Collimare

LED Model Features

- LED and Cross Hair Lasers on with single button press.
- LED and/or Lasers off with a single button press.
- LED on only (lasers off) with a single button press and hold for 1 second.
- Lasers on only (LED off) with a single button press and hold for 2 seconds.
- Programmable LED on time by simply holding the lamp button while applying power to the unit. After 2 seconds the lasers will flash every second with each flash representing a 15 second interval increase (i.e., hold and release after 1 flash for 15 seconds, ..., 8 flashes for 2 minutes).
- Advanced LED control circuitry with proprietary LED direct heat sink surface mounting for high thermal performance, increased output stability and extended life.
- Thermal safety function with indicator (lasers flash every second).
- LED light field is very bright (>24 foot candles) and uniform with significantly less edge roll off and high edge contrast ratio (typically around 7:1).
- LED light output is a blue white color spectrum that is highly visible in brighter room conditions.
- Universal power input (12VDC, 24VDC or 24VAC). Note: 24VAC must be an isolated supply.
- LED model draws less than 24W (24VDC @ 1A).
- Light field adjustments are accessible without taking the housing off.
- Optional remote LED and/or laser on inputs.
- Optional accessory rails.
- Optional DAP meter mounting rails.

Collimare, LLC
13401 W 43RD DR
Unit # 7
Golden, CO 80403
P: 303.278.1496
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www.collimare.net

LED LIGHT SOURCE MODEL

Important Installation Information

OPERATION:

LED and Lasers ON:

Press the Lamp on Button one (1) time for LED and Cross Hair Lasers to come ON.

LED and/or Lasers OFF:

Any time they are on press the Lamp on Button again to turn the LED and Cross Hair Lasers OFF.

LED ON and Lasers OFF:

Press and Hold the Lamp on Button for 1 second for the LED only to come ON. (No Lasers)

Cross Hair Lasers Only (service mode pre-alignment mode only):

Press and hold the Lamp on Button until the Cross Hair Lasers come ON.

Program the LED on Time:

With the power turned off Press and Hold lamp button while applying power to the unit. After 2 seconds the Lasers will flash every second with each flash representing a 15 second interval increase (i.e., hold and release after 1 flash for 15 seconds, ..., 8 flashes for 2 minutes).

THERMAL SAFETY LIMIT:

Should the LED be on for more than 7 to 8 minutes continuously, a thermal sensor will turn the LED off. The lasers will flash every second indicating the LED has overheated. Turn the unit off and allow it to cool for 10 to 15 minutes.

POWER REQUIREMENT:

Universal: 12 VDC @ 2 AMPS OR 24 VDC @ 1AMP or 24 VAC @ 1 AMP

Requires an ISOLATED, fused 24 VAC transformer or 12 VDC or 24 VDC power supply properly rated for 24 watts of power (i.e., 24VAC @ 1A, 12VDC @ 2A, or 24VDC @ 1A).

LED REPLACEMENT:

The LED is part of the circuit board assembly and must be replaced as a whole.

Collimare®

Collimator Operator & Installation Instruction Manual

For Models:

CCL
CPL
CML

Part Number: CP-15-0002
Rev: A 007

Original draft written in English.

Collimare, LLC
13401 W 43rd Drive
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Revision Record:

Revision: A 001	Initial Release	Date: 04.16.2014
Revision: A 002	Revised Voltage and Current Date	Date: 04.16.2014
Revision: A 003	Revised Laser Standards	Date: 05.14.2014
Revision: A 004	Revised Environmental Range & Information Statement	Date: 08.20.2015
Revision: A 005	Included AR, Notified Body and ETL Mark Information	Date: 08.20.2015
Revision: A 006	Included Extra Mounting Instruction Information	Date: 09.04.2018
Revision: A 007	Included External Laser Adjustment Information	Date: 08.01.2019

Model Specifications as identified by the Catalog # on the Serial Tag:

Catalog #:	Usage Type	Voltage & Current	Frequency	Skin Guard	Certified Human Use	Lamp Type
CCL All Models	Portable	12VDC @ 2A / 24VDC or 24VAC @ 1A	DC/50/60Hz	Yes	YES & NO	LED
CPL All Models	Portable	12VDC @ 2A / 24VDC or 24VAC @ 1A	DC/50/60Hz	Yes	YES & NO	LED
CML All Models	Clinical	12VDC @ 2A / 24VDC or 24VAC @ 1A	DC/50/60Hz	No	YES & NO	LED

The Authorized Representative:

EC REP

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Tel: 0330 414 1353
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Conforms to ANSI/AAMI STD ES60601-1
Certified to CSA STD C22.2 No. 60601-1

ETL CLASSIFIED

C ETL LISTED US

Intertek
3137240

Guidance and manufacturer's declaration – electromagnetic emissions		
The Collimare Models are intended for use in the electromagnetic environment specified below. The customer or the user of the Collimare Models should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Collimare models use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Collimare Models are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic emissions			
The Collimare Models are intended for use in the electromagnetic environment specified below. The customer or the user of the Collimare Models should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±□6 kV contact ±□8 kV air	±□6 kV contact ±□8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±□2 kV for power supply lines ±□1 kV for input/output lines	Not applicable	Not applicable
Surge IEC 61000-4-5	±□1 kV line(s) to line(s) ±□2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable	Not applicable

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If degradation occurs, it may be necessary to position the Collimare Models further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic emissions

The Collimare Models are intended for use in the electromagnetic environment specified below. The customer or the user of the Collimare Models should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Collimare Models including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	Not applicable	$d = 1{,}2\sqrt{P}$
			$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Collimare Models referenced in the above chart is used exceeds the applicable RF compliance level above, the Collimare Models referenced in the above chart should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Collimare Models referenced in the above chart over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Collimare Models

The Collimare Models are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Collimare Models can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Collimare Models, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

ESSENTIAL PERFORMANCE AND RISK ANALYSIS

SUMMARY

Testing performed for: Collimare, LLC

Product Used for Life Support: NO

For use in Shielded Enclosure: NO

The following information on Test Mode and Essential Performance was determined by manufacturing:

Mode of Operation	Essential Performance / Degradation of Performance
For all emissions testing, the Collimare Models were operated at the maximum level of performance utilized by the end user per instructions provided herein. **For all immunity testing** of the Collimare Models, the system was operated in a test mode that is typical for the end user. All user functions including: lamp on and laser on was exercised and the full cycle was repeated for the duration of the test. The front panel switch was pressed to re-activate the lamp and laser on function for all the Collimare Models	**Unallowable Actions during system operation:** The lamp and lasers to stay off. **Essential Performance:** The lamp and lasers must stay on or come back on. **Degradation of Performance Not Allowed:** Requirement of a power reset to restore function. Not to turn on during or after the event. **Allowable Degradation of Performance:** Lamp and lasers may go out during the event but must come back on after the event either automatically or by pressing the front panel switch.

INSTALLATION INSTRUCTION ADVISORY

TO: INSTALLERS, SERVICE PERSONNEL, AND TECHNICIANS

It is required to read and carefully review the instructions and cautions contained within this manual even if very familiar with the installation and operation of similar equipment. It is necessary for the assembler/installer to verify compliance. A series of tests, when performed at the time of installation, will indicate compliance with 21CFR, Sub-Chapter J, Part 1030, Performance Standards. These tests which are described in Section 4, "Compliance Verification," and must be performed before releasing the collimator for use. A record sheet is provided at the end of Section 4 and should be completed by the installer. In order to facilitate a timely installation and ensure compliance it is recommended that the installer review this manual in its entirety and then starting at the beginning; follow all procedures in each section in order.

Upon request Collimare will make available all circuit diagrams, component parts lists, and all other information as available to assist Service Personnel in the service and repair of the unit.

The useful x-rays and scattered radiation are dangerous to both operator and others in the vicinity unless safe exposure procedures are strictly observed. Failure to follow the procedures and requirements in this manual may result in an electrical and/or mechanical safety hazard and failure to meet governmental requirements, as well as damage to the collimator.

This unit utilizes two low power (<700 μ watt 650 nm, IEC 60825-1:2007) Class 1 lasers to produce an alignment crosshair. **Per OSHA Laser Classification—Summary of Hazards Table, Class 1 lasers pose no hazard to direct ocular, or diffuse ocular exposure.**

Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50 dated July 26, 2001

Environmental Range

Altitude: (All Modes), 0 to 10,000 feet (0 to 3048 meters)
Air Pressure: (All Modes), 70 to 106 kPa
Ambient temperature (Operating): +50°F (+10°C) to +80°F (+27°C)
Ambient temperature (Shipping, Storage): -4°F (-20°C) to +122°F (+50°C)
Relative Humidity (Operating): 5 to 85% Non condensing
Relative Humidity (Shipping, Storage): 5 to 95% Non condensing

LED USAGE shall not exceed 2 minutes of accumulative on time (4 thirty "30" second or 2 sixty "60" second cycles) without a cool down period of 2 minutes.

The LED heat sink and LED may be hot enough to cause severe burns. Do not touch any objects in the LED area with bare skin.

The intensity of the LED light output is sufficient to temporarily impair your vision if allowed to enter the eyes directly. Make sure that the power is off when removing the LED heat sink. Do not turn the power on with the LED heat sink removed. Take precautions to prevent direct or accidental light from the LED to directly enter the eyes.

Disconnect primary power to the Collimator anytime the covers are off.

End of Life Disposal: This Collimator contains lead, a hazardous material, and other recyclable materials and should be properly disposed of according to local regulations and by specialized companies.

TABLE OF CONTENTS

LISTS OF FIGURES

LISTS OF TABLES

1.0 INTRODUCTION

This manual contains information for the assembly, installation, adjustment, testing and maintenance of the collimators manufactured by Collimare, LLC.

CCL, CPL and CML MODEL DIMENSIONS

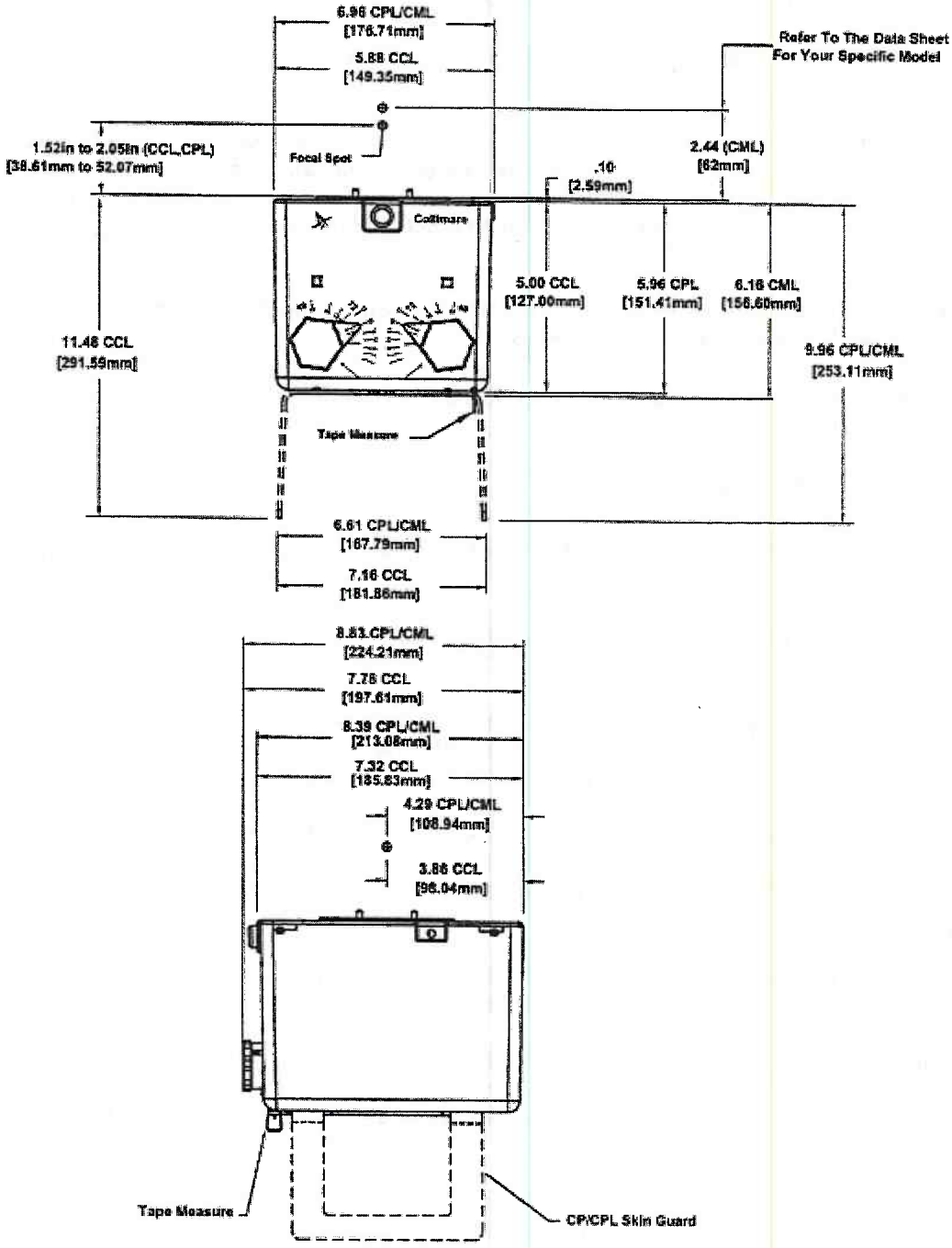


Figure 1 - General Dimensions

Note: The Focal Spot to X-Ray Tube Mounting Plate Top Surface Dimension "Collimator Mount" can be 1.52" - 2.44" +/- 1/32" (38.6 – 52.0mm +/- 1mm) depending on model. Be sure to include any x-ray tube mounting plates or spacers when calculating the Focal Spot to Collimator Mounting distance per the equipment and x-ray tube manufacturers' published date.

1.1 YOU HAVE LEGAL OBLIGATIONS

The manufacturers of beam limiting devices are required to provide instructions for the assembly, installation, adjustment and testing adequate to assure compliance with applicable provisions of DHHS Performance Standards 21 CFR Sub-Chapter J. Part 1020.

Those who assemble or service beam limiting devices must follow the instructions of the original manufacturer and process the FDA-2579 Assemblers Report where applicable.

You assume responsibility for compliance of this product if you fail to follow the original manufacturer's instructions or modify any component which affects radiation safety.

The FDA (CDRH) requires that manufacturers must include a specific requirement that the assembler perform all applicable tests at the time of installation. A thorough explanation of the equipment required and step-by step instructions must be provided by the manufacturer. The instructions include a requirement to record key data to demonstrate at a later time that all tests were performed and that the equipment was left in full compliance with the standards.

As an assembler, you must perform these tests for the applicable requirements at the time of installation and following any repairs which could alter the performance.

A Compliance Data Log is provided in this manual to record the results of the tests.

1.2 BACKGROUND / INTENDED USAGE

The operation of an X-Ray collimator is restricted to a trained and licensed x-ray technician/personal or physician.

An X-ray collimator functions as an apparatus for regulating the cross-sectional size and shape of a beam of radiation which emerges from an X-ray tube.

The source of radiation is virtually a point-source and, due to the tube housing design, emerges from the port as a solid diverging cone of radiation. The finite angle of the anode surface limits the X-ray beam on the anode side (heel-effect) forming a "D" shaped X-ray field, limiting the useful coverage.

In "collimating" a beam to a given size and shape, a flat-pair of lead shutters are moved perpendicularly into the beam to absorb the unwanted portion of the emerging beam. A second flat-pair of shutters are positioned at right angles to the first pair, and again are moved perpendicularly into the beam. In this manner a continuously variable square/rectangular beam is formed.

The landing area of the beam will contain a radiographic or fluoroscopic image receptor located in a plane perpendicular to the beam at pre-determined distances from the radiation source (focal spot).

The size and shape of the image receptor will determine the maximum useful cross-sectional size and shape of the beam in the plane of the image receptor. The source to image receptor distance (SID) determines the actual shutter opening required to regulate the beam size and shape in the plane of the image receptor.

The primary objective of the collimator is to limit the beam to the size of the image receptor and to provide other standardized operations consistent with the DHHS Performance Standards 21 CFR Sub-Chapter J. This is accomplished by measuring the size of the image receptor and the distance (SID) involved, then adjusting the collimator accordingly or by visual means of the light field with respect to the area of interest or image receptor size whichever is smaller.

CONTROL PANEL

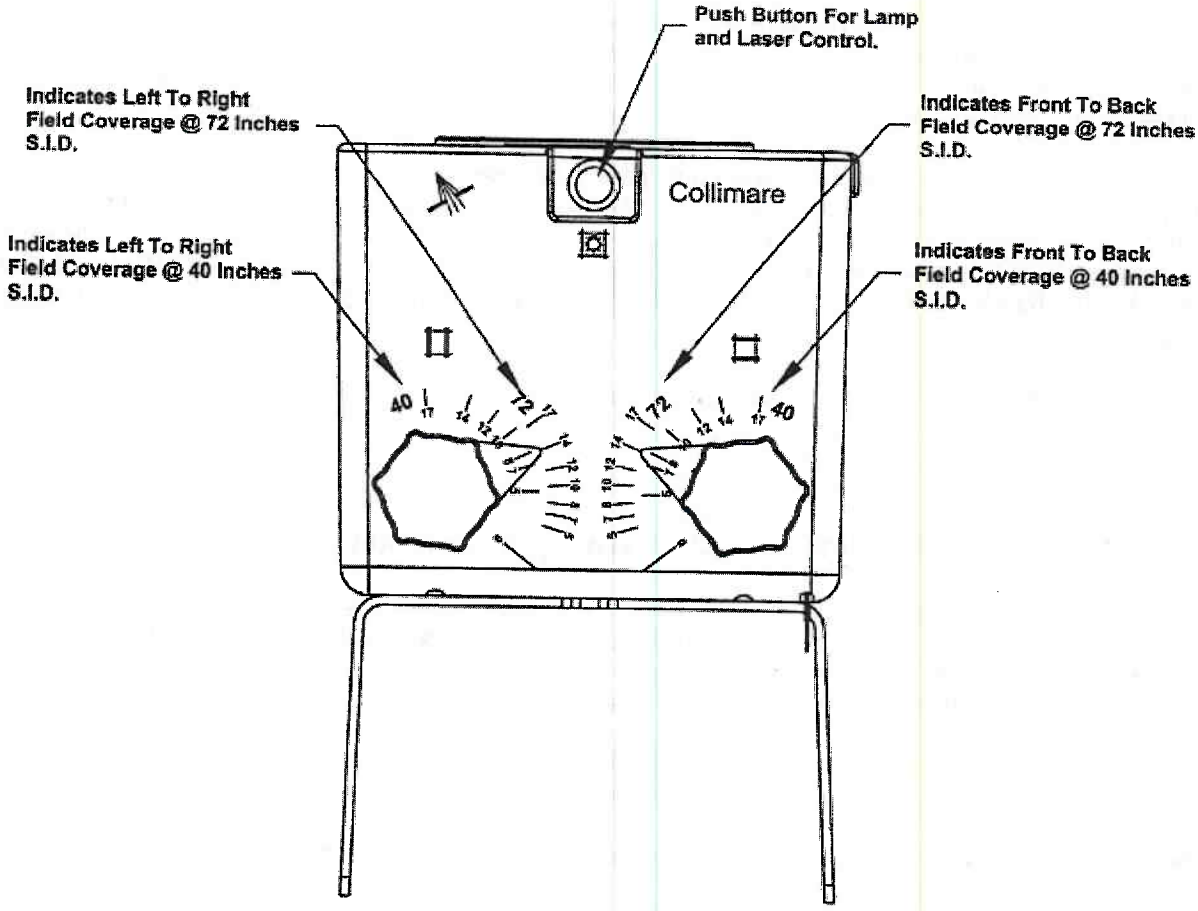


Figure 2 - Control Panel

1.3 RADIATION AND MECHANICAL/ELECTRICAL WARNING (from NEMA Standards Publication/No. XR8-1979)

Radiation  **Warning for Diagnostic X-Ray Systems**

X-rays are dangerous to both operator and others in the vicinity unless established safe exposure procedures are strictly observed.

The useful and scattered beams can produce serious, genetic or potentially fatal bodily injuries to any persons in the surrounding area if used by an unskilled operator. Adequate precautions must always be taken to avoid exposure to the useful beam, as well as to leakage radiation from within the source housing or to scattered radiation resulting from the passage of radiation through matter.

Those authorized and licensed to operate, test, participate in or supervise the operation of the equipment must be thoroughly familiar and comply completely with the currently established safe exposure factors and procedures described in publications such as Sub-Chapter J of Title 21 of the Code of Federal Regulations, "Diagnostic X-Ray Systems and their Major Components", and the National Council on Radiation Protection (NCRP) No. 33, "Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MeV-Equipment Design and Use", as revised or replaced in the future.

Failure to observe these warnings may cause serious, genetic or potentially fatal bodily injuries to the operator or those in the area.

Mechanical/Electrical  **Warning for Diagnostic X-Ray Systems**

All of the moveable assemblies and parts of X-ray equipment should be operated with care.
Only properly trained and qualified personnel should be permitted access to any internal parts. Live electrical terminals are deadly; be sure line disconnect switches are opened and other appropriate precautions are taken before opening access doors, removing enclosure panels, or attaching accessories.

Do not remove the flexible high tension cables from the X-ray tube housing or high tension generator or the access covers from the generator until the main and auxiliary power supplies have been disconnected.

When disconnecting high voltage cables, they must be grounded immediately in order to dissipate any electrical charge that may remain on the cables or the tube.

Failure to comply with the foregoing may result in serious or potentially fatal bodily injuries to the operator or those in the area.

1.4 COMPATIBILITY

The collimators are compatible and can be adapted for use with X-ray tube/housing assemblies that meet all of the following factors:

1.4.1 Focal Distance X-ray Tube:

The focal spot to x-ray tube mounting ring (Figure 1) top surface distance must be 1.52 - 2.0 inches, + or - 0.031 inches (1/32") for the CP model or 2.44 inches,+ or – 0.031 inches (1/32) for the CM model.

Do not rely on tube markings, reference the x-ray tube data sheet or literature.

1.4.2 Leakage radiation:

Maximum leakage radiation from the X-ray tube/housing assembly must not exceed 100 mR/hr at 1 meter (40 inches) at 125 kVp at 4 ma or 150 kVp depending on model (see the serial tag for kVp rating).

1.4.3 Inherent Filtration and Half-Value Layer:

The Collimators have a minimum value of 1.4 mm aluminum equivalence at 80 kVp. This value plus any tube inherent filtration plus any added filtration must meet the minimum requirements of 21 CFR Sub-Chapter J, part 1020.30 (m) (1) Table 1 on beam quality (e.g., minimum HVL at 100 kVp must be 3.6 mm Al)

1.4.4 Application:

The intended application is for portable, over-table general purpose radiographic fluoroscopic equipment including tomographic and chest applications. Maximum tube rating must be125 kVp or less, and 150 kVp for CM150 models.

1.4.5 Installation:

Must be made with supplied hardware including mounting flange, spacers (as required), and four (4), ¼" x 20 or 6mm x 25mm bolts equally spaced on a 3.62" diameter bolt center. Portables may be mounted per the manufactures requirements. Refer to manufacturers documentation for mounting specifications.

1.4.6 Collimator Electrical Requirements

This is a CLASS I electrical device and must be wired in accordance with all applicable electrical codes and regulations. The power supply cable from the power supply to the Collimator must be sized to handle the full continuous rated load taking into consideration the distance from the collimator to the power supply.

Power Supply Requirement(s) (to comply with light output requirement):

12VDC @ 2A / 24VDC & 24VAC 50/60Hz @ 1A

Requires an isolated, primary and secondary fused AC transformer or DC power supply.

1.5 MAINTENANCE

The collimator system must be properly maintained to assure both compliance with the CDRH regulations and useful life.

Preventive maintenance is to be performed once every twelve months. This includes inspection of the collimator tube mount, electrical cables, electrical connections and lubrication of the collimator.

Checkout should also occur if any of the following conditions occur:

Lamp or LED replacement.
Premature electronic component failure.
When the collimator is removed from tube/housing assembly.
When the collimator has been subjected to external damage.
If the operator had determined there is a problem.

Cleaning & Disinfecting

Turn off power to Collimator before cleaning.
Never use a solvent based, abrasive, spray/aerosol, wax, acid or alkaline type cleaners.
Never use any type of spray or foaming cleaner, instead apply to soft damp cloth.
Housing: Use only a soft cloth lightly moistened with a mild detergent soap.
Crosshair window: Use only a soft cloth lightly moistened with a mild detergent soap.
Field light mirror: Use only a soft cloth, lightly moistened with isopropyl alcohol and allow to air dry.
Disinfect control surfaces before each use with a 70% isopropyl alcohol dampened soft cloth.

Mechanical Components

Tube mount should be disassembled, cleaned and reassembled using a **Synthetic Brake Grease** at the contact surfaces of the plastic tube mount, aluminum mounting ring and the bottom pads of the tube mount. The top surface of the collimator that contacts the tube mount should be cleaned.

Internal shutters and shafts should be cleaned with a light alcohol spray, wiping the surfaces clean while moving the shutters back and forth. **DO NOT GREASE. THE SHUTTERS ARE DESIGNED TO RUN DRY.** If any lubricant is needed a light silicon spray can be applied and then wiped off.

The drive cables can be greased lightly at the drive cams with Synthetic Brake Grease.

Synthetic Brake Grease such as CRC is available at most auto stores and Walmart.

**** DO NOT USE A LITHIUM BASED GREASE. ****

1.6 COMPLIANCE REQUIREMENTS

It is necessary for the assembler to verify compliance. A series of tests, when performed at the time of installation, will indicate compliance with 21CFR, Sub-Chapter J, Part 1030, Performance Standards. These tests which are described in Section 4, "Compliance Verification," and must be performed before releasing the collimator for use. A record sheet is provided at the end of Section 4 and should be completed by the installer.

1.7 OPERATION AND FEATURES

UNIT POWER:

The unit is powered by the x-ray system. There is no independent power switch.

LED and Lasers ON:

Press the Lamp on Button one (1) time for LED and Cross Hair Lasers to come ON.

LED and/or Lasers OFF:

Any time they are on press the Lamp on Button again to turn the LED and Cross Hair Lasers OFF.

LED ON and Lasers OFF:

Press and Hold the Lamp on Button for 1 second for the LED only to come ON (No Lasers).

Cross Hair Lasers Only (service mode pre-alignment mode only):

Press and hold the Lamp on Button till the Cross Hair Lasers come ON.

Program the LED on Time:

With the power turned off Press and Hold lamp button while applying power to the unit. After 2 seconds the Lasers will flash every second with each flash representing a 15 second interval increase (i.e. Hold and release after 1 flash for 15 seconds, ... 8 flashes for 2 minutes.).

THERMAL SAFETY LIMIT:

Should the LED be on for more than 7 to 8 minutes continuous a thermal sensor will turn the LED off. The lasers will flash every second indicating the LED has overheated. Turn the unit off and allow it to cool for 10 to 15 minutes.

LED REPLACEMENT:

The LED is part of the circuit board assembly and must be replaced as a whole.

CCL & CPL PORTABLE MOUNTING ASSEMBLY

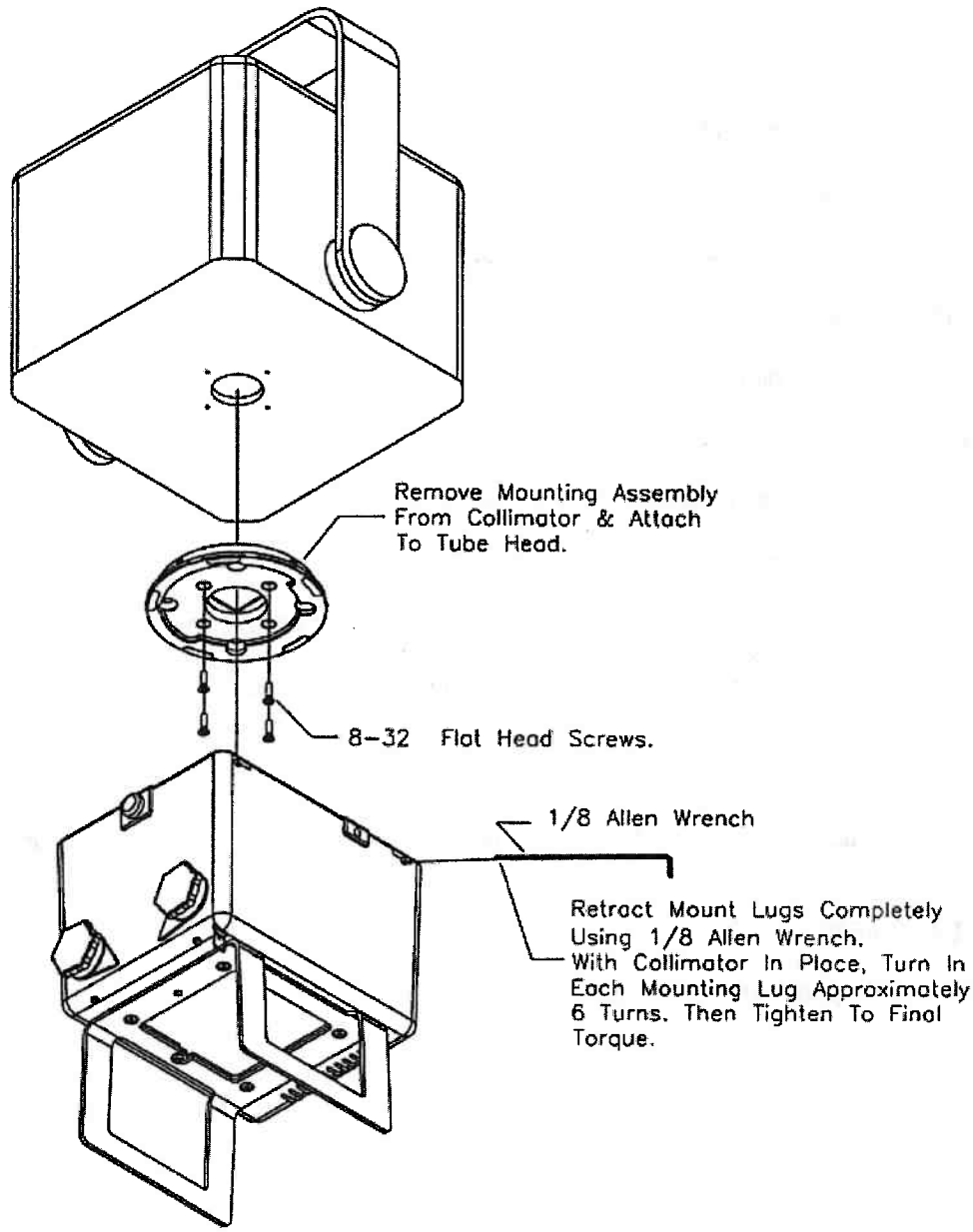


Figure 3A - Portable Head Mounting Assembly

1.8 PORTABLE-SPECIFIC MOUNTING INSTRUCTIONS

Provided below are detailed instructions for mounting a Collimare collimator on a Portable system:

1) The tube mount assembly for the collimator is shipped underneath the mounting lug slides on the top of the collimator. Remove the tube mount assembly by gently retracting the mounting lug slides fully (using a 1/8" Allen wrench) and lifting the tube mount assembly out.
2) With the tube mount assembly removed, gently extend one of the mounting lug slides back out by turning the screw (which is on the inside of the mounting lug) clockwise with the same Allen wrench. Gently tug on the mounting lug slide while it is turning. When the mounting lug slide comes free of the interior screw, simultaneously remove the mounting lug slide and stop turning the screw.
3) With the mounting lug slide removed, apply a small amount of Blue Loctite (243) to the interior of the threaded hole on the mounting lug slide.
4) Place the mounting lug slide back onto the end of the screw it was removed from. Gently apply pressure to the mounting lug slide while starting to turn in the opposite direction (counter-clockwise) until the mounting lug slide is fully seated back into the mounting lug.
5) Steps 2 through 4 are shown in this video:

   https://www.dropbox.com/s/xf6sce24hd55zcm/IMG_8190.MOV?dl=0

   Repeat steps 2 through 4 for the other three mounting lug slides.
6) Mount the tube mount assembly onto the mono-block. Place the collimator up onto the tube mount assembly carefully such that the mounting ring is not pushed up, moved out of place, or angled. Mounting spacers can be placed in between the top of the mounting ring and the bottom of the mono-block to help make sure the mounting ring does not get accidentally pushed up.
7) Locate once again the interior screw of each mounting lug slide. Turn each of these screws roughly three revolutions to push each of the mounting lug slides out. This will help to center the collimator on the mounting ring. (If each mounting lug slide is not able to screw in at least three revolutions, then the mounting ring is not in the proper position. If this is the case, you will need to unscrew the mounting lug slides and check the positioning of the mounting ring.)
8) Confirm once more that the mounting ring is level, nearly flush with the top of the collimator top cover. Make sure that the mounting ring is not angled, uneven, or resting above the top cover of the collimator after mounting. If the mounting ring is not mounted properly, the mounting lug slides may not seat into the

correct positions on the mounting ring. Instead, they may latch onto the outer diameter of the mounting ring and may ride up or over the flange (or lip) of the mounting ring. If this were the case, the collimator would feel tight at first but could become loose and potentially fall off later. Please see Figure 3B below (particularly at the center of the picture) for a visual reference of how the mounting lug slide should be seated over the top flange of the mounting ring.

9) Align the center of the collimator with the center of the x-ray field by adjusting the mounting lug slides as needed (for FLOATING MOUNT STYLE ONLY).

10) Once the collimator has been centered, use a torque screw driver to apply torque incrementally up to 20 inch-pounds (2.26 Newton meters) to the mounting lug screws. For example, apply 10 inch-pounds (1.13 Newton meters) to each of the four mounting lug screws sequentially, then apply 15 inch-pounds (1.69 Newton meters) to each of the four mounting lug screws sequentially, and then finally apply 20 inch-pounds (2.26 Newton meters) to each of the four mounting lug screws sequentially. With proper execution of this procedure, there should be only slight drag in the rotation of the collimator on the mounting ring. If the amount of drag is considered to be too much, then this step (Step 10) should be repeated using a lower torque value.

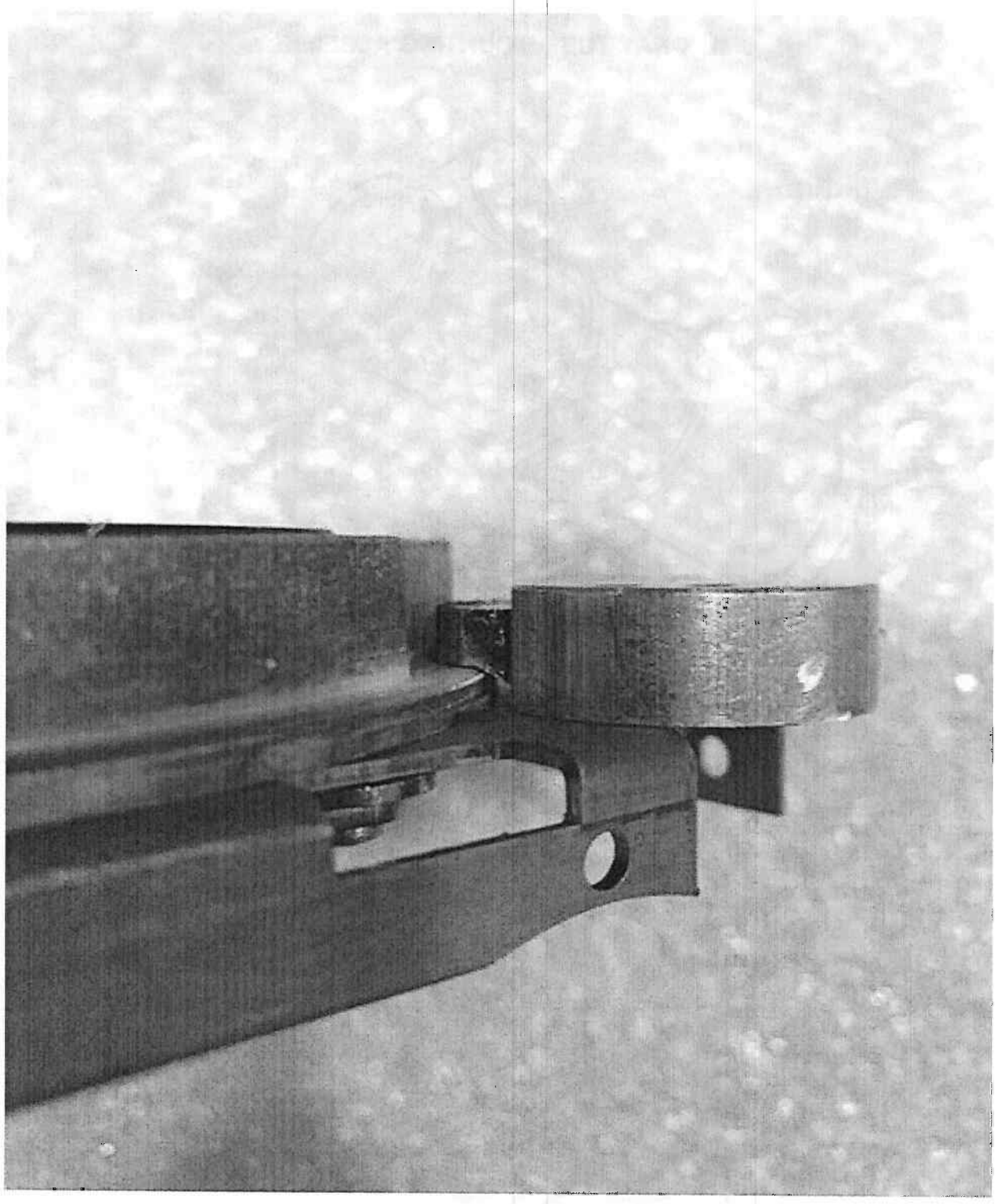


Figure 3B - Properly Seated Mounting Lug Slide on the Flange of the Mounting Ring

CML X-RAY TUBE MOUNTING ASSEMBLY

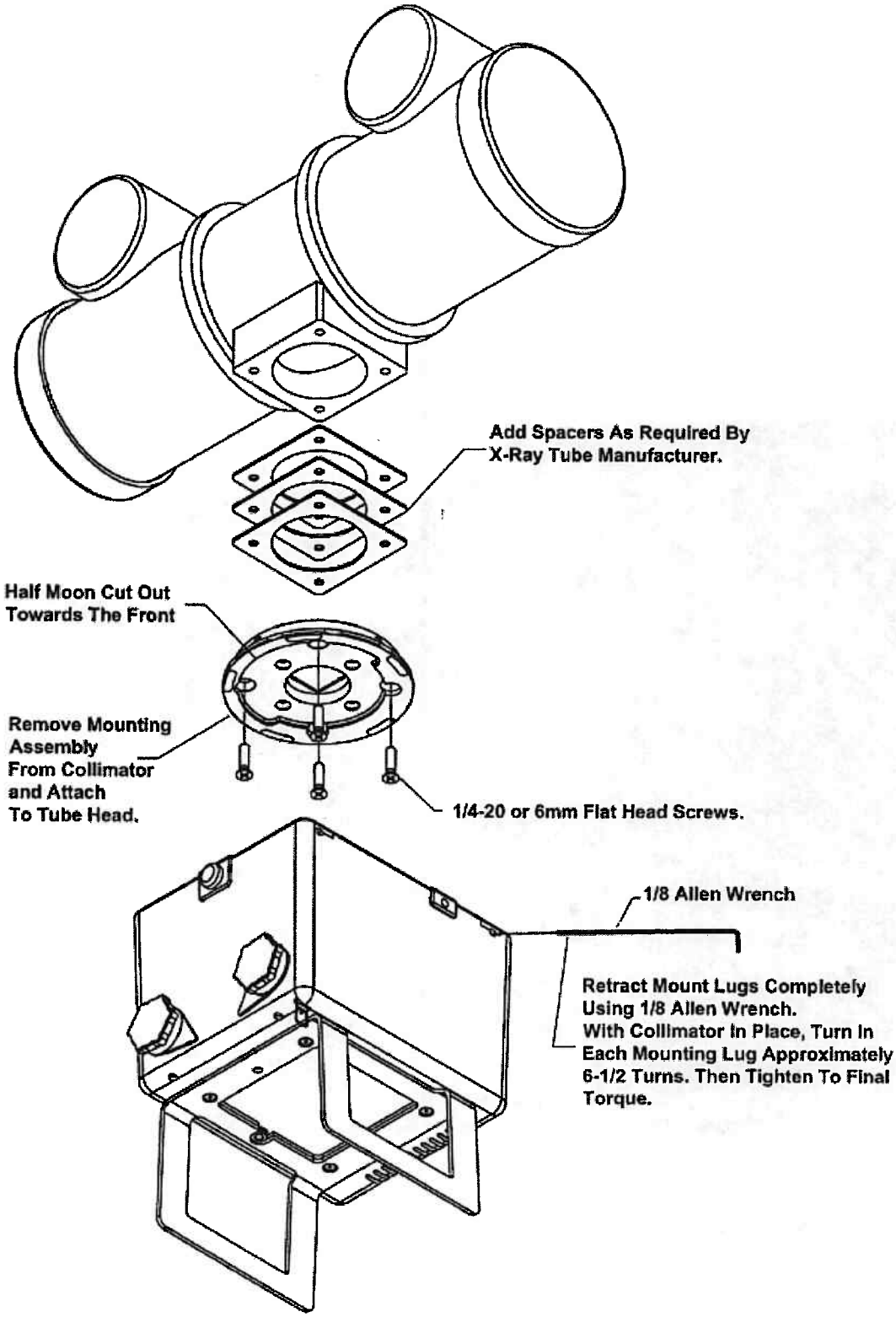


Figure 3C - CML X-Ray Tube Mounting Assembly

2.0 INSTALLATION

Carefully unpack the equipment and check for visible damage incurred during shipment. Any damage should be referred to the agency that delivered the equipment. Verify all contents against the packing list and collect published data for further reference. Take care in handling the collimator and do not set it down on the output window.

2.1 COLLIMATOR MOUNTING (Figures 3A & 3C)

Determine the Collimator mounting top plate surface to focal spot distance from the data supplied with the X-ray tube. (Figure 1) (Do not rely on an inscribed mark on the tube housing.)

The Collimator will not perform properly unless the focal spot to upper tube mounting plate distance is 1.52"- 2.0" (1.52 - 2.0 inches, 38.6 - 52 mm) + or - 1/32" (.031 inches, 1mm) (Figure 1). Be sure to include any permanent tube mounting plates (Figures 3A & 3C) in the focal spot to port boss distance to the top of the housing stated in the tube manufacturer's data.

The Collimator is designed to be used with a lead aperture, diaphragm or input cone in the plastic port of the X-ray tube (Figure 3C). Ensure that there is not any mechanical interference between the collimator and the lead aperture, diaphragm or cone in the port of the X-ray tube. If it is found that lead diaphragms or cones require removal or modification, consult the factory.

In order to insure a safe and secure mounting of the collimator to the X-ray tube housing, the following installation guidelines should be followed.

1. Screws may or may not be provided with the Collimator. Determine the correct length of screw to use, taking into account the collimator spacing requirements and/or peculiarities of the tube housing port boss per the manufactures literature and specifications.

   NOTE: FOR CONVENIENCE, TRUNION MOUNTED TUBE HOUSINGS MAY BE ROTATED UPWARD TO FACILITATE MOUNTING OF THE COLLIMATOR. ANOTHER APPROACH WOULD BE TO USE A BOX TO SUPPORT THE COLLIMATOR AND CAREFULLY BRING THE TUBE HOUSING DOWN TO THE COLLIMATOR.

2. Clean the screws and housing port boss with alcohol and if necessary, remove any debris which may be present in the tube housing mounting holes.

3. Securely fasten the upper mounting ring and spacers to the collimator mounting surface. As a precaution, a medium strength thread locking compound, such as Loctite #242, should be applied to the screws before fastening the collimator mounting ring to the tube housing

   Verify that the collimator mounting screws engage the tube housing by at least five (5) threads.

4. Carefully support the collimator in place and re-engage the mounting clamps by turning each in approximately 6 turns and then apply final torque.

5. After mounting the collimator and/or performing any service to it or the tube housing, inspect the fit of the collimator and tube housing assembly while inspecting for loose joints or gaps between the tube/collimator assembly as well as other tube mounting areas.

Failure to adhere to the above guidelines may result in loosening, damaged screws or mount failure which could result in heavy components falling during use. Incidents of loose system components should be reported immediately to X-ray service personnel for repair.

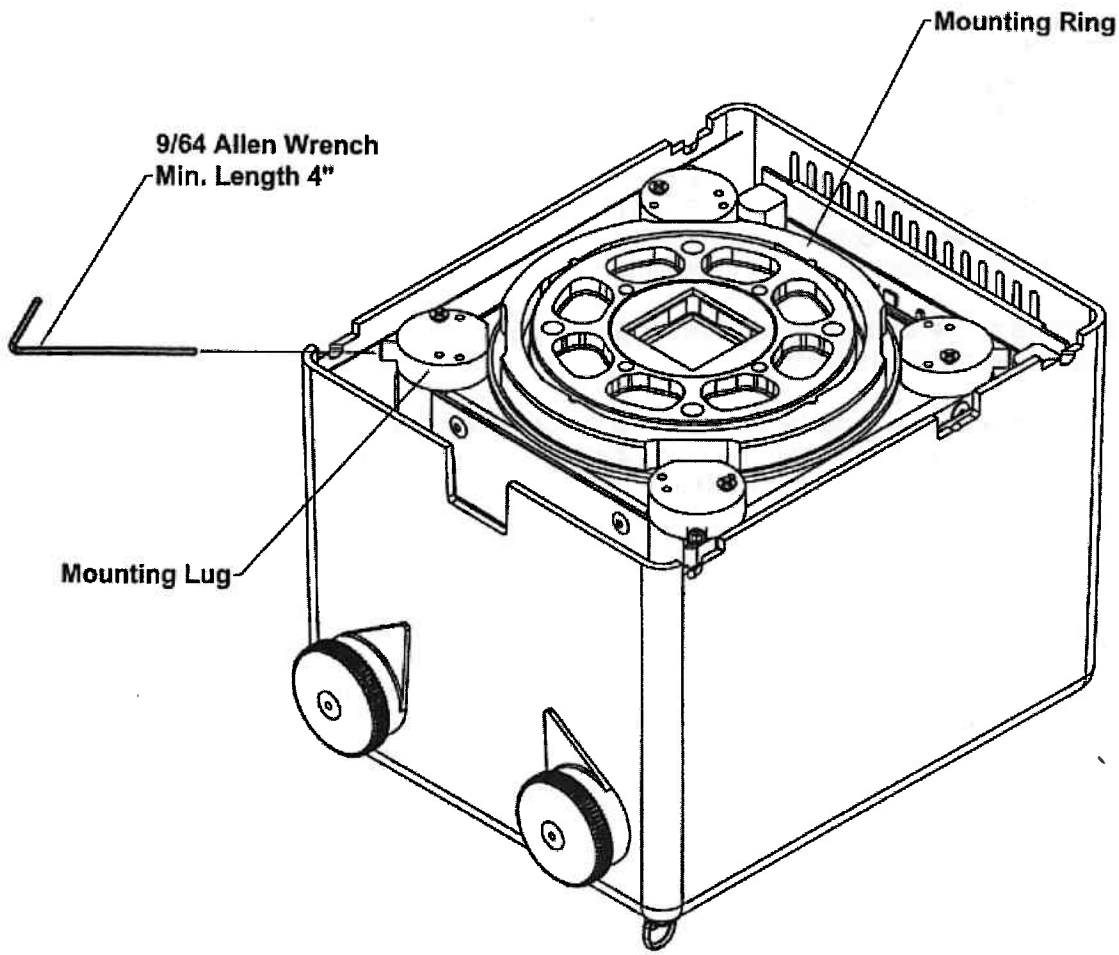


Figure 3D - Portable Collimator Alignment

2.2A CCL & CPL Portable Model Only ALIGNMENT OF X-RAY FIELD TO LIGHT FIELD

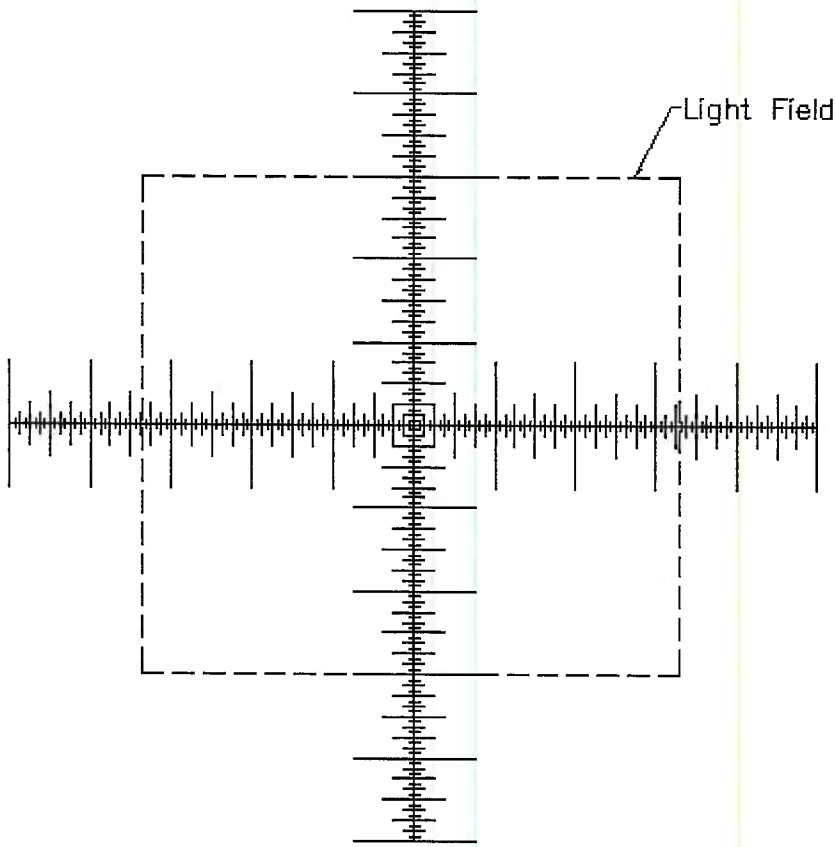
CAUTION: DO NOT REMOVE HOUSING TO ALIGN LIGHT FIELD OR LASERS.

- The light field and lasers are aligned to the center of the collimator at the factory and should not require further adjustment.
- The collimator mount must be adjusted by the mounting lugs to the center of x-ray per the following instructions (see previous Figure 3D).

Carefully insure that both the x-ray source/collimator assembly and target are properly leveled in x and y and that the SID is set at 1 meter (40 inches). Any error in x-ray source/collimator and/or target level/alignment will cause errors is the alignment procedure. A beam parallel tool will help establish proper alignment. Follow the manufactures instructions for the beam parallel tool.

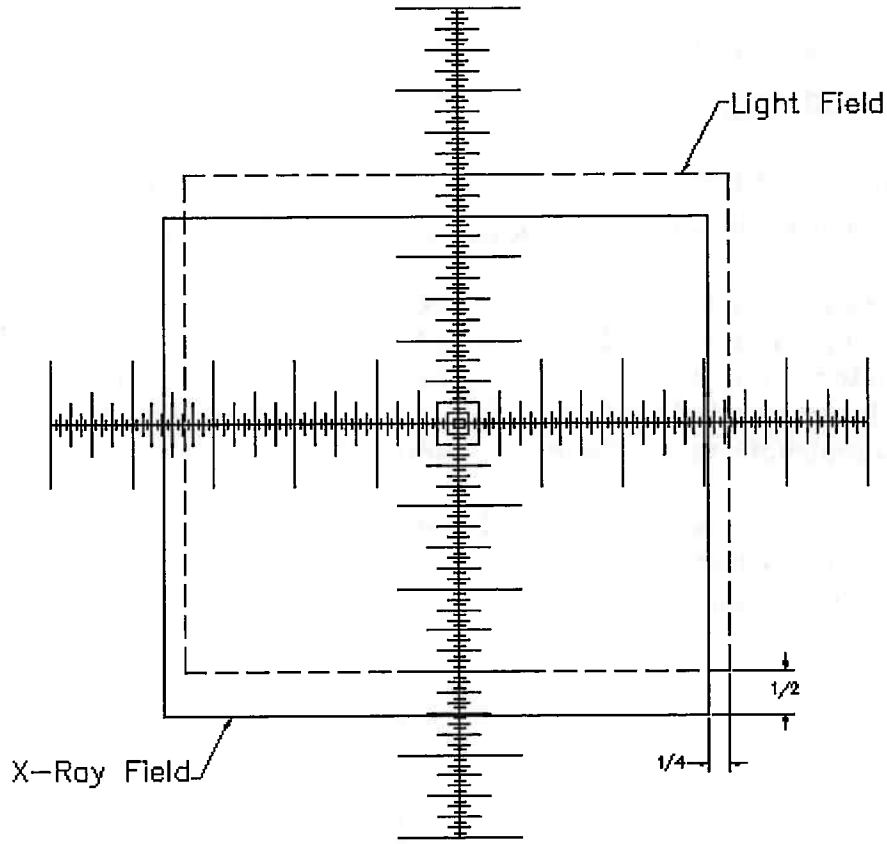
1. Place a Collimator Test Target on the Cassette directly or in the bucky. Adjust the shutters to produce a 10 x 10 inch light field. Turn on the collimator light/laser cross hairs and center the test tool with the light field and lasers.

Test Target:



2. Expose the film and compare the alignment of the x-ray field to the light field.

3. Example:

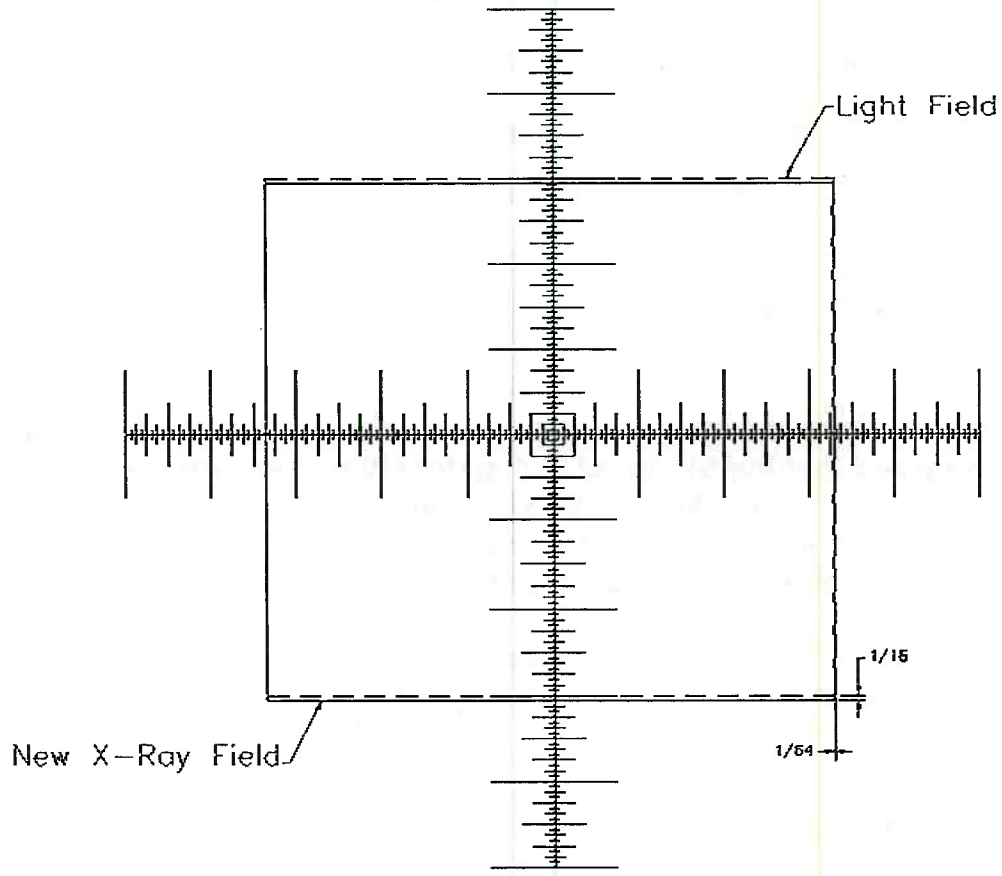


4. As shown, the x-ray field is ½ inch forward and ¼ left of the light field. Align the x-ray field to the light field by moving the collimator in the direction you wish to move the x-ray field. Only move the collimator in one direction at a time. To move the collimator to the right, loosen the screws on the left by no more than one turn and tighten the screws on the right. One half turn of the screws will move the collimator ¼ inch. To move the collimator ½ inch to the back, loosen the screws at the front and turn in the screws at the back one full turn (***1/2 turn = 1/4inch movement***).

5. Turn on the collimator light/laser cross hairs and re-center the test target to the light field/lasers.

6. Using a new Cassette take another exposure. Compare the new location of the x-ray field to the light field.

7. An example is shown on the next page:



8. As seen in the figure above, the x-ray and light field are not quite in alignment. This is because the light field moves slightly as the x-ray field moves. Continue to align the collimator/x-ray field to light field as described in steps 3 through 5 until the fields are aligned satisfactorily.

9. Tighten the mounting lug screws to finish the alignment process. The mounting lug screws provide a lot of force so do not over tighten. If the collimator is hard to rotate back off the mounting lug screws slightly.

10. Turn on the collimator light/laser cross hairs and center the test tool with the lasers. Rotate the collimator 90 degrees. The laser cross hairs should remain centered on the target. Keep in mind that if there is any off angle alignment error in the x-ray tube to target the light field may shift slightly when rotated. Confirm tube to target alignments and re-center the target then take a new exposure to confirm the x-ray field is also centered on the target. If the x-ray field is not centered, additional alignment is required as described in steps 2 through 5.

NOTE: If the x-ray to light field alignment can not be done satisfactorily within 2% of SID total error, per FDA allowance, then the x-ray source/collimator level and alignment are incorrect or the focal spot of the x-ray source is too far out of tolerance to provide accurate centering of the collimator.

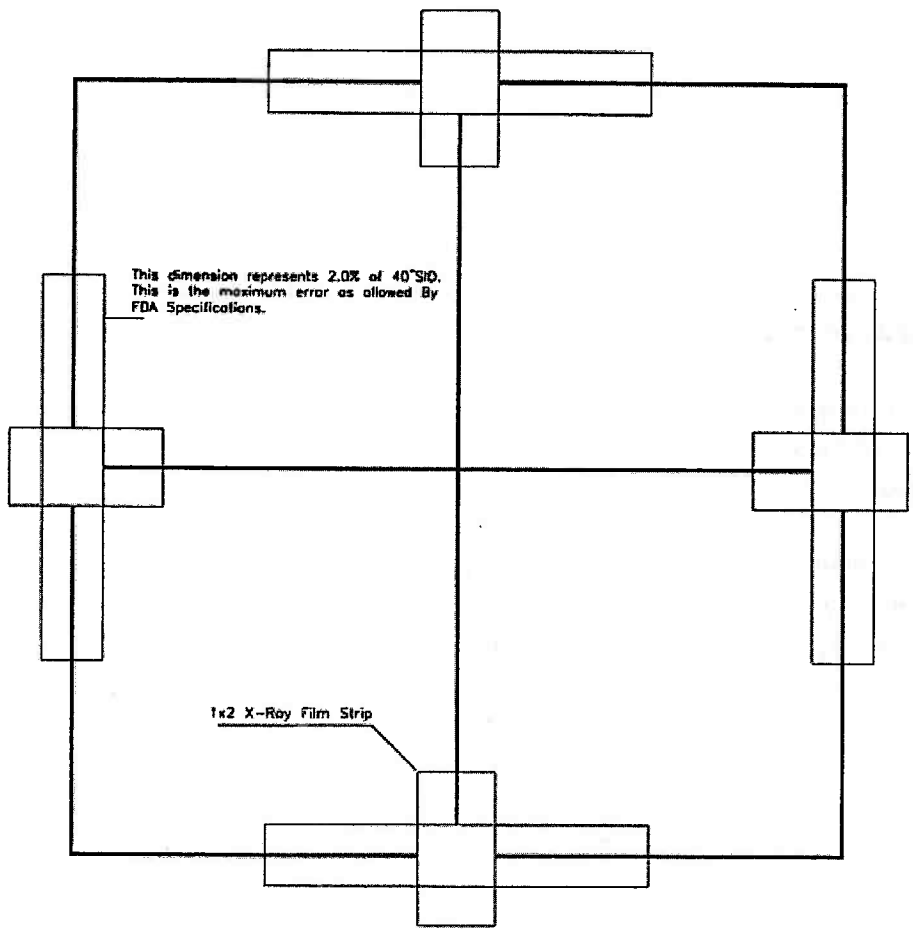
2.2B CML Only ALIGNMENT OF LIGHT FIELD WITH X-RAY FIELD

CAUTION: DO NOT REMOVE HOUSING TO ALIGN LIGHT FIELD OR LASERS.

- The light field and lasers are aligned to the center of the collimator at the factory and should not require further adjustment.
- The collimator mount is not adjustable for transverse or longitudinal alignment. Align the light field to match the x-ray field per the following instructions:

Carefully insure that both the x-ray source/collimator assembly and target are properly leveled in x and y and that the SID is set at 1 meter (40 inches). Any error in x-ray source/collimator and/or target level/alignment will cause errors is the alignment procedure. A beam parallel tool will help establish proper alignment. Follow the manufactures instructions for the beam parallel tool.

11. Place a Collimator Test Target (shown below & provided in shipping container) on top of the table. Using the turn knobs, adjust the field size to 10in x 10in @ 40in SID.



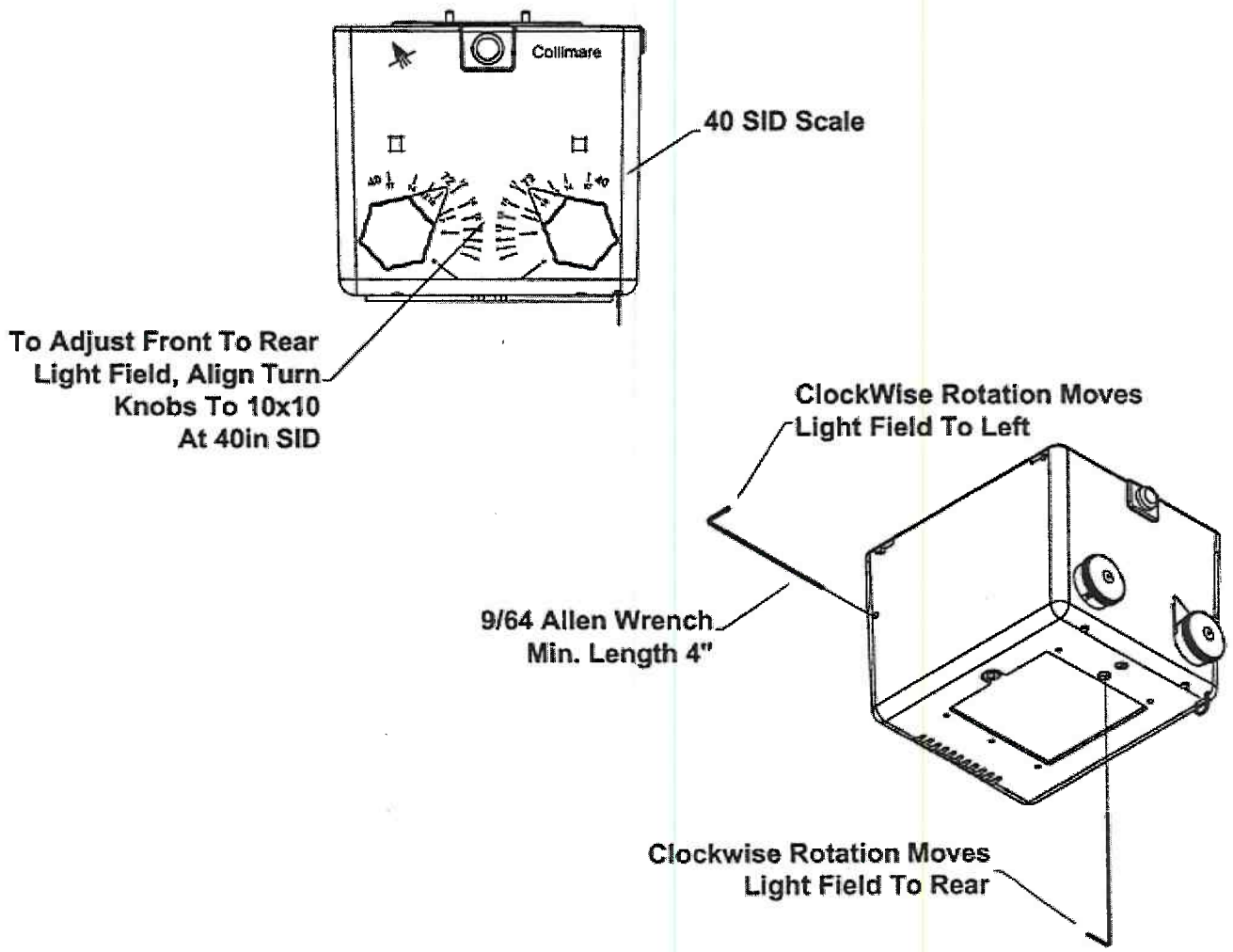
12. Turn on the collimator light/laser cross hairs and move the Collimator/ X-ray Tube Assembly so the lasers align with the center lines of the target.

13. Take several warm-up exposures to expose the 1x2 film strips. Refer to test target.

14. If the x-ray to light field alignment is not satisfactorily within 2% of SID total error, per FDA allowance, then the light field alignment can be corrected. Use the 9/64 Allen wrench provided to align the light field to the x-ray exposure lines on the film strips.

15. To adjust the longitudinal light field, insert the Allen wrench into the adjustment screw from the left side of the collimator. Turn the wrench in the clockwise direction to move the field to the left.

16. To adjust the transverse light field, first rotate the turn knobs to the positions shown below. The longitudinal knob should indicate a field size of 12 or greater on the 40 SID scale and the transverse knob should indicate a field size of 5, or smaller on the 40 SID scale. Insert the Allen wrench into the adjustment screw from the bottom front of the collimator. The adjustment screw is located approximately 2-1/2 inches up from the bottom of the collimator. Turn the wrench in the clockwise direction to move the field to the rear.



2.3 ELECTRICAL CONNECTIONS (Figure 4)

Collimator Electrical Requirements

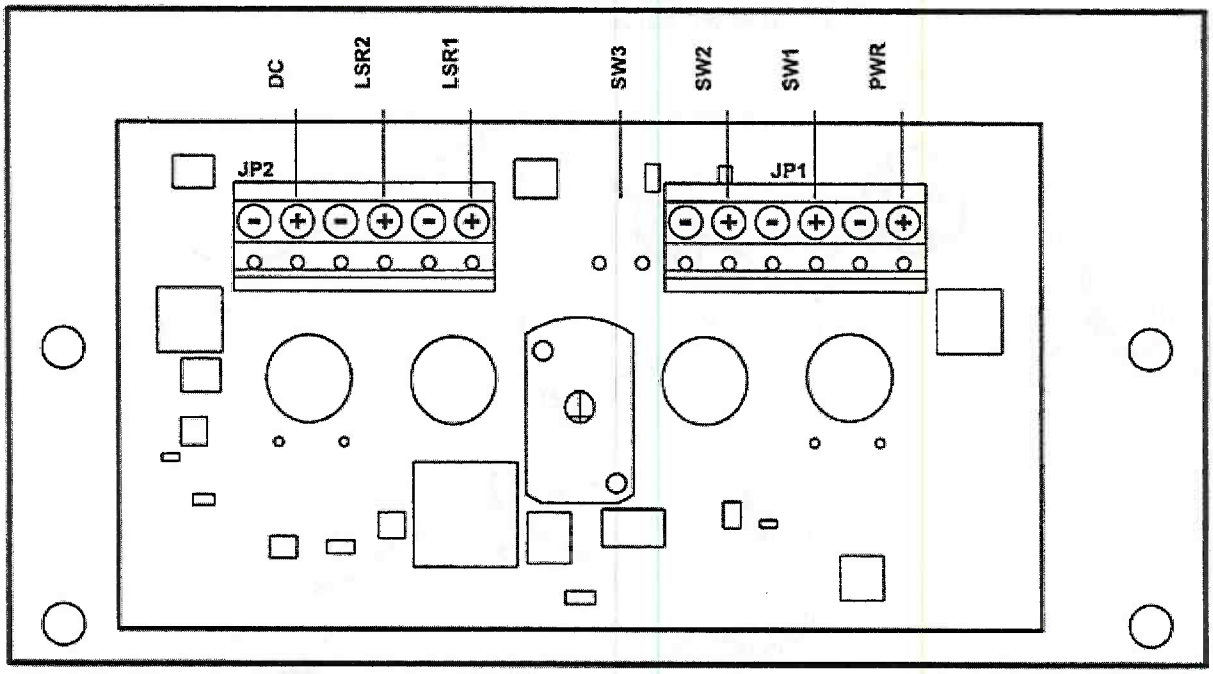
This is a CLASS I electrical device and must be wired in accordance with all applicable electrical codes and regulations. The power supply cable from the power supply to the Collimator must be sized to handle the full continuous rated load taking into consideration the distance from the collimator to the power supply.

Power Supply Requirement(s) (to comply with light output requirement)

12VDC @ 2A / 24VDC & 24VAC 50/60Hz @ 1A

Requires an isolated, primary and secondary fused AC transformer or DC power supply.

ELECTRICAL CONNECTIONS



JP1 PWR + Power AC/DC Wire (Blue)
JP1 PWR - Power AC/DC Wire (Brown)

JP1 SW1 + Main Switch Wire(White)
JP1 SW1 - Main Switch Wire(White)

JP1 SW2 + Laser Switch
JP1 SW2 - Laser Switch (Optional)

JP1 SW3 + Not Used
JP1 SW3 - Not Used

JP2 LSR1 + Laser 1 +3.5 DC Wire (Red)
JP2 LSR1 - Laser 1 Common Wire (Black)

JP2 LSR2 + Laser 2 +3.5 DC Wire (Red)
JP2 LSR2 - Laser 2 Common Wire (Black)

JP2 DC + Purple Wire
JP2 DC - Gray Wire

Chassis Ground Screw -
Power Cable Green/Yellow or Green Wire

Figure 4 - Collimator Electrical Connections

COLLIMATOR KNOB REMOVAL

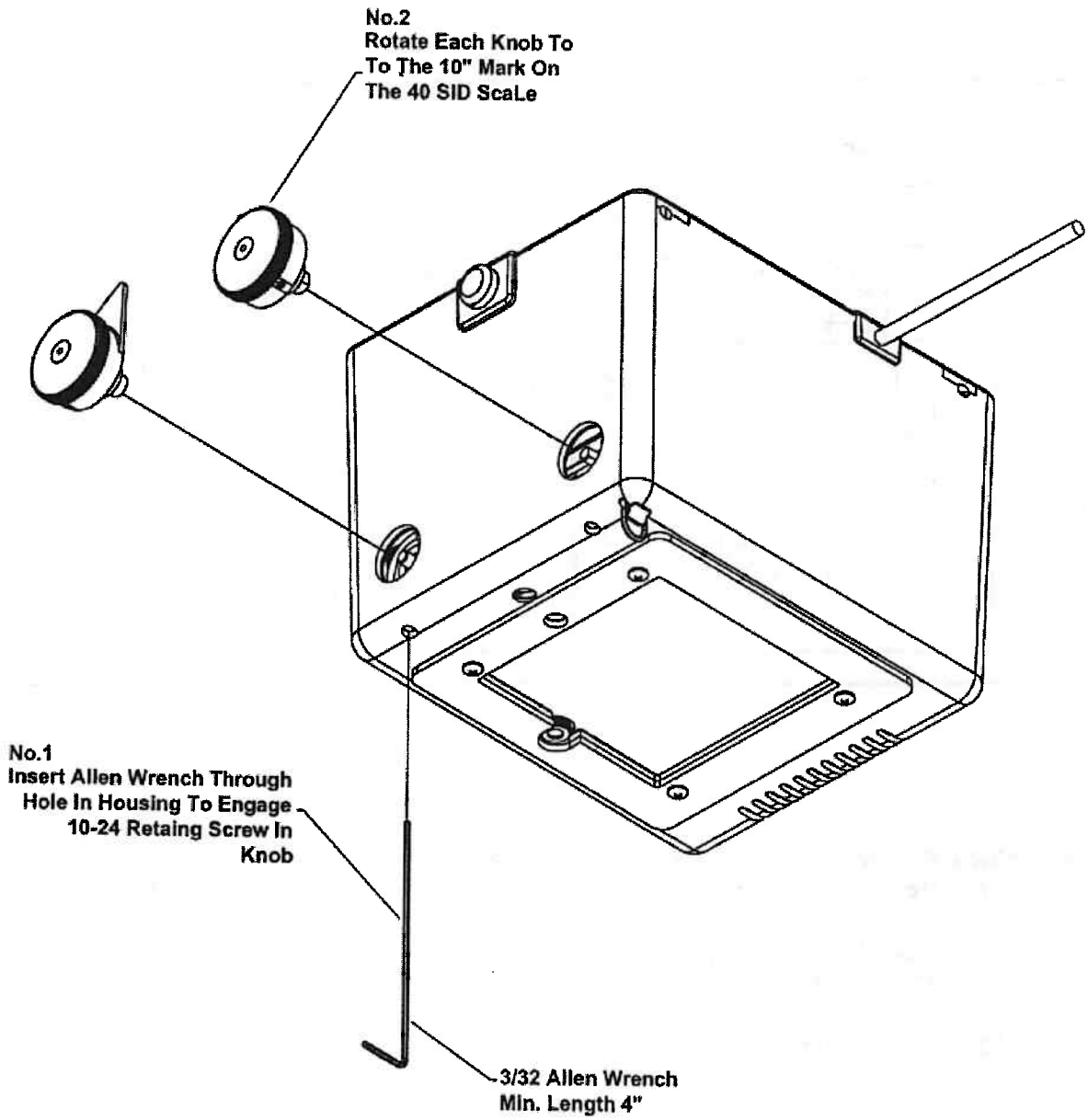


Figure 5 - Control Knob Removal

HOUSING REMOVAL

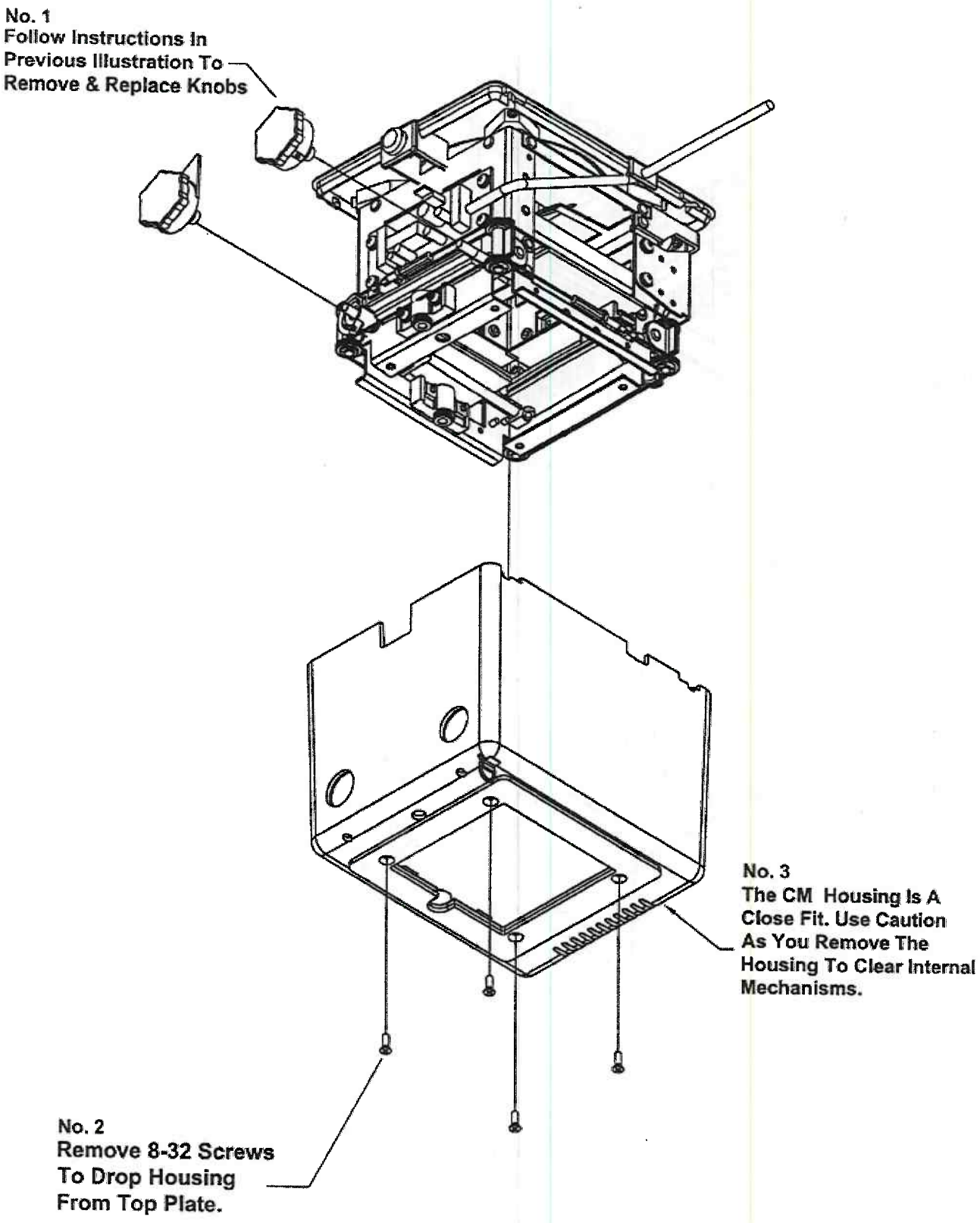


Figure 6 - Housing Removal

CCL & CPL PORTABLE SKIN GUARD REMOVAL

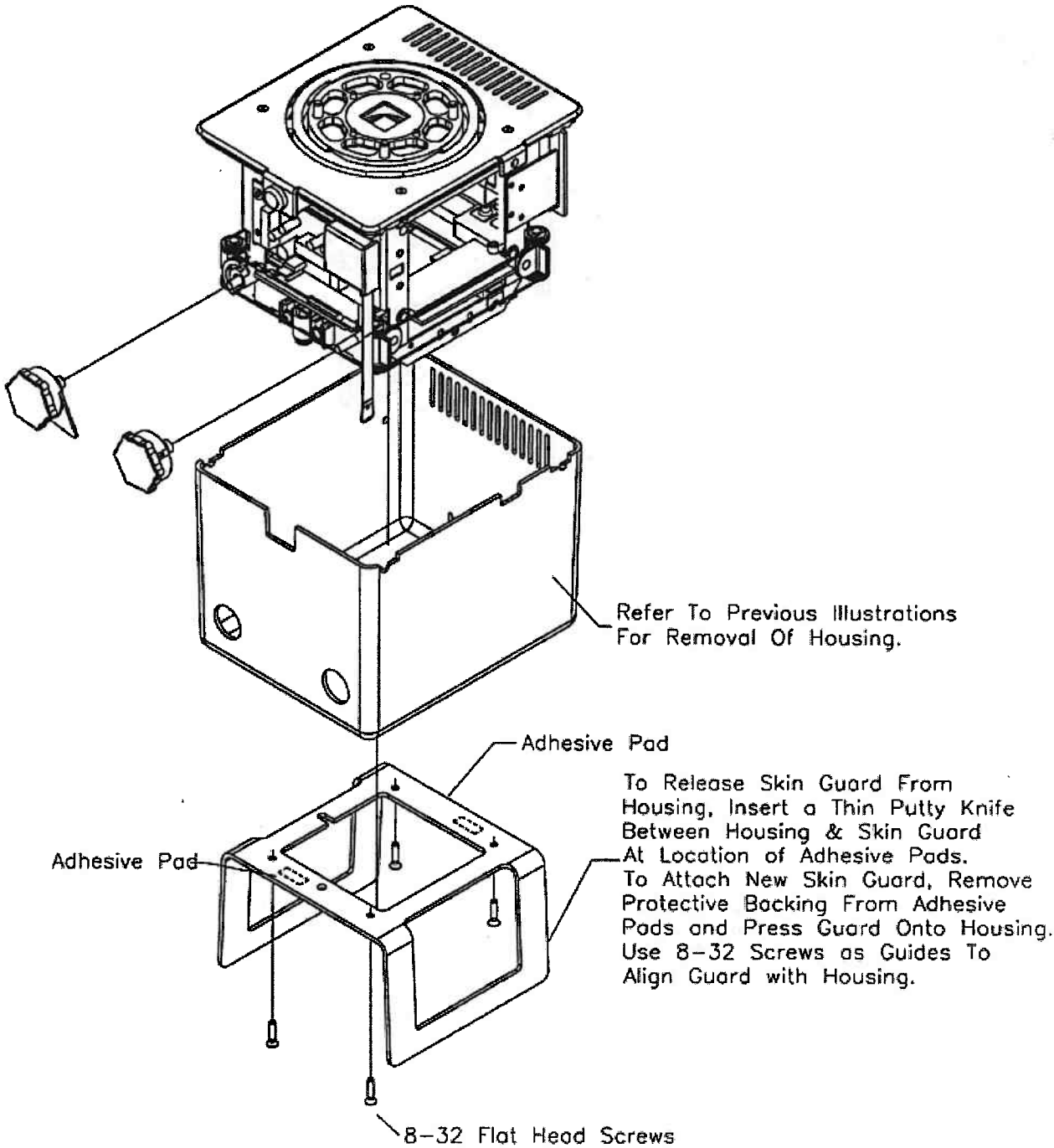


Figure 7 - Skin Guard Removal

LED REPLACEMENT

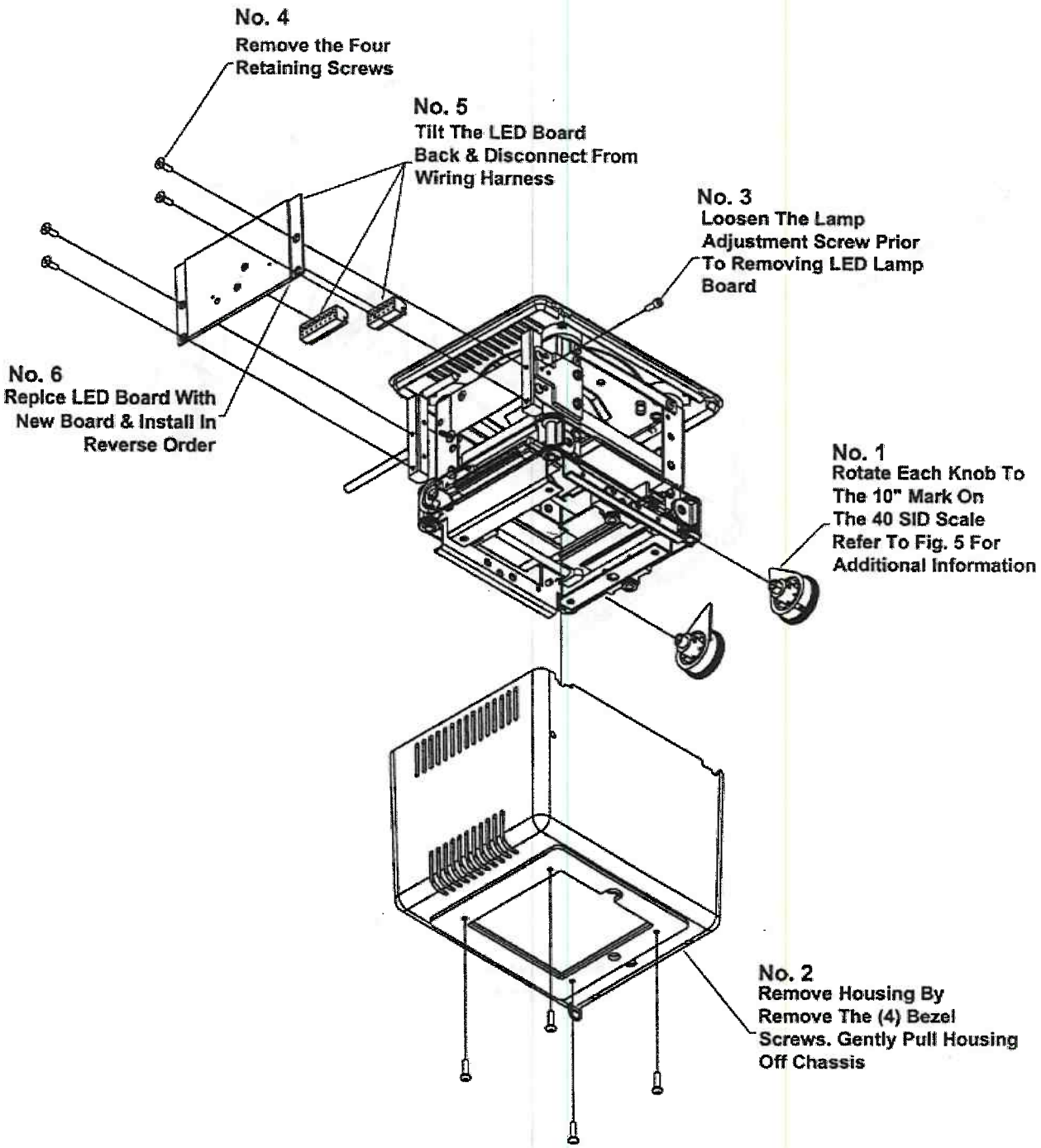


Figure 8 - LED Replacement

LIGHT FIELD ADJUSTMENT

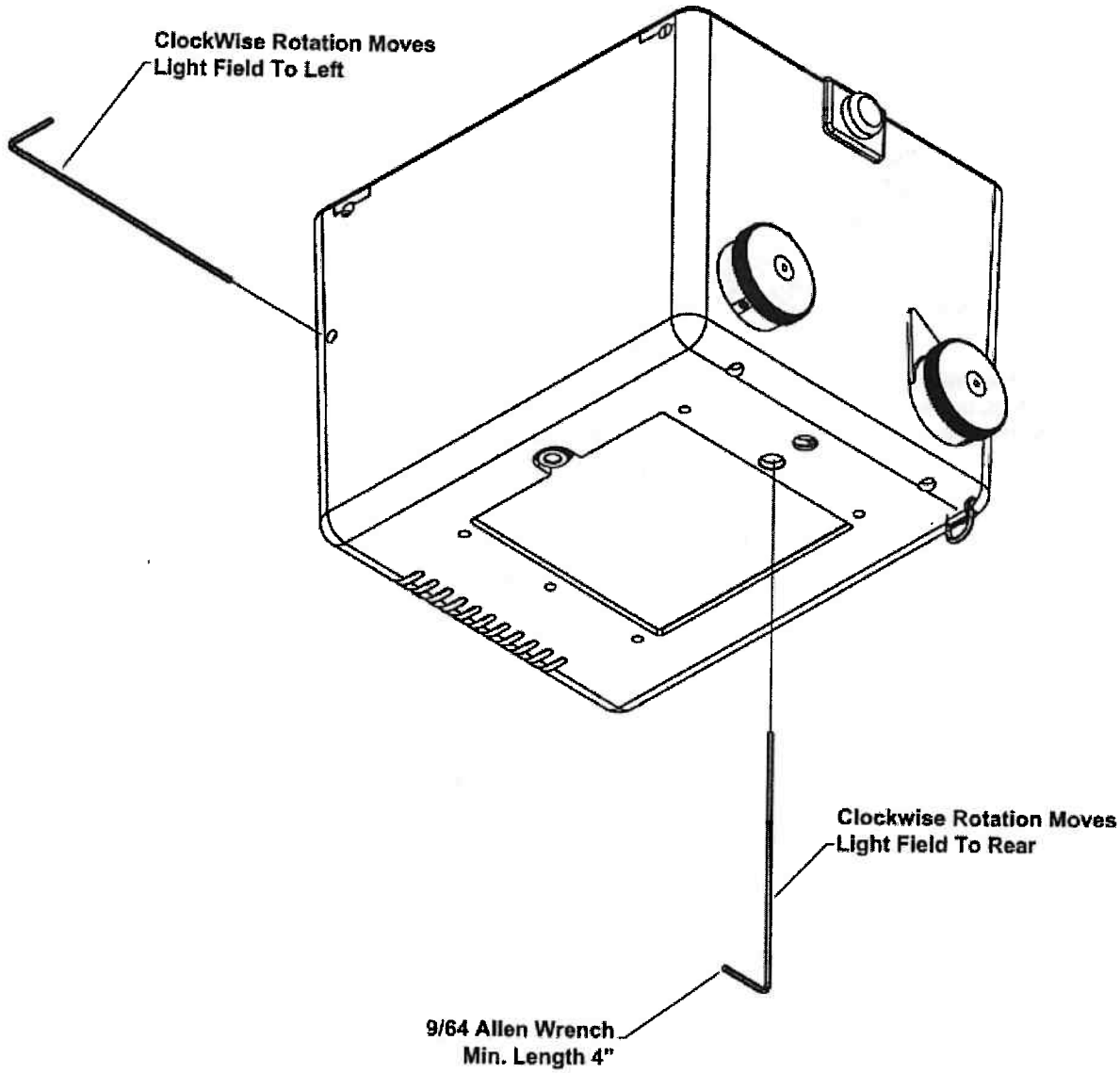


Figure 9 - Light Field Adjustment

LASER ADJUSTMENT
Old Style Lasers before S/N: A08323

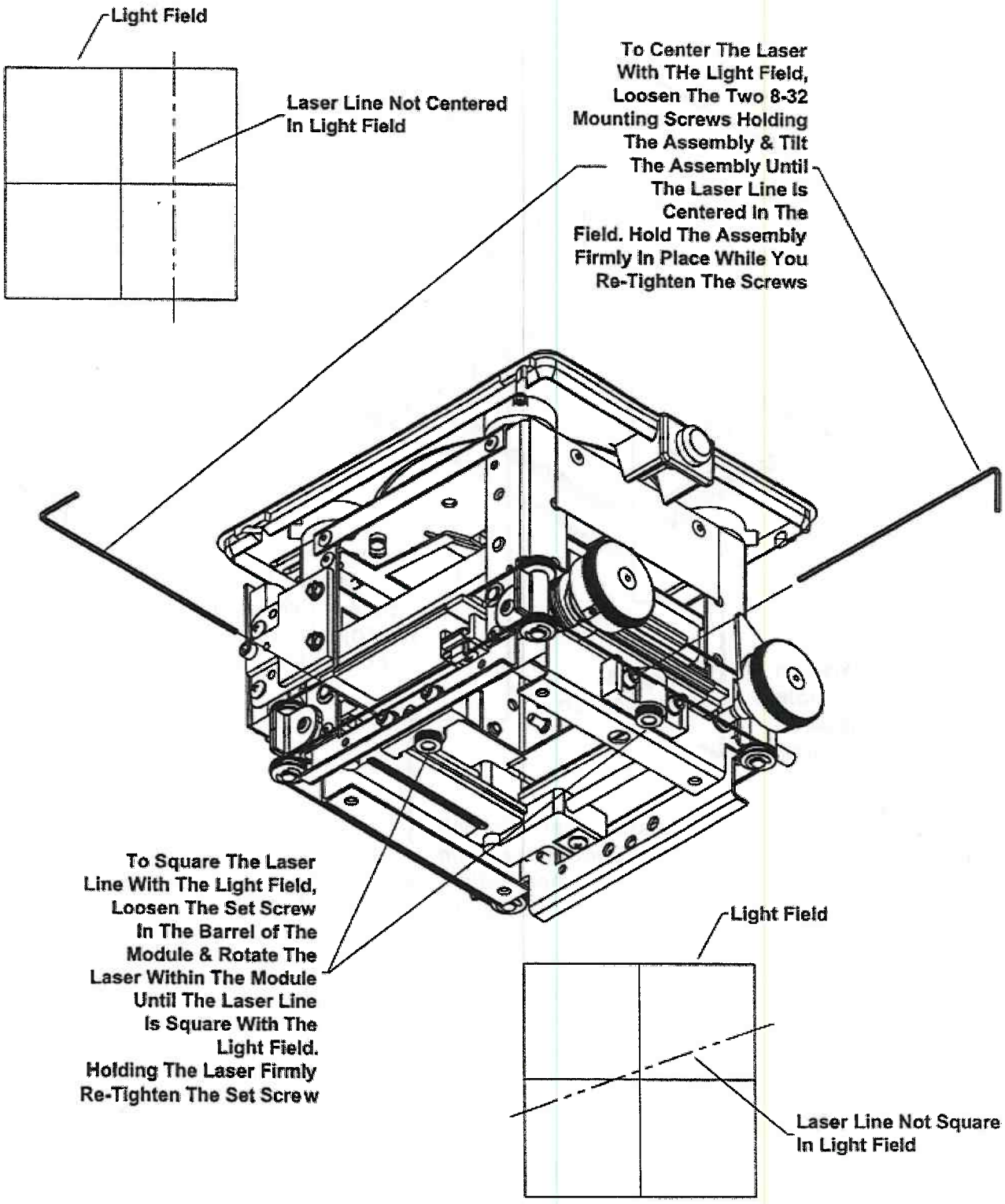


Figure 10 - Laser Adjustment

LASER ADJUSTMENT
Adjustable Lasers after S/N: A08322

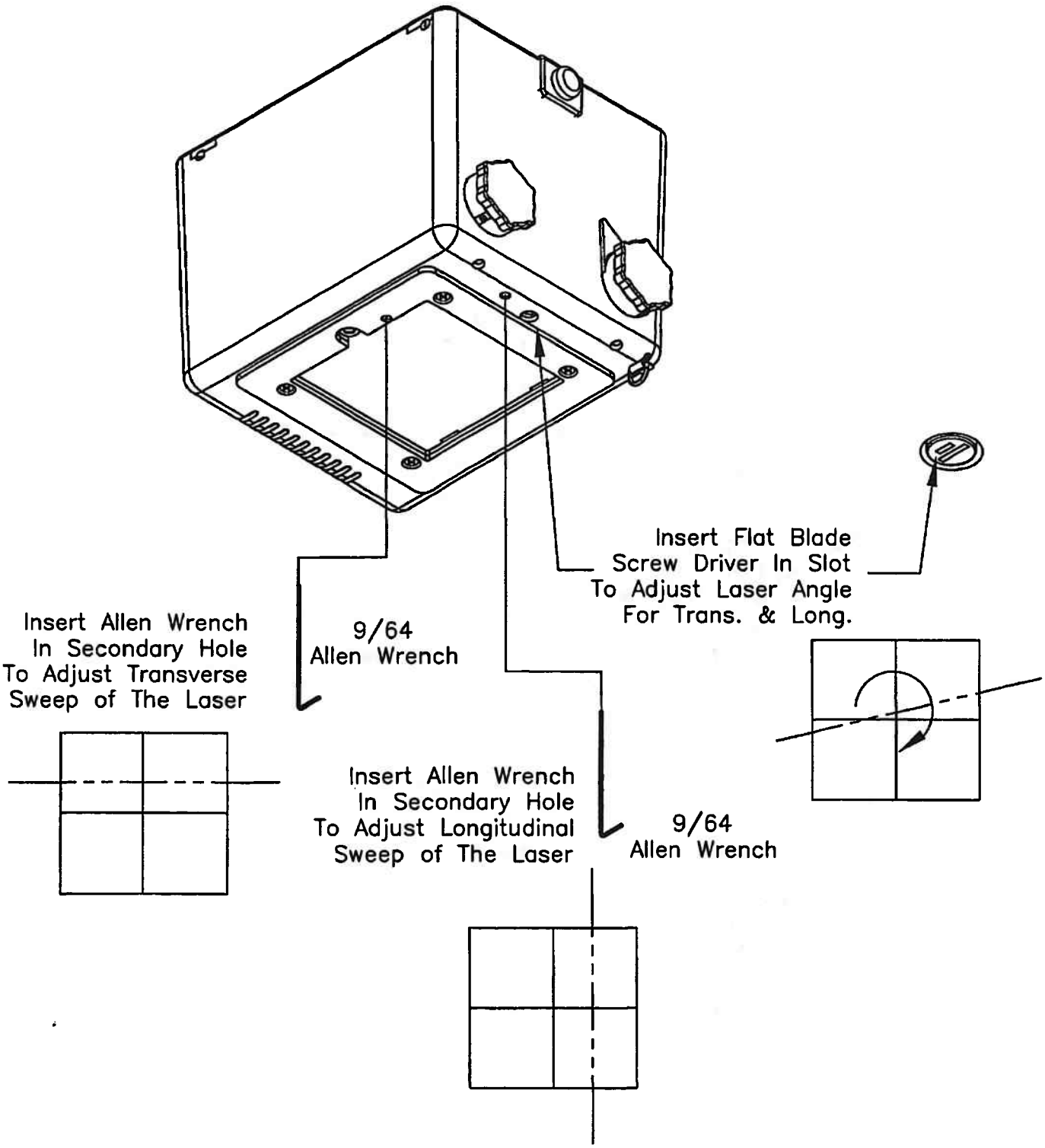


Figure 10 - Laser Adjustment

3.0 ADJUSTMENT PROCEDURES

The following adjustment procedures are performed with the collimator located in a single fixed position above a test pattern located on the tabletop.

The adjustments are made while observing the light field edges. Therefore, it is necessary to confirm that the light field accurately represents the X-ray field. By establishing a defined light field and exposing a film to produce a density of 1.0, the X-ray field (image) can be compared to the light field.

The Performance Standards 1020.30 (b) (22) and (45) define the edges of the light field as the locus of points at which the illumination is one-fourth of the maximum and the edges of the X-ray field as the locus of points at which the exposure rate is one-fourth of the maximum.

The X-ray field should be determined by exposing a film to a density of 1.0 on the developed image and observing the points at which the density is just visibly increased above the base for background of the film.

In a similar manner, the light field edges should be determined by observing the light field on a white background. By observing the points at which the light field is just visibly increased over the background illumination and comparing this with the X-ray field (and to the tolerance marks on the pattern), comparisons may be made.

PLEASE NOTE: All Collimators have been 100 percent tested and calibrated at the factory. Our intention is that you will only have to confirm operation.

EQUIPMENT REQUIRED:

A. Collimator test pattern included with this manual.
B. Measuring tape (ruler).
C. 14" x 14" X-ray film cassette.

3.1 LED REPLACEMENT & LIGHT FIELD ADJUSTMENT

This adjustment must be performed upon initial installation and when the field projection LED is altered from its original position or is replaced.

THE LED AND HEAT DEFLECTORS MAY BE HOT ENOUGH TO CAUSE SEVERE BURNS. DO NOT TOUCH ANY OBJECT IN THE LAMP AREA WITH BARE SKIN.

THE INTENSITY OF LIGHT OUTPUT IS SUFFICIENT TO TEMPORARILY IMPAIR YOUR VISION IF ALLOWED TO ENTER THE EYES DIRECTLY.

3.1.1 LED replacement see Figure 8 on page 25

3.1.2 CCL & CPL Portable Model Only follow instructions 2.2A on page 15

3.1.3 CML Clinical Model Only follow instructions 2.2B on page 18

3.2 CROSS-HAIR LASER ADJUSTMENTS

Remove the main Collimator housing per prior instructions/illustrations (Figure 6) on page 23.

Laser Adjustments - See Figure 10 on page 27:

To adjust line to center of field slightly loosen the two screws holding the laser housing assembly and angulate until aligned. There is a small hole on each side of the module to allow the insertion of a small Allen to provide leverage if needed. To adjust the rotation (angle relative to the center) of the laser slightly loosen the two screws holding the laser housing and rotate the laser module by carefully grasping the top and rotate the module.

4.0 COMPLIANCE VERIFICATION

It is necessary for the assembler to verify compliance. A series of tests, when performed at the time of installation, will indicate compliance with 21 CFR, Sub-Chapter J, Part 1020, Performance Standards.

The following tests are from the NEMA Standards Publication, No. XR 8-1979 (Test Methods for Diagnostic X-ray Machines for Use During Initial Installation).

For each compliance item, there may be a variety of test methods described. Which method is used will depend on the tester's experience, availability of equipment, time, or special requirements of the HUESTIS MEDICAL Collimator. Any reference tolerances on compliance items are referenced directly from 21 CFR, Sub-Chapter J, Regulations. They do not take into account inaccuracies brought about by the test equipment, instrumentation, or the human element. These factors must be considered when these tests are performed and the compliance of the equipment is being determined.

4.1 VERIFICATION TESTS TO BE PERFORMED

Test Procedure or Requirement	Applicable Paragraph
1. Determination of Half Value Layer (Beam Quality)	XR8/2.09
2. Visual Definition of X-ray Light-Field	XR8/2.14
3. Intensity of Light Field Illumination	XR8/2.15
4. X-ray Field/Receptor Center Alignment	XR8/2.17
5. Indication of Field Size	XR8/2.18
6. X-ray Field Limitation and Alignment	XR8/2.20
7. Record Sheet	

RECORD THE RESULTS ON THE RECORD SHEET SUPPLIED AT THE END OF THE SECTION.

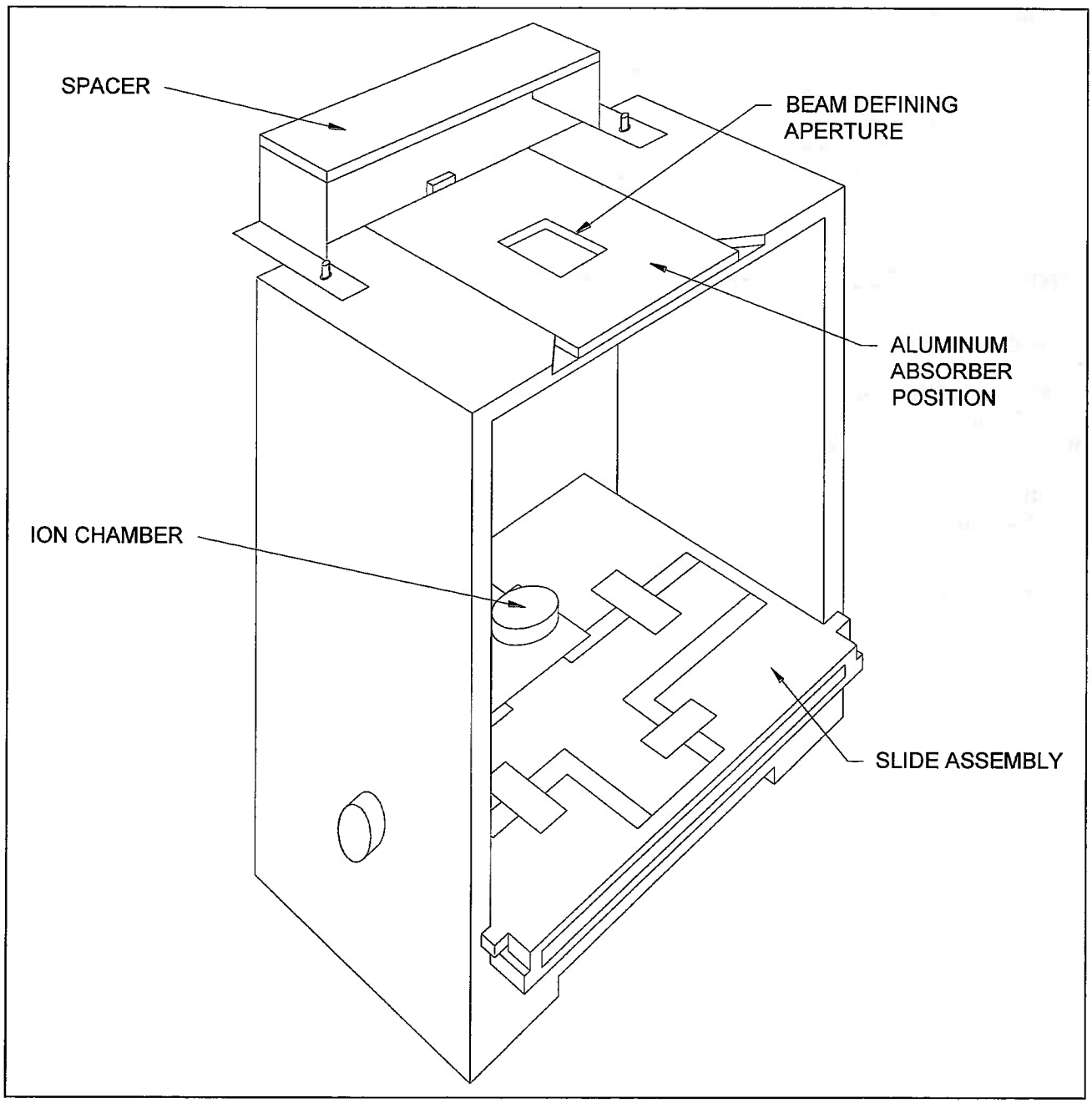


Figure 11 - General Set-up BRH/FDA Test Stand

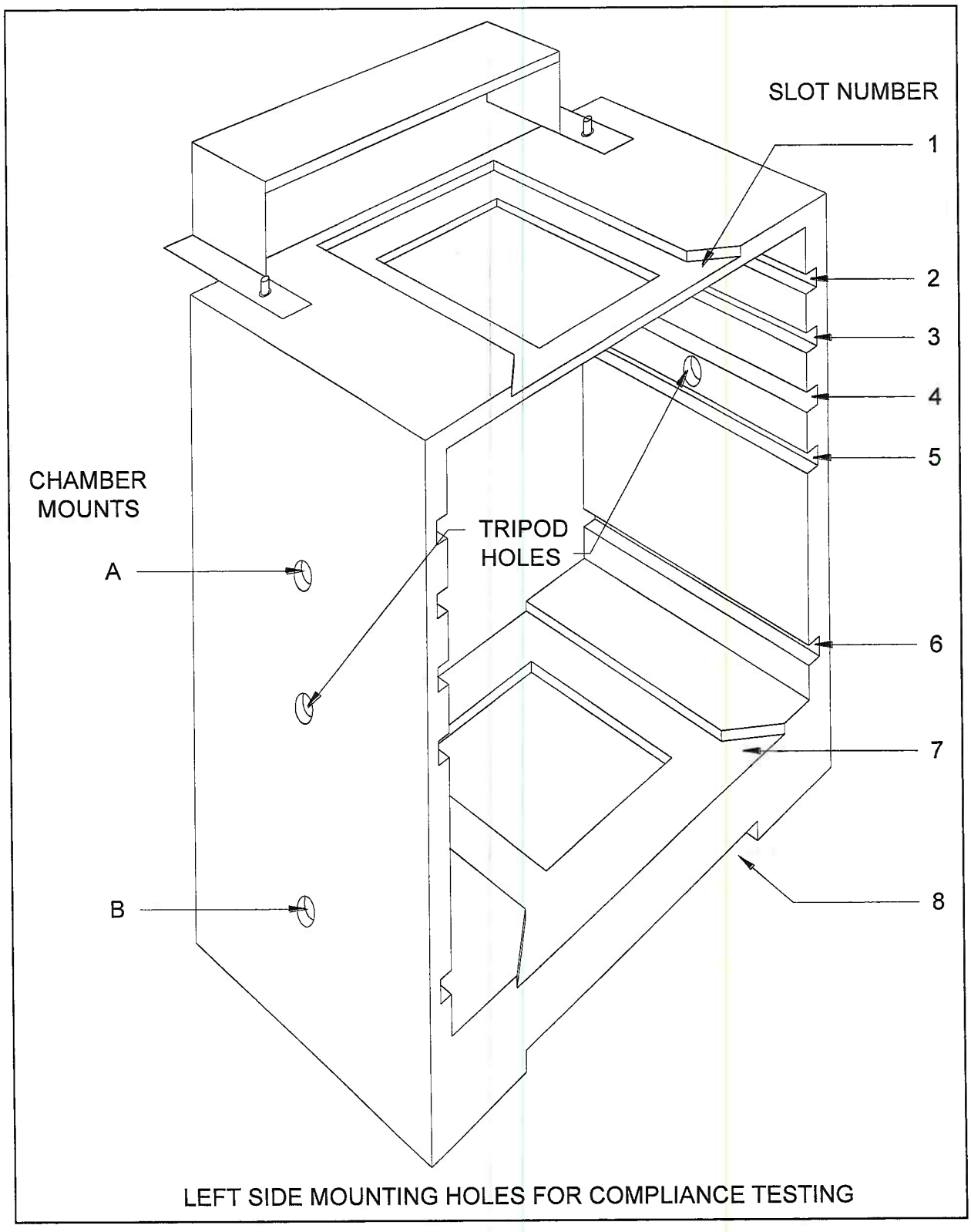


Figure 12 - BRH/FDA Test Stand Showing Chamber Mounting Slots

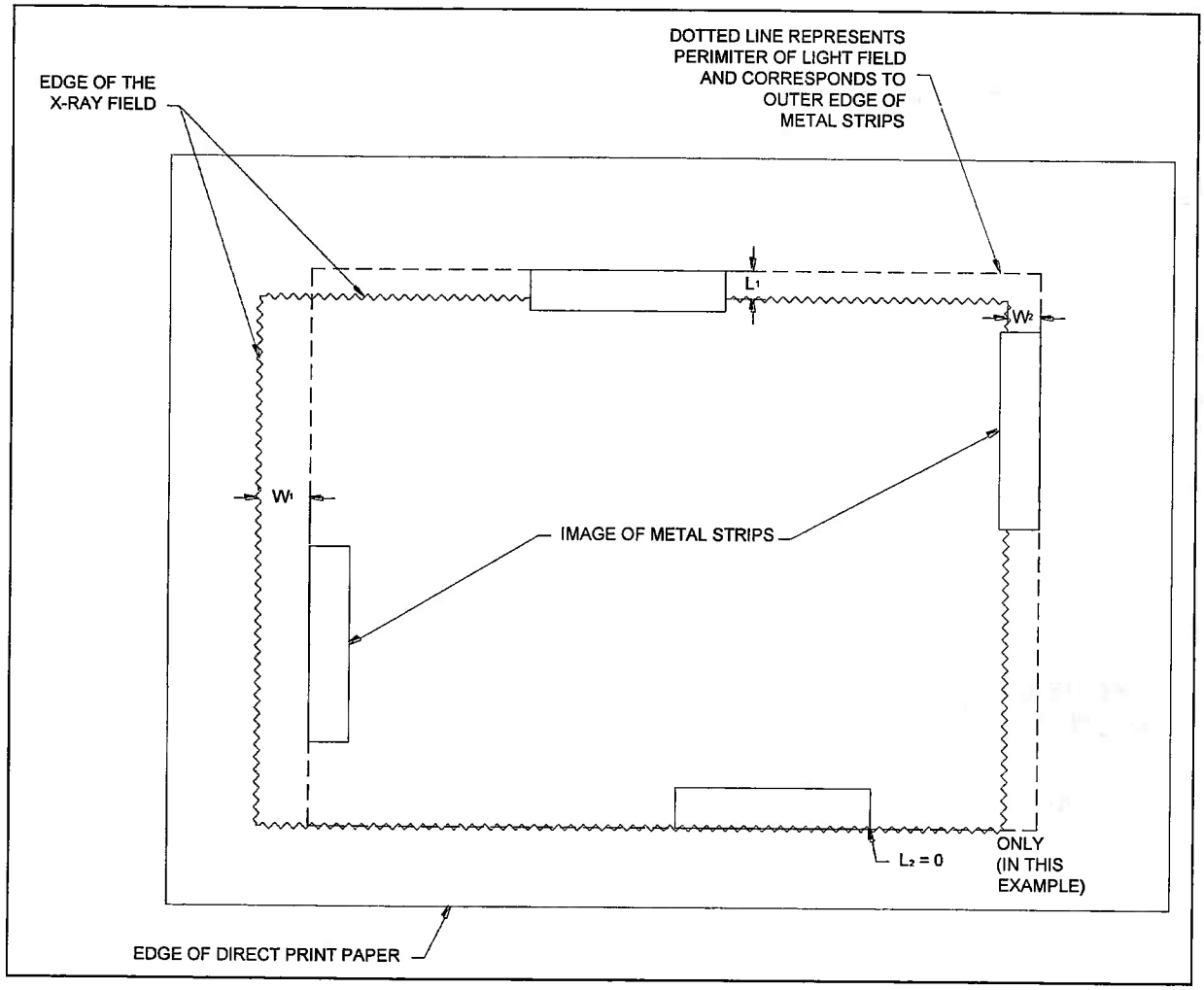


Figure 13 - Light Field vs. X-Ray Field Error Measurements

XR 8-2.09 BEAM QUALITY (HALF-VALUE LAYER (HVL))

REQUIREMENT - The minimum beam quality requirements listed in Table 1 shall be met. (See 21 CFR 1020.30(m).)

.01 METHOD I - VISUAL DETERMINATION OF HALF-VALUE LAYER (HVL)

A. General

The above HVL requirement will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table 2.

B. Equipment

None required.

Table 1 Minimum Beam Quality Requirements

KVp Range	Measured kVp	HVL (mm Al*)
Below 51	30	0.3
	40	0.4
	49	0.5
51 to 70	50	1.3
	60	1.5
	70	1.8
Above 70	71	2.5
	80	2.9
	90	3.2
	100	3.6
	110	3.9
	120	4.3
	130	4.7
	140	5.0
	150	5.4

*Type 1100 aluminum alloy as given in Aluminum Association Publication No. ASD-1, Aluminum Standards and Data.

Table 2 Aluminum Equivalent Of Primary Beam Total Filtration

OPERATING VOLTAGE (kVp)	TOTAL FILTRATION (mm Al Equivalent)
Below 50	0.5
50 - 70	1.8
Above 70	2.5

C. Procedure

Visually inspect the system and determine the aluminum equivalence of the total filtration in the primary beam. This includes the inherent filtration of the X-ray tube, X-ray tube housing, beam-limiting device, and any additional filtration that may have been added in the useful beam (in fluoroscopic systems the tabletop is included as part of the added filtration).

D. Verification Of Compliance

The aluminum equivalence of the total filtration must be equal to or greater than the amount specified in Table 2.
NEMA Standard 5-15-1979

.02 METHOD II - STANDARD ABSORBER METHOD

A. General

This test is to be used when the surveyor cannot remove or see the total filtration equivalence.

The HVL determinations obtained from the following procedures are to be compared with those illustrated in Table 1. The HVL in millimeters of aluminum of the system being tested must be greater than or equal to the values shown in Table 1.

B. Equipment

1. Radiation detector.

2. Standard absorber with equivalent filtration of 2.5 millimeters of aluminum.

C. Procedure

1. With the detection device positioned horizontally, an exposure is made at a preselected technique factor of 80 kVp and appropriate mA and time. The reading of the radiation output is recorded.

2. Position a total of 2.5 millimeters of aluminum at the port of the beam-limiting device and repeat the exposure using the same technique factors. Record the radiation output.

   For X-ray units operating at low kVp (less than 50) and for mammography units, it will be necessary to use an aluminum absorber of 0.6 millimeters at 49 kVp.

D. Verification Of Compliance

Verify that the radiation output in Step 2 is greater than or equal to 50 percent of the radiation output in Step 1.
NEMA Standard 5-15-1979

XR 8-2.13 ACTUAL VERSUS INDICATED SOURCE-TO-IMAGE DISTANCE (SID)

REQUIREMENT-Means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the source to image distance (SID), and to indicate the SID to within 2 percent.
[See 21 CFR 1020.31(e)(1).]

.01 Method I - Direct Measurement Method

A. General
In order to perform this test it is necessary that the focal spot location be known.

B. Equipment
Graduated scale.

C. Procedure
1. Set the tube unit to an appropriate SID and record this value.
2. Using the graduated scale measure the distance from the plane of the image receptor to the surface of the table top and record this distance as distance A.
3. Using the graduated scale measure the distance from the tabletop to the bottom of the beam limiting device and record this distance as distance B.
4. Add distances A and B to the known focal spot location; this quantity is the actual SID.
5. Multiply the actual SID determined in Step 4 by 2 percent and record.

D. Verification and Compliance
The indicated value of the SID recorded in step 1 must fall within the value of the actual SID determined in step 4 plus or minus the value determined in step 5.

NEMA Standard 5-15-1979

.02 Method II - Triangulation Method

A. General
1. The image of the radiation field on the film must be of uniform density with sharply defined edges.
2. The graduated template is utilized to minimize the amount of error introduced into the measurement and calculation of the SID.

B. Equipment
1. Manufacturer's recommended test stand.
2. Cassettes with film or direct print paper.
3. Graduated template.

C. Procedure
1. Align the tube unit with the image receptor and select an appropriate SID with the normal operating aids (detents, scales, lights, etc.) provided.
2. Load the cassette and insert into the image receptor.
3. Position the test stand according to the manufacturer's instructions.
4. Load a second cassette and place in the designated position on the test stand. Make certain that the graduated template is in a position above the second cassette (see Figure 14 Determination Of SID).
5. Select the proper technique factors, make an exposure, and develop the film or direct print paper.
6. Calculate the magnification factor by measuring the distance between the same two points on the graduated template image on each of the two films. The two points chosen must be as far apart as possible. Divide the larger measurement by the smaller measurement to determine the magnification factor.
7. If the source to test stand film distance is known, calculate the actual SID by multiplying the magnification factor by the source to test stand film distance.

8. If the source to test stand film distance is not known, measure the actual distance4 from the graduated template position to the test stand film plane (distance Z - see **Error! Reference source not found.**).
9. Calculate the source to template distance (distance X) using the following formula:

$$A/B = X/X+Z \text{ or } X=AZ/B-A$$

where

A= two points on the graduated template
B = magnification of the same two points on the graduated template

10. Calculate the source to test stand film distance by adding the distance X and the distance Z. Multiply the source to test stand.

XR 8-2.14 VISUAL DEFINITION (RADIOGRAPHIC) OR X-RAY LIGHT-FIELD

REQUIREMENT - Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam. (See 21 CFR 1020.31(d)(2).)

.01 METHOD I - BRH/FDA COMPLIANCE TEST METHOD

A. Equipment Required

1. BRH/FDA compliance test stand (including slide assembly).
2. Four metal marker strips.
3. Plastic cassette, loaded with direct-print paper or film.

B. Procedure

1. Attach the spacer, positioned out of the primary beam to the test stand. Center the stand on the table. Center the source over the stand, assure by the means provided that the axis of the X-ray beam is perpendicular to the plane of the image receptor, and bring the beam-limiting device down into firm contact with the spacer. Select the MANUAL mode of operation (there must not be a cassette in the cassette holder).
2. Insert the slide assembly, grid side up, into slot 6 of the test stand and the focal spot assembly into slot 1. Place cassette loaded with direct-print paper or film into the slide assembly.
3. Adjust the collimator such that no part of the light-field intersects any portion of the top of the test stand. (Further collimation to a light-field of less than 15 by 20 centimeters (6 by 8 in) on the slide assembly grid may be desirable to assure that the X-ray field will be fully contained on the direct-print paper or film in the slide assembly).
4. Position the outer edge of each metal strip to correspond with each side of the light-field. One end of the metal strip shall extend to the center line of the respective grid arm.
5. Select proper technique factors and make an exposure (may require several exposures to obtain 1 R to the direct-print paper).
6. Develop the direct-print paper or film.

C. Verification Of Compliance

For determination of misalignment, compare the edges of the X-ray field to the edges of the light-field as defined by the outer edges of the metal strips. On each side of the rectangular fields, measure the separation between the X-ray field and the outside edge on the image of the respective metal strip. Sum these measured separations for opposite sides of the X-ray field to yield a total misalignment in the length and width dimensions. Record the length misalignment and width misalignment, both without regard to sign.

D. Calculations

Calculate the source-to-image distance (SID) per the following formula (to slot 6) as the indicated source-to-table-top distance minus 4.7 centimeters (1.85in) and record. Calculate 2 percent of this SID and record. Both the length and the width misalignment must be less than 2 percent of SID (to slot 6).

$$\frac{2.5}{S} \quad \frac{X}{X + 13.95}$$

$$2.5X + (2.5)\ 13.95 = XS$$

$$(2.5)\ 13.95 = XS - 2.5X$$

$$34.875 = X\ (S - 2.5)$$

$$X = \frac{34.875}{S - 2.5}$$

The misalignments are calculated:

Length misalignment = L1 + L2 $\leq$ 2% SID
Width misalignment = W1 + W2 $\leq$ 2% SID

Calculate 2 % of the measured SID. Each of the misalignments, length or width, must be less than or equal to 2 % of the measured SID for compliance. NEMA Standard 5-15-1979.

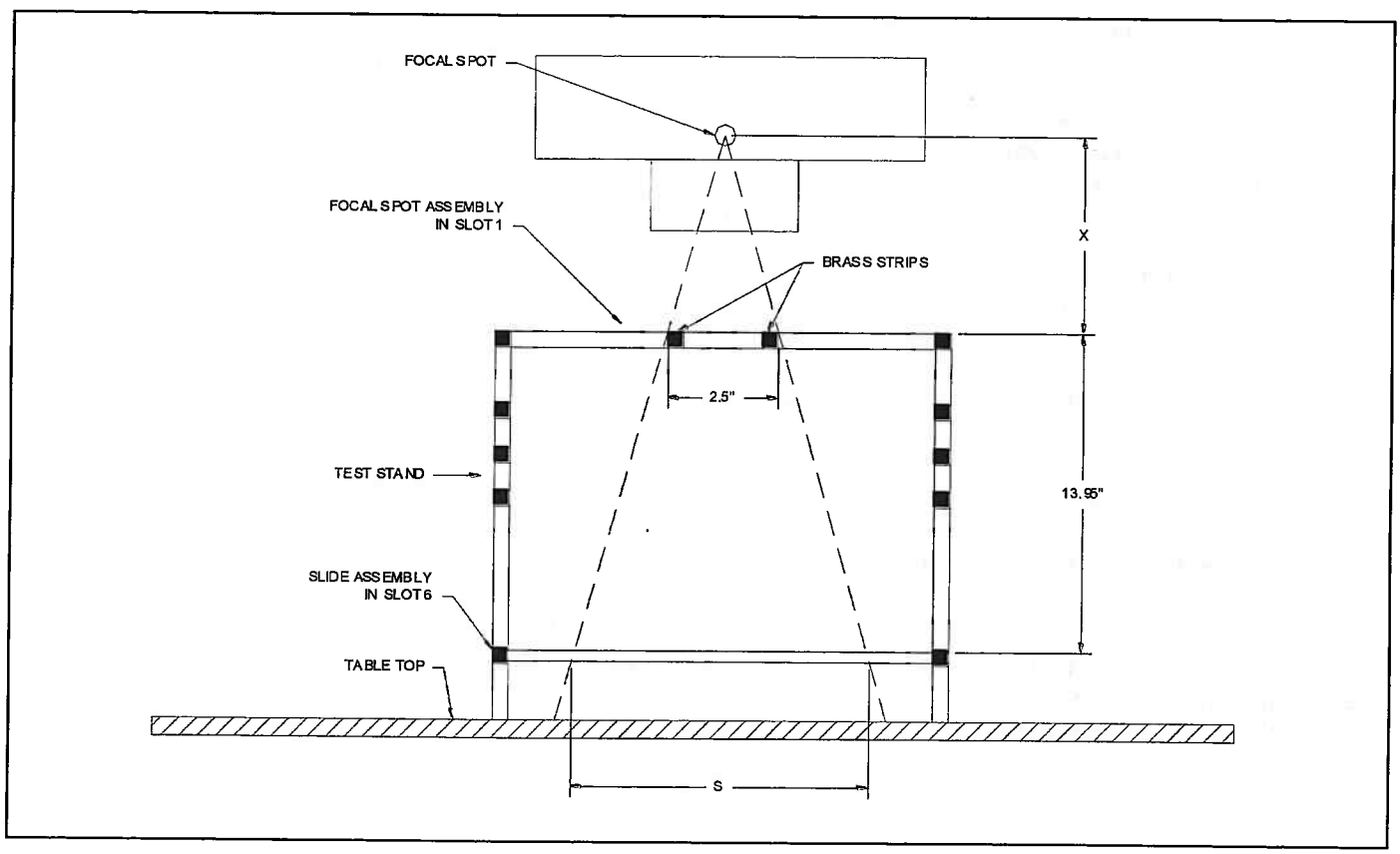


Figure 14 - Determination of SID

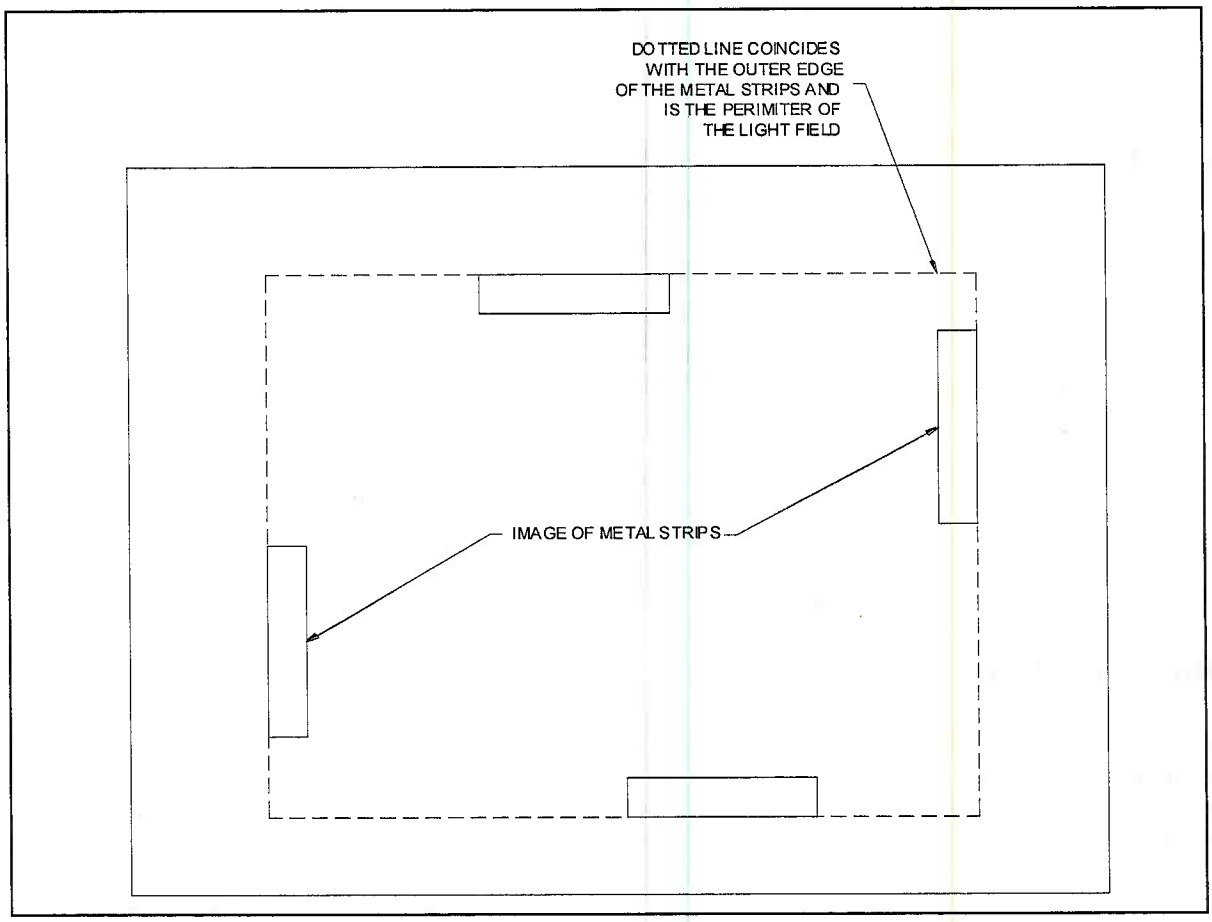


Figure 15 - Metal Marker Method

.02 METHOD II - METAL MARKER METHOD

A. General

The actual versus indicated source-to image distance (SID) test must be performed prior to attempting this test.

B. Equipment

1. Plastic cassette with direct-printer paper or film.

2. Radio-opaque markers.*
   *Each marker is approximately 1/32 inch galvanized sheet metal having the dimensions of 1.5 by 1.5 inches.

C. Procedure

1. Adjust the source assembly and the beam-limiting device so that they are approximately centered over the table and perpendicular to the table top. Then position the beam-limiting device to the SID previously determined and record the indicated value.

2. Insert the cassette and turn on the light-field. **Adjust the beam-limiting device to the next size smaller than the cassette size being used.
   **Make a note to record the field size indicated on the dial of the beam-limiting device for the SID being used.

3. Position the outer edge of each metal marker on the tabletop to correspond with each side of the light-field.

4. Select the appropriate technique factors and make an exposure.

5. Develop film or direct-print paper.

D. Verification Of Compliance

For determination of misalignment, compare the edges of the X-ray field to the edges of the light-field as defined by the outer edges of the metal strips. On each side of the rectangular fields, measure the separation between the X-ray field and the outside edge of the image of the respective metal strip. Sum these measured separations for opposite sides of the X-ray field to yield a total misalignment in the length and width dimensions. Record the length misalignment and width misalignment, both without regard to sign.

E. CALCULATIONS

$$\frac{2.5}{S} \quad \frac{X}{X + 13.95}$$

$$2.5X + (2.5)\ 13.95 = XS$$

$$(2.5)\ 13.95 = XS - 2.5X$$

$$34.875 = X\ (S - 2.5)$$

$$X = \frac{34.875}{S - 2.5}$$

The misalignments are calculated:

Length misalignment = L1 + L2 $\leq$ 2% SID
Width misalignment = W1 + W2 $\leq$ 2% SID

Calculate 2 % of the measured SID. Each of the misalignments, length or width, must be less than or equal to 2 % of the measured SID for compliance. NEMA Standard 5-15-1979.

.03 METHOD III - ALTERNATE TEST STAND METHOD

A. General

1. The image of the radiation field on the film must be of uniform density with sharply defined edges.
2. The graduated template is utilized to minimize the amount of error introduced into the measurement of the X-ray field size.
3. The actual versus indicated source-to-image distance (SID) must be determined prior to performing this test.

B. Equipment

1. Manufacturer's recommended test stand.
2. Cassettes and film.
3. Graduated template.

C. Procedure

1. Align the tube unit and image receptor and set the SID with the normal operating aids (detents, scales, lights, etc.)
2. Load cassette and insert into image receptor.
3. Close shutters to a size smaller than that of the cassette placed into the image receptor.
4. Position the test stand in accordance with the manufacturer's instructions.
5. Energize the field light and record or define the position of the four light field edges as shown on the graduated template or position four metal markers so that the outer edge of each metal marker corresponds to an edge on each side of the light-field or both.
6. Select proper technique factors, make an exposure, and develop film.

D. Verification Of Compliance

1. Calculate 2 percent of the actual SID and record.
2. Compare the edges of the X-ray field to the edges of the light-field as defined by the outer edges of the metal markers or by the graduated scale.
3. Measure the distance between the edges of the two fields for each side of the rectangular fields.

4. Arithmetically sum the misalignment of opposite sides, regardless of sign, of the rectangles, to yield misalignment in each of the two directions.

Length misalignment = L1 + L2 $\leq$ 2% SID
Width misalignment = W1 + W2 $\leq$ 2% SID

Both the length and the width misalignment must be less than 2 percent SID as calculated in Step 1.

NEMA Standard 5-15-1979

XR 8-2.15 INTENSITY OF LIGHT-FIELD ILLUMINATION

REQUIREMENT - When a light localizer is used to define the X-ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum source-to-image distance (SID), whichever is less. The average illumination shall be based on measurements in the approximate center of each quadrant of light-field. (See 21 CFR 1020.31(d)(2)(ii).)

.01 METHOD I - DIRECT TEST

A. General

1. Make certain that all surfaces in the light path are clean.

2. Reduce ambient light level as much as is feasible.

B. Equipment

Photometer capable of measuring 160 lux (15 footcandles).

C. Procedure

1. Place the photometer in the tabletop and set the diagnostic source assembly such that the sensing area of the photometer is at 100 centimeters or the maximum SID, whichever is less.

2. Open the beam-limiting device to assure that each quadrant of the light-field is larger than the sensing area of the photometer.

3. Refer to the manufacturer's instructions for proper use of the photometer.

4. Turn on the light localizer.

5. At or near the center of a light-field quadrant, determine the illuminance by subtracting the ambient light level from the corresponding light level as measured when the light localizer is energized. Do not move the photometer between measurements.

6. Repeat the procedure for the remaining three quadrants.

7. Determine the average illuminance of the four light field quadrants.

8. Record the model number, serial number, and the date of calibration of test instrument.

D. Verification Of Compliance

Verify that the average illumination is not less than 160 lux (15 footcandles).

NEMA Standard 5-15-79

.02 METHOD II - INDIRECT TEST

A. General

1. This indirect test is feasible after the correlation between light output and voltage is made; the manufacturer then specifies a voltage to be measured or adjusted, or both.

2. Make certain that all surfaces in the light path are clean and unobstructed.

B. Equipment

Digital Voltmeter.

C. Procedure

1. Remove trim covers to gain access to the lamp socket.
2. Verify that the specified lamp is in the socket.
3. With the light-field energized, measure the voltage across the lamp socket terminals.
4. Record the voltage measured.
5. Record the model number, serial number and calibration date of the digital voltmeter.

D. Verification Of Compliance

The voltage recorded shall be within the tolerances specified by the manufacturer.

NEMA Standard 5-15-1979

XR 8-2.17 X-RAY FIELD/RECEPTOR CENTER ALIGNMENT

REQUIREMENT - Means shall be provided to align the center of the X-ray field with respect to the image receptor to within 2 percent of the source-to-image distance (SID). (See 21 CFR 1020.31(e)(1).)

A. General

1. All exposures taken during this test must have a uniform film density of approximately 1.0.

2. Actual versus indicated SID must be determined prior to performing this test.

B. Equipment

Radiographic cassette loaded with film (8 by 10 inches).

C. Procedure

1. Load cassette with film and place into the bucky tray.

2. Assure that the X-ray beam is perpendicular to the image receptor and centered over the bucky tray.
3. Set the SID to the value determined in the actual versus indicated SID test.

4. Reduce the X-ray field to approximately 6 by 8 inches.

5. Make an exposure and develop the film.

6. To determine as accurately as possible the corners of the image recorded on the film, locate two points on each of the four sides of the image. Through the two points on each side draw a straight line. These four lines, when extended, intersect making a rectangle which is a close approximation of the actual X-ray field. Draw a diagonal across the image to determine the center of the X-ray image.

7. To determine the center of the X-ray film draw diagonals across the film (the point where these two lines cross is the center of the film), or fold the film into quarters (the point where the two folds cross is the center of the film).

8. The distance from the film center mark to the image center mark is measured and recorded as the linear displacement or misalignment or the centers of the X-ray field and the image receptor.

D. Verification Of Compliance

Verify that this distance is less than or equal to 2 percent of the SID.

NEMA Standard 5-15-1979

XR 8-2.18 INDICATION OF X-RAY FIELD SIZE

REQUIREMENT - Means shall be provided on the beam-limiting device to indicate field size in the image receptor plane to within 2 percent of the source-to-image distance (SID). (See 21CFR 1020.31(e)(1).)

A. General

The actual versus indicated SID test must be performed prior to beginning this test.

B. Equipment

A 24-by 30-centimeter or a 10 by 12 inch cassette with film.

C. Procedure

1. Set the SID to the value determined in the actual versus indicated SID test.
2. Center the film cassette in the cassette tray and insert into position.
3. Adjust the field size to 15 by 15 centimeters or 8 by 8 inches by means of the numerical indicators on the beam-limiting device.
4. Make an exposure and develop film.
5. Measure and record the length and width dimensions of the image.

D. Verification Of Compliance

The deviation of any of the recorded dimensions must not exceed 2 percent of the SID in Step 1.

NEMA Standard 5-15-1979.

XR 8-2.20 X-RAY FIELD LIMITATION AND ALIGNMENT

REQUIREMENT - The X-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the X-ray field differs from that of the image receptor by greater than 3 percent of the source-to-image distance (SID) and that the sum of the length and width differences without regard to sign be no greater than 4 percent of the SID, when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. (See 21 CFR 1020.31(e)(2)(ii).)

.01 METHOD I - FDA/CDRH TEST STAND METHOD

A. Equipment

1. BRH/FDA compliance test stand with accessories.
2. Slide assembly.
3. Plastic cassette containing a sheet of direct-print paper or X-ray film.
4. Ruler.
5. Cassette (preferably 8 by 10 inches or smaller).

B. Procedure

1. Using the means provided, align the source assembly such that the beam axis is perpendicular to the image receptor.
2. Place the stand on the table.
3. Position the spacer so as not to intersect the primary beam and secure with the pushbutton connectors.
4. Center the source assembly over the test stand using the means provided, e.g., the light-field used to define the X-ray field.
5. Bring the source assembly down onto firm contact with the spacer.
6. Center the cassette tray with the source assembly using the means provided, e.g., bucky light.
7. Insert the plastic cassette into the slide assembly. Then insert the slide assembly into slot 5. (See Figure 12 BRH/FDA Test Stand Showing Chamber Mounting Slots)
8. Center the film cassette in the cassette tray and insert into position. If the positive-beam limitation will not operate at this SID, raise the source assembly and lock in position at the first operable SID.
9. Make an exposure. Develop the image. Measure and record the length and width dimensions of the image.
10. Calculate the field size correction factor as the SID/A where:
    a. SID is the indicated source-to-image receptor distance, and:
    b. A is the indicated source-to-tabletop distance less 7.7 inches. Multiply each of the measured dimensions by the correction factor.

X-ray field length at

$$\text{under-table image receptor} = \frac{\text{SID}}{\text{A}} \times (\text{X-ray field length at slot 5})$$

X-ray field width at

$$\text{under-table image receptor} = \frac{\text{SID}}{\text{A}} \times (\text{X-ray field length at slot 5})$$

Determine the difference without regard to sign between the corrected length and width dimensions and the corresponding cassette film size dimensions (8 by 10, 5 by 7, etc.). Each of these differences must be less than 3 percent of the SID, and the sum of these differences must be less than 4 percent of the SID.

.02 METHOD II - ALTERNATE TEST STAND METHOD

A. General

Prior to performing this test, the magnification factor must be determined in accordance with the X-ray/Light-Field Alignment Test - Method III.

B. Equipment

1. Manufacturer's recommended test stand.
2. Cassette with film.

C. Procedure

1. Align the tube unit and image receptor and set SID to the value determined in the actual versus indicated SID test.
2. Insert empty 8 by 10 inch cassette into bucky tray.
3. Position test stand in accordance with manufacturer's instructions.
4. Load a second cassette and place in the designated position.
5. Select the proper technique factors, make an exposure, and develop film.
6. Measure the length and width of the X-ray image on the film.
7. Multiply each measurement by the magnification factor previously determined.

D. Verification Of Compliance

Verify that the X-ray field size in the plane of the image receptor does not differ from that of the image receptor by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign is no greater than 4 percent of the SID.

NEMA Standard 5-15-1979

.03 METHOD III - CASSETTE METHOD

A. General

This can be used only when capability is provided for overriding positive-beam limitation.

B. Equipment

1. Large cassette with film.
2. Small cassette, empty.

C. Procedure

1. Insert empty smaller cassette into bucky tray.
2. Switch system to the override mode.
3. Remove the smaller cassette and insert the loaded large cassette.
4. Select the proper technique factors, make an exposure, and develop film.
5. Measure the length and width of the X-ray image on the film.

D. Verification Of Compliance

Verify that the X-ray field size in the plane of the image receptor does not differ from that of the image receptor (smaller cassette) by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign is not greater than 4 percent of the SID

NEMA Standard 5-15-1979

RECORD SHEET

This sheet is to be used by the assembler to assure that all points of compliance are covered. It will also serve as a maintenance log.

HOSPITAL_____ ROOM #_____

DATE OF INSTALLATION_____ ASSEMBLER_____

_____

Requirements	Applicable Paragraph	Installation Date	Date	Date	Date
Determination of Half-Value Layer	XR8/2.09				
Actual vs. Indicated SID	XR8/2.13				
Visual Definition of X-Ray Light Field	XR8/2.14				
Intensity of Light-Field	XR8/2.15				
X-Ray Field/Receptor Center Alignment	XR8/2.17				
Indication of Field Size	XR8/2.18				
X-Ray Field Limitation & Alignment	XR8/2.20				
Cassette Tray/ Inspection Cleaning					
Electrical Cable Inspection					
INITIALS:					

RECORD SHEET NOTES:

5.0 REPLACEMENT PART LISTING

Collimare CPL and CML Parts List

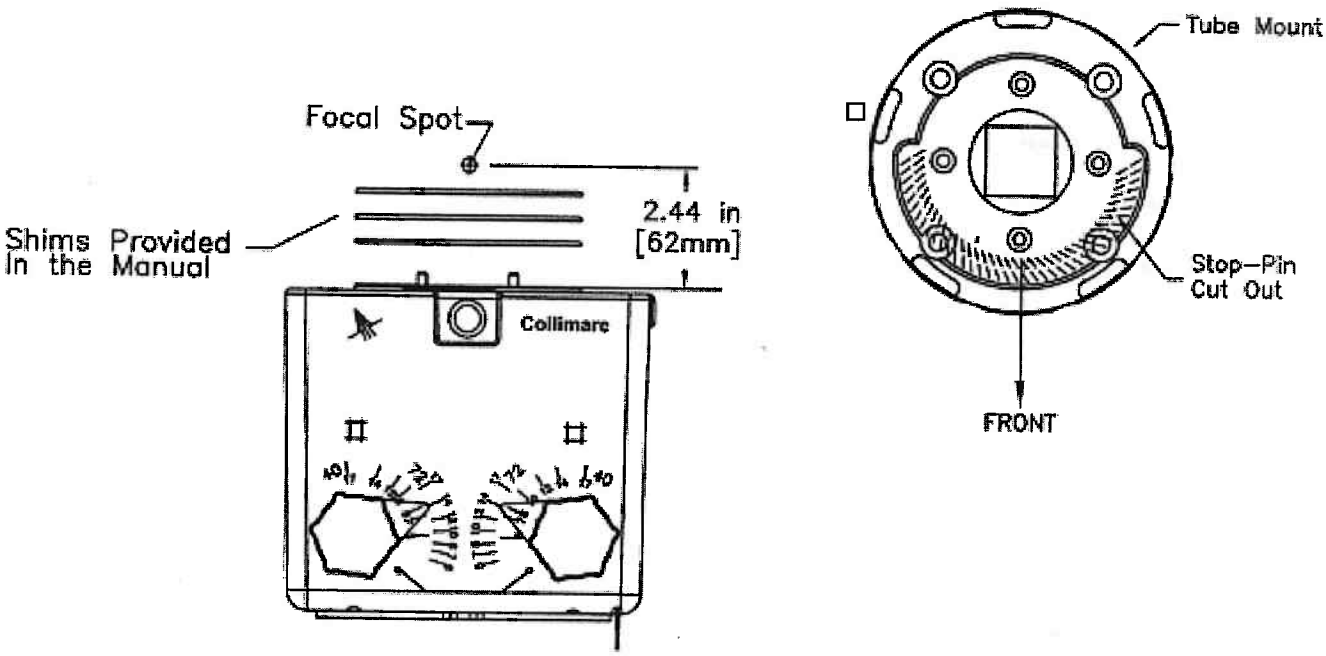
Model:	CML	CPL	Source Ray	MinxRay
Description				
Tape Measure Assembly	CM-11-0004	CP-11-0004	CP-11-SR04	CP-11-0004
Top Cover	CP-12-0006	CP-12-0006	CP-12-0006	CP-12-MX06
Output Window Bezel & Tape Assembly	CP-11-0120			
Skin Guard Assembly		CP-11-0007	CP-11-0007	CP-11-0007
Transverse Knob Assembly	CM-11-0060	CP-11-0060	CP-11-0060	CP-11-0060
Longitudinal Knob Assembly	CM-11-0061	CP-11-0061	CP-11-0061	CP-11-0061
Housing Assembly	CM-11-0129 (125)	CP-11-CL05	CP-11-SR05	CP-11-MX05
** CM Housing doesn't Include bezel	CM-11-0128 (150)			
Decal, LED Face Plate	CM-16-0096 (Used with plain housing part number CP-99-0005)			
LED Circuit Board	CP-13-0002	CP-13-0002	CP-13-0002	CP-13-0002
Laser Module	CP-13-0010	CP-13-0010	CP-13-0010	CP-13-0010
Mirror	CP-12-0042	CP-12-0042	CP-12-0042	CP-12-0042
Turn Knob Indiciator	CP-12-0036	CP-12-0036	CP-12-0036	CP-12-0036
Output Window and Tape Assembly	CP-11-0080	CP-11-0080	CP-11-0080	CP-11-0080

6.0 DETAILED MOUNTING INSTRUCTIONS

Step 1:

Back the mounting lug adjustment screws all the way out to remove the tube mount assembly from the collimator. Install the tube mount assembly on the x-ray tube with the stop-pin cutout to the front as shown in the diagram below.

Use the tube mount shims provided in the manual to install the tube mount assembly to a focal spot distance of 2.44 inches per the x-ray tube manufacturer's specifications.

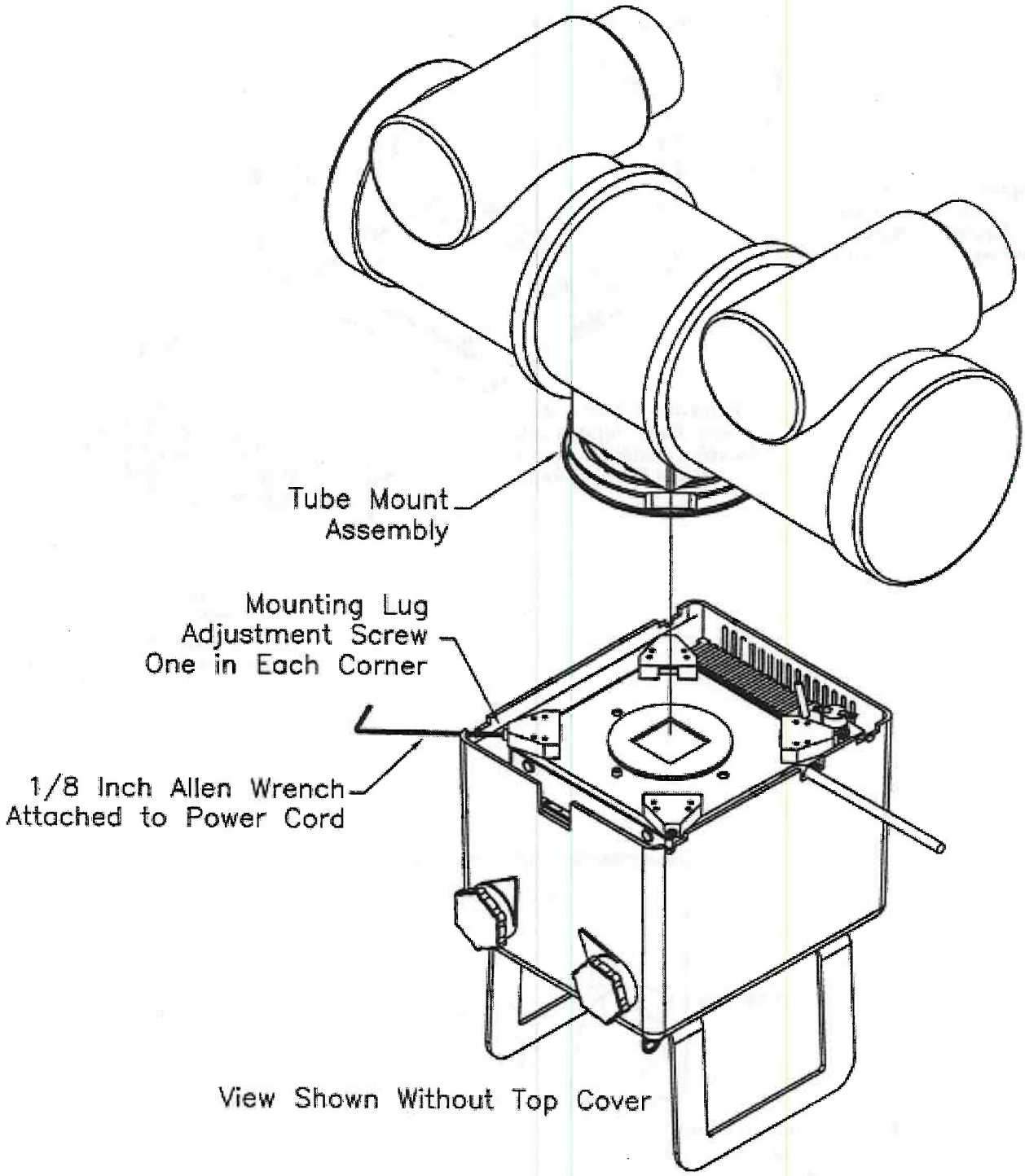


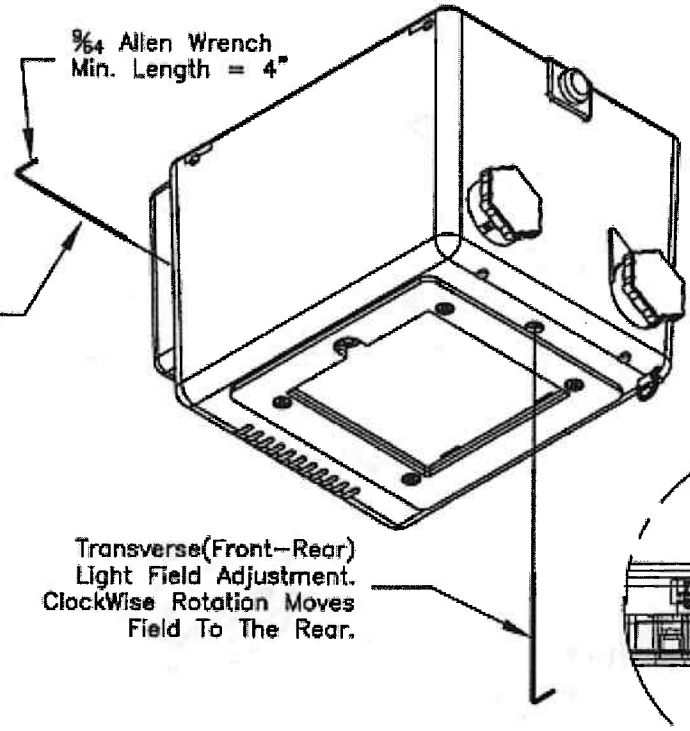
Step 2:

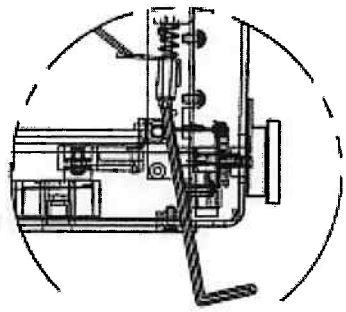
Lift the collimator up to engage the mounting ring. Using an 1/8" Allen wrench, tighten the mounting lug screws to an even pressure. Once the screws are tight, back off each screw 1/8 turn and rotate the collimator to align the laser crosshairs with the table or bucky.

Step 3:

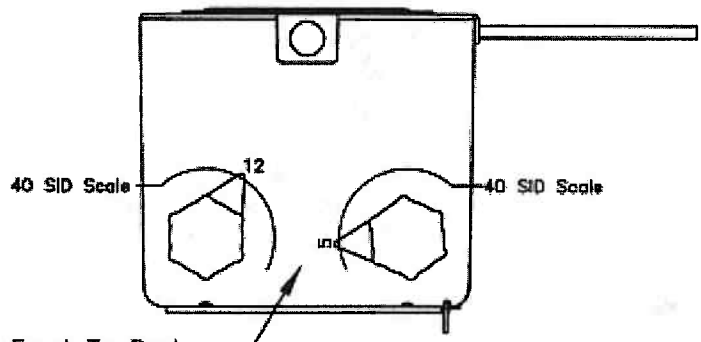
To align the light field and x-ray field, refer to page 2 of this fold-out and follow its instructions.


Tube Mount
Assembly
Mounting Lug
Adjustment Screw
One in Each Corner
1/8 Inch Allen Wrench
Attached to Power Cord
View Shown Without Top Cover





Tilt Allen Wrench Towards
Front of the Collimator.
The Adjustment Screw is
Approximately 2–1/2 inchs
up into the Collimator



To Adjust Front To Back
Light Field, Align Turn
Knobs To 12in x 5in
At 40in SID As Indicated.