

***NEXT* 1998**

Protocol for the Survey of Pediatric Chest Radiography

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**Committee H-4 on the *Nationwide Evaluation of X-Ray Trends*
(*NEXT*) of the Conference of Radiation Control Program
Directors (CRCPD), Inc.**

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NEXT 1998 PEDIATRIC CHEST PROTOCOL

Introduction

These survey procedures have been developed to obtain certain information concerning the production of a diagnostic radiographic image. Data to be recorded are shown on the following pages. The facilities to be surveyed are chosen randomly from a nationwide list or roster and each State is informed of the facilities in the sample from that State and is requested to survey these facilities using the following protocol. Although the amount of information requested has been kept to a minimum, it still is different from that which many States normally collect during x-ray facility visits.

Through the selection of a national sample and the use of a complete protocol by all participants for this small number of surveys, the total amount of the data collected can be reduced. However, for success and completeness of the project, every facility in the sample must be surveyed and every data element must be acquired except as noted in this protocol.

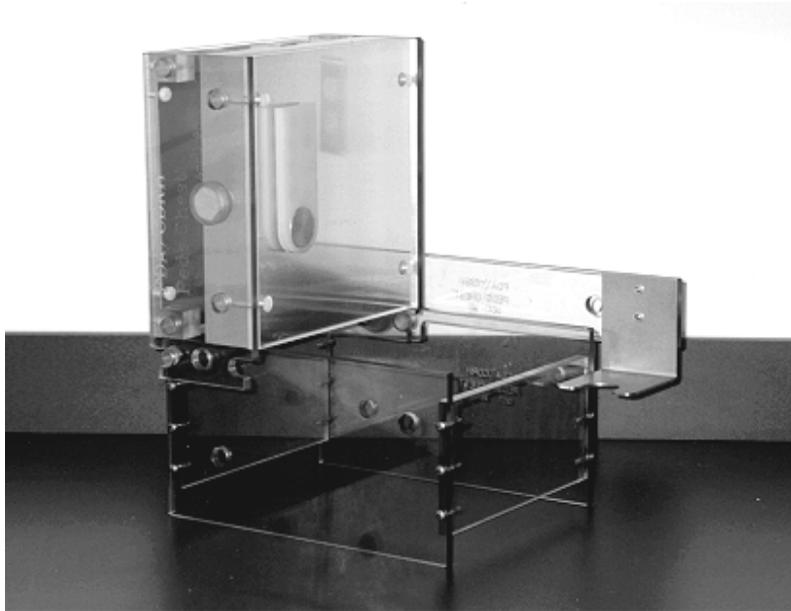
General Instructions

The survey form should be completed in pencil. If an error is made, erase it and enter the correct value in the appropriate boxes. Avoid crossing out errors and writing outside boxes.

Groups of boxes for a single entry **must** be filled with leading and trailing zeros as appropriate unless indicated otherwise in this protocol. For example, if an exposure measurement of 78.0 mR is obtained, it must be coded 0078.0.

Make a PHOTOCOPY of your completed survey form for your records!

The Pediatric Phantom



**The NEXT pediatric phantom is representative
of a 15 month old 24 pound infant.**

The phantom can accommodate surveys of either PA or AP projections, as reviewed in the section on phantom set-up. Because this phantom is equipped with a spine-heart shadow insert, it is important that the phantom be assembled correctly in order to accurately reflect the orientation of the heart during these examinations.

A complete description of phantom assembly is provided at the end of the protocol in Appendix A. It is highly recommended that you do NOT completely disassemble the phantom body by removing the side plates.

Conducting the survey

To ensure the success of this NEXT survey, follow the guidelines below when conducting your surveys.

1. **Determine** from the technologist which radiographic unit the facility uses most frequently for pediatric chest studies.

Do not make guesses about the facility's
procedures or equipment - ask !!

2. **Prior to taking measurements** BE CERTAIN that your phantom is set up correctly.
3. **Inspect and score radiographs** *prior to leaving the facility.* This will ensure that you leave the facility with good data and films.
4. **IF YOUR DATA SEEMS QUESTIONABLE:**
 - a. Repeat the exposure / test to verify your measurement
 - b. Check with the technologist that equipment is operating properly
 - c. Check with other comparable data to verify. For example, if film processing is very low but your phantom film density and exposure levels are reasonable, your STEP test may need to be repeated.

The Pediatric NEXT Kit

Each time you conduct a NEXT pediatric survey, be sure to take the following with you:

1. The complete NEXT pediatric phantom: Phantom with Lucite removable base, probe arm, test tool and Plexiglas filter plate
2. Pediatric protocol with survey forms
3. NEXT supplement
4. MDH survey meter
5. Sensitometer and densitometer (recently calibrated)
6. Aluminum for HVL measurements
7. Calculator
8. Tape measure
9. Roll of tape
10. Fog folder or other equivalent means for measuring darkroom fog levels
11. Calibrated film for STEP test

What to send to the FDA when a survey(s) is completed.

1. Completed survey form
2. Phantom film with test tool image
3. Darkroom fog film
4. STEP film and worksheet
5. HVL plot

Final Notes:

1. We have issued control film that should be adequate for surveying daylight processing units. Process a STEP film in the daylight processor after obtaining assistance with the technologist.
2. If the facility has a computed radiography unit (CR), please survey the system as best possible. Computed radiography is a digital means of image capture that uses the same existing x-ray equipment, but uses digital storage plates instead of film cassettes. These digital storage cassettes may look similar to film cassettes, but are processed by a different means. If possible, obtain and evaluate films as you would for conventional surveys.

Please make it clear on the survey form that you are evaluating a Computed Radiography unit.

If you have questions regarding a possible survey of a CR unit, please contact an FDA person associated with the NEXT program or contact a state radiation control person who may be able to assist in the matter.

If you have questions regarding these survey procedures while at the facility, you may contact David Spelic or Richard Kaczmarek for assistance: dcs@cdrh.fda.gov

FACILITY DATA

Facility Identification

Facility Name: Enter the name of the hospital, medical group, or corporation at which the x-ray system is located. Otherwise use the name of the physician, so forth, if the x-ray system is located in a private office.

Person Interviewed: Write the initials, last name and title or position of the person who provided the information regarding the system.

State Code

Select the appropriate two letter or two digit code from the Table of State and Agency Codes (Section A, NEXT Supplement - Codes and Addendum) and enter in the space provided.

STATE CODE

EXAMPLE

| V | A |

Facility Identification Number

Enter the facility identification number. This is an identification number assigned by your State program. Space is provided for ten (10) characters. If your identification number has less than ten (10) characters enter it with leading blanks as appropriate. **The number may NOT be totally blank.** Letters or numbers may be used in any combination. Hyphens (-) are acceptable but **no other symbols are allowed.**

FACILITY IDENTIFICATION NUMBER

EXAMPLE

|2|3|4|5|6|B|7|C|3|2|

or if less than 10 digits:

FACILITY IDENTIFICATION NUMBER

EXAMPLE

| | | | |B|7|C|3|2|

Date of Survey

Enter the date on which the survey was done. Note the boxes are for month, day, and year, in that order. Always use two-digit numbers. For example: September 26, 1998 would be coded:

DATE OF SURVEY

EXAMPLE

|0|9|2|6|9|8|
MO DAY YR

Tube Number

Enter the tube number here. This five-digit number is to be assigned by the surveyor in a manner such that no two tubes within a given facility have the same tube number. Letters and numbers may be used in any combination. Hyphens (-) are acceptable but no other symbols are allowed; leading blanks are acceptable. It may be helpful to further identify the tube in the comments section by giving information pertaining to the make and type of x-ray machine and room number so that if the facility is re-surveyed, the same number can be assigned to the same tube. One method might be to use the last five digits of the tube's serial number for ease of identification.

TUBE NUMBER

EXAMPLE

|2|B|-|8|5|

Type of Facility

Determine the type of facility from the list below and enter the corresponding code in the boxes. If code 99 (meaning "other") is used, please specify the type of facility under Surveyor's Comments.

TYPE OF FACILITY

EXAMPLE

|0|1|

In selecting codes for facilities where more than one code would apply, use the first applicable code listed. For example, a medical school hospital could be coded "02 hospital" or "05 school" under Type of Facility. The proper code will be "02 hospital" since it appears first on the list.

Type of Facility Codes

- 01 = Private Practice:* An individual practitioner or a group of practitioners engaged in the same specialty. This includes a group of general practitioners. *If 01 is used then Type of Practice must also be coded.*
- 02 = Hospital:* A facility that has beds for overnight care of patients.
- 03 = Multiple Specialty Practice:* A group of practitioners having different specialties. This includes school infirmaries and clinics.
- 04 = Mobile Unit:* An x-ray machine transported by motor vehicle.
- 05 = School:* An educational institution. School infirmaries or clinics are coded 03. Medical school hospitals are coded 02.
- 06 = Private Laboratory:* A commercial facility that takes diagnostic radiographs by prescription but is not involved in film interpretation.
- 07 = Health Agency:* Voluntary and governmental health agencies that do not fall under any of the above categories.
- 08 = Industry:* A plant dispensary or first-aid station.
- 09 = Nursing Home:* A facility with provisions for long-term care of patients.
- 10 = Breast Clinic:* A facility specializing in mammography and breast disease.
- 99 = Other:* Enter a brief description on a comment line.

Type of Practice

This code is applicable only to private practice. If the Type of Facility is coded "01" Private Practice, determine the type of practice from the code list below and enter the appropriate code. If the facility is not coded "01" Private Practice, code type of practice the boxes "XX."

Type of Practice Codes

01 = DENTAL (EXCEPT ORTHODONTICS)	08 = PEDIATRICS
02 = ORTHODONTICS	09 = ORTHOPEDICS
03 = MEDICAL G.P.	10 = GASTROENTEROLOGY
04 = RADIOLOGY	11 = CHIROPRACTIC
05 = INTERNAL MEDICINE	12 = PODIATRY
06 = SURGERY	13 = OSTEOPATHY
07 = UROLOGY	14 = OB/GYN
	99 = OTHER

TYPE OF PRACTICE

EXAMPLE

|0|3|

Type of Hospital

This section is applicable **only** if you selected code 02 (Hospital) for 'Type of Facility' code on page 10. Indicate below whether the hospital facility is a standard full-service hospital or one that specializes in pediatric care. To be specific, a pediatric hospital is a facility that is strictly classified as being such a facility (e.g., "Childrens' National Medical Center").

N = Non-pediatric (standard) hospital facility

P = Hospital that specializes **ONLY** in pediatric care. Only pediatric patients are treated at this facility.

D = Hospital having a DEPARTMENT that specializes in pediatric care. This type of facility should have a radiology department that serves **ONLY PEDIATRIC PATIENTS**. However, adult patients are also treated at this type of hospital.

EXAMPLE :

TYPE OF HOSPITAL

|N|

Facility Units

Determine the total number of x-ray units in the facility that are routinely used for performing the projection being surveyed: **pediatric chest**. Record this in the boxes provided.

Number of Units in Facility for this Projection

EXAMPLE

|0|1|0|

Total Facility Weekly Projection Workload

Enter the number of PEDIATRIC CHEST projections taken normally in this facility per week. The actual workload or an estimate must be entered with a minimum of one projection per week. Take some time to assure this value is as reliable as possible.

The workload refers only to the specific projection selected and should reflect the number of **PATIENTS, NOT THE NUMBER OF FILMS!** For example, if the projection selected is the pediatric (AP), and 200 patients per week are given AP and lateral pediatric films, the projection workload is recorded as 200 NOT 400 for the facility.

TOTAL FACILITY WEEKLY
PROJECTION WORKLOAD

EXAMPLE

|2|0|0|

Total Tube Weekly Projection Workload

Enter the total number of these projections taken normally with this tube per week. The actual workload or an estimate must be entered with a minimum of one projection per week. Take some time to assure this value is as reliable as possible.

The workload refers only to the specific projection selected and does not include any other films of that particular series. For example, if the projection selected is the pediatric (AP), and 50 patients per week are given AP and lateral pediatric films, the projection workload is recorded as 50 NOT 100.

TOTAL TUBE WEEKLY PROJECTION WORKLOAD

EXAMPLE

|0|5|0|

EQUIPMENT DATA

Year of X-Ray Control Manufacture

Determine as best possible the year of manufacture for the x-ray control unit. Often this is indicated by a label on the x-ray unit. Code the boxes XX if this information is not available.

YEAR OF X-RAY CONTROL MANUFACTURE

EXAMPLE

|8|5|

X-Ray Control Manufacturer

Determine the manufacturer of the x-ray unit and write the name in the space provided. Determine the code for the manufacturer from the list in Section B, NEXT Supplement - Codes and Addendum and enter the appropriate code in the boxes.

X-RAY CONTROL
MANUFACTURER

EXAMPLE

|C|G|R|M|

TYPE OF EQUIPMENT

Determine which category best describes the radiographic unit you will be surveying.

- S = Standard radiographic unit with a conventional x-ray tungsten/tungsten alloy tube.
- C = Computed radiography (CR) unit, using a storage phosphor cassette to produce x-ray images.
- D = Other digital form of x-ray detection. These units may use conventional tungsten targets but will have some other means of digitally detecting the x-ray image other than CR storage cassettes.

TYPE OF EQUIPMENT

EXAMPLE

|S|

Generator Phase

Determine whether the system is single-phase or three-phase, using one or more of the following methods:

- a. Consult the user information provided by the high-voltage generator or x-ray control manufacturer.
- b. Many times the manufacturer lists the phase of the system along with other electrical characteristics on the identification plate of the high-voltage generator.
- c. Observe the time settings on the control panel. Single-phase timer settings are usually expressed as common fraction multiples of 1/120 second, while three-phase system usually have timer settings expressed as decimals. Select the code from the list and enter in the box provided.

Generator Codes

S = Single-phase
T = Three-phase (Not falling load)
F = Three-Phase Falling Load
D = DC Filtered or Capacitor Discharge
C = Constant Potential
H = High Frequency
U = Unknown

GENERATOR
PHASE

EXAMPLE

|T|

Scatter Suppressor

Determine the method of scatter suppression, code (G) if grid, (A) if air gap, or (N) for no scatter suppression used. If the suppression technique cannot be determined, enter "U" for unknown in the box. An air gap for purposes of this survey is considered to be a gap BETWEEN THE PATIENT AND IMAGE RECEPTOR exceeding 5 inches (12.7 cm). If both air gap and grid are used, code scatter suppressor "A" and indicate proper grid ratio.

Scatter Suppressor Codes

G = Grid
A = Air Gap
N = None
U = Unknown

SCATTER SUPPRESSOR

EXAMPLE

|G|

Grid Ratio

If a grid is used as a scatter suppressor, determine from the operator the grid ratio. If the operator does not know and the grid is easily removed from the unit, have the operator remove the grid. The grid ratio should be marked on the grid. In units with automatic film changers, the grid may not be readily accessible. For many of the film-changer units, the installer has marked the grid ratio on the outside of the unit. If the unit does not use a grid, code the boxes "XX". If the grid ratio is not obtainable, code the boxes "UU" for unknown.

GRID RATIO

EXAMPLE

|1|2| : 1

**Film Brand, Film Type,
Screen Brand, Screen Type**

Determine from the operator the film-screen combination used with this tube/projection. Record this combination on the lines provided and from Appendices D and E determine the film and screen codes, respectively, and enter in the appropriate boxes. If the film/screen codes are not on the list, write the complete names, and the name, address and telephone number of the supplier in the comment section.

NOTE: *If computed radiography is used, enter CRAD for the film brand, AND write the vendor name (e.g. 'FUJI') below the FILM BRAND entry. Leave blank the film type, screen brand and screen type.*

	FILM BRAND	FILM TYPE
<u>EXAMPLE</u>	<u> E K C O </u>	<u>R O C </u>
	<u>KODAK</u>	<u>ORTHO-C</u>

and...

	SCREEN BRAND	SCREEN TYPE
<u>EXAMPLE</u>	<u> E K C O </u>	<u> L N M </u>
	<u>KODAK</u>	<u>LANEX MED</u>

Film Size

Enter the film size that the facility typically uses for pediatric exams in inches or centimeters. The **transverse** is the dimension across the body, the **vertical** is the dimension along the long axis of the body (head to toe). Be sure to specify the units of measure.

Example:

FILM SIZE:	Transverse	Vertical	Units
	1 1 .0	1 4 .0	I N

PATIENT RESTRAINT Information

Ask the technologist whether the facility typically uses a patient restraint device for pediatric patients: **the standard NEXT pediatric patient for this survey is a 15 month old 24 pound child.** If the facility has more than one, then record the facility's 'first choice' for a standard pediatric chest exam.

Select from the codes below the appropriate category for means of restraining the pediatric patient, and fill in the code as illustrated by the example below.

- 1 = pigg-O-stat
- 2 = any other form of restraining chair in which the child **sits** upright.
- 3 = papoose board or any other *ADDITIONAL* flat surface that the child **lies** on and is restrained by.
- 4 = restraint provided by adult
- 5 = no restraint used

PATIENT RESTRAINT

EXAMPLE

|4|

NOTE: If it is possible to obtain the vendor name of the restraining device, please write this information on one of the comment lines provided on the survey form.

TECHNIQUE DATA- General Instructions

At this time ask the technologist to configure the x-ray unit as it would be for a pediatric chest exam of the standard NEXT pediatric patient: **a 15 month old infant weighing 24 pounds**. This includes the following:

1. **Position any patient restraining device** that may be used during clinical exams. This is especially important for upright exams where the source-to-film distance is determined by where the technologist positions the restraint device such as a Pigg-o-stat.
2. **Provide a loaded film cassette** and load the cassette into the holder OR position the cassette as it would be clinically (see NOTE below).
3. **Set the x-ray unit** for the appropriate orientation (upright or table top) and the source-to-film and source-to-table top distances.
4. **Inspect the restraining device** (if one is used) and determine whether the device introduces additional material into the useful x-ray beam. If so, you will use the brown Plexiglas filter with the phantom. This is discussed further in the section on phantom set-up.
5. **Configure the x-ray unit** for the exposure mode (manual/AEC) and select the technique factors appropriate for the pediatric exam.

Pediatric Technique Methods

NOTE: Although the typical film size used for this examination was recorded above, it is recommended that for the purposes of this survey that a film size minimally of dimensions 11" x 14" be used to ensure adequate coverage of the x-ray field. Be CERTAIN, however, that you use film of the SAME BRAND AND TYPE, if you make this change.

Determine how the facility sets their techniques for the pediatric patient from the categories below. Fill in the appropriate response as illustrated by the example.

- 1 = Based on patient's age ALONE
- 2 = Based on patient's weight ALONE
- 3 = Based on patient's AP thickness ALONE
- 4 = Both age AND weight are considered.
- 5 = Both age AND AP thickness are considered.
- 6 = Both weight AND AP thickness are considered.
- 7 = same technique is used for ALL pediatric INFANTS up to a certain age (such as 3 or 4 year old).
- 8 = Other - **DESCRIBE ON COMMENTS LINE**

TECHNIQUE METHODS

EXAMPLE

| 1 |

Source-To-Film Distance (SID)

MEASURE the source-to-film distance in inches or centimeters, and enter it in the space provided. Estimate to the nearest tenth of an inch or centimeter. If the SID is provided by the technologist, verify with a measurement.

NOTE:

☞ The source is the x-ray tube target. For tube housings where the tube target location is unknown, assume that the source is two inches toward the tube port from the central axis of the tube housing.

☞ For cassettes, assume the film to be at the center of the cassette.

Distance from source to: FILM(SID)

EXAMPLE |1|7|1|.5|

SKIP THE SPACE FOR entry of SOURCE-TO-FRONT PLATE / TABLE TOP DISTANCE. Enter the units used for the distance measurements in the boxes as "IN" for inches or "CM" for centimeters.

MEASUREMENT UNITS (in/cm)

EXAMPLE |C|M|

SOURCE-TO-FRONT PLATE / TABLE TOP DISTANCE

At this time the restraint device should still be positioned as it would for clinical exams. Measure the **SOURCE-TO-FRONT PLATE / TABLE TOP** distance. The pediatric patient may be positioned so that the child's back, for example, is several centimeters forward of the film cassette (instead of resting directly against it). ***Inquire with the technologist if you are unsure of this position.*** This is an important measure because you will need to position the phantom at this same location as best possible.

Distance from source to:

FRONT PLATE/TABLE TOP

EXAMPLE

|1|6|5|.4|

USE THE SAME UNITS (cm or inches) as you did when you recorded the SOURCE-TO-FILM distance.

Selected technique factors

Exposure Mode

There are two general types of systems: manual and automatic exposure controlled. If the unit is normally operated in the manual mode for this examination then code the box "M" and survey the unit in the manual mode. If the unit is normally operated in the automatic exposure controlled mode for this examination then the survey should be done in that mode and the box coded "A."

M = Manual A = Automatic

EXPOSURE MODE

EXAMPLE |A|

Projection View

Enter the two-character code that indicates the type of view for the survey- either AP or PA view. ***Be certain your phantom is configured for this view, especially if you have previously performed a survey having a different projection view!*** See appendix A.

AP or PA

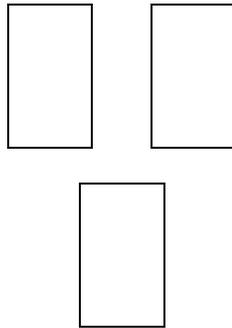
Projection View

EXAMPLE |A|P|

Detector Configuration

AEC Units Only. Ask the operator what detector configuration is used for the projection. Most AEC units are of the three detector type; these units should be coded according to the configuration code list shown below. If the unit is not one of the three detector types, code the configuration as "6," and indicate by a sketch, in the comment section of the form, the type of detector configuration if known. If the unit is not an AEC unit code the box "X." If you cannot determine the detector configuration, code the box "U."

Detector Configuration



- 1 = A & B Only
- 2 = A or B Only
- 3 = C Only
- 4 = A, B, and C
- 5 = A & C or B & C
- 6 = Other (Specify)

EXAMPLE

| 1 |

Density Setting (AEC ONLY)

Ask the technologist what density control setting is normally used for this projection. The first box can be coded as "+" or " - ", or blank. The second box can either be coded " N" for normal density or a numeric or letter value depending on the system. If the system is a manual unit then code as "XX." Shown below are two examples of data entry.

DENSITY SETTING

EXAMPLE

| | N |

or

EXAMPLE

| - | 1 |

kVp, mA and mAs *pre-selected* factors

☞ If the survey is done in the **Manual** mode....
(For AEC mode go to the next pg)

With the unit set up for an examination of the standard pediatric patient (the standard "NEXT" patient is a 15 month old, 24 lb infant), record the kVp and mA selected. If the mA is not preselected, then code the mA boxes "XXXX." Record the time and/or mAs as described in 4 below (see note).

	<u>SELECTED kVp</u>	<u>SELECTED mA</u>
<u>EXAMPLE</u>	0 6 0	1 0 0

Pre-selected Time and mAs

If time is preselected as part of the technique then record it in the appropriate boxes. Time values are recorded in **seconds**. Some units have preselected mAs; for these units record the mAs value selected in the boxes and code mA boxes and time boxes with Xs (see note). If the exposure time is given in fractional decimal format such as 1/10, 2/10, etc., then record these values on a comment line as shown below.

EXAMPLE

<u>M A N U A L M O D E O N L Y</u>	
Selected TIME (sec)	Selected mAs
0 . 0 2 5	and/or 0 0 6 7

Record **decimal fractions** on the comment line. For Example,

Comments Exposure time setting was at 1/5 th of a second

or.....

☞ If the survey is done in the **AEC** mode.....

With the unit set up for an examination of a standard patient (as defined above), record the kVp and mA selected. If the unit is falling load (mA not preselected), code mA as "XXX."

	<u>SELECTED kVp</u>	<u>SELECTED mA</u>
<u>EXAMPLE</u>	0 6 0	1 0 0

NOTE: The purpose here is to capture the facility's SELECTED technique factors. DO NOT use the MDH meter values of exposure time at this point. Only those values that are selected PRIOR to exposure should be recorded here.

PHANTOM SET-UP FOR PEDIATRIC EXAMS

General Instructions

It is difficult to incorporate a restraining device into the survey exposure measurements to account for the additional attenuation such a device may add to the primary x-ray beam. Therefore, the brown Plexiglas filter will be attached to the phantom in order to simulate such a restraining device.

IT IS VERY IMPORTANT THAT YOU DETERMINE WHETHER THE FACILITY'S DEVICE PROVIDES ADDITIONAL ATTENUATION OF THE USEFUL X-RAY BEAM.

The following three sections describe set-up for the pediatric phantom based on how the facility performs their exams. Specifically the three sections discuss the following:

- A.** Beam collimation for Manual and AEC exposure techniques
- B.** Positioning the phantom based on patient restraint devices.
- C.** Placement of the imaging test tool

FOR EACH SURVEY:

1. **Review section A** for guidelines on collimation for manual and AEC set-ups.
2. **Follow section B** below for guidelines on positioning the phantom based on whether or not the facility uses any patient restraining devices.
3. **Refer to Section C** for positioning the test tool.

Section A. Beam Collimation for Manual Versus AEC Exposure Techniques

NOTE: *This section describes how to position the x-ray beam with respect to a bucky or stand-alone film cassette for manual and AEC modes. Note that the phantom is not yet positioned for the survey.*

1. Manual Technique

- a. If a manual technique is normally used, center the x-ray beam onto the film cassette and adjust the field size to a 10" x 10" projection onto the front plate / table top or film cassette. Have the technologist assist with this as necessary.

NOTE: If a restraining device such as a Pigg-O-Stat is used, collimate the beam while the film cassette is positioned in the restraining device.

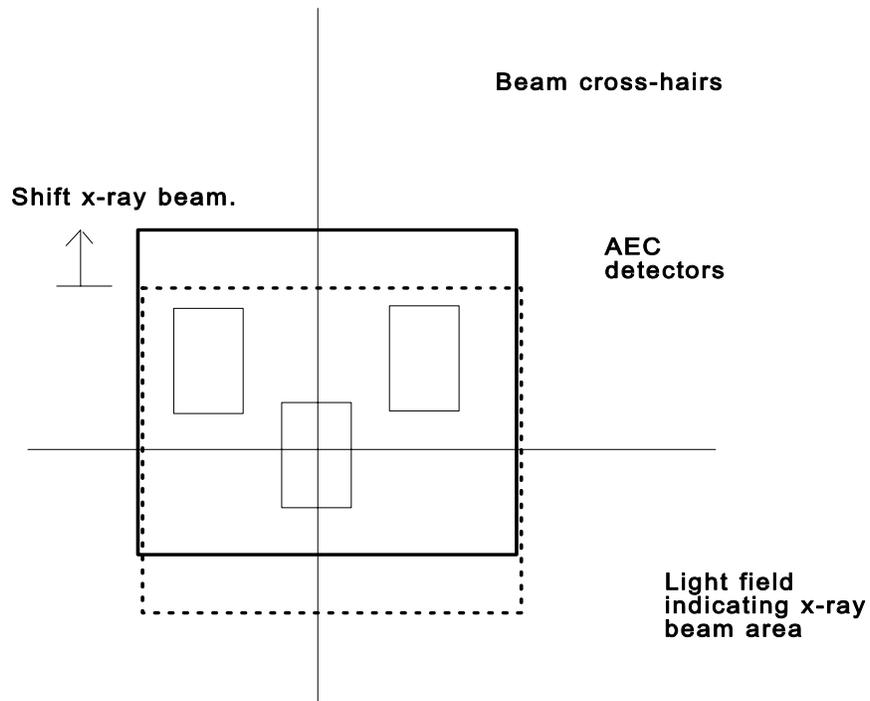
- b. You are all set to position the phantom into the collimated beam. Refer to section B for the applicable set-up geometries.

2. AEC Technique

- a. If an automatic exposure control (AEC) technique is normally used, first collimate the beam to a 10" x 10" field size at the patient support surface.

NOTE: If a restraining device such as a Pigg-O-Stat is used, collimate the beam while the film cassette is positioned in the restraining device.

- b. Adjust the tube until the beam is centered horizontally and vertically with respect to the film cassette.
- c. Align the x-ray beam vertically with the left and right detectors as illustrated below. This will ensure that the AEC detectors are within the x-ray beam and attenuated by the phantom. You may need to verify that the film cassette is centered in the beam after this step.



- d. If possible, verify that you have adequately covered all detectors- the technologist may be able to verify this. (Also, many units have the detectors outlined on the face of the front plate or delineated with a light field.)
- e. Refer to section B for the exact positioning of the phantom.

Phantom Set-up

You may now remove the facility's restraining device. Position the phantom for either AP or PA measurement using the following guidelines for the type of orientation and patient restraint. Refer to the appropriate section listed below.

-
- Section:**
- I. Upright exams with a patient restraint device
 - II. Upright exams with no patient restraint device
 - III. Table top exams with a patient restraint device
 - IV. Table top exams with no patient restraint device
-

Section I. For upright exams done with a restraint device: pigg-O-stat, restraining chair, etc.

If the facility performs the exam without using a wall bucky, then you will be performing the survey with the phantom positioned on the table top. Follow instructions 1 through 7 below. If the facility uses a wall bucky, then refer to page 36 instructions for phantom set-up. **It is important** that the geometry that you determined earlier with the restraining device in position (i.e. SID and patient to front plate/table top distances) be reproduced at the table top/bucky.

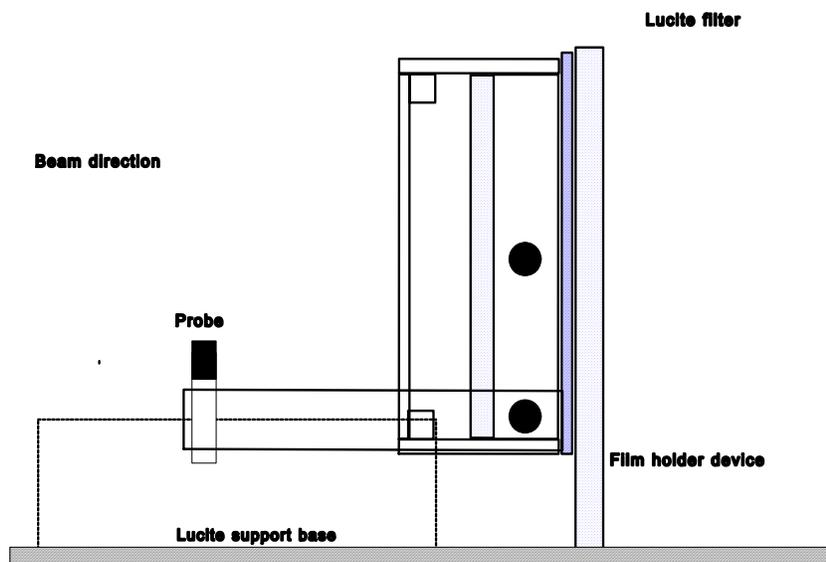
For set-up without a wall bucky:

1. Attach the phantom to the provided plastic support base and set the phantom upright near the end of the table top. **VERIFY THAT THE 'HEAD'** direction of the phantom is properly oriented.
2. If the plexiglas filter is to be used, attach the plexiglas filter to the BACK of the phantom (the surface facing AWAY from the target, TOWARD the film cassette.)
3. Adjust the x-ray tube position with respect to the phantom such that the SOURCE-TO-FRONT PLATE/TABLE TOP distance is in agreement with the value you determined from the technologist.

NOTE : The x-ray beam should already be collimated.

4. Position the film cassette such that the SOURCE-TO-IMAGE distance is in agreement with the value you determined from the technologist. (If the pediatric patient rests directly against the film cassette, for example, then the film cassette would be positioned directly against the 'back' of the phantom.) The film cassette may need to be elevated so that it is centered with the phantom- most facilities will have positioning foam which can be used for this.
5. Place the MDH probe into the probe holder. *Check that the probe is fully within the x-ray field* as indicated by the light field. If there is doubt, extend the collimated field outward to incorporate the probe.
6. **Check the collimation-** The beam should extend to the edge of the phantom on all four sides. Especially verify that the probe is within the x-ray field as indicated by the light field.
7. Refer to Section C for proper placement of the imaging test tool.

Check your set up with the illustration below.



Side view of Plexiglas filter placement for simulation of patient restraint device. Here the film cassette is shown positioned directly against the phantom. Other geometries may require that there be a small gap between the back of the phantom and the film cassette.

For set-up with a wall bucky:

1. Attach the phantom to the plastic support base and position the phantom so that the surface facing the wall bucky is positioned at the same distance (source-front plate/table top) you determined with the restraining device in place. The phantom (as with the pediatric patient) may not be resting directly against the front plate! Ensure that any relevant AEC detectors, if so used, are adequately covered.
2. Make sure that the brown plexiglas filter is attached to the phantom on the side facing the wall bucky.
3. Place a loaded cassette into the holder.
4. Attach the MDH probe into the probe holder on the phantom.
5. **Check the collimation-** The beam should extend to the edge of the phantom on all four sides. Especially verify that the probe is within the x-ray field as indicated by the light field.

Section II. Upright exams done with no form of patient restraint device.

1. Place the phantom directly against the patient support unit- wall Bucky, film cassette, etc., so that the phantom is centered within the collimated beam. You may need to attach the plexiglas phantom support stand to assist in properly elevating the phantom in accordance with the form of exposure- manual or AEC, as outlined in Section A. **VERIFY THAT THE 'HEAD'** of the phantom is properly oriented.
2. Place the MDH probe into the probe holder.
3. **Check the collimation-** The beam should extend to the edge of the phantom on all four sides. Especially verify that the probe is within the x-ray field as indicated by the light field.
4. Refer to Section C for test tool placement.

Section III. Table-top exams with patient restraint device

1. Place the Plexiglas filter onto the table top within the area of collimation that prepared in Section A above.
2. Place the phantom directly onto the Plexiglas filter. Verify that the HEAD of the phantom is properly oriented (Note the markings on the phantom indicating the orientation of the HEAD).

NOTE: Manual and AEC technique surveys should follow the same steps above. You should have already collimated the beam and adjusted the beam coverage of any pertinent AEC detectors in Section A.

3. Verify that the phantom is centered with the beam as indicated by the light field. This is especially important if AEC mode is used.
4. Attach the MDH probe to the probe holder.
5. **Check the collimation-** The beam should extend to the edge of the phantom on all four sides. Especially verify that the probe is within the x-ray field as indicated by the light field.
5. Refer to Section C for proper placement of the test tool.

Section IV. Table top exams without a patient restraint device.

1. Place the phantom directly onto the patient support surface so that the phantom is centered within the collimated beam. The beam should already be collimated and properly positioned for AEC exposures, if applicable. **VERIFY THAT THE 'HEAD'** direction of the phantom is proper.
2. Place the MDH probe into the probe holder.
3. **Check the collimation-** The beam should extend to the edge of the phantom on all four sides. Especially verify that the probe is within the x-ray field as indicated by the light field.
4. Refer to Section C for test tool placement.

Section C. Placement of the imaging test tool

General Instructions

Place the test tool on the phantom as shown below for the PA and AP projections. Since the phantom has a spine and heart insert, the test tool must be placed such that it does not overlap the inserts OR ANY RELEVANT AEC DETECTORS. Generally the test tool is placed on the side opposite the MDH probe, and toward the 'feet' end of the phantom, lengthwise, to avoid as best possible, interference of the L and R AEC detectors, if so used. Two diagrams below illustrate the placement of the test tool for PA and AP projections. **When you have positioned the test tool**, continue to the page for Source-To-Front Plate / Table Top Distance verification.

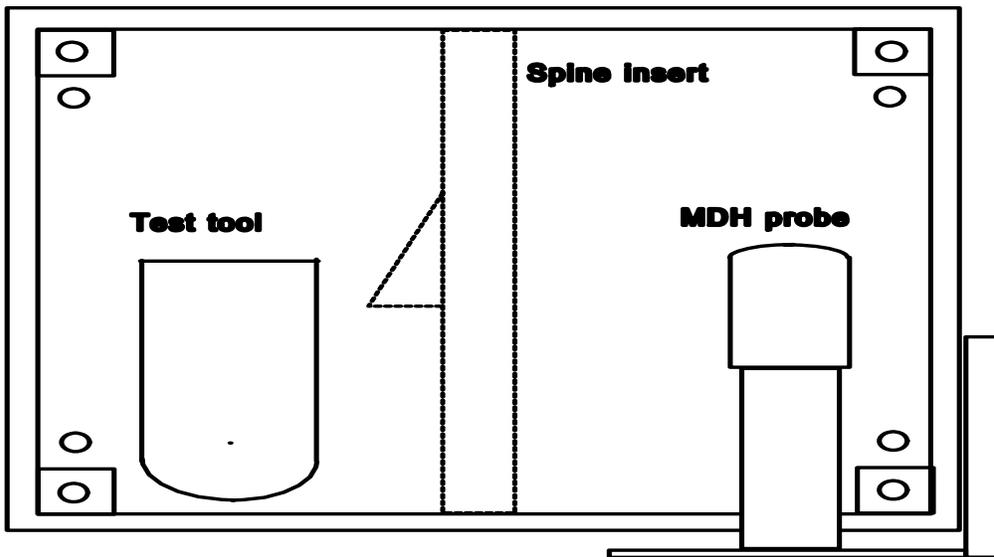
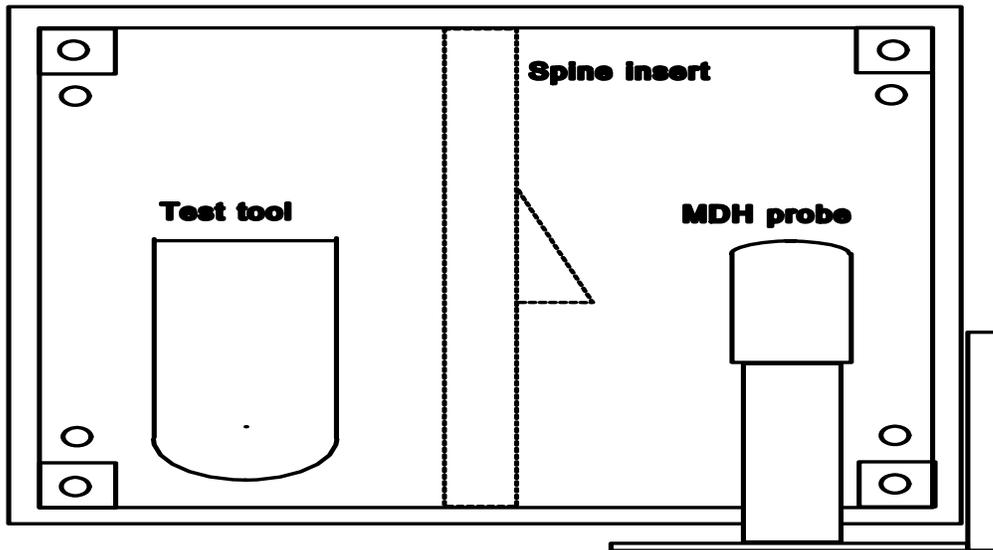


Illustration of placement of imaging test tool for PA orientation



Placement of imaging test tool for the AP view. **Note the only difference** between this set-up and the above one for PA view is that the heart shadow now is on the RIGHT side of the spine insert.

Important!
Check your film images to be sure that the test tool is imaged completely, and is not obscured in any manner.

VERIFY your SID and Source-to-Front Plate/Table Top Distances

At this time RE-MEASURE the SID and Source-to-Front Plate / Table Top distances especially if you are doing an upright exam. This will serve as a check for your set-up, since the phantom should be positioned relative to the tube where a patient would be.

If the values you obtained after re-measuring are not in agreement with the values you determined, then you need to check your set-up.

EXPOSURE DATA

BEFORE YOU GO ANY FURTHER, *Is your phantom correctly assembled for either AP or PA exams? Is the orientation of the HEAD correct?* Check these before proceeding.

You will be making a total of **four** exposures during this part of the pediatric survey. **Two** good phantom films will be required: One will be used for image quality evaluation, and a second one will be needed for darkroom fog evaluation. Since the darkroom fog test is done after you have completed this section, it is suggested that you use the last exposure to make a second, good phantom image. Hence...

<i>1st exposure measurement valuation.</i>	<i>--></i>	<i>obtain phantom film- for image quality</i>
<i>2nd and 3rd exposure measures</i>	<i>--></i>	<i>can use same piece of film- no images required.</i>
<i>4th exposure measurement</i>	<i>--></i>	<i>obtain second phantom film- for darkroom fog.</i>

***Each exposure should be taken with the SAME cassette,
loaded with film !!***

NOTE:

***The operation of the MDH meter is explained in detail toward
the end of the NEXT Supplement document.***

MDH Exposure; MDH Measured Time

Before the MDH can be used to measure exposure time, it must first be initialized. Set the MDH selector switch to the "Pulse Exposure" mode. The pulse fraction threshold should be set at .2 for single-phase units and .5 for three-phase units. *If the phase of the unit is not known, use a threshold of .5.*

CAUTION

Do NOT manually reset the MDH to zero between exposures.

Without making any changes in the standard patient techniques, and with the phantom and MDH probe properly positioned :

1. **initialize the MDH** by making an exposure.
2. **Record this exposure** as Exposure 1; **DO NOT RECORD THIS EXPOSURE TIME** from the MDH meter.
3. **Process** the film and reload the **SAME** cassette.
4. **Inspect the processed film** for quality- check especially that the probe **AND** test tool are fully imaged.
5. **If the film is acceptable**, label the film with the facility name, date and 'Pediatric phantom film'.

Your MDH meter is now initialized from exposure 1 above, and you are ready to make subsequent exposures.

6. **Make two more exposures** with the same **loaded** cassette. (A good phantom film is not needed for exposures 2 and 3, hence use the same piece of film.) For each exposure, record the exposure measurement in the appropriate space on the data form. Next, switch the MDH to the "Pulse Duration" mode and record the displayed exposure time as "MDH Time" on the survey data form. **PAY ATTENTION TO THE UNITS OF TIME DISPLAYED ON THE METER READOUT.** The MDH can display either milliseconds OR seconds. The film in your cassette can then be discarded.
7. For your **fourth** exposure, reload the **SAME** cassette with a new piece of film. Make your fourth exposure and record the exposure and time on the survey form. **DO NOT PROCESS THIS FILM YET.** Place a marker (POST-IT note, etc.) on the edge of the film cassette toward the head orientation of the phantom. This will aid in positioning the fog folder when you perform the darkroom fog evaluation.

When you measure darkroom fog you will be using the film from the final (fourth) exposure. Check the optical density of your first phantom film before removing the phantom for an optical density of about 1.2 or greater.

IF YOUR FIRST PHANTOM FILM HAS AN OPTICAL DENSITY BELOW 1.0:

Make a FIFTH phantom film, adjusting the exposure to increase the optical density to above 1.2. For the fog test to be valid, the OD must be high enough such that the film is indeed sensitive to fogging.

Below are examples of entering your values of exposure and time measurements.

If your MDH meter displayed an exposure of 17.4 mR and an exposure time of 33.8 milliseconds, then records these data as follows.

	<u>MDH EXPOSURE 2</u>	<u>MDH TIME 2</u>
<u>EXAMPLE</u>	0 0 1 7 .4	0 0 3 3 .8

If the exposure or time is less than 100, the MDH value should be recorded to the nearest tenth. For example, 78.4 mR would be coded:

	<u>MDH EXPOSURE 2</u>
<u>EXAMPLE</u>	0 0 7 8 .4

If the time or exposure exceed 99.9, Then the right most box will be coded zero. For example, 102 msec would be coded:

	<u>MDH Time 2</u>
<u>EXAMPLE</u>	0 1 0 2 .0

If the exposure or time are greater than 1 R or 1 sec respectively, the values are recorded as 1000 mR per R or 1000 msec per second. For example, 1.2R and 1.4 seconds would be coded:

	<u>MDH EXPOSURE 2</u>	<u>MDH TIME 2</u>
<u>EXAMPLE</u>	1 2 0 0 .0	1 4 0 0 .0

PHANTOM IMAGE QUALITY EVALUATION

Image Evaluation

Using the facility's viewbox, determine the number of low contrast holes you can observe on the disc and the number of high contrast meshes (grids) you can observe on the radiograph.

1. Meshes are counted if a rectangular pattern can be clearly discerned.
2. Holes are counted if the circular periphery of the hole can be visualized.
INCLUDE THE CENTER HOLE IN YOUR COUNT.

	Number of <u>Holes Seen</u>	Number of <u>Meshes Seen</u>
<u>Example</u>	4	5

Phantom Film Density

In general you are asked to determine the film density of three regions on the phantom film:

- a. Background density of the phantom
- b. Central portion on the spine insert
- c. Heart shadow insert

The diagram on the following page illustrates where to measure the three densities specified above.

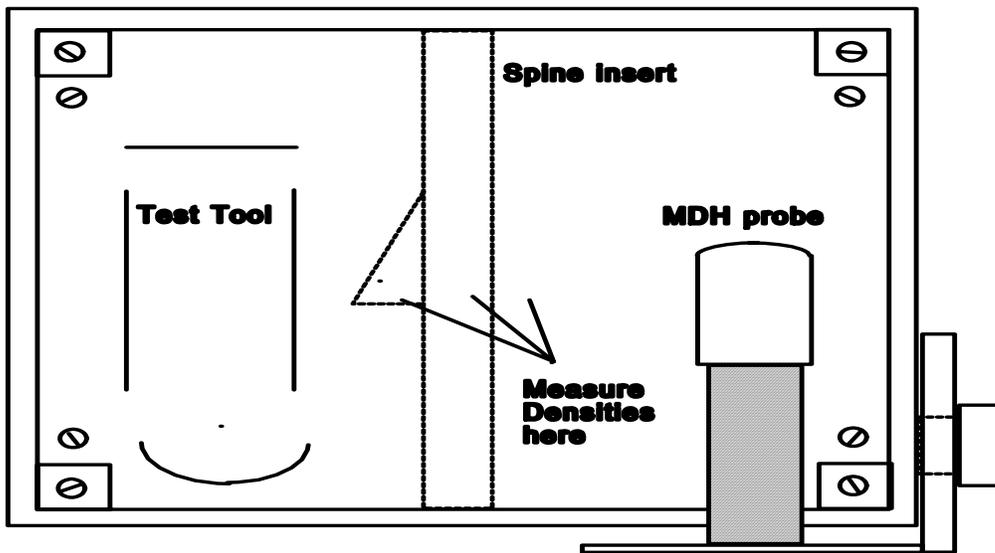


Illustration showing locations for measurements of phantom film optical densities.

NOTE:

1. Repeat the measure for each region to be sure your values are representative of the density levels on the film.
2. You may have to cut a slot in the film in order to access the above regions with your densitometer. But **DO NOT CUT INTO THE TEST TOOL IMAGE !**

The background optical density of the pediatric phantom films should be between 1.0 and 2.0. Densities substantially less than 1 or greater than 2.0 are questionable. The technologist should be questioned to see if they normally accept light or dark radiographs. If this is the case then the films are acceptable. If the films are not acceptable, have the technologist recheck the techniques used and check the facility's film processor by completing the STEP procedure. Poor processing can lead to lighter-than-normal films.

Background

EXAMPLE

| 1 | . | 3 | 7 |

HVL DATA

HVL's are to be measured in the manual mode using the following procedure:

- a. **Reduce** the distance FROM THE **SOURCE** TO THE **PROBE** to approximately 24 inches- this will provide an increase in the exposure to the probe without making a significant adjustment to the technique.
- b. **Adjust the phantom** so that the probe is now centered in the x-ray field.
- c. **Collimate to the smallest beam size** that still allows the beam to cover the sensitive volume of the probe.
- d. **Set the unit** to operate in the manual mode.
- e. **Verify that the kVp** selected is the same value used to obtain the exposure values for your phantom films.
- f. **Make an exposure.** If necessary, adjust the technique so that this first exposure with NO aluminum in the beam is above 500 mR.

Record your first exposure value as illustrated below, e.g., 885.0 mR is coded as 0885.0.

mR with 0 mm Al

EXAMPLE |0|8|8|5|.|0|

- g. **Securely tape** a piece of aluminum of thickness 1.5 mm over the front of the collimator and make a second exposure. Record the output in mR in the spaces provided for and exposure #2 respectively.

mR w/ 1.5 mm Al

|0|7|2|9|.|0| mR

- h. **MAKE successive exposures**, each time increasing the amount of aluminum by 1 mm. After each exposure record the MDH exposure reading corresponding to the total amount of aluminum placed in the x-ray beam.

Estimated HVL

Using the graph sheet provided, plot the exposure versus the aluminum thicknesses used. Determine the HVL to the nearest tenth of a millimeter of aluminum by drawing the best straight line fit to **all but the first (0 mm Al)** data points (see Supplement Section G).

ESTIMATED HVL

EXAMPLE |0|3|.6| mm

Darkroom Fog Measurement

The following procedure is to be used to measure the darkroom fog level. A darkroom fog test tool has been provided for this measurement and should be used whenever possible.

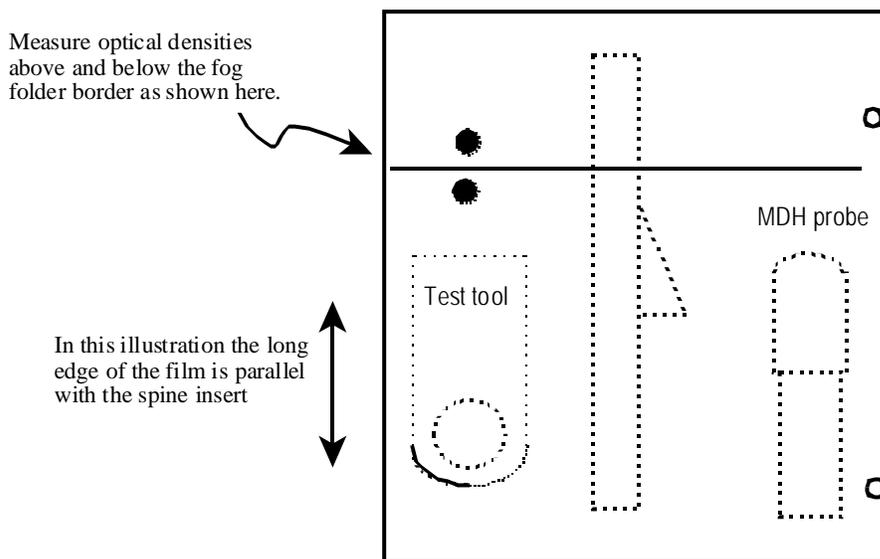
Use the final radiograph of the phantom (which should still be undeveloped) for this test. This will provide a test film with a region of uniform optical density, rather than the range of densities obtained using the Step-Wedge Method.

It is important that the film have a reasonable level of optical density (about 1.2 or greater) in order to be sensitive to slight levels of darkroom fog.

If your first phantom film is too light, then you may need to re-shoot another phantom film with suitable exposure to give a good dark film.

1. **Enter the darkroom** and if possible, locate a place where you can open the film cassette which is **not** directly below any overhead safelight.
2. **Quickly remove the film** from the cassette (note the orientation of the HEAD as indicated by marker on cassette and insert the film into the darkroom fog folder. *If possible* insert the film into the fog folder such that the edge of the folder would cut across the spine image of the phantom (see illustration next page).

3. **Position the film** and folder in an area of the darkroom, usually on the workbench, **closest to a safelight**. This should represent, in your opinion, an area where film is routinely handled and has the highest probably of safelight exposure. (If there appears to be another area in the darkroom which could contribute to darkroom fog you should evaluate that area also.)
4. **Expose the uncovered half** of the film to normal safelight conditions for two minutes. Make sure that you are not accidentally shielding the film from other potential fog sources such as other nearby safelight or digital light sources.



5. **After two minutes** have elapsed, quickly remove the film from the folder, and process normally.
6. **If a visible border** (corresponding to the folder) and the letters "**FOG**" appear on the film, record the optical densities of the unfogged and of the fogged areas of the film- Do this by reading the densities near the fog border (see illustration below). Subtract the two optical densities and record the fog level in the boxes provided.

IF THERE IS NO VISIBLE FOG LEVEL, then enter XX.X for both the unfogged and fogged optical densities and then enter 00.0 for the net fog level.

The reason for entering zero for the net fog density if you can not observe any visible fog is that typically the optical density fluctuations may be as much as any fogging which is present. Attempting to measure a level of fog which is not much greater (if at

all) than the random (or systematic such as heel effect) density fluctuations is not good physics !!

7. **Fogging can either be attributed** to improper bulb wattage, close safelight positioning, too many safelights, wrong safelight filter for the film processed, aged safelight, damaged safelight, or any combination of these factors.

Examples:

FILM DENSITY
w/o FOG

| 1 | . | 1 | 8 |

FILM DENSITY
w/ FOG

| 1 | . | 3 | 5 |

and...

DARKROOM
FOG LEVEL

| 0 | . | 1 | 7 |

FILM PROCESSOR EVALUATION

Processor Brand and Model
Chemistry Brand and Type

Determine from the operator the processor-chemistry combination used for the processing of the exposure films. Record the data on the lines provided and from Appendices F and G determine the processor and chemistry codes, respectively, and enter them in the spaces provided.

PROCESSOR BRAND
FUJI

PROCESSOR MODEL
RU

EXAMPLE | F | U | J | P |

| R | U | - |

CHEMISTRY BRAND
FUJI

CHEMISTRY TYPE
HIR

EXAMPLE | F | U | J | P |

| H | I | R |

Day light Processing

Indicate below with either a 'Y' or 'N' value whether the facility does daylight processing. If this is the case, it is requested that you still attempt to evaluate the processing. The STEP film should be of adequate size to accommodate the requirements of most daylight systems. *Ask the technologist for assistance if you are unfamiliar with these systems.*

DAYLIGHT PROCESSING
(Y/N)

EXAMPLE |Y|

Processor Speed Index: STEP

Here you will evaluate the quality of the film processing with the STEP test. You should conduct this test only if your sensitometer and densitometer have recently (within a year) been calibrated by CDRH. Control film explicitly for the STEP test is provided along with a worksheet for calculating the processing speed.

- ☞ If the facility has **daylight processing**, we ask that you attempt to evaluate this with the STEP test. The film provided should be adequate for the daylight systems to work with.

- ☞ If a **dedicated processor** is used, and attached to a standard film changer, you may not be able to use the STEP procedure. Inquire of the technologist if it is possible to feed in a flashed film. Do so if possible. If it is impossible, skip the STEP procedure and indicate why in the comment section.

EACH TYPE OF FILM (AND ALSO BATCH) HAS ITS OWN UNIQUE REFERENCE STEP NUMBER !! Be certain that you use the correct worksheet with the film you use for the STEP test. The NEXT survey control film provided for you should only be used with the worksheet provided. Use no other film.

IF you do not have a STEP form, you should still run a STEP film. FDA will compute the processing speed for the facility from the returned STEP film.

IMPORTANT : DO **NOT** USE MQSA FILM !!

Conducting the STEP test

1. **With the control film provided** for the project and the darkroom/processor servicing the x-ray unit/tube surveyed, flash the control film (with the sensitometer) once on each edge of the film (total of 4 exposures). Process this film normally as film from the x-ray unit surveyed would be processed.
2. **Zero the calibrated densitometer** and determine the optical density (OD) of the **base (background) plus fog** of the processed control film. Record in the space provided on the data form and on the STEP worksheet.
3. **Determine the speed density** by adding 1.00 to the optical density of the base (background) and fog. **Record** *this optical density on the plotting and worksheet form.*

Ex: Base plus Fog = 0.13 so.... Speed density = 1.13.
4. **Select the two steps** that have optical densities above and below the speed density. (The step number is labeled on the film.) Read the optical density of each of these two steps (once on each of the four sensitometric strips on the film), record this optical density as well as the steps selected on the worksheet. If one strip of densities is dramatically different from the remaining three sets, then discard the optical density values for this one 'bad' strip.
5. **Average the measured densities** for each step. On the worksheet form, plot the step number and the **average** optical density for the two steps you chose in step b, using the graph provided. Connect these two points with a straight line.
6. **Locate on the Y-axis** the optical density corresponding to 1+base+fog, and follow this over horizontally to the straight line you drew in step 5 above. After locating this optical density on the straight line, follow down to the x-axis and read of the resulting step number for this point. **NOTE THAT THIS WILL BE A FRACTIONAL STEP NUMBER**, such as 9.7 or 12.3.
7. **Using the look-up table on the STEP worksheet**, determine the resulting processing speed value. Record this value on the STEP form and on the data form.

STEP test result

EXAMPLE |1|3|1|

ALSO RECORD THE REFERENCE STEP FOR YOUR FILM- OBTAIN THIS NUMBER FROM THE FILM BOX YOU USED.

REFERENCE STEP NUMBER
FOR YOUR FILM

EXAMPLE |1|3| . |1|

RETURN THE STEP FILM ALONG WITH YOUR PHANTOM AND FOG FILMS.

NOTE:

1. **If the processing speed is very low** (below 70), **repeat the test** to be certain. Check your equipment for the proper color mode (green/blue).
2. **If the processing speed again results in a low value**, review your results for optical density and exposure values. If the exposure values seem reasonable, and the optical density is also good (around 1 to 1.6) then there is still a problem with the STEP test.

PHANTOM ASSEMBLY

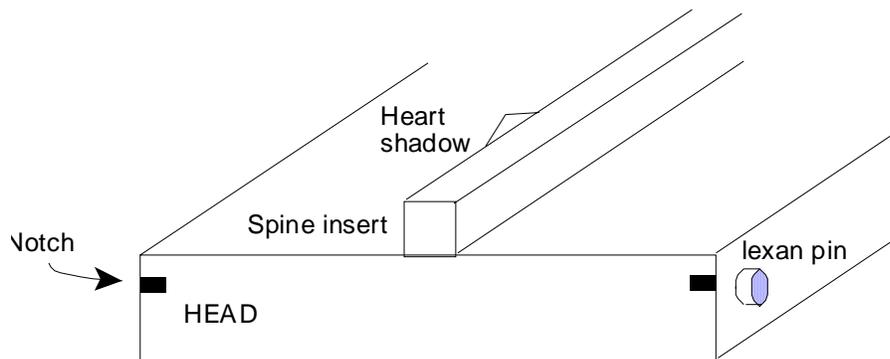
PHANTOM ASSEMBLY AND SET-UP PROCEDURE

The pediatric phantom was constructed with flexibility to allow for the simulation of both AP and PA exams. Follow the instructions below closely to avoid erroneous assembly of the phantom.

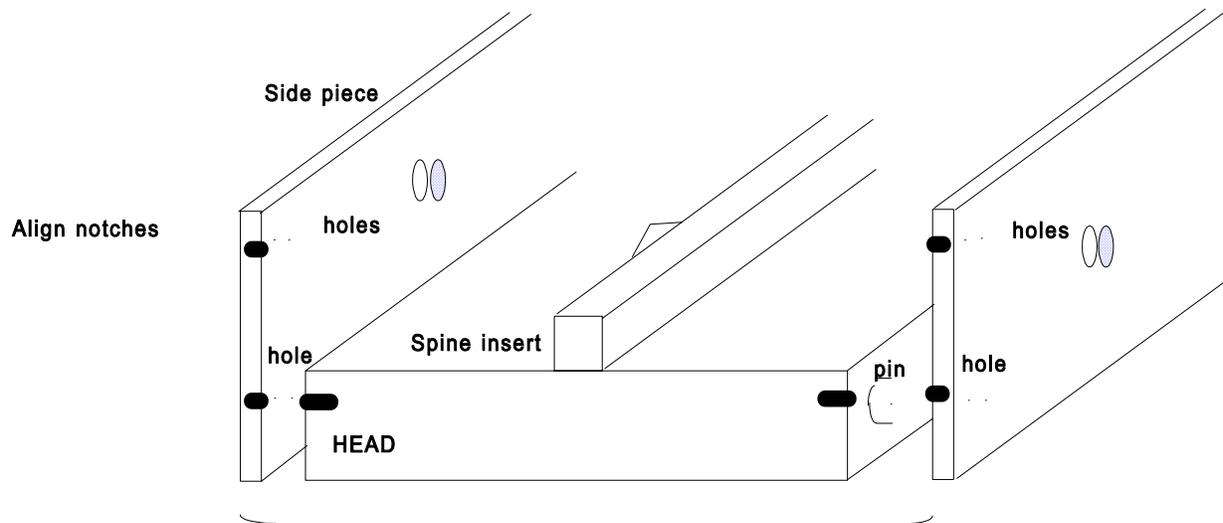
NOTE: The phantom was shipped with the actual body portion already assembled. It is recommended that you do **NOT** disassemble the actual phantom body by removing the Plexiglas side plates.

I. Phantom Body Assembly

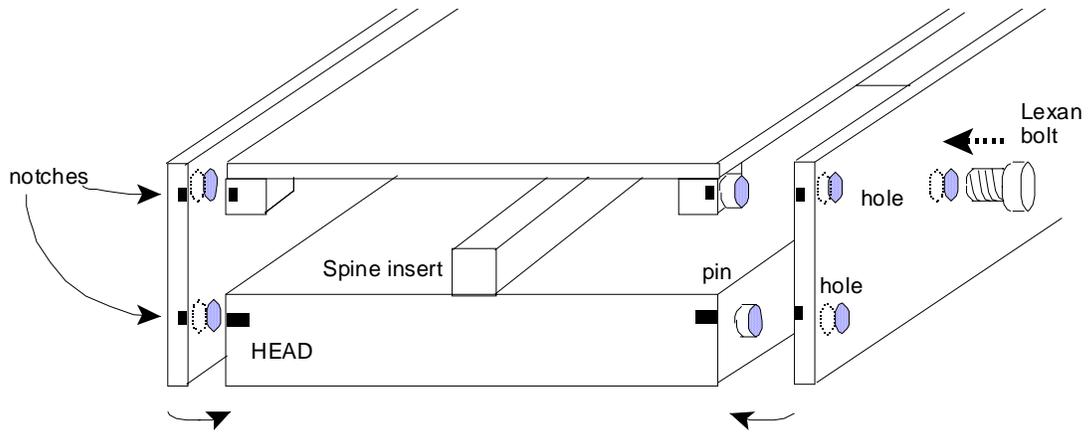
- A. Lay the thicker body panel which has the heart and spine inserts on a flat surface with the inserts facing upward. You should see the word 'HEAD', and two notches on one side edge of this phantom panel as illustrated below.



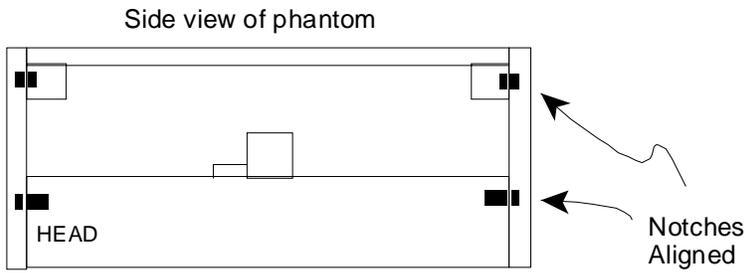
- B. Inspect each of the two Plexiglas side pieces for two similar notches on their edges as shown below. Loosely attach the two Plexiglas side pieces with provided Plexiglas bolts (do not tighten yet), such that the notches on all three pieces coincide with one another as illustrated below. **NOTE.** If done correctly, the etched letters 'FDA/CDRH' should be readable on one of the Plexiglas side pieces.



- C. Inspect the remaining (thinner) phantom body panel for two more notches. Install this remaining panel such that these notches align with the two remaining notches on the side pieces as shown below. Fasten the large Plexiglas bolts through the side pieces into the phantom and tighten.



Verify that your assembly is correct- the four sets of notches should be aligned as illustrated below.

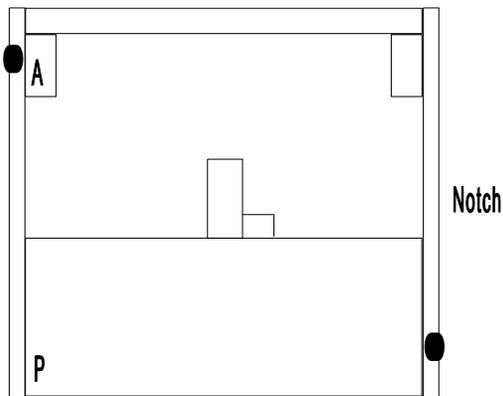


Placement of probe holder: AP vs. PA views

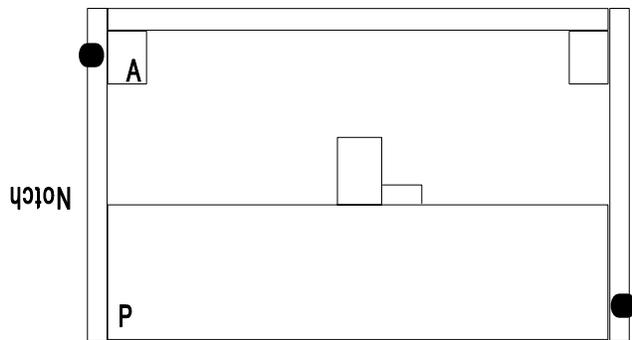
The phantom has two means of accommodating the probe arm, depending on AP or PA views.

1. Place the phantom on a smooth surface so that the anterior surface is oriented for the selected view as shown below. There should be a **single** notch in the upper left and lower right corners, and the letters 'A' and 'P' should be visible.

AP view



PA view



2. Attach the probe arm to the right hand side of the phantom using the Plexiglas bolt as illustrated below for the AP view. The probe arm is etched with a notch which will align with a similar notch on the phantom side piece when the probe arm is correctly installed.

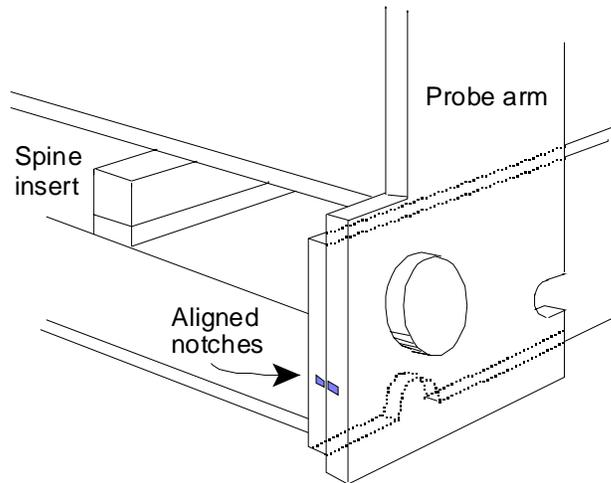
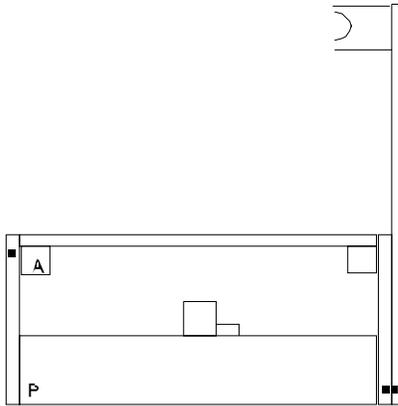
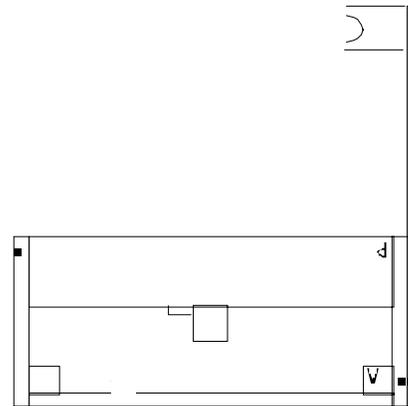


Illustration of proper mounting of probe arm to phantom for the AP view. Note the alignment of the notches in the above diagram.

3. Verify your installation of the probe arm for the selected view (AP or PA) from the diagrams below.



AP view



PA view

Final view of phantom for the AP and PA views.

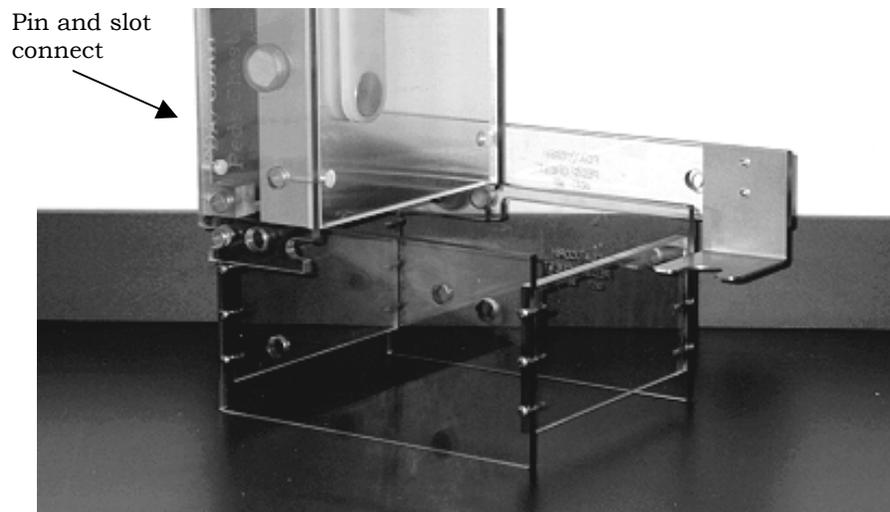
NOTE: The spine/heart insert of the phantom implies that it is possible to orient the phantom 'upside down' (heart shadow not in proper orientation) when positioning for radiographic measurements.

THE PROBE SUPPORT ARM IS POSITIONED TOWARD THE PATIENT'S FEET

Optional attachment of the Lucite base support

Attach the Lucite base support to the phantom by sliding the pin located on the base into the groove on the phantom (see illustration below). **NOTE:** You may need to first remove the probe arm and place the phantom body into the base support.

This additional phantom attachment is not required in order to use the phantom for exposure measurements.



Final view of phantom assembly showing optional Lucite base support attached to phantom and placement of test tool. Note that above set-up is PA configuration.