



ADIA PUBLICATIONS

ADIA GUIDELINES

X-Ray in the Dental Practice

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DISCLAIMER

This is an overview document prepared as a general outline. Where the reader is in need of specific facts to guide building work (for example) we strongly suggest you engage professional assistance. This document is a genuine attempt to put current information in a form that is easily understood however the ADIA and the authors will not accept liability for misinformation contained within.

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1. Outline

The use of X Ray equipment in the Dental Practice is widespread but the knowledge of how to acquire it, prepare the Practice and use it is the cause of some confusion – and when it comes to registration, compliance to standards and testing there is widespread uncertainty. In an attempt to provide ADA members with practical information the ADIA has prepared this document. It is not an official text, and it is not claimed to be comprehensive – but it is an honest attempt to put into one ‘easy to read’ document most of the important current issues and requirements for the safe and effective use of X Ray in your Practice.

This document also attempts to explain the basics of operation of dental X Ray, what are the differences between AC and hf or DC units; film & processing issues, and the different types of digital imaging currently offered. We also try to assist with suggestions on how you should choose your X Ray equipment supplier and service support, and compliance/ testing/ reporting issues apply. Necessarily this will be a little general given the different rules applying in each State.

(Note: there is a current effort supported by the ADIA to have ARPANSA set a common National set of standards and testing, however given the various state and national entities involved this may take some time)

2. Basics & background information

2.1 Equipment types:

Common to both Intra Oral and OPG/ Panoramic X Ray units is the type of X Ray Generator which produces the radiation output. Earlier systems used a comparatively simple design called ‘AC’ or ‘single phase’ This type of unit converts the incoming 50 Hz (cycles) 240 volt power supply to high voltage to generate the X Ray output.

There are two types of ‘AC’ or single phase units ...

‘Half wave’ rectified systems use half the incoming power to deliver 50 pulses of radiation per second. ‘Full wave’ rectified X Ray units convert more of the incoming energy to generate the X Ray output, delivering 100 pulses of radiation per second. There are some such units which offer both economy in purchase price and which meet compliant requirements. More about that below.

The new technology most companies offer today is called ‘DC’ or ‘constant potential’ and it differs from the above AC system in that modern electronics can now take the incoming 50Hz mains supply and convert it to a much higher frequency – typically 50,000 to 150,000 Hz and in some cases even higher. The same process of rectification converts this alternating high voltage to a constant output to produce an X Ray beam of much more homogenous output.

Look at the waveforms below to accentuate the effect of peak kV and of the valleys where kVp is much lower for AC units. When (for example) 70 kVp is selected with an AC unit, the peak output is 70kV, and the remainder of the output is a mix of kV energies down to about 57kV (the mandatory aluminium Port filter blocks energies below that) Now look at the waveform for the typical DC unit. The waveform is very different with a very short wavelength and very little difference between the peak energy levels and the ‘valleys’.

In summary, that is why DC units are said to produce higher output, better clinical images and lower patient dose. Dose as measured by Physicists is as much as a 20 – 25% lower than the equivalent AC exposure.

Another very significant issue is that modern digital electronics are much more accurate (and reliable) than older analog systems and some older AC units on the market have very inaccurate timers which seriously affect digital imaging. It must also be said that there are

some good AC units on the market which have accurate modern control and timing electronics.

There may be some low quality AC & DC units which have poor output control and unstable energy levels, and it is usually for these reasons that your X Ray unit may fail on Compliance test. For new units which do meet compliance standards always ask for the TGA Approvals Number to ensure that the manufacturer meets the required Australian Standards. Your local Compliance Tester will confirm which products are stable and pass the tests easily.

TGA (Therapeutic Goods Administration) is a national Government organization charged with registering, controlling and tracking medical instrumentation, drugs etc. Its key role is in managing invasive equipment and drug regimes, and recalls if ever they be necessary. For dental X Ray equipment their task is more as a 'gatekeeper' to ensure that what is sold in Australia meets the relevant Australian Standards, which are formulated almost totally on the IEC (European) rules. You should not purchase an X Ray unit unless the Supplier can quote you a relevant listing (or approval) number. That will be either an R or L followed by a few numbers.

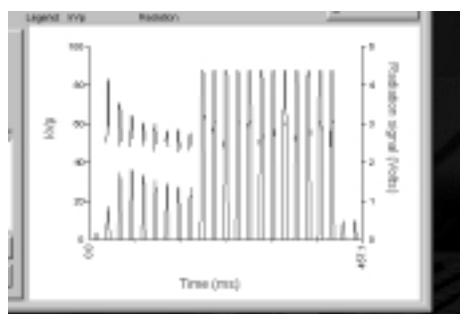
TGA listing means the product meets local requirements – but you still must have the State authorised Compliance test.

Please note that FDA (US market approvals) is not directly relevant in Australia however there is a slow move between the USA and Europe to reach a common standard.

A word of explanation on exposure factors ...

- kVp refers to the peak (or mean) kV output or electron energy selected, further kVp relates to 'tissue contrast' Lower kV visualises soft tissue and higher kV displays hard tissue (ie: bone/ teeth) effectively. For example a Periodontist is interested in soft tissue detail, and the general Practitioner is more interested in an overall image showing all tissue. Hence the advantage of a variable kV unit.
- mA is the 'quantity' of radiation produced.
- Time x mA = mAs (or the total output over time)

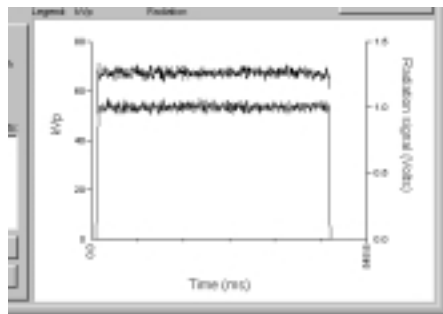
Graph 1



Typical AC waveform

Primary waveform shows radiation out put, & secondary waveform(upper) shows kVp

Graph 2



Typical high frequency waveform

2.2 Installation issues

The Installer should be a State Radiation Control Board registered person and the installation should comply with the various standards and State codes (also see Section 2.3 –

Safety & Shielding issues). The voltage requirements must meet the manufacturer's specifications. (in Australian 240 VAC +/- 5%)
Your warranty may be jeopardised if a person other than a qualified Installer is used.

2.3 Compliance Testing:

The objective of the tests being done are to confirm that your X Ray unit installed in your Practice is performing to the required standards. Whilst we all react to 'yet another Govt. fee' this test every 5 years is important to confirm that selected parameters are accurately delivered every time. Your Tester is checking for (amongst other parameters) ...

- ❑ KVp accuracy
- ❑ Consistent radiation output linearity
- ❑ Timer accuracy
- ❑ Radiation leakage
- ❑ Environmental issues (shielding etc)

Reliable performance of your X Ray equipment is essential for you, your staff and patients, and may impact on liability issues. With good quality tested equipment and a proper QA system in place, this will help if you face such a situation.

It is your responsibility to maintain your X Ray system in good condition, serviced regularly. And to maintain a regular QC Program to maintain that compliant performance; and if anything significant changes during that period (including for example changing the X Ray tube it is your responsibility to arrange another compliance check

2.4 Safety & shielding

We all know that 'radiation is a health hazard' BUT – many operators are careless in their day to day use of their X Ray systems. Radiation is not visible, it does not hurt, and we all know that overall dose levels in dentistry are fairly low (compared for example to Radiology)

Indications are that any radiation can be damaging – and that every exposure is cumulative. We need to study complex data to develop any realistic understanding of the statistical risks, but there is no doubt whatever that radiation avoidance is very important. You and your staff are working with this equipment all day, every day and the doses do add up over time. Take care, shield the Surgery, and manage the facility with great care.

Shielding requirements vary from State to State however a sensible shielding plan should always be adopted irrespective of current State rules. Whenever you refurbish or build, add lead or its equivalent to walls where X Ray equipment is used. By that we mean that as a matter of routine shield Surgery walls if they are stud/ plaster type etc. If they are brick, (excludes Besser blocks and similar light density products) typically they will be adequate but use the contacts resource listed below to make sure. A Consultant Physicist can prepare a radiation plan for your new surgery and we recommend this approach for a new facility. In preparing a plan the Consultant Physicist takes into account the number of X Rays taken per day/ month, the type of exams, the size of the rooms and the occupancy of adjacent areas. From this a calculation of the risk and therefore total shielding required can be made. All materials are rated according to their absorption equivalent to lead sheet (Pb)

Having said that, for almost all dental X Ray installations (including OPG) typically 1 mm of lead is sufficient for the walls and including the door and viewing window. Intra oral is often a little less. Be sure to consider the floor and ceiling if of timber construction and it is a multi level building.

Additional to the above comments be aware that there are new draft regulations being prepared in NSW by the EPA, and possibly elsewhere and those requirements will eventually have to be met.

2.5 Film & chemistry

Presently there are three types of x-ray films "D, E & F". Traditionally 'D' film is used, however the newer films are faster and with better characteristics justifying their regular use. We suggest that you contact your film Supplier for details and recommendations.

Standardisation is absolutely necessary for all aspects of diagnostic Radiography. Once an x-ray unit has been calibrated and certified that it is performing to consistent standards by testing there are still other variables which affect film quantity that must be taken into consideration

One of these variables is the Focal Film Distance (FFD) which in Dental Radiography is achieved by intelligent use of the 'Cone'.

The other major factor lies with *Film Processing*

There are basically three types of chemistry available for processing Radiographs.

Manual chemistry is designed for processing films by developing at 20C and in a manual Tank. This involves developing for 3 minutes, fixing for 6 minutes and rinsing for another 6 minutes (a total of 15 minutes) - plus drying time.

This manual chemistry developer has a high oxidation rate and will oxidise (turn coffee coloured) rapidly when exposed to air and if used after oxidation the results will be at best a poor image with high dose. Manual chemistry is available either as a supplied powder which has to be dissolved in a prescribed volume of water or as a fluid concentrate. Measurements of volume are not always correct and results may vary considerably as a result.

The second (and preferable) type of chemistry is supplied in ready mixed form which do not have to be diluted or mixed. This form of chemistry may be used for manual processing (3 minutes at 20C) but is principally manufactured for automatic film processors which process the film at higher temperatures (e.g. 27-28 degrees C) in order to speed the processes from 3 minutes to 1 minute for full development. This chemistry is typically supplied in plastic Winchester's each containing 5 litres of developer or fixer.

You can also purchase some chemistry formulated for long life meaning it is typically viable for up to 4 – 6 weeks under controlled conditions.

An **Automatic** Processor holds a number of key advantages and is the only practical method of quality control in processing. These systems usually include some form of daily or fully automatic chemical replenishment of both DEVELOPING AND FIXING SOLUTIONS to maintain concentrations (measured by specific gravity)

Some other tips relating to film & processing ...

- Film should be stored until the day before use in a refrigerator at about 8C degrees.
- If a dark room is in use it must be fitted with a Universal safelight to avoid film fog. A "red painted globe is not sufficient protection for all types of film.

We have talked above about processing issues however what is the effect of degraded chemistry and poor processing ?

Modern film is very stable however excessive heat, long term storage, bad chemistry and processing at too high or low a temperature will increase base fog (that is background gray level) The effect clinically is to reduce the diagnostic quality of the image – meaning more dose to the patient, and a poor quality image.

2.6 Digital acquisition systems.

The comments below are intended only as a brief overview of current digital X Ray sensor systems. There are currently two approaches available as follows.

Indirect capture – or phosphor plate.

The basis of this system is a photostimulable material that reacts to X Rays by ‘capturing’ a latent image on its surface. This image is not visible to our eye, but can be ‘seen’ when viewed in the infrared spectrum. This image can be erased using UV light – so it operates at either end of the visible light spectrum. The image plates can be re-used many times subject to careful handling.

After exposure, this image plate is placed in a laser scanner which reads the image ‘line by line’ with an infrared laser and digital pickup. The image data is collected in your PC and then displayed on the PC Monitor. After the image has been recovered a bright UV light in the scanner, sunlight or bright lamps of appropriate type clears the image ready for re-use. The image plate can be handled in subdued room light both before and after exposure, but must not be left in bright sunlight or some types of fluorescent lights between X Ray exposure & scanning.

The phosphor plates are fully re-useable and do not deteriorate significantly by repeated exposure to X Rays or light. They are available in film size equivalents of 0,1,2,3,4, Pan & Ceph.

The advantages of the PSP system are ...

- The plates are inexpensive and can be used many times.
- They are flexible and can be placed in the mouth like film.
- One scanner can service multiple operatories.
- It is moderately difficult to damage the plates unless physically mishandled.
- The same scanner can be used for intra-oral imaging as well as OPG & Ceph.
- Approximately 60% reduction in exposure required for each radiograph compared to D-speed film.

The disadvantages of the PSP system are ...

- The intrinsic resolution can be lower than a good CCD
- They need to be manually loaded into a scanner
- The scanner typically takes 15 – 80 seconds to read an intra oral image – 2.5-5 minutes for OPG & Ceph. However, multiple plates can be read simultaneously.

At the time of preparation of these notes there were three such systems available, and these systems follow imaging techniques which are widely used in Hospital and larger Radiology Practices with their CR (Computed Radiography) systems.

The basic difference between dental market units and the Hospital systems is Reader resolution and scan times. Hospital systems have >5 times the image performance, take only 10 seconds to read (process the image) – and cost much more. (\$150k >>)

As always, improvements will alter the balance of factors which will affect your buying decision.

Direct capture - CCD Sensors:

There are two types of these solid state Sensors ...

1. CCD (Charged Couple Device) which 'reads' the X Ray by converting the X Ray image to visible light with a layer of fluorescent material, the light output of which is then read by the CCD elements or pixels.
2. CMOS Sensors where the X Ray information is captured directly by the digital electronic cells – there is not visible image energy transfer.
3. At time of writing this Guideline, new Sensors have been shown which use either of the image capture approaches above but are not directly connected to the PC. One approach has a digital memory in the Sensor which is downloaded after removal from the patient mouth – and the other announced system incorporates a high frequency transmitter to send the image to the PC. Be sure to check that such systems work in your Practice without RF (radio frequency) interference problems.

Most digital intra oral systems are CCD, and aside what the advertising states, at this time CCD appears to offer a better image quality. With the fast rate of development new technical approaches will show progress. Incremental improvements in image quality are resulting from the use of more pixels (discrete picture elements), improved dynamic range (gray levels) and smarter software which enhances the displayed image. An example of recent advance is the patented molecular metal coating across the front of the CCD elements which produces a marked improvement in image quality by reducing image noise (spurious electronic noise which degrades the image) and again reducing radiation dose. On the topic of new developments, one promised development which is unlikely to happen anytime soon is the flexible digital Sensor. There are too many major complications involved in making such a device reliable for it to be released soon.

The major practical issue involved in using digital CCD Sensors is that because they are inflexible they cannot be placed where you normally place your dental film. A modified technique must be adopted using a Sensor Holder which places the Sensor more into the middle of the mouth where the patient can tolerate it and compensate for the magnification effect using the software. The advantages are that the image is always parallel to the beam and the tooth and that the image is not distorted because the film was twisted (curved) Measurements can always be made off the digital image by measuring some item in the image (tooth crown etc) and applying that to the calibration scale on the PC. Thereafter each measurement on that image is accurate in both axes.

Other important issues associated with the purchase and implementation of digital imaging in the Practice includes the following ...

1. the cost and practicality of seamless network operation
2. the ease of use of the system software and its integration with your Practice Management facility.
3. Staff training on both system software and clinical use (positioning) of the Sensor.
4. On going sales support from the Manufacturer/ Distributor/ Agent.

3. Quality Control

We have already discussed the need to regulate and manage unnecessary radiation dose, and the absolute necessity for your Practice to deliver high quality imaging with minimum practical dose to your patients. Because of the often subjective nature of what is a good image and the difficulty sometimes of assessing why an image is not good, **a Quality Control Program should be implemented in every Practice.** Such a program establishes a reference point or standard of image quality and allows regular (weekly) comparison of current results compared to that reference standard. Using a sensitive but simple and cost effective test you can identify change (if any) and have a starting point from which to work toward correction.

Such a QC program gives you and your staff confidence in the Practice imaging performance, maintains high standards for your patient's benefit, and gives the Practice proof of performance and standards in any litigation proceedings.

3.1 The ADIA X Ray Quality Control Program

To be effective, and to be widely accepted and used such a program must be easy to use and of modest cost. The new ADIA QC Program for Dental X Ray is designed with these guidelines in mind and incorporates a simple contrast check which you can perform once a week (or daily/monthly if you choose) at the cost of one film or digital exposure. Here is how it works...

At the start of the QC program a control image is taken using the standard ADIA Tester which establishes a baseline contrast image comprising a number of density steps (typically 15% increments) - the CONTROL IMAGE.

This gives you a basic performance guideline image expressed in grey level steps which your X Ray unit delivers at a standard setting, and with your processor/ chemicals in good condition.

You repeat that exposure weekly/ monthly using the ADIA tester which reproduces exactly the earlier exposure. If the resulting image differs from the CONTROL IMAGE you have a problem which needs action.

It is beyond the scope of this modest QC Program to diagnose problems, so if after changing chemistry and checking obvious causes have not improved the situation, you will need to call for technical assistance. 90% of all film based system problems will be processor or chemistry; and a high proportion of digital fault will be associated with PC/ Monitor set-up issues.

This is a low cost, simple and sensitive test designed to flag an early warning to the Practice.

The CONTROL IMAGE is best taken immediately after a new installation or following a Compliance test of an existing X Ray unit. Alternatively, if you are confident your current X Ray unit is delivering satisfactory results, then establish your CONTROL IMAGE at any time so you can monitor any subsequent changes.

The ADIA X Ray Quality Control Program KIT will be available at a modest charge from any ADIA Branch, and includes the Tester and full instructions. If you need additional assistance you will find your local Compliance Tester enthusiastic to assist.

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Published by the

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