above, as well as the calibration dose factors measured by the Medical Physicist and programmed into the control console.
- As the exposure progresses, the Elapsed and Backup Timers count UP to the time on the SET display.

Normal Treatment Termination

- When the Elapsed Time equals the Set Time the exposure ends. An approximate 1-second tone will sound. The following indications will be displayed:
    - COMPLETE will be displayed in the Status and Exposure areas.
    - The calculation of total absorbed dose to the skin surface in cGy will be displayed as Actual Dose.
    - A backup safety timer will continue with the remainder of a 192 second countdown that began with commencement of X-ray exposure. If allowed to fully count down, the system will return to READY. If it is necessary to make another exposure before the countdown in finished press the STOP button and the rest of the countdown will be cancelled.
    - To prepare the system for another exposure, the RESET button must be pressed to return all the TIME displays to 0.00. After a short STANDBY period, the system will return to Ready Mode.
- When completed, return the key switch to the “SAFE” position.

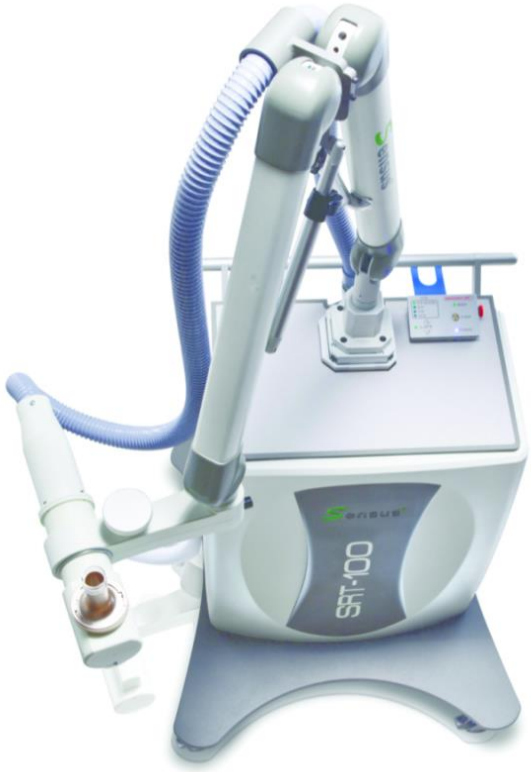
Abnormal Exposure Termination

- Exposures can be terminated at any time prior to reaching the SET time by any one of the following:
    - Pressing the STOP button
    - Pressing either of the two Emergency OFF switches.
    - Activation of any Facility Interlock (e.g., door interlock)
    - Loss of power
    - Activation of hardware backup timer
    - Key switch moved to the SAFE position

NOTE:

- If the exposure is terminated before the prescribed fractional dose is completely delivered, the remaining dose will be delivered via two methods depending on the mode of termination. If the beam was terminated using the STOP button, then simply pressing the START button without pressing the RESET button. The unit will 'remember' how much time was delivered and continue with the remainder. This also applies to beam termination via door interlock, etc.
- If the beam was terminated with either of the Emergency OFF methods, the remainder of the delivery time must be entered as Treatment Time and Beam On started as if a new treatment (i.e., the operator must know how much time was delivered before the Emergency OFF; subtract that from the prescribed delivery time to determine the remaining time to be delivered). This also applies to termination via power failure.

P4: Quality Assurance Procedures for Superficial Radiation Therapy



The Quality Assurance Program for the Sensus Healthcare SRT-100™ is comprised of several procedures. These procedures encompass regulatory requirements for ionizing radiation therapy devices for X-ray energies of 100 kV and less, as well as standards of quality practices delineated in AAPM Task Group 61 "AAPM protocol for 40–300 kV X-ray beam dosimetry in radiotherapy and radiobiology."

Commissioning

- Perform after unit's initial arrival on-site
- Perform before first patient treatment
- Conduct 'Area Radiation Survey' to determine safety and adequacy of treatment room shielding
- Test and verify functionality of safety systems
- Determine for each beam:
    - Beam Energy Half Value Layer (HVL)
    - Absolute Output for 5 cm,10 cm, 18x8 cm Applicator Cones
    - Relative output for remaining 15 cm SSD Applicator Cones
    - Output for remaining 15 cm SSD Applicator Cones
    - Input calibration values into machine and establish daily QA Baseline (RAD Check)
    - Verify Flatness and Symmetry of each beam is within ±3%
- Create report of all findings
- Report to be maintained on site with SRT-100™
- Provide report to State Regulatory Authorities if required

SRT-100™ Superficial Radiation Therapy testing and Commissioning Equipment

- Superficial Radiation Therapy testing and commissioning equipment (i.e. pancake chambers, ion chambers) that will be used to test or commission a SRT-100™ shall be calibrated at least every two years or as recommended by the manufacturer.
- Copies of the equipment calibration are typically included in/with the commissioning report, and shall be maintained along with the report in the document binder.
- Equipment outside limiting criteria must be removed from service by Physicist until repaired. Equipment must be rechecked prior to returning to service.

Daily QA

- Warm-up (Automatic Sequence if greater than 8 hrs. since last beam on)
- Check of Safety Systems (Door Interlocks and X-RAY ON light)
- RAD Check
    - **97% to 103% = OK to Treat**
        - A variation of 100% ±3% perfectly normal within an acceptable range.
        - A variation of 100% ±3% does not change dose output.
    - **≤96% or ≥104% = DO NOT TREAT**
        - Notify physics and RSO and/or authorized user (Physician)
- Record findings
- Perform each day patients are being treated, but at least three times per week if patients are not being treated

Monthly QA

- Normal testing required on a monthly basis is adequately performed during the Daily QA
- In certain states, monthly spot checks may be State mandated
    - If required, forward to physics for review

Annual QA

- Do before first patient treatment
- Conduct 'Area Radiation Survey' to determine safety and adequacy of treatment room shielding
- Test and verify functionality of safety systems
- Determine for each beam:
    - Beam Energy Half Value Layer (HVL)
    - Absolute Output for 5cm,10cm, and 18x8 cm Applicators
    - Relative output for remaining 15cm SSD Applicators
    - Output for remaining 15cm SSD Applicators
    - Input calibration values into machine and establish daily QA Baseline (RAD Check)
    - Verify Flatness and Symmetry of each beam is within ±3%
- Create report of all findings
- Report to be maintained on site with SRT-100™ documentation
- Perform on an approximate annual basis (or less than 365 days since last Annual, if dictated by State requirements)

Area Radiation Survey

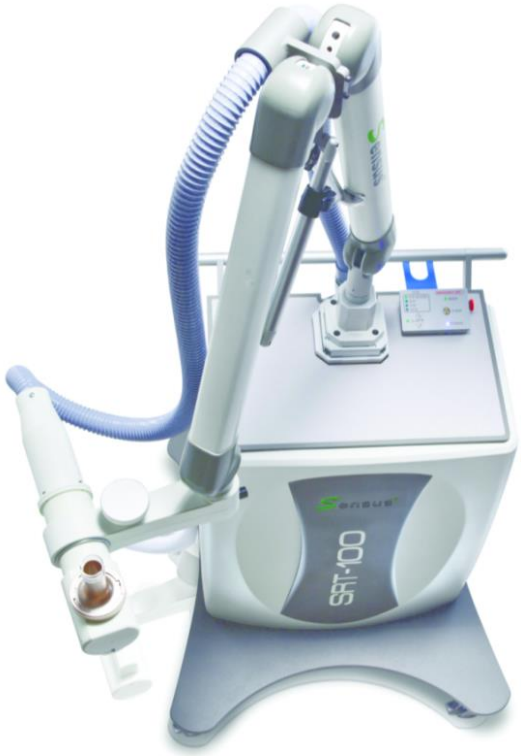
- Use Ion Chamber-type area radiation survey instrument.
- Instrument must be calibrated at least once each twelve months.
- Simulate Beam down geometry: Use 10cm applicator cone directed down towards container of approximately 10cm or more of water (simulating treatment of patient anatomy with cone directed downward on patient or anatomical part > 5cm thickness). End of cone in contact with water. Survey each potentially occupied space directly outside each treatment room wall for each energy beam. This verifies adequate shielding to protect non-controlled areas from the worst case radiation scatter.
- Simulate Beam horizontal geometry: Use 2.5cm applicator cone with approximately 0.5cm wax in contact with cone end (simulating treatment of patient appendage e.g., ear or nose). Beam directed horizontally toward nearest treatment room wall. Survey each potentially occupied space outside the treatment room using each beam of energy. This verifies adequate shielding to protect non-controlled areas from the worst-case primary beam.

SRT-100™ QA Review

- The SRT-100™ Superficial Radiation Therapy unit shall routinely be evaluated for compliance to applicable state and federal regulations.

- The SRT-100™ Superficial Radiation Therapy unit shall be commissioned upon receipt and annually thereafter. The commissioning shall be performed by a certified physicist that meets the compliances warranted by state and federal regulations.
- The SRT-100™ Superficial Radiation Therapy unit shall be evaluated as recommended by the AAPM in Task Group 61 report.
- Copies of the commissioning shall be maintained in the document binder.
- The SRT-100™ Superficial Radiation Therapy Unit shall have a Daily QA procedure performed to check the constancy of each therapeutic energy, prior to patient treatments.
- The Daily QA procedure is performed with the RAD Check sensor/applicator.
    - If more than 3% different from the reference value, service/re-calibration is required and the system should not be operable until service is completed.
- The QA results from the daily RAD Check are documented daily on a Quality Assurance log.
- Be sure to review:
    - Radiation Monitoring Requirements
    - ALARA and overexposure notification procedures
    - Radiation safety procedures
    - SRT-100™ Superficial Radiation Therapy unit operator requirements
    - Training requirements
    - Quality Control and Commissioning Tests
    - SRT-100™ Superficial Radiation Therapy Maintenance Logs and Operation Manuals
    - Posting and signage
    - Incident actions

P5: Emergency Procedures



Emergency Procedures

- The SRT-100™ produces radiation only when energized (i.e., beam is turned on).
- Radiation ceases to be emitted when the beam is turned off, power switch is turned off, or power plug is pulled.
- Emergency procedures, which contain as a minimum the phone numbers of persons to call in an emergency, should be located near the control console and known by all workers in the area.
- Follow this procedure in case of an emergency:

1. **Turn OFF equipment at Control Console.**
    - **Press the Stop Button or the Emergency Stop Button**
2. **Turn OFF SRT-100™'s main power switch in back of Base Unit.**
3. **Remove patient from treatment room, if present.**
4. **Post a sign on the equipment to prevent its use during incident investigation.**
5. **Call one of the individuals listed below immediately.**
6. **Call Sensus Healthcare if unit needs repair: 1-800-324-9890.**
7. **Safeguard radiation badges to prevent loss.**

Emergency Contact Numbers

Dr. (Dermatologist)	xxx-xxx-xxxx
Dr. (Physicist)	yyy-yyy-yyyy

P6: Morning QA Procedure

P7: Quality Management Program

P8: Administrative Clinical Controls Procedure

P9: Radiation Safety Operations Manual

Clinical Applications Appendices

Appendix A:
SRT-100™ System Troubleshooting

Fault Messages and Detection & Recovery

When system or interlock faults are detected by the system, Error Messages are displayed on the LCD screen. When the problem is cleared, the Error Message on the LCD will disappear. The following table describes each Error Message, its cause, the corrective action that the operator can take to resolve it and the steps necessary to resume a treatment if it has been interrupted by an Error Message.

Error Message	Cause	Corrective Action	How to Resume Treatment
Comm. Error	Communication between the Control Console and the Base Unit has failed.	Check the data cable connections. If problem persists, contact SERVICE personnel.	Turn the circuit breaker off and restart the system.
Interlock 1 Open	A door or other protective enclosure device connected to Interlock Circuit 1 is not in the correct position.	Remove key from front panel keyswitch, check the corresponding door/enclosure to make sure it's in the right position.	The Resume Exposure function allows restarting of the exposure. Press START to continue the treatment exposure.
Interlock 2 Open	A door or other protective enclosure device connected to Interlock Circuit 1 is not in the correct position.	Remove key from front panel keyswitch, check the corresponding door/enclosure to make sure it's in the right position.	The Resume Exposure function allows restarting of the exposure. Press START to continue the treatment exposure.
kV/mA Accuracy	Either the kilovoltage or the tube current deviate from their nominal values by 3% or more.	If problem persists, contact SERVICE personnel.	Resume only after Service Attention.

Error Message	Cause	Corrective Action	How to Resume Treatment
Low Filament Current	The system has detected low filament current, preventing exposure if the high voltage cable has become disconnected from the X-ray tube head.	If problem persists, contact SERVICE personnel.	Resume only after Service Attention.
Low Filament	HV cable disconnected or X-ray tube failure	Contact SERVICE personnel	Resume only after Service Attention.
No Applicator	The applicator sensor has detected that no applicator is in place, or that applicator is installed incorrectly.	Remove applicator. Inspect mounting area of X-ray Tube Head to identify and remove any foreign objects. Reinstall applicator.	If this error is displayed during the period of an exposure, contact SERVICE personnel.
Over-Current	Internal circuitry has determined that there is a current regulation problem	Contact SERVICE personnel	Record the elapsed time of the treatment and consult with medical direction for retreatment.
Over-Voltage	Internal circuitry has determined that there is a voltage regulation problem KV has exceeded set value by 10%.	Contact SERVICE personnel.	Record the elapsed time of the treatment and consult with medical direction for retreatment.
Port-Block Applicator Required	Warm-up selected or required and Port Block Applicator not installed	Install Beam Block Applicator.	Operation (Warm-up) resumed with Start pushbutton.
Power Failure	The power to the system was interrupted during an exposure. The displayed Elapsed exposure time indicates the exposure time completed when the power failure occurred.	Restart the system and continue treatment with the remaining time.	Restart the system and continue treatment with the remaining time.

Error Message	Cause	Corrective Action	How to Resume Treatment
RAD Check Error	The RAD check system has detected a 3% difference in output rate.	Contact SERVICE personnel	Resume only after Service Attention.
Remote X-ray Switch	A door or other protective enclosure device connected to Interlock Circuit 1 is not in the correct position.	Remove key from front panel keyswitch, check the corresponding door/enclosure to make sure it's in the right position.	The Resume Exposure function allows restarting of the exposure. Press START to continue the treatment exposure.
Service Required Extended Idle	X-ray tube has been unused for a longer time than can be conditioned by Auto-Warm-up feature	Contact SERVICE personnel to perform a manual warm-up.	Resume normal operation after service attention.
Tube Arc	The internal circuitry has detected a momentary interruption in the high voltage potential The system has detected arcing internally within the X-ray tube head.	Perform manual warm-up procedure, then repeat treatment. If problem reoccurs, contact SERVICE personnel.	After performing a manual warm-up, restart the treatment. If it occurs later in the exposure, contact service.
Water Flow Low	Flow Sensor in the coolant path detects insufficient flow (less than 4.2 LPM).	Check hose connections at tube head for leaks. Reseat connections.	Record the remaining time (difference between the Set time and the Elapsed Time). Reset unit and set the remaining treatment time on the unit. Press START to continue the treatment exposure.

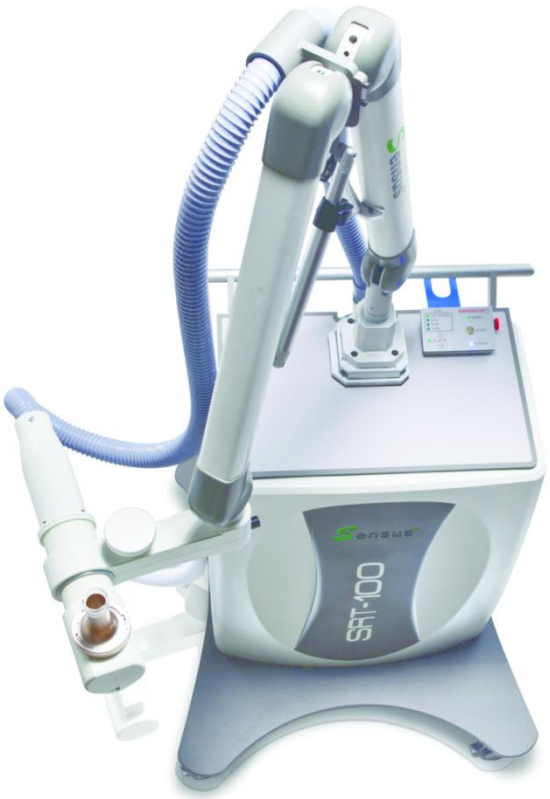
Error Message	Cause	Corrective Action	How to Resume Treatment
Water Over Temp	Internal coolant water temperature sensor indicates that coolant temperature is at maximum (42° C. or higher).	Check that Base Unit louvers are unobstructed, to allow free movement of air through the system.	Record the remaining time (difference between the Set time and the Elapsed Time). Reset unit and set the remaining treatment time on the unit. Press START to continue the treatment exposure.
Water Level Low	There is insufficient coolant in reservoir to ensure X-ray tube cooling	Follow procedure in the Technical Manual to add coolant to the coolant reservoir in the Base Unit.	Reattempt exposure after adding coolant.
X-ray Filter	The X-ray Filter Changer Assembly has detected an invalid filter/kV combination. The X-ray filter positioned in the tube head port does not match the selected kV setting. NOTE: The LEDS on the case control panel blink on and then off at power up until the automatic filter changer cycles through a self-test.	Turn system OFF, wait 1 minute, and then turn back on. If problem persists, contact SERVICE personnel. NOTE: There is a method to manually position the filter assembly by removing the screw in the endcap of the X-ray tube head, inserting a 7/64 hex key and turning the filter carriage until the proper indication is visible on the Base Control Panel.	Record the remaining time (difference between the Set time and the Elapsed Time). Reset unit and set the remaining treatment time on the unit. Press START to continue the treatment exposure.

Troubleshooting

Most problems that occur before or during an exposure are detected by the system. Messages are placed on the LCD screen notifying the operator of the condition. Incorrect operation or incompatible settings are also indicated this way. However, in several cases, the system may not be able to display an error message. In these few cases, use the chart below to isolate and resolve the problem.

Problem	Possible Causes	Corrective Action
Arm lift inoperative	Arm extended out of safe (closed) position.	Return arm to safe (closed) position and retry.
Arm will not balance in raised position.	Internal spring in arm detached or broken.	Do not use system, contact service personnel.
Liquid leaking from X-ray Tube Head	Coolant hoses not seated properly.	Re-connect coolant hoses.
Unit circuit breaker trips OFF at the beginning of or during exposure.	Power source not supplying adequate current.	Recheck specification of power source.
Unit will not turn on when Power Switch is pressed to ON.	System not connected to power source.	Check that system is properly connected to power source and that power source has power applied to it.
	Emergency OFF switch disengaged.	Check that both Emergency OFF switches are “armed” (rotate in the direction of arrows to “arm” the switch).
	LCD blank.	Check whether individual power and status lamps are lit. If they are, a problem with the system operation is likely.

Appendix B:
Patient Consent Form



Consent for Superficial Radiation

I hereby request, authorize, and give my consent to _____, M.D./D.O., and/or his/her associates or assistants, to perform Superficial Radiation and/or any other treatment(s) or technical procedure(s) deemed necessary or advisable in the diagnosis or treatment of my case including, but not limited to the pathology, radiology, and laboratory services.

I understand that early side effects of radiation include irritation, redness, and ulceration of the skin as well as possible skin infection.

I understand that late effects of radiation can include skin atrophy (thinning of the skin), telangiectasia (visible, small blood vessels in the skin), increased skin pigmentation (darkening of the skin), hair loss in the area treated, non-healing ulcer (rare), and/or a different type of skin cancer can develop in the area treated (very rare).

I acknowledge that no guarantee or assurance has been given by anyone as to the results that may be obtained, that there is no 100% cure rate for skin cancers, and that the practice of medicine and surgery is not an exact science for which assurances regarding cure rate can be made.

I consent to photographing the treatment, including appropriate portions of my body, for medical, scientific or educational purposes.

I understand that it is my responsibility to undergo regular and periodic check-ups (at least yearly) to detect recurrent or new skin cancers, and agree to follow instructions regarding treatment sites(s).

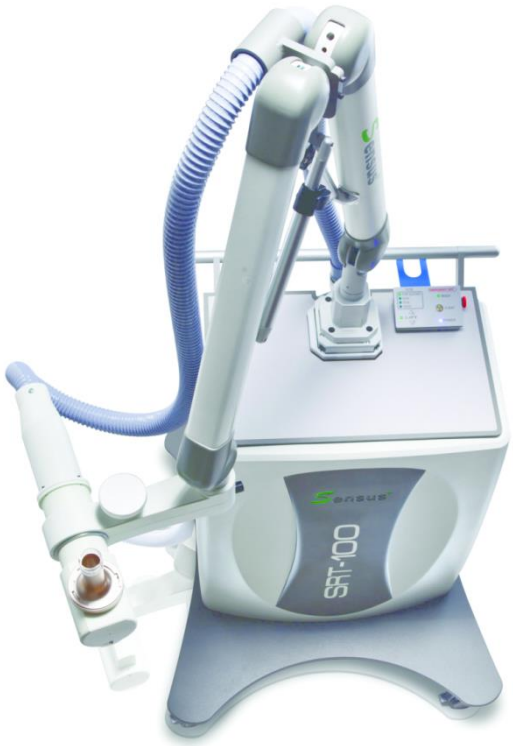
The possible risks and complications of Superficial Radiation and the possible risks and complications of failing to undergo or delay treatment have been explained to me and any questions that I may have had have been answered to my satisfaction

Printed name of patient or person authorized to consent for Patient: _____

Signed: _____

Date: _____

Appendix C: General Skin Care Recommendations



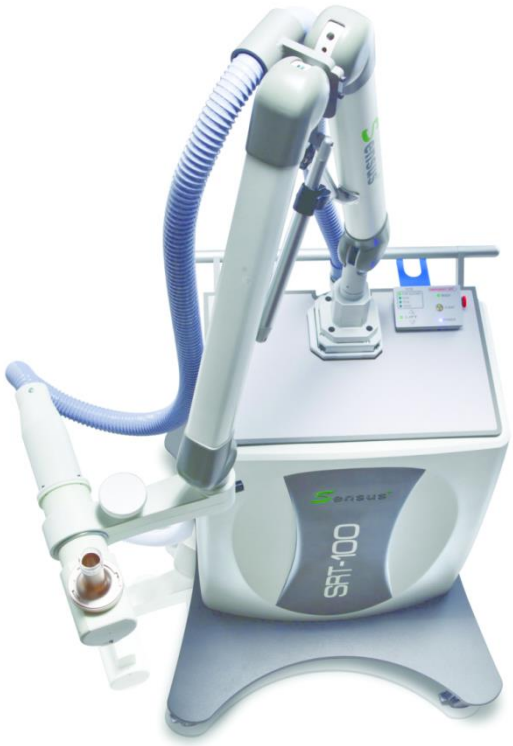
General Skin Care Recommendations

Washing: Patients should be encouraged to wash the irradiated skin daily using warm water and non-perfumed soap. The use of wash cloths may cause friction and are therefore discouraged. The use of a soft towel to pat dry is recommended.
Use of Deodorants: Patients may continue to use deodorants (excluding antiperspirants containing aluminum) during radiation therapy.
Other Skin Products: Patients are discouraged from using any perfumed products which may possess chemical irritants and induce discomfort. Products such as gels or creams should not be applied. Patients should be encouraged to use products advocated by the radiation department.
Hair Removal: The use of an electric shaver is recommended and wax or other depilatory creams are discouraged. Patients are asked not to shave the axilla if it is within the treatment field.
Swimming: Patients may continue to swim in chlorinated pools but should rinse afterwards. Patients experiencing a radiation skin reaction which has progressed beyond dry desquamation should avoid swimming.
Heat and Cold: Patients are encouraged to avoid direct application of heat or cold to the irradiated area i.e. ice or electric heating pads.
Band-Aids, Tape and Clothing: Rubbing, scratching and massaging the skin within the treatment area causes friction and should be discouraged. The use of Band-Aids or tape on the skin should also be avoided. Wearing loose fitting cotton clothing may avoid traumatic shearing and friction injuries. The use of a mild detergent to wash clothing is also recommended.

Post Treatment Skin Care Recommendations

Sun Exposure: Patients should be instructed to avoid direct sun exposure and cover the irradiated skin. The use of sunscreen products with at least SPF 30 are recommended for at least one year following treatment.

Appendix D:
Clinical Presentations & Care



Appendix A: Clinical Presentation & Care

Table of Contents

Non-Urgent Clinical Presentation & Care

Clinical Presentation

Erythema:

- Pink to dusky coloration
- May be accompanied by mild edema
- Burning, itching and mild discomfort

Dry desquamation:

- Partial loss of the epidermal basal cells
- Dryness, itching, scaling, flaking and peeling
- Hyperpigmentation

Reaction Assessment

Assessment to include:

- Location
- Size of area
- Color
- Discomfort (burning, itching, pulling, tenderness) – erythema
- Discomfort (dryness, itching, scaling, flaking, peeling) – dry desquamation

Promote Cleanliness

- Use non-perfumed soap. Bathe using warm water and palm of hand to gently wash affected skin. Rinse well and pat dry with a soft towel
- Wash hair using warm water and mild, non-medicated shampoo such as baby shampoo

Promote Comfort

- Avoid petroleum jelly based products
- Avoid irritant products containing alcohol, perfumes, or additives and products containing Alpha Hydroxyl Acids (AHA)

Post Treatment/Reduce Inflammation

- Alleviate pruritus and inflammation. Corticosteroid creams may be used sparingly as ordered by the physician

Urgent Clinical Presentation:
Requires medical attention within 24 hours

Clinical Presentation

Moist Desquamation:

- Sloughing of the epidermis and exposure of the dermal layer
- Blister or vesicle formation
- Serous drainage
- Pain

Reaction Assessment

Assessment to include:

- Location
- Moist areas
- Dry areas
- Size of area
- Wound base: granular tissue, eschar or necrotic tissue
- Exudate
- Type
- Amount
- Odor
- Discomfort (burning, itching, pulling, tenderness)
- Signs of clinical infection
- Fever
- Foul odor
- Purulent drainage
- Pain and swelling extending outside of radiation area

Promote Cleanliness

- Cleanse with warm or room temperature normal saline

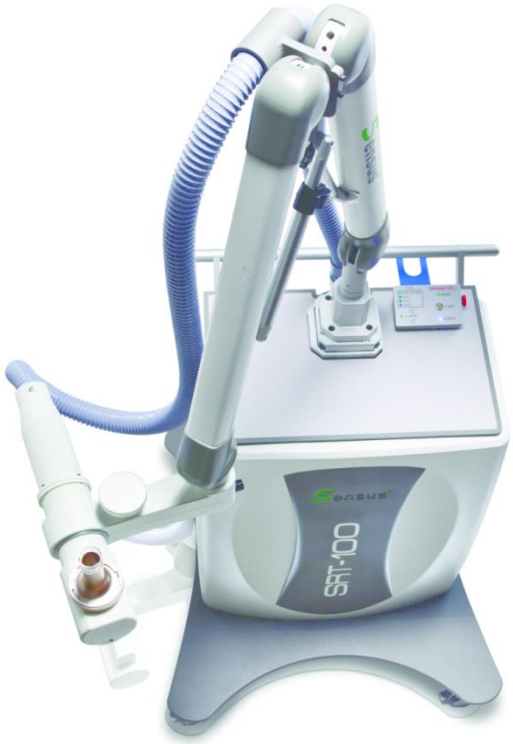
Manage Pain (During Treatment Break)

- Assess pain at each appointment
- Administer analgesics as ordered by the physician (clean area upon restart of treatments)

Prevention of Infection

- Regularly assess for signs of infection
- Culture wound if infection suspected
- Apply antibacterial/antifungal products as ordered by the physician

Appendix E:
Declaration of Pregnancy



Form Letter for Declaring Pregnancy

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, or you may write your own letter.

Declaration of Pregnancy

To: _____

In accordance with the NRC's regulations in 10CFR20.1208, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in the Month and Year indicated below:

_____
Month & Year of Conception

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (5 millisievert) {*unless the dose has already been exceeded between the time of conception and submitting this letter*}. I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

_____
Signature of Person Declaring Pregnancy

_____
Name (PRINTED) of Person Declaring Pregnancy

_____
Date

Appendix F:
Keloids:
Documentation for Clinical Treatment

Keloid
SRT Patient Eligibility and Treatment Selection

Name: _____ DOB: _____ Field Number: _____

Pathology: _____ Site: _____ Field Names: _____

Patient Eligibility and Treatment Selection

Functional Status (check one):____ 0 (fully active) ____ 1 (ambulatory, light activity) ____ 2 (ambulatory, performs self-care)
____ 3 (limited, performs self-care) ____ 4 (completely disabled)

Relevant Functional Limitation: _____ N/A

Surgery Date: _____ Age of Keloid: _____

Relevant Medical History (check all that apply):

Systemic: ____ History of MRSA infection
____ Congestive Heart Failure
____ Cardiac Disease
____ Pacemaker
____ Pulmonary Disease
____ Requires O2
____ Peripheral Vascular Disease
____ Bleeding Disorder
____ Anticoagulation: _____
____ Immune suppression
____ Diabetes
____ Advanced Dementia
____ Other: _____

local: ____ Lower Extremity edema
____ Cutaneous Atrophy
____ Poor Local Circulation
____ Poor Tissue Mobility
____ Local Infection
____ Other: _____

Indications for Keloid Superficial Radiation therapy:

____ Needed to improve the functioning of a body part
____ Pain Reduction
____ Medically necessary even if the surgery also improves or changes the appearance of a portion of the body

Indications for not performing Superficial Radiotherapy:

____ Previous Radiation therapy to the area of concern
____ Pacemaker or defibrillator within the treatment area

Physician: _____ Date: _____

Physician: _____ Date: _____

Keloid
SRT Simulation and Treatment Device Design

Name: _____ DOB: _____ Field Number: _____

Site: _____ _____ Field Name: _____

Shielding and Treatment Devices Used: A lead of 0.762 mm thickness is utilized to form a custom shield with a ____ x ____cm opening to encompass the Incision size with a treatment margin. The custom lead shield is adequate to accommodate the appropriate applicator and provide adequate shielding to organs of critical risk and to limit scatter to surrounding normal tissue. Additional shielding (as noted below) may be used to protect sensitive areas such as cavities of the body.

Field Size (applicator): ___1.5cm ___2.0cm ___2.5cm ___3.0cm ___4.0cm ___5.0cm ___10.0 cm____18x8cm

	Shields / Treatment Devices Used	Simple / Complex Device
External:	____ Lead Apron Covering, ___Breasts, ___Abdomen, ___Pelvis/Groin	Simple
	____ Therapeutic Head Holder	Simple
	____ Thyroid	Simple
	____ Lead External Eye Shields	Simple
	____ Lead Lined Glasses	Simple
	____ Molded, Custom, Site-Specific Lead Shield	Complex
Internal:	____ Lead Ear Canal Shield L/R	Complex
	____ Lead Intranasal Shield L/R Both	Complex
	____ Lead Intraoral / Dental Shield	Complex
	____ Silver lined Lead Eye Shield	Complex
	__1__ Clear Plastic Wrap used as a border between patient's skin and Lead	

Total Complex Treatment Devices used: ____ *Total Simple Treatment Devices used:* ____

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Clinical Photographs: ____ Incision with Margins ____ Incision with Shields ____ Patient positioning

Patient Treatment Position: Prone ____ Supine ____ Sitting ____ lying on Side: R / L

Description of Patient Position if different from above description:

_____

_____

Physician: _____ Date: _____

Keloid
SRT Treatment Time Calculation

Name: _____ DOB: _____ Field Number: _____

Site: _____ _____ Field Name: _____

Field Size (applicator): _____cm Energy: _____ kV

Selected Fractionation Scheme: _____

Subset Dose per Fractionation: _____ cGy = Subset Treatment Time: _____ Min
Radiation Output Rate: _____ cGy/min

Calculated Subset Treatment Time: _____ Min Console Subset Treatment Time: _____ Min.

Physician: _____ Date: _____

Keloid
SRT Superficial Radiotherapy Prescription

Name: _____ DOB: ____/____/_____ Field Number: _____

Pathology: _____ Field Name: _____

Incision Size____ x ____ mm Treatment Margin: ____ mm

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid Fractionation Scheme: 1300cGy in 1 Fraction

Energy: 50kV / 70kV / 100 kV Depth**: Surface** Fractions within 72Hr: __1___ BED: __30____

Applicator: ___1.5cm ___2.0cm ___2.5cm ___3.0cm___4.0cm ___5.0cm____7.3cm ___10.0cm____12.7cm____18x8cm

Custom lead Shielding Size: _____X_____

Number of Subsets: __3__ Dose per Subsets 433.33cGy (rounded up): _____cGy

Each Subset's Treatment Time: _____min

Daily Fractionation Dose: _____cGy (3 subsets added together)

Overall Total Dose from selected Fractionation Scheme: _____ cGy (all fractions added together)

Physician: _____ Date: ___/_____/_____

Fx#	DOSES	Treatment Energy	SSD	TX Time (Min)	Dose Per Subset (cGy)	Total Dose (cGy)	Date	Initials (MD)
Fx1	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Subset 3	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Total Dose	Add Together All 3 Dose Subsets				(cGy)	/ /	

Keloid
SRT Superficial Radiotherapy Prescription

Name: _____ DOB: ____/____/_____ Field Number: _____

Pathology: _____ Field Name: _____

Incision Size____ x ____ mm Treatment Margin: ____ mm

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid Fractionation Scheme: 1600cGy in 2 Fractions

Energy: 50kV / 70kV / 100 kV Depth**: Surface** Fractions within 72Hr: __2___ BED: ___30____

Treatment Applicator: ___1.5cm ___2.0cm ___2.5cm ___3.0cm___4.0cm ___5.0cm____7.3cm ___10.0cm____12.7cm____18x8cm

Custom lead Shielding Size: _____X_____

Number of Subsets: __2__ Dose per Subsets 400 cGy (rounded up): _____cGy

Each Subset's Treatment Time: _____min

Daily Fractionation Dose: _____cGy (2 subsets added together)

Overall Total Dose from selected Fractionation Scheme: _____ cGy (all fractions added together)

Physician: _____ Date: ___/_____/_____

Fx #	DOSES	Treatment Energy	SSD	TX Time (Min)	Dose Per Subset (cGy)	Total Dose (cGy)	Date	Initials (MD)
Fx1	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx1	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx1	Total Dose	Add Together 2 Dose Subsets				(cGy)	/ /	
Fx2	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx2	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	_____	/ /	
Fx2	Total Dose	Subsets added Together				(cGy)	/ /	
	Overall Total Dose	Add Fx 1 and F2 Total Doses together				(cGy)	/ /	

Keloid
SRT Superficial Radiotherapy Prescription

Name: _____ DOB: ____/____/_____ Field Number: _____

Pathology: _____ Field Name: _____

Incision Size____ x ____ mm Treatment Margin: ____ mm

CLEAR PLASTIC WRAP IS USED AS A BORDER BETWEEN THE KELOID INCISION AND THE LEAD CUTOUT

Keloid Fractionation Scheme: 1800cGy in 3 Fractions

Energy: 50kV / 70kV / 100 kV Depth**: Surface** Fractions within 72Hr: __3___ BED: ___30____

Treatment Applicator: ___1.5cm ___2.0cm ___2.5cm ___3.0cm___4.0cm ___5.0cm____7.3cm ___10.0cm____12.7cm____18x8cm

Custom lead Shielding Size: _____X_____

Number of Subsets: __2__ Dose per Subsets 300 cGy (rounded up): _____cGy

Each Subsets Treatment Time: _____min

Daily Fractionation Dose: _____cGy (2 subsets added together)

Overall Total Dose from selected Fractionation Scheme: _____ cGy (all fractions added together)

Physician: _____ Date: ___/_____/_____

Fx #	DOSES	Treatment Energy	SSD	TX Time (Min)	Dose Per Subset (cGy)	Total Dose (cGy)	Date	Initials (MD)
Fx1	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx1	Total Dose	Subsets added Together				(cGy)	/ /	
Fx2	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx2	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx2	Total Dose	Subsets added Together				(cGy)		
Fx3	Subset 1	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx3	Subset 2	50kV/70kV/100kV	15/25/30	(Min)	(cGy)	----------	/ /	
Fx3	Total Dose	Subsets added Together				(cGy)	/ /	
	Overall Total Dose	Add Fx 1,Fx2,Fx3 Total Doses together				(cGy)	/ /	

Keloid

(Used with 2 or 3 Fractionation schemes)

Evaluation and Management for Keloid Superficial Radiotherapy

Name: _____ DOB: _____ Field Number: _____

Pathology: _____ Site: _____Field Name: _____

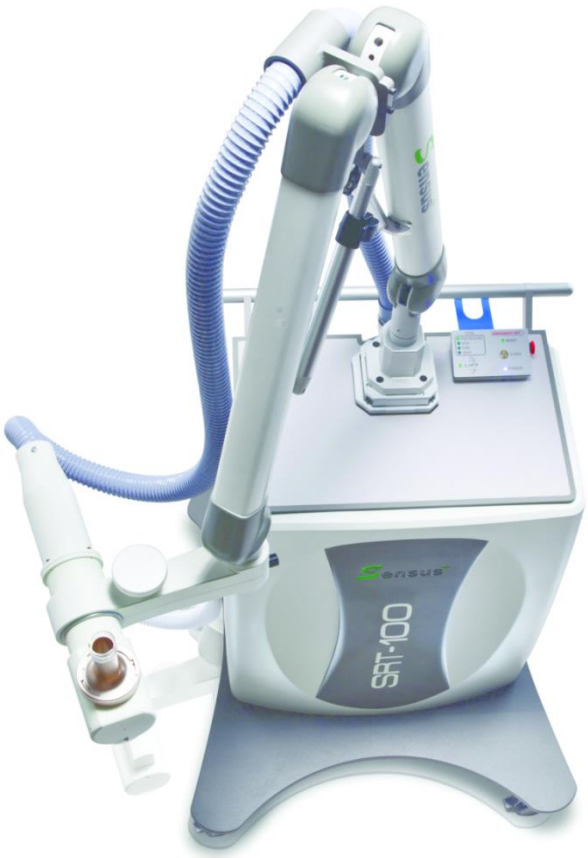
	Post Treatment	Fractionation valuation
	Date	
Subjective	None	
(√=present)	Redness	
	Pruritus	
	Pain	
	Drainage	
	Fatigue	
	Other	
Objective	Erythema	
(√=present)	Atrophy	
	Scaling	
	Crusting	
	Erosion	
	Ulceration	
	Edema	
	Purpura	
	Tenderness	
	Warmth	
	Drainage	
	Other	
	Cumulative Dose (cGy)	
Plan	Dose Reviewed	
(√=complete)	Dosimetry Reviewed	
	Simulation Reviewed	
	Clinical set-up Reviewed	
	External Shields Reviewed	
	Internal Shields Reviewed	
	Special care	
	Comments	
MD		

Additional Comments_____ _____

Post-SRT Follow up: _____ Physician: _____

Appendix G:

Morning QA Form



Daily QA Log for SRT-100™ Superficial Radiation Therapy

RAD Check QA Results								
50KV Energy	70KV Energy	100KV Energy	Door Interlocks	Stop Button	X-ray Light Illuminates	Date	Initials	RSO

Daily QA Log for SRT-100™ Superficial Radiation Therapy

RAD Check QA Results								
50KV Energy	70KV Energy	100KV Energy	Door Interlocks	Stop Button	X-ray Light Illuminates	Date	Initials	RSO

Daily QA Log for SRT-100™ Superficial Radiation Therapy

RAD Check QA Results								
50KV Energy	70KV Energy	100KV Energy	Door Interlocks	Stop Button	X-ray Light Illuminates	Date	Initials	RSO

Appendix H:
Annual ALARA Review of Radiation Safety Program

Annual ALARA Review of the Radiation Safety Program

Year: _____

Date of Review: _____

Licensee: _____
_____
_____

License Number: _____

Date of Expiration: _____

Radiation Safety Officer: _____

The ALARA Review evaluates the methods and implementation of the Radiation Safety Program. The following is a list of items that were examined during this review:

Posting of Notices and Signs

Rooms or Areas are properly posted with a CAUTION – RADIATION AREA sign to indicate the presence of a Radiation Area.

Yes _____ No _____ N/A _____

A copy of the NOTICE TO EMPLOYEES is posted for use by individuals participating in the licensed activities.

Yes _____ No _____ N/A _____

A copy of the State Regulations is available for use by those individuals participating in the licensed activities.

Yes _____ No _____ N/A _____

Annual ALARA Review of the Radiation Safety Program

Copies of the Amendment Letters are incorporated into the current license and are available for use by those individuals participating in the licensed activities.

Yes _____ No _____ N/A _____

A copy of the Emergency Operating Procedures applicable to licensed activities is properly posted.

Yes _____ No _____ N/A _____

Personnel Monitoring Records

Records of current occupational radiation exposures to individuals are being maintained in accordance with State Regulations.

Yes _____ No _____ N/A _____

Records of cumulative occupational radiation dose are maintained for each radiation worker in accordance with State Regulations.

Yes _____ No _____ N/A _____

Personnel monitoring records are reviewed at least on a quarterly basis in accordance with ALARA Level I & II guidelines.

Yes _____ No _____ N/A _____

Operating Procedures and Manuals

The facilities' Radiation Safety In-Service program for all radiation workers is being conducted at the time of orientation and at least on an annual basis.

Yes _____ No _____ N/A _____

A Radiation Safety Procedures Manual is written and copies are made available for the use of all radiation workers.

Yes _____ No _____ N/A _____

The Radiation Safety Officer reviews and signs radiation documents at least on a quarterly basis.

Yes _____ No _____ N/A _____

Misadministration

Was a misadministration reported to the DRH during the calendar year involving the administration of a diagnostic X-ray radiation machine exposure to a patient?

Yes _____ No _____ N/A _____

Administrative Actions

At the time of this ALARA Review, this facility was found to substantially comply with State and NRC Regulations.

_____ _____
Radiation Safety Officer Date

Appendix I:
Radiation Safety Training Sign-In Sheet

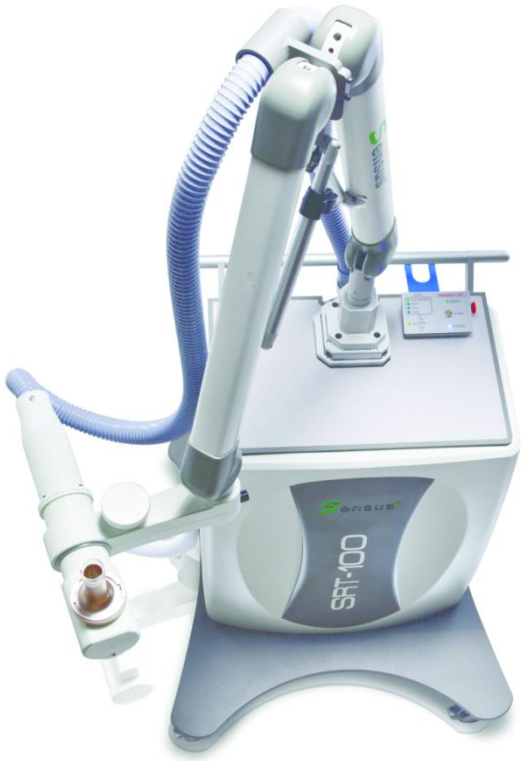
Radiation Safety Training

The following individuals have successfully completed Sensus Healthcare's radiation safety training:

Site Name: _____

Printed name	Signature	Date

Appendix J:
Keloids:
SRT-100™ Training Sign-In Sheet



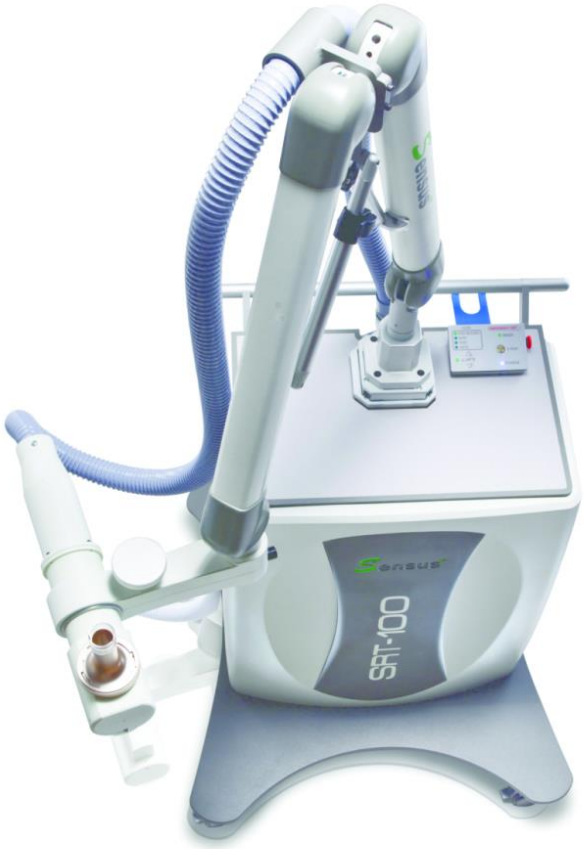
Keloid
SRT-100™ Training

The following individuals have successfully completed clinical training for the Sensus Healthcare SRT-100™:

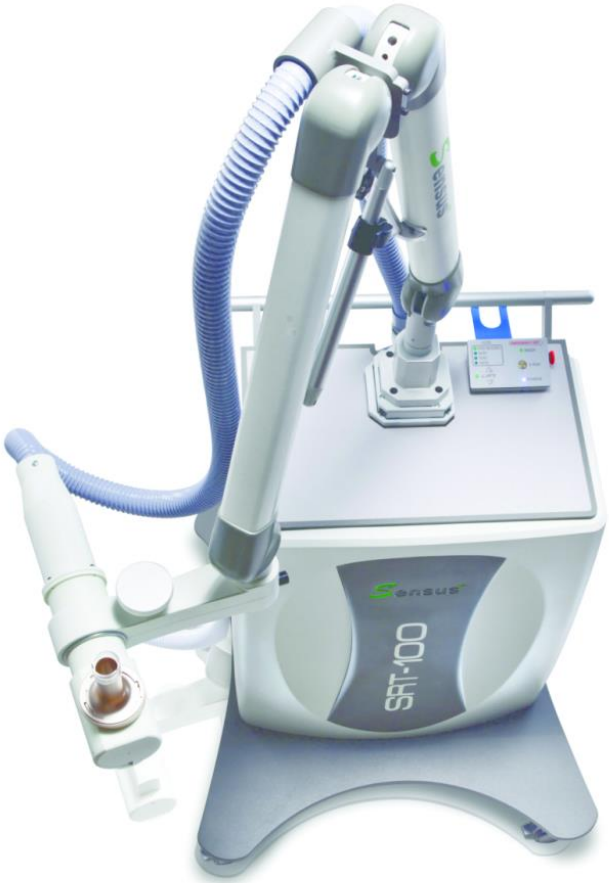
Site Name: _____

Printed name	Signature	Date

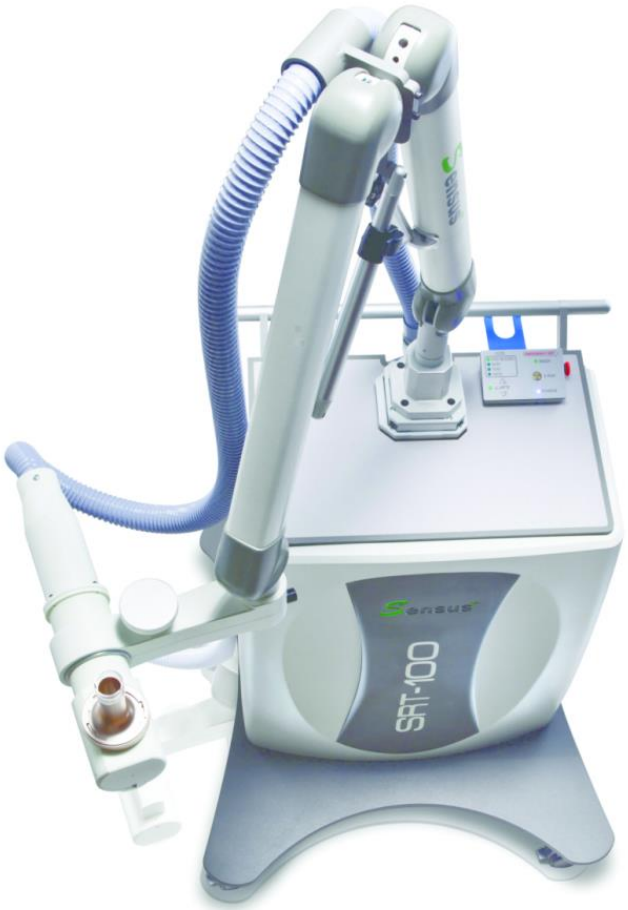
Appendix K:
X-ray Sign



Appendix L:
Badge Reports

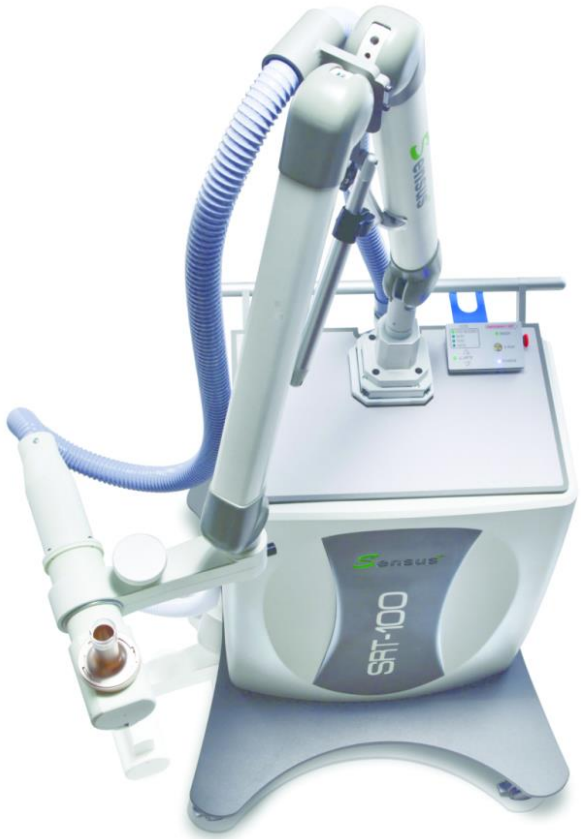


Appendix M:
Commissioning Report

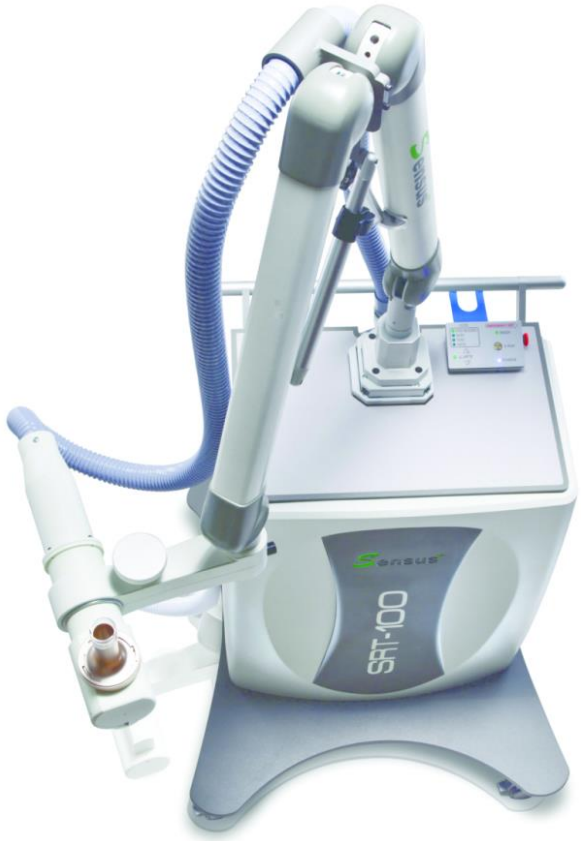


Appendix N:
Final Survey Report

Appendix O:
Commissioning Output Sheet



Appendix P:
Keloids:
Subset Tables: 50kV, 70kV, & 100kV



Keloid	1 Fractionation	Scheme	Subset Dose
	50kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Keloid	2 Fractionation	Scheme	Subset Dose
	50kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Keloid	3 Fractionation	Scheme	Subset Dose
	50kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Keloid	1 Fractionation	Scheme	Subset Dose
	70kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Keloid	2 Fractionation	Scheme	Subset Dose
	70kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

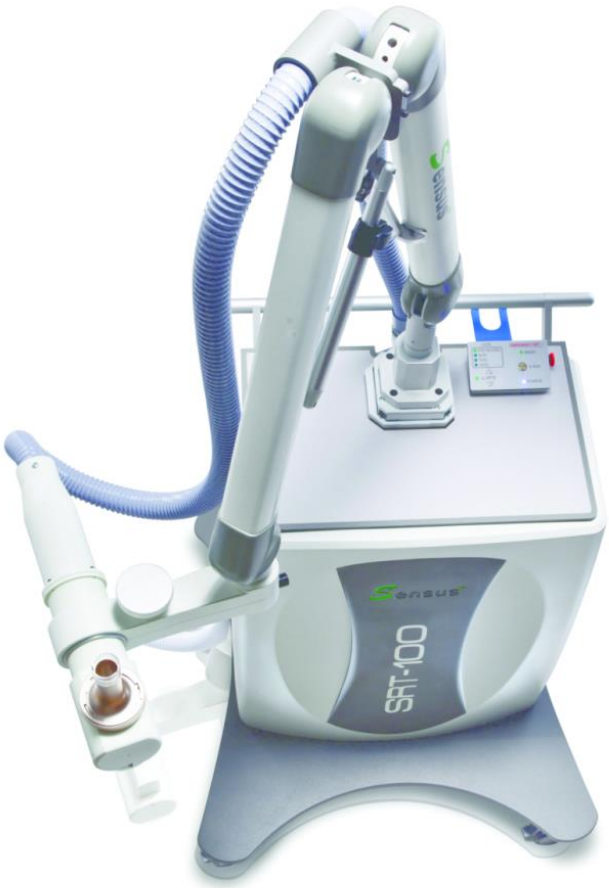
Keloid	3 Fractionation	Scheme	Subset Dose
	70kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Keloid	1 Fractionation	Scheme	Subset Dose
	100kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Keloid	2 Fractionation	Scheme	Subset Dose
	100kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

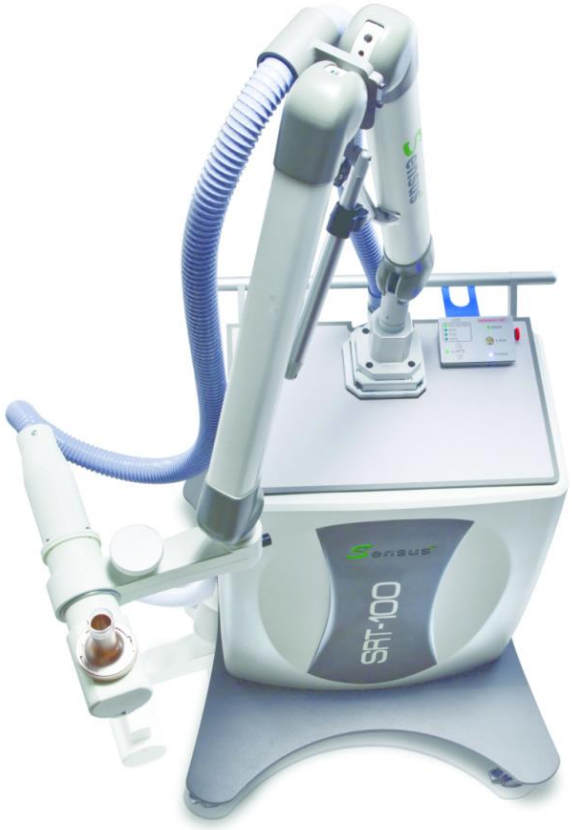
Keloid	3 Fractionation	Scheme	Subset Dose
	100kV	TX Timetable	
Applicator Size	cGy/ per Minute	Treatment Time	Dose Per Subset
1.5 cm			
2.0 cm			
2.5 cm			
3.0cm			
4.0 cm			
5.0 cm			
10.0 cm			
18.0x8.0 cm			

Appendix Q:
Notice to Employees



Appendix R:
State Regulations

Appendix S:
Authorized User Form



Authorized Users

Authorized Users are physicians or staff members who have been approved to use the SRT-100 through state regulations. In addition to other responsibilities, the Authorized User must comply with all requirements for a Radiation Worker. The Authorized User's radiation use must follow the approved procedures and conditions stated in the SRT-100 programs and procedures.

The Authorized User has the primary responsibility for ensuring the health and safety of anyone participating in the procedure or treated SRT-100 under the Authorized User's direction or supervision.

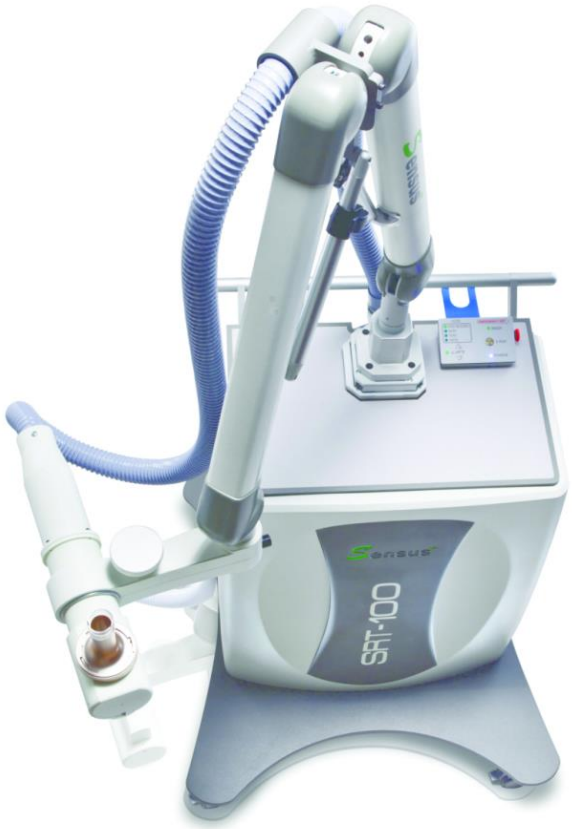
The Authorized Users ensures that supervised employees comply with relevant regulations, policies, and procedures.

Facility: _____

Authorized Users:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Appendix T:
Authorized Physicist Form



Authorized Physicist

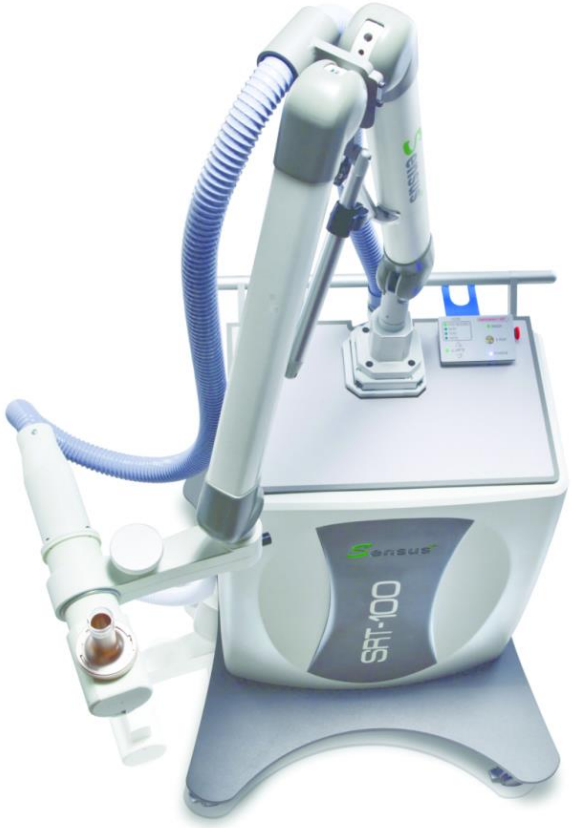
The Authorized Physicist must be registered with the state in order to give physics support.

Facility Name: _____

Authorized Physicist: _____
_____

Date: _____

Appendix U: Citations



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Chapter 22: Keloids: Clinical Treatment Planning for Physicians

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Chapter 23: Keloids: Clinical Treatment Documentation

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