Handheld X-ray in Dental Practices

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Hurricane Katrina
August 2005

- Hurricane Katrina was the strongest hurricane ever recorded on the Gulf of Mexico.
- Made landfall in Louisiana on August 29, 2005
- Over 1 million people were told to evacuate
- Over 1,000 people died from Hurricane Katrina
- More than 700 people died in New Orleans alone

Facts-Lack of Preparation

- 1 million people were told to evacuate the Gulf Coast
  - Lack of busses to transport these people
  - Not enough ambulances to evacuate hospitals and nursing homes.
  - 1,800 people lost their lives as a result of the storm-most in Louisiana(over 1,500.
    - Some directly from the storm but others from the chaos that followed.
  - 80% of New Orleans was flooded
    - Flood management system was built by the Army Corps of Engineers but wasn't nearly good enough.
    - 80% of the housing was destroyed

Lack of Government Support

- Federal government has been accused of not doing enough to help the people who were impacted
- Mismanagement of the response and relief efforts at all levels of government
  - Officials from FEMA and in the City of New Orleans were removed or resigned as a result of their actions or lack there-of

What does the History of Katrina Have to do with Hand-Held Dental Equipment

- The Nomad™ was designed for use by the Army to help identify the bodies
  - Portable
  - Rechargeable, battery operated
  - Marginally light weight
  - ALARA compliant when used by properly trained personnel

The Need to Identify the Dead

- This was a daunting task
  - Hot, humid weather. Plus post Katrina storms.
  - Hospitals and morgues were damaged and over-crowded
  - Need to rapidly identify the victims and locate surviving family
  - Dental records destroyed
    - This was in the early days of digital x-ray and not all dental offices were connected to the cloud….it just kept raining

How to Identify the Dead

- As the bodies decayed or remained immersed in water the task of identifying the dead grew more difficult
  - X-ray became the main modality of identification
    - How can you use an x-ray machine with no electricity?
      - Portable generators are extremely heavy and where could you put them when there was so much structural damage to Louisiana?

Different Handheld Dental Units

Handheld with Medical Capabilities

Advantages of Hand-Held Equipment

- Lower Cost
- Portable
  - Practice doesn’t need an x-ray machine in each operatory
- Battery Operated
  - Can be used if you loose power
    - Provided somebody charged the battery

Disadvantages

- Some surprising or not so surprising pitfalls of handheld units

It is Harder to Take Consistently Good X-rays With a Handheld Unit

- Handheld x-ray units emit x-ray at a lower power than a high-quality wall mounted or mobile x-ray unit
- You need to look at the amperage or current output.
  - This is designated in mA or milliamps. When the power output is lower, it is more difficult for the sensor or film(if you are a Brontosaurus) to separate the signal to noise and can result in a lower quality image.
    - Many of the handheld units operate as low as 2 or 2.5 mA.
    - Wall mounted units range from 7-10 mA.
    - X-ray power is proportional to the mA so if all the other parameters are the same or similar a 2mA handheld unit generates the x-ray beam at about one quarter of the power of an 8mA unit.

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- To compensate for the potential of increased noise the exposure time is increased.
- Longer exposures create issues with keeping both the patient and the x-ray unit still.
  - This can be a challenge for some offices.

Forgetting to Charge the Handheld Unit

- Ooops!!!!!!!!
- Most units operate on a lithium-ion battery pack. They can't be operated without a charged battery.
  - Most units last about 100-200 images
  - Who is responsible for charging the battery pack
    - Should one person be responsible? What happens if they are sick or on vacation
    - Should you have a back-up battery pack?
      - This isn't fail-safe either…
        - This pack may not have been charged either
        - This is a problem if the back-up hasn't been used for an extended period of time

The Hygienist has to Carry the Handheld During the X-ray Examination

- Most units now weigh about 5 pounds. This is equal to a large bag of flour.
- The operator no longer has her/his hands free to adjust either the receptor or the patient.
  - The unit must be put down to make any adjustments that are necessary
- Because the weight of the entire unit is held up and supported by the operator, it is much more of a challenge to be spot on and motionless.
- Because of the lower output a more precise technique is required to get a diagnostic image

Loss of Productivity

- There will be a longer wait time between exposures-studies may take longer to do.
  - The duty cycle or duty factor tells you how long any unit needs to wait before it is ready for the next exposure.
  - It represents the ratio of exposure time to wait time.
  - Some wall mounted or portable units have a duty cycle that is a ratio of 1:15.
  - If the exposure lasts ¼ of a second, then the unit will be ready to make the next exposure in less than 4 seconds. (15 x 0.25 = 3.75)
  - Many handheld units have a duty cycle of 1:60 or worse.
    - The same ¼ second exposure now means a wait time of 15 seconds.
    - Remember that the lower power is often compensated by a longer exposure time.
      - If you increase the exposure time to 0.5 seconds you will need to wait 30 seconds between exposures….this can equal almost 10 minutes of extra time per patient if you do an adult full mouth series. That is a really long time for a hygienist to hold the unit and keep it properly positioned!

Distance is One of the MOST Effective Protections to Reduce Radiation Exposure

- Staff using the equipment daily are the most at risk of long-term exposure issues.
- Remember the “Inverse Square Law”---
  - The effective dose if you are 1 foot away from the source is 100 time greater than if you are 10 feet away.
  - The further away the less radiation you will receive.
  - Also remember that we exist in a “Linear No Threshold” environment-
  - No amount of radiation is good for you but sometimes we need to expose people to determine disease states or treat the disease.

Testing has Been Performed to Prove Staff Safety

- I found 4 abstracts regarding operator exposure levels for the Nomad handheld unit.
- I did not find anything in print regarding other manufacturers' devices.
- 3 were from the U.S.
- 1 from the UK
- All were published in different journals

University of Nevada-Las Vegas, Risk Management and Safety Department-Published in Health Physics, 2012, Aug: 103(2 Suppl 2)

Maintaining radiation exposures as low as reasonably achievable (ALARA) for dental personnel operating portable hand-held x-ray equipment

- A handheld unit and a pair of manikins were used to measure the dose to a simulated operator
  - 2 different scenarios were tested
    - Exposures made according to the manufacturer's recommendations
    - Exposures made according to the manufacturer's recommendations except for the removal of the x-ray unit's protective backscatter shield
    - An array of personal dosimeters and a pair of pressurized ion chambers were used to evaluate the dose received.
    - The results indicate the dose to an operator will be less than 0.6 mSv y if the device is used according to the manufacturer's recommendations. This is well below 1.0 mSv y. T
    - This level of annual dose is similar to those reported as typical dental personnel using fixed x-ray units. It also appears to satisfy the ALARA principal for this class of occupation exposures.

UNLV School of Dental Medicine, Las Vegas, Nevada Published J. Forensic Science, 2009 Mar; 54(2)

- Used an Aribex NOMAD hand-held, portable x-ray device
- 715 digital and/or film-based dental radiographs and 200 study control exposures were made.
- The results showed the reproductive organs received the highest dose and the thyroid the least.
- Average operator whole body dose was determined to be 0.047 mSv (4.47 mrem) or 0.09% of the annual MPD.
- The data was extrapolated as an expression of averaged annual operator exposure resulting in a whole-body dose of 0.4536 mSv (45.36 mrem). This is 0.9% of the annual MPD.
- These results are well below established occupation exposure dose limits and were found to be compatible with what the manufacturer stated.

University of New York-Stony Brook Published in Dentomaxillofacial Radiology 2007 Feb;37(2)

- Radiation exposure with the NOMAD portable x-ray system
- The system was tested though the existing heavy metal compounds surrounding the x-ray tube, backscatter radiation the lead-filled acrylic shield attached at the end of the exit tube and patient exposure.
- This test used a DXTRR phantom and a water phantom.
- All Measurements were recoded using a calibrated TLD, calibrated Unfors Model 583L dosemeter and a calibrated Radcal MDH model 1015 dosemeter.
  - Settings for all exposures were 60kVp, 2.3 mA and 0.25 s using Kodak Insight (Class F) film.

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- Results: all backscatter measurements, in front of the shield, behind the shield, at the finger of the operator, operator's chest, eyes and gonads were significantly below the maximum permissible radiation leakage as per UFDA regulations (100mR/hr(-1).
  - Exposure would be well within the occupational maximum permissible dose for an occupationally exposed person.
  - Film dose was consistent with the manufacture's recommendations.
    - State of New York Bureau of Environmental Radiation Protection granted this site a variance to use the NOMAD on a case-by case basis.

Positions that the NOMAD was tested

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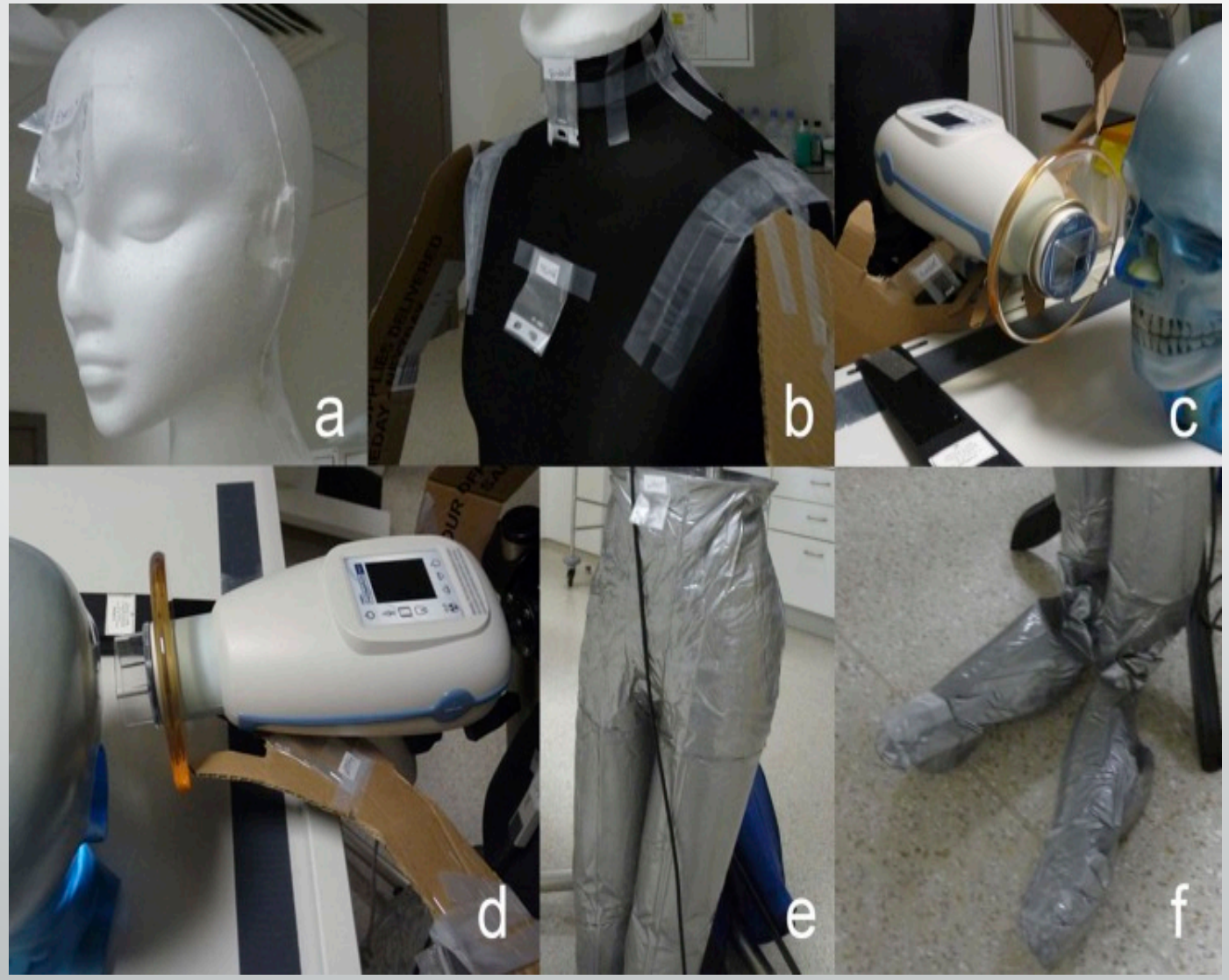
Areas of Personnel That Were Monitored



Legs

Abdomen/Pelvis

Thyroid/Chest

Regulations on Handheld Units vary by state and by Manufacturer

- Each state's health department is monitoring this equipment very closely
- Minnesota has rescinded the need for a Variance if you follow MDH Rules

Is Your Office Considering Buying One of These Units?

- Things to consider
  - 1. Is the unit legal in Minnesota
  - 2. How will the installation/acceptance testing be completed?
  - On-site or drop-shipped
  - 3. Is the service provider/installer that is doing the acceptance testing registered with the MDH. Doesn't matter if they are on-site or in Maine-they have to have a State Registration Number and there testing equipment must be current on its calibration also. They also have to be qualified to do installations. Not all are.
  - 4. If drop shipped, the unit needs to be rechecked on arrival.
  - 5.What kind of applications training is included with the purchase?
  - 6. Who will be responsible for charging the battery pack?
  - 7. Can repair be done on site or does the unit need to be sent someplace for repair?
  - 8. Performance evaluations
    - On-site or drop-shipped
    - Service Provider must be registered with the MDH and the equipment they use must be in current calibration. This service tech may be different than the one who did the installation calibrations.

X-ray Unit Information Notice Hand-Held Dental X-ray Equipment 7-1-2017

- Minnesota Rules, Chapter 4732
- Laws 2017, 1st Special Session, Chapter 6, Article 10, Section 58

On-Site, Staff Related Responsibilities

1. Where is the operator's manual
2. Is there anything the staff needs to do to comply
3. The Radiation Safety Officer (RSO) needs to write policies and procedures for the unit and then train the staff on those items
4. The RSO and Registrant need to agree on how the unit is secured and stored when not in use. Policy and Procedure for this a must.

Some Required Staff Responsibilities

1. There must be a backscatter shield that complies with the following:

- Is composed of a leaded polymer or a substance with a substantially equivalent protect capacity;
- Has at least 0.25 mm of lead or lead=shielding equivalent; and
- Is permanently affixed to the handheld dental equipment

RSO Responsibilities

- Must adhere to MDH Rule parts 4732.055 and 4732.0505
- Provide Procedures and safety instructions under part 4732.0510
- Quality assurance and ALARA program requirements under parts 7432.0520 and 4732.0530
- Annual review with the registrant that includes a program audit found in 4732.040
- Requirements for radiographic practice standards, under parts 472.0550, radiographic equipment processing parts 4732.0555 and ordering radiographic procedures, 4732.0580, Item C

Theft

- The REGISTRANT-not the RSO is responsible for reporting theft of the device to the MDH immediately after the theft is known.

RSO Duties (Continued)

- Calibration of the equipment is performed 4732.0600
- All general equipment requirements listed in part 4732.0880 excluding Subpart 2, Item B
- All requirements for intraoral dental radiographic systems listed in part 4732.0880 EXCLUDING Subpart 2, Item C.

AN INDIVIDUAL WHO IS OPERATING THE HAND-HELD DENTAL X-RAY EQUIPMENT MUST BE PROTECTED BY A PERSONAL PROTECTIVE GARMENT

Calibration of Equipment

- RSO is responsible to make sure this is done at the proper intervals.
  - Must be calibrated according to parts 4732.1100 Subparts 1,2,& 11

Compliance With Rules

- Except for the prior exemptions and or clarifications a registrant using handheld dental x-ray equipment must comply with Minnesota Rules, chapter 4732.

This became effective July 1, 2017

Prohibited Use

- If the equipment’s backscatter shield is broken or not permanently affixed to the system

Location of Device

- It is not limited to use where it is impractical to transport the patient.

Storage of the Unit

- Must be stored when not in use.
- Must be s in a stored in a secured, restricted, locked area of the facility

Calibration Requirements

- Calibrated initially
- Then at intervals not to exceed 24 months (730 days)

Calibration **must** include the tests specified in Minnesota Rules, part 4732.1100 subpart 11!

Exemptions

- Handheld dental x-ray equipment used according to this section and according to manufacturer instructions is exempt from certain shielding requirements.
  - Shielding requirements found in Mn Rules, part 4732.0365 and
  - Requirements for the location of the x-ray control console or utilization of a protective barrier found in Minnesota Rules, part 4732.0800, subpart 2, item B, sub-items (2) and (3) provided the equipment utilizes a backscatter shield that satisfies the requirements in subdivision 2, paragraph (a) clause (2)

Questions

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Sources

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