Instruction Manual

MTR 108 - MTR 108 DHHS

MANUAL RADIOLOGICAL COLLIMATOR

Confidential Information

Ralco
X-RAY COLLIMATORS

SERIES R 104/A

DATE OF ISSUE:

29.03.2019

REVISION LEVEL:

F - 26.10.2023

ISSUED BY:

RALCO DIR RALCO AQ RALCO M.T.

LEGAL WARNING

The information contained in this manual is confidential. The contents of this manual, including “RALCO SRL” software and the collimator itself, cannot be copied nor reproduced in any way.

The contents of this manual must only be used for the proper intended use, function and maintenance of the Ralco collimator.

RALCO does not expressly or implicitly grant any proprietary rights over the RALCO name nor rights to market the RALCO collimator by any other name.

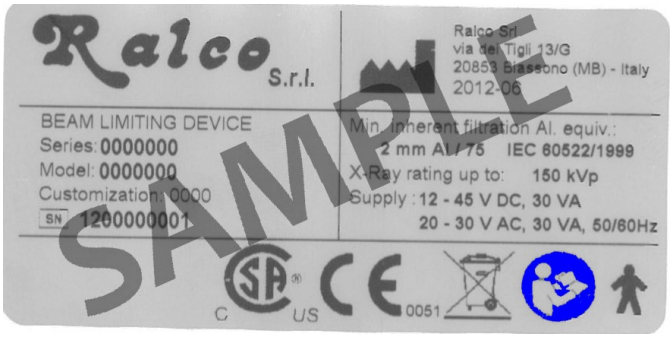
RALCO srl will pursue any and all legal remedies available under the law to recover damages incurred based upon the above violation(s).

Pictures shown in this manual are provided for illustrative purposes only.

Model		Certifications
R 108	Standard Version	CE 0051
R 108 DHHS	FDA Certified Version - available on request	CE 0051 C SA® US

Revision Level:

Rev. Index	Date	Reference
A	15.11.2019	MRD/044/19
B	17.04.2020	MRE/006/20
C	08.04.2021	MRD/001/21
D	28.06.2021	MRD/013/21
E	04.10.2021	ACD/012/21
F	26.10.2023	ACD/008/23 - MRE/015/23



This instruction manual provides the specifications, dimensions, and functions for a standard collimator. Personalizations are available upon request. With personalized collimators, the customer must ensure the following has been provided:

- Your specific code is clearly visible on the back label after **"Customization"**, above the serial number, to ensure the correct personalized collimator has been provided (see above).
- The chapter entitled **"Personalizations"**, which includes relevant information regarding your personalization.
- Other provided attachments which refer to your personalizations.

Table of Contents

INTRODUCTION

GENERAL SAFETY INFORMATION

RALCO products are designed and manufactured to meet the international safety standards for medical equipment. However, all medical electrical equipment requires proper installation, operation and servicing, particularly with regard to human safety.
Read, note, and strictly observe all safety tags on the equipment. Strictly observe all safety directions, all warnings and all cautions that are mentioned in this chapter and throughout this service documentation. In order to protect the personal health of service personnel, operators and patients, ensure the proper servicing and operation of the system.

Intended Use of the Collimator

This collimator is designed to be used with a Radiological system producing ionizing radiation for medical or veterinary use. Whomever is authorized to operate or service the radiological equipment must be thoroughly familiar with the procedures related to radiation protection and equipment use and maintenance.
RALCO is not responsible for any personal injuries or damage to property from misuse or unintended use of this collimator.
This manual must be made available to the installer and operator.

Installer and Operator Responsibility

The installer and operator must verify that ALL safety standards are followed immediately after installation of the collimator and before any subsequent use. All procedures regarding the installation and proper use of the collimator must be strictly followed.

X-Ray Equipment Manufacturer Responsibility

The collimator electronics supplies a signal defined as READY. The X-Ray equipment manufacturer will manage this signal as the X-Ray consent. In the event of a collimator failure, the liability for the correct bypass of this signal, in order to always ensure the X-Ray consent, devolves upon the X-Ray equipment manufacturer.

If the X-Ray equipment manufacturer does not use the READY signal, allowing X-Ray exposures regardless of collimator state or status, all liability falls upon the X-Ray equipment manufacturer. In the event of an emergency where the READY or ERROR signals have been bypassed allowing X-Ray exposures, all liability falls upon the X-Ray equipment manufacturer.

Reporting

Information regarding accidents that have occurred while using this collimator must be reported immediately to RALCO S.r.l.

Limitation of Liability

RALCO is not liable if the provided instructions are not complied with. Furthermore, RALCO is not liable if one or several of the following instances apply:

The unit is specifically designed per client specifications and the certification was the duty of the client;
The collimator was modified in any way by the OEM or operator;
The collimator was installed without respecting the instructions, as provided in this manual;
The collimator was used in a way outside its intended use;
The collimator was not installed by competent personnel;

The collimator was not operated safely or in a way contrary to the instructions in this manual;
The collimator was not subject to routine inspection and maintenance by competent personnel;
The collimator was repaired with non-RALCO spare parts;
The collimator was used in a way not reasonably foreseen by RALCO.

RALCO is not liable for any direct or indirect damage caused if the procedures in this manual are not followed.
The collimator complies with current standards for static load, a non-wearing class. This statement is based on studies and tests performed on the collimator performance and its weight. If the final system, through tilting movements or other dynamic movements, increases the risk factor other than those studied and tested, it is the responsibility of the customer to ensure there are no dangerous conditions.

The collimator described here, is used on Radiological systems and is classified as a type IIB according to Attachment IX. The collimator has been designed and manufactured in compliance to Attachment II of Legislative Decree, 2 February 1997, N. 46, Implementation of Directive 93/42/EEC of 14 June 1993 and successive modifications applying Directive 2007/47/EEC.

List of Applicable Standards, to which RALCO adheres:
IEC 60601-1:2005 + Am1:2012 (ed. 3.1), North American market deflections (US+CA)
IEC 60601-1-2:2014 (ed 4)
IEC 60601-1-3:2008 + Am1:2013 (ed. 2.1)
IEC 60601-2-54:2009 + Am1:2015 (ed. 1.1)
IEC 60601-2-45:2011 + Am1:2015 (ed. 3.1) Applicable in Mammography instead of IEC 60601-2-54:2009
IEC 60601-1-6:2010 + Am1:2010 (ed. 3.1) (Usability)
IEC 62304:2006 + Am1:2015 (ed. 1.1) (Software)
IEC 60825-1:2014 (LASER - if applicable)
IEC 62471:2006 (LED - if applicable)
ISO 9001:2015
ISO 13485:2016
21 CFR subchapter J (FDA)
8750 01 & 8750 81 (CSA)
CE
*RALCO can provide documentation regarding its adherence to any of the above standards.
EN 60601-1 par. 5
Protection against electric hazards: “Class I” equipment.
Protection against direct and indirect contacts: Type B equipment with applied parts.
Protection against water see page: “Common equipment”.
Safety of operation in the presence of inflammable anaesthetics with air or oxygen or nitrous oxide: Equipment not suited to application in the presence of inflammable anaesthetic mixtures containing air or oxygen or nitrous oxide.

- Operation conditions: Equipment for continuous operation at intermittent loads - See Chapter *“OPERATION INSTRUCTIONS”*.
- Should label data on the collimator not correspond to the specifications herein, inform RALCO of the non-conformity.
- Verifications of the specifications are to be performed according to the indicated equipment standards.

Inherent Danger of X-Rays

The collimator has been constructed to current standards to meet the safety requisites of Directive 2007/47/EEC and all other applicable standards. However, due to Radiology being an inherent dangerous activity which cannot be completely safe guarded against, it is crucial that all safety procedures are followed. The installer and operator must follow ALL established procedures (including those mentioned in this manual) to reduce the inherent danger of X-Rays.

The inherent risk of using collimators in Radiological systems is deemed reasonable as determined by applicable standards. The use of collimators for Radiological systems is strictly regulated. RALCO follows all applicable standards. It is up to the installer and operator to ensure that all possible steps are followed to ensure the health and safety of the patient and operator.
The contact with the moving parts can be considered impossible and may occur only during installation or maintenance (low hazard). The internal parts are protected by a mechanical safeguard in the form of a metal or plastic sheath which impedes access. Also motor units are not accessible as knobs are fixed using the Allen screws and can be removed only by using a tool, in accordance with paragraph 5.92.3 of EN 60601-1 and EN 60601-2-54 par. 201.9.2.2.5. In addition the collimator has been tested in accordance with EN 60601-1, paragraph 4.8.2.

Read all information in this chapter carefully.
The installer and/or operator are responsible to take all safety precautions and to follow all safety instructions, thus preventing any potential harm to self or others.

TECHNICALLY QUALIFIED PERSONNEL ONLY!

- Only technically qualified Field Service Engineers (FSEs) may do the service work. The FSEs must be appropriately and successfully trained and instructed.
- All service tasks such as installation, maintenance and repair must be performed with strict compliance to the provided safety instructions.
- All actions including unpacking, installation, testing and replacement must be performed as set forth in this manual.
- All service tasks must be performed in strict compliance with the local regulations concerning safety, health, accident prevention, and medical X-Ray devices.
- System parameters or components which reduce mechanical or electrical safety, or radiation protection properties of the product must not be changed or tampered with.
- Equipment may not be modified without the explicit authorization of RALCO.
- Any unauthorized modification may cause malfunction or deterioration of performance and quality and can therefore lead to personal injury, clinical misdiagnosis or clinical mistreatment.
- Any unresolved issues of the product may affect the safety of the product and must be avoided
- Spare parts must be acquired via RALCO'S distribution channel.
- All relevant safety checks of the product must be performed prior to operator use.
- Prior instructions or procedures may have changed from initial installation or previous servicing.

Failure to follow these instructions may result in risk of serious injury or death.

The temperature of the collimator cover, under normal operating conditions and at the maximum ambient operating temperature **(40°C)**, **could exceed 41°C**. According to the **Table 24** of the General **IEC 60601-1 standard**, contact with the collimator cover must be **less than 1 minute**, both for the operator and for the patient. During the diagnostic test .the operator must ensure the patient does not come into contact with the collimator surface for more than 1 minute.

Failure to follow these instructions may result in risk of serious injury.

PRECAUTIONS AGAINST MECHANICAL HAZARDS

Rotating machinery handling

- Never service rotating machinery, bands or chains when rotational movements are activated.
- Ensure rotational movements are switched off prior to servicing.
- Ensure the movements may not be accidentally switched on.
- Block the movement, if necessary.

Tilting machinery handling

- Never service tilting machinery when tilting movements are activated or brakes are released.
- Ensure tilting movements are switched off prior to servicing.
- Ensure the movements may not be accidentally switched on.
- Block the movement, if necessary.

If machinery is tilted during installation or servicing:

- Comply with the specific service instructions.
- Ask a second person to release the brake and to keep the tilting movement under control.
- Avoid uncontrolled tilting movement.
- Never release the brake longer than necessary.

Heavy load hazard

- Appropriate protective clothing, such as safety boots and gloves, must be worn.
- Take care that heavy loads are correctly lifted or carried to avoid any physical injury.
- Ask other persons for help to handle very heavy or awkwardly shaped loads.
- Use mechanical devices when possible.
- Adhere to the installation instructions regarding:
  - suitable tools
  - lifting devices
  - lifting/support points
  - particular safety measures

Failure to follow these instructions may result in risk of property damage.

Light source handling

Light sources and their adjacent parts may be hot which could cause serious burns.

- Never touch the light source, light source socket, or light source bracket immediately after use.
- Allow light source and adjacent parts cool before handling.

PRECAUTIONS AGAINST ELECTRICAL HAZARDS

Electrical shock hazard

During installation, maintenance, and servicing, there is electrical hazard risk.

- Follow the general instructions provided in this chapter.

Failure to follow these instructions may result in risk of property damage.

General precautions against electrical hazards

- Switch off the main power supply.
- Ensure the system may not be accidentally switched on.
- Ensure all UPS power components are not supplied.
- Use a voltmeter to verify all line disconnects are opened.
- All jewelry such as bracelets and rings should be removed to prevent short circuits.

Working when connected to voltages

- Switch off the main power supply when working at the equipment. This rule does not apply for certain measuring and adjustment procedures that are only possible when the product is switched on.
- Never measure or adjust equipment with power-on unless another person is present.
- Be very careful when working close to live contacts.
- Never perform any work on live parts (> 50 V).
- Prevent unwanted or sudden movements of the system because they are dangerous. If the procedure involves mechanical movements, take every precaution especially when working with moving and rotating parts. Use the service switch or the EMERGENCY STOP button before working within the dangerous movement area of a product.
- Check the ground connections before touching conductive system parts.
- Use tools and measuring instruments, which are suitable for the respective procedure only.
- Ensure test and adjustment points are accessible without any risk of injury. If safe access is not possible, switch off the system.
- Turn off the power supply immediately after finishing the test or adjustment procedure.

High-voltage cables handling

- When the mains and auxiliary power supplies are disconnected: Wait at least two minutes before removing the flexible high-voltage cables from the X-Ray tube housing or the generator.
- Discharge any residual charge before touching the contact pins (briefly connect them to ground).

Malfunction through electromagnetic fields

The equipment fulfils all requirements concerning electromagnetic compatibility (EMC).
Nevertheless, powerful high frequency transmitters used near the electronic components can cause malfunction of electronic components under unusual circumstances. This malfunction causes unwanted risks for patients, operators, and service personnel.

- Switch off your mobile phone in designated areas.

Failure to follow these instructions may result in risk of property damage.

Installation and servicing precautions

Electrical installations must comply with the requirements of each country.

- Always use a separate conductor for ground connection. The neutral conductor is not considered as ground connection.
- Do not use a three-to-two pins adapter to connect equipment provided with a power cord. Always connect the equipment to properly grounded, three-pin power outlets.
- Connect to power supply after all other installation steps are completed.
- Ensure all protective earth conductors are installed and connected before switching on the system.
- Ensure the power is switched off when installing any part to the equipment.
- Ensure the large internal capacitors are completely discharged.
- Water or other liquids inside the equipment may cause short-circuits or corrosion.
- After installation or servicing of electrical components, the following tests must be performed to ensure IEC 62353 compliance:
  - Touch voltage
  - Protective earth conductor resistance
  - Earth leakage measuring.

PRECAUTIONS AGAINST MATERIAL DAMAGE

Environmental conditions for safe operation

- The oxygen content of the ambient air during operation must be lower than 25%
- The X-Ray equipment must not be operated along with combustible anaesthesia substances.
- Ensure the indoor temperature is within +10 - +40°C.
- Ensure the indoor relative humidity is within 10 - 75%.
- Ensure the air pressure is within 700 - 1060 hPa.

Cleaning and disinfection

- Do not use aggressive cleaning agents to clean the product.
- When using cleaning agents such as detergents and disinfectants, make sure they do not contain explosive substances as they may create explosive gas mixtures.
- Follow all manufacturer instructions regarding cleaning agent/disinfectant/cleaning cloth usage

Processor overheating

The processor can get damaged within a few seconds.

- Do not operate the processor without cooling.

Failure to follow these instructions may result in risk of property damage.

Damage by electrostatic discharge (ESD)

ESD can destroy or partially damage electrostatic sensitive devices such as printed circuit boards (PCB). The damage can lead to instant or later failures of the device.

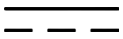
- Follow all instructions for ESD protection located with the Electrostatic sensitive device symbol below.
- Take all necessary precautions to protect electrostatic sensitive devices.

Failure to follow these instructions may result in risk of property damage.

The regulations concerning ESD protection apply to both new and old devices.
Old devices are to be replaced and sent back to RALCO's Service Department.

ADDITIONAL SYMBOLS ON THE COLLIMATOR (IF APPLICABLE)

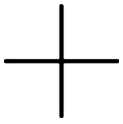
or **AC: Alternating Current**, No. 01-14 Ref. IEC 417-IEC 503



or **DC: Direct Current**, No. 01-18 Ref. IEC 417-IEC 5031

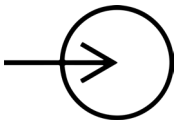
or **AC/DC: Alternating and Direct Current,** No. 01-19 Ref. IEC 417-IEC 5033

Protective Ground, No. 01-20 Ref. IEC 417-IEC 5019

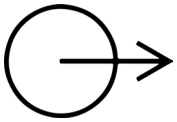


Plus, Positive Polarity, No. 01-27 Ref. IEC 417-IEC 5019

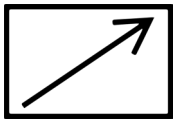
Minus, Negative Polarity, No. 01-28 Ref. IEC 417-IEC 5006



Input, No. 01-36 Ref. IEC 417-IEC 5006



Output, No. 01-37 Ref. IEC 417-IEC 5034



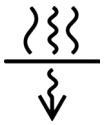
Remote Control, No. 01-38 Ref.

Manual Control, No. 01-45 ISO 7000-096

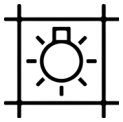
Automatic Control (Closed Loop), No. 01-46 ISO 7000-0017

Iris Diaphragm: Open, No. 01-69 ISO 7000-0017

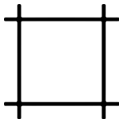
Iris Diaphragm: Closed, No. 01-70 Ref. 417-IEC 5324



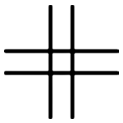
Radiation Filter or Filtration, No. 04-51 Ref. 417-IEC 5381



Light Indicator of Radiation Field, No. 04-51 Ref. 417-IEC 5381

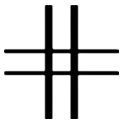


Beam Limiting Device: Open, No. 04-55 Ref. 417-IEC 5385



Beam Limiting Device: Closed, No. 04-56 Ref. 417-IEC 5386

Beam Limiting Device with Separate Opening of the Shutters, No. 04-57 Ref. 417-IEC 5387



Beam Limiting Device with Separate Closing of the Shutters, No. 04-58 Ref. 417-IEC 5388

Cassette Size Sensing Device

Device Requiring Proper Disposal, Attch. 4 Ref. 2002/95/CE

Type B Applied Part, No. 02-02 Ref. 601-I-IEC (Not applicable for R 915, R 915 S and R 915 S DHHS)

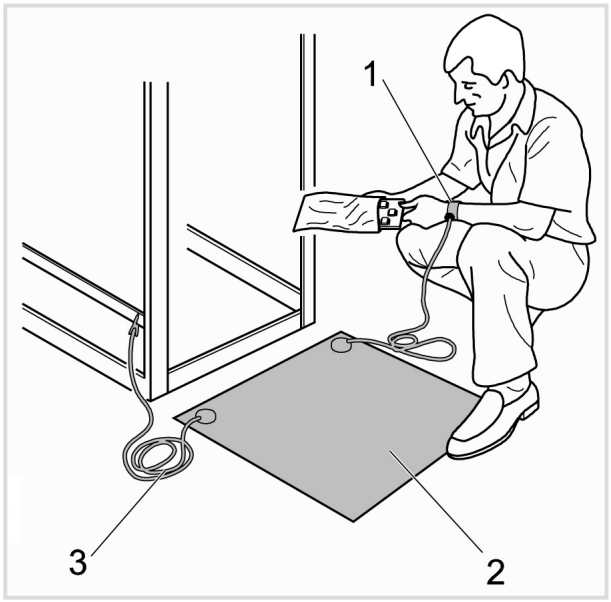
Follow Instructions for Use, Ref. ISO 7010-M002 (see collimator label).

General Warning Sign, No. 03-02 Ref. IEC 601-1

Caution: Laser Radiation, Ref. 60825-1

This symbol identifies electrostatic sensitive devices.

- Always transport electrostatic sensitive devices (such as PCB) in their static shielding bags or boxes.
- Always use the ESD protection service kit when handling electrostatic sensitive devices.
  - Attach the wristband to your wrist (1) and connect the ground cable of the wristband to the conductive work surface (2).
  - Connect the second ground cable (3) to the conductive work surface (2).
  - Attach the crocodile clip to a reliable ground of the cabinet or console, where the PCB has to be installed.
- Place the PCB on the conductive work surface before installing them.
- Place the PCB on the conductive work surface for hardware settings or replacement of components.
- Never remove or disconnect the wristband before all electrostatic sensitive devices are installed.
- Never remove or disconnect the wristband before all removed electrostatic sensitive devices are safely packed in their static shielding bags or boxes.



ESD protection kit

Safety Signs on the Product

- Do not remove or change safety signs.
- Replace illegible safety signs by genuine spare parts.
- Clean soiled safety signs.
- Refer to the labelling drawings of the components to locate the positions of the labels (see Section *"R 108 - R 108 DHHS - LABEL LOCATION DIAGRAM"* in Chapter *"SPARE PARTS"*).

Safety of Personal Protective Equipment

- The collimator does not contain polluting materials or products with the exception of the lead that composes the shutters and the inner lining of the collimator cover, if properly disposed of at the end of its life cycle.
- Avoid direct contact with lead, especially for prolonged periods.
- Gloves must be worn when handling the disassembled collimator, especially when handling the lead components.
- Gloves used to handle lead components must not be used for any other task.
- Disposable gloves may also be worn and disposed of in unsorted trash.

Disposal

- Dispose any material, batteries and X-Ray equipment in accordance with the requirements of national legislation.
- Do not dispose X-Ray equipment together with domestic waste.

RALCO products conform to **RoHS**.

RALCO products conform to **REACH**.

SAFETY ADVISORIES

WARNING

This symbol, combined with **"WARNING"**, indicates a hazardous situation which, if not avoided, may result in death or serious injury.
Failure to follow these instructions may result in risk of serious injury or death.

CAUTION

This symbol, combined with **"CAUTION"**, indicates a hazardous situation which, if not avoided, may result in minor or moderate injury.
The shown symbols may be replaced by other symbols indicating the specific risk.
Failure to follow these instructions may result in risk of minor to moderate injury.

Material damage

NOTICE

This symbol, combined with the **"NOTICE"**, indicates a hazardous situation which, if not avoided, may result in damages, such as material damage. This damage is not related to personal injury.
Failure to follow these instructions may result in risk of property damage.

Other messages

IMPORTANT

This symbol, combined with the "**IMPORTANT"**, indicates important information regarding guidelines, parameters, conditions or restrictions which must be observed.

For any inquiries or notifications, please contact us at:
Ralco S.r.l.
Via dei Tigli 13/G
20853 Biassono, (MB) - ITALY
Telephone: +39 039 2497925
Fax: +39 039 2497799
E-mail: ralco@ralco.it

DESCRIPTION

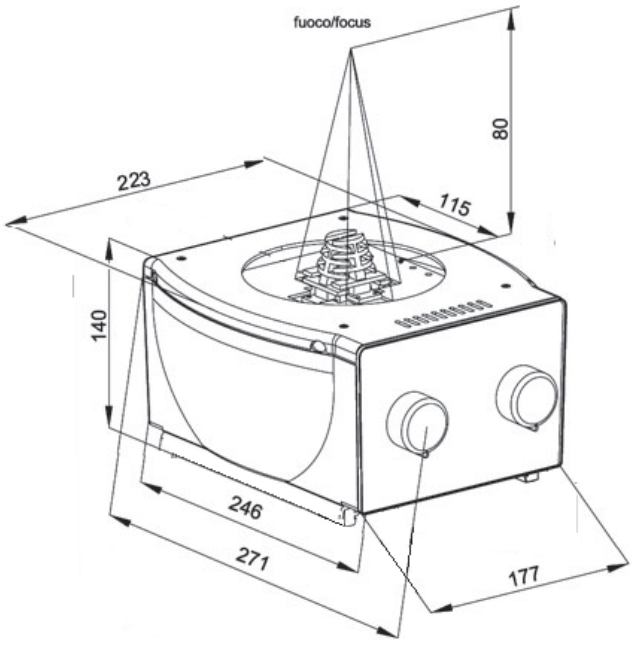
Multilayer, square field, manual collimation system with a lightweight, compact design intended for installation on mobile X-Ray equipment. This device has been designed and manufactured for skeletal investigations and ER applications.

The X-Ray field is defined by six pairs of shutters, four of which are lead-lined. The six pairs of shutters move perpendicularly within the X-Ray field. Two pairs of brass shutters are located near the focus, two are located near the entrance window and two are located near the exit window of the X-Ray beam from the collimator. The latter shutters serve to accurately define the X-Ray field edges.

Shutter movements are manual and controlled by two knobs on the collimator front panel

CHARACTERISTICS

- **Mounting plane:** at 80 mm (3.15”) from the focus.
- **Continuous Film Coverage** from Min: 00 x 00 cm to Max: 43 x 43 cm at 100 cm (40”) SID
- **Maximum Radiation Leakage:** 150 kVp - 4 mA.
- **Accessory Guides** used for accessories and additonal filtration.
- **Retractable Tape Measure** mounted on the collimator to measure focus/patient distance.
- High luminosity provided by a **White LED** simulating the X-ray field. The light field is controlled by an electronic timer.
- **Minimum Inherent Filtration:** 2 mm aluminium equivalent.
- **Metal Fixed Mounting Flange:** 20mm thickness, 136mm diameter
- **“GC-LED-4A”** timer board for light source supply and operation



R108 - R108 DHHS with Exterior Dimensions

This collimator may have the following optional items; a detailed description is provided in Chapter *"OPTIONAL ITEMS"*.

RO	DESCRIPTION
RO 002	Iron mounting flange spacer: 1.5mm thickness
RO 051	Metal rotating mounting flange, 18mm thickness, +/- 90° with mechanical stop, 136mm diameter (not available with RO 318)
RO 063	Final quality test report documentation (Light field, luminosity, light to X-ray field correspondence, light field border contrast ratio, x-ray leakage, control of general functions)
RO 074	External housing and guide rails in customized color
RO 082	Glass mirror with minimum internal inherent filtration: 1mm Al equivalent
RO 096	Wiring customization
RO 107	Knob color customization
RO 109	Front panel frame color customization
RO 111	Front panel customization
RO 240	Focal-spot to skin spacer
RO 242/1	Single laser line to align collimator and detector center: Class 2
RO 253	Accessory guide rail spacers painted in standard housing color (unless RO 074 selected)
RO 258	Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu+1mm Al or (3) 0.2mm Cu+1mm Al or (4) 2mm Al (only available with RO 278)
RO 258/1	Additional variable filtration - manual selection. 4 position rotating wheel with selectable filters (clockwise): (1) empty or (2) 0.1mm Cu or (3) 0.2mm Cu or (4) 0.3mm Cu (only available with RO 278)
RO 278	Fixed near focal shutters (single layer collimation) for use with a mounting plane of 80mm from the X-ray focus
RO 318	Self-centering top-cover bracket; Resin rotating mounting flange: 20mm thickness, 0° detent, 140mm diameter
RO 332/A	Resin rotating mounting flange: 15mm thickness, +/-0° detent, 140mm diameter including fixing screws (only available with RO 318)
RO 344	Accessory guide rail spacers with support painted in standard housing color (unless RO 074 selected)
RO 356	Shutter position verified by potentiometer: Output signal managed by customer
RO 367	Resin rotating mounting flange: 18mm thickness, +/-120° mechanical stop, 140mm diameter (only available with RO 318)
RO 369	Resin rotating mounting flange: 20mm thickness, +/-90° mechanical stop, 140mm diameter (only available with RO 318)

RO	DESCRIPTION
RO 370	Resin rotating mounting flange: 20mm thickness, +/-120° mechanical stop, 140mm diameter (only available with RO 318)
RO 395	Single laser forming a crosshair to center the patient to the detector at a fixed 1-meter SID: Class 2
RO 405	Housing customization: Aluminum
RO 441	Resin rotating mounting flange: 20mm thickness, +/-50° detent, 140mm diameter (only available with RO 318)
RO 442	Resin rotating mounting flange: 20mm thickness, +/-90° detent, 140mm diameter (only available with RO 318)
RO 445	Metal rotating mounting flange, 20mm thickness, +/-90° mechanical stop, 140mm diameter (only available with RO 318)
RO 489	Resin rotating mounting flange: 20mm thickness, +/-45° detent, 140mm diameter (only available with RO 318)
RO 524	Glass mirror + aluminum plate with minimum internal inherent filtration: 2.5mm Al equivalent
RO 525	Knob customization
RO 535	Rubber caps to close housing mounting access
RO 553	Manual shutter movement from the front and rear of the collimator
RO 586	Single laser line to align collimator and detector center: Class 1
RO 602	Substitution of LED light field with a 24V 100W halogen lamp and GC338 timer board
RO 606	Substitution of LED light field with a 12V 100W halogen lamp and GC338 timer board
RO 618	Customized mechanics to accommodate customized covers
RO 651	Shutter position verified by potentiometer: Output signal managed by customer

SPECIFICATIONS

IMPORTANT	
	**The table here below shows the specifications of the basic version of the collimator.**

POWER SUPPLY	
Power supply	24 V DC/AC - 2 A
Fuse for power supply protection - collimator (not supplied by Ralco)	T 2.5 A
Fuse for power supply protection - motor (not supplied by Ralco)	n.a.
Motor controlled by collimator board:	n.a.
Potentiometers/Encoders: Square Field Round Field	 n.a. n.a.

ELECTRONIC SPECIFICATIONS	
Software for GC 007	n.a.
Power Supply, External PCB	n.a.
Fuse for External Board	n.a.

RADIOLOGICAL SPECIFICATIONS	
Inherent Filtration, Al Equivalent X-Ray beam = 75 kV EN 60601-1-3 par. 7.3; 7.4	Min. Al Eq. 2 mm
Filtration, Additional X-Ray beam = 75 kV EN 60601-1-3 Par. 7.5	n.a.
Limitation of Extra Focal Radiation Set Focus Distance, SID 100 cm (40”) EN 60601-2-54	< 150 mm
Square X-Ray Field Selection 100 cm (40”) SID - (± 1% SID) EN 60601-2-54	Min: 00 x 00 cm Max: 43 x 43 cm

RADIOLOGICAL SPECIFICATIONS	
Round X-Ray Field Selection 1 m SID - (± 1% SID) EN 60601-2-54	n.a.
Light Field Indicator Luminosity at 1 m from the focus, field size set at 35x35 cm. EN 60601-2-54	> 160 lx
Light Field Indicator - Contrast Edge Contrast Setting 35x35 cm at 1 m SID EN 60601-2-54	>4:1
Light Field Indicator Precision Light Field/X-Ray Field Correspondence EN 60601-2-54	< 1 % SID>
Accuracy of X-Ray field as shown on the front display versus actual X-Ray field dimension	n.a.
X-Ray Field Indication Precision Settings on an Index Scale EN 60601-2-54	< 2% SID>
SID: (optional) Precision of Measurement with Retractable Tape EN 60601-2-54	< 2% SID
Maximum Radiation Leakage Measured at 100 cm with X-Ray Beam = 150 kVp - 4 mA EN 60601-1-3	< 0.4 mGy/h

GENERAL SPECIFICATIONS	
Operation Environment Ambient temperature Relative humidity Atmospheric pressure	 10°- 40°C 10%- 75% 700 - 1060 hPa
Storage Environment Ambient temperature Relative humidity Atmospheric pressure	 -40° - +70°C 10% - 95% 500 - 1060 hPa
Weight* **The weight may vary according to the optional items mounted to the collimator*	6.8 Kg

GENERAL SPECIFICATIONS	
Dimensions	L: 271 mm W: 223 mm H: 140 mm
Maximum load for accessory rails and dimensions for accessory	Static load: 70 N (about 7.1 Kg); Dynamic load: 15 Nm (approx. 1.5 Kgm)
Distance between rail slots	151 mm (+/- 0.5 mm)**

WARNING	
	***** The distance between two rails varies and depends on the collimator model.*** ***Prior to inserting accessories in the rails make sure that the dimensions of the accessory matches with the distance between two rails slots (tolerance max. ± 0,5 mm).*** ***An incorrect dimension can lead to dangerous situations and/or to the accessory falling.*** ***See Chapter "OPTIONAL ITEMS" if the rails differ from the standard ones.***

INSTALLATION

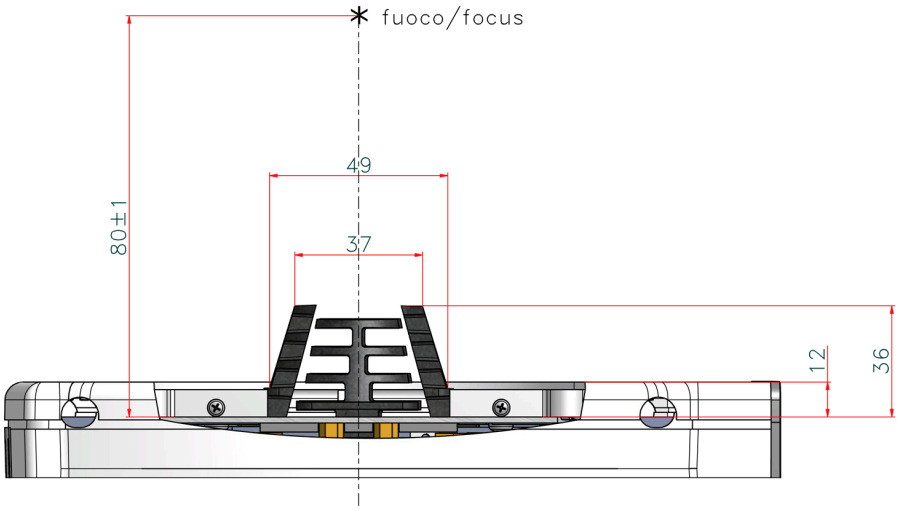
WARNING	
	The collimator must be installed to the X-Ray tube through a mounting flange. RALCO provides various flange options which may not be interchangeable. Only the flanges provided with the collimator may be used. End-users may install their own flanges; however, RALCO cannot guarantee compatibility. Any preexisting flange on the end-user system must not be used
	When a flange is provided with the collimator bearing a matching serial number, ensure they always remain coupled. It is mandatory they remain together and the correct flange part number is used.
	The contents of the instructions below should be strictly adhered to. RALCO is not liable for any property damage or resulting harm if non-RALCO components or non-compatible RALCO components are used during the installation process.

X-RAY TUBE COMPATIBILITY

1. Consulting the dimensions in Fig. **"Tube Compatibility"** below, ensure the near port shutters of the collimator may be placed in the X-Ray tube port without interference.

WARNING
The min. inherent filtration and max. radiation leakage values of the entire assembly (i.e. X-Ray tube housing and collimator) must comply with those prescribed by the applicable standards.

2. The distance between the X-Ray tube focus and the flange mounting plane (collimator upper plate) must be: 80 mm (3.15"), tolerance +/- 1 mm (0.04 ").

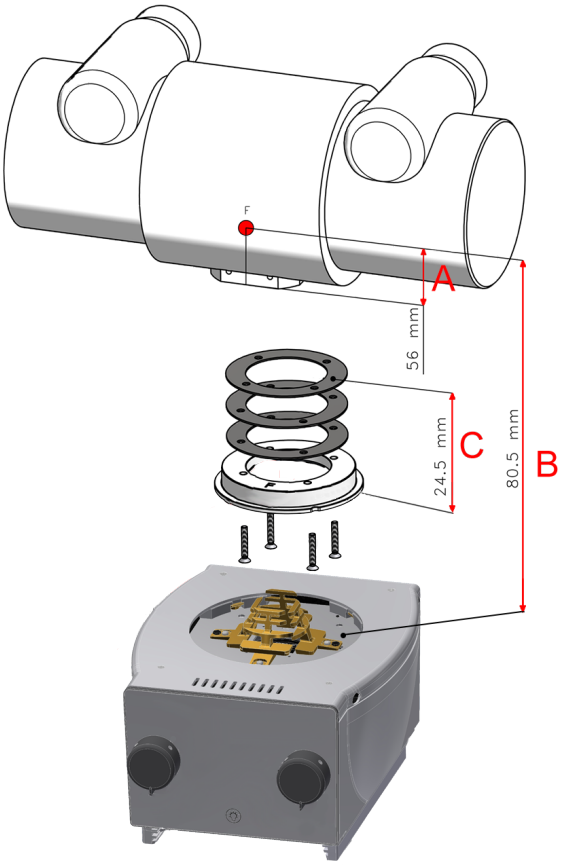


Tube Compatibility

3. Carefully remove the collimator and the mounting flange from their packaging.

4. Consult the X-Ray tube housing datasheet to determine the distance from the focal spot to the X-Ray tube port, see Pos. **“A”** in Figure **“Collimator installation“**.
5. Subtract the resulting distance from the source flange distance **“B”** and determine the number of spacers (1.5 mm) which, combined with the thickness of the mounting flange, will make up the difference **“C”**. Allowable tolerance is 1 mm. (0.04”), see Fig. **“Collimator Installation”**.
6. Once the mounting plane distance has been confirmed, proceed with the installation of the mounting flange to the X-Ray tube.

Note: **the flange fixing screws and the spacers of the previous flange may be reused if the flange thickness is the same.**



Collimator Installation
(illustrative purpose only)

MOUNTING THE FLANGE TO THE X-RAY TUBE

IMPORTANT

The following mounting instructions are only applicable for compatible flanges. If you are unsure whether the mounting flange your collimator is equipped with is compatible, please consult your personalization page provided with this manual to locate the flange part number (RO reference). Follow the mounting instructions set forth under the specific RO reference in this manual.

WARNING

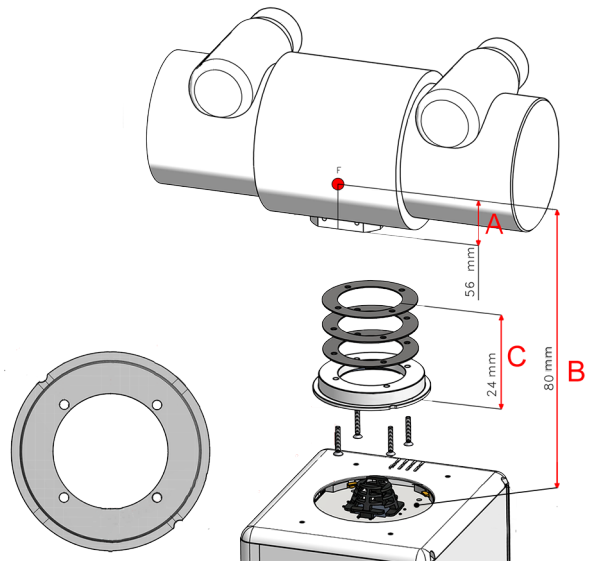
Flanges may be provided by RALCO or by the system manufacturer. Flanges may not be interchangeable. Only the flange provided with the collimator being installed with a specific part code may be utilized. Any pre-existing flanges may not be used. If there are any questions regarding compatibility, please contact RALCO.

CAUTION

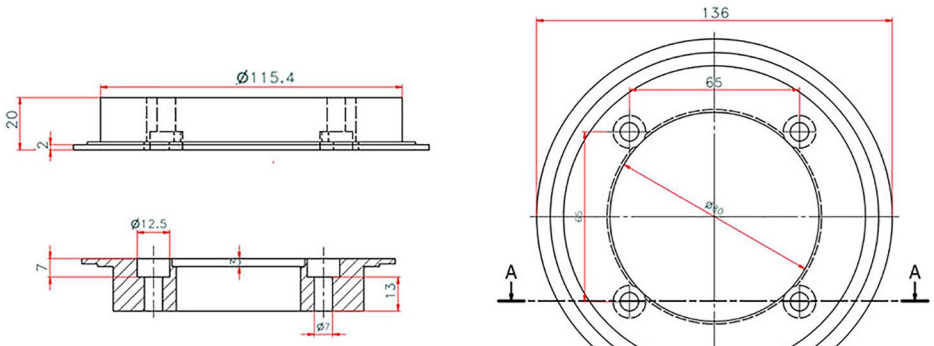
RALCO cannot guarantee compliance with radiation standards concerning safety if this control has been omitted.

1. Place the flange on the X-Ray tube port, see Fig. **Flange Installation**.
2. Mount the mounting flange and spacers (optional) to the X-Ray tube port using 4 screws.**

** *Please ensure no conflicting information nor dangerous conditions exist due to adhering to these instructions or those provided by the X-Ray tube manufacturer. When in doubt please contact the X-Ray tube manufacturer and/or RALCO.*



Flange Installation
(illustrative purpose only)



Mounting Flange
(illustrative purpose only)

CAUTION	
	**Ensure to select the correct screw type for the mounting flange provided. It is the responsibility of the End-User to guarantee all safety measures are implemented to ensure the screws are appropriately tightened, including the use of any necessary threadlocker ("Loctite®").**
	**The 4 screws must be tightened to the X-Ray tube head securely, strictly adhering to the instructions of the X-Ray tube manufacturer, and with a max. tightening force of 0.45 Nm.**

ALIGNMENT OF X-RAY TUBE FOCUS AND COLLIMATOR

RALCO guarantees the correct collimator functionality, format compliance and light/X-Ray field alignment only if the mounting flange and the collimator have been installed exactly in the center of the X-Ray beam.

All RALCO collimators are aligned on our test bench utilizing specific references/values for our X-Ray tube focus, detector and Source to Image Detector Distance (SID). The customer must know and verify all known variables which may influence the X-Ray tube focus and collimator alignment. These may include, the X-Ray tube focus position tolerance, distance from X-Ray tube focus to collimator mounting plane, or the SID.

Alignment Device

X-Ray tube manufacturers provide tolerance ranges for the positioning of X-Ray tube focuses, therefore it is very important to make sure that the collimator mounting flange is correctly aligned to the X-Ray beam.
To verify that the flange is correctly aligned with the center of the X-Ray beam, RALCO recommends the use of a focal alignment device (see Fig. **"Focal Alignment Device"**), which - upon request - may also be supplied by RALCO.

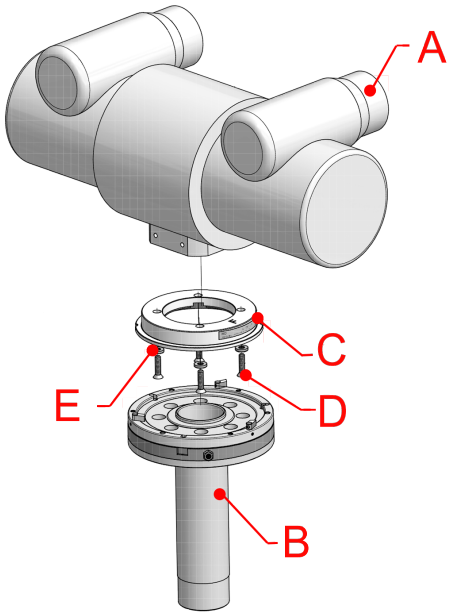
By mounting the alignment device to the flange and making an exposure, it is possible to verify perpendicularity and concentricity using the fixed references on the X-Ray image.

Once the mounting flange is aligned the collimator light/X-Ray field should also be aligned (within specific tolerances).

Please consult the technical specifications of your X-Ray tube to find the maximum tolerance for the position of the focus.

Should the use of an alignment device not be possible, RALCO collimators allow for the regulation of the light field.

Legend
A - X-Ray tube - B - Focal Adjustment Device
C - Mounting Flange
D - Screw - E - Washer



Focal Alignment Device

MOUNTING THE COLLIMATOR TO THE FLANGE

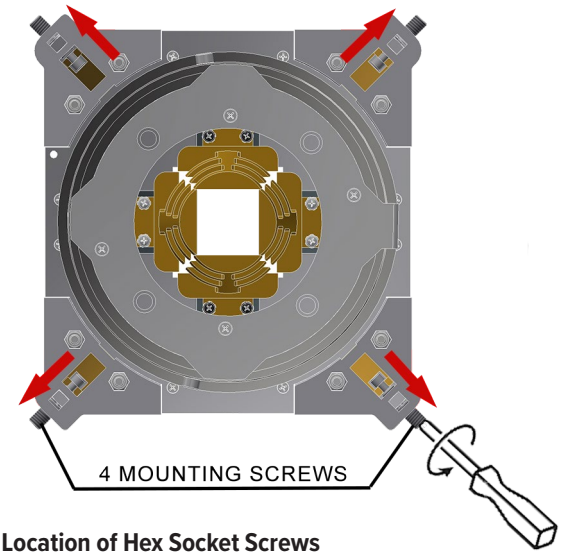
IMPORTANT	
	All mounting flanges supplied by RALCO (if applicable) are subjected to testing pursuant to all applicable standards.
	Mounting bracket tabs conform to EN60601.

WARNING	
	Pursuant to applicable standards, RALCO has tested the collimator and the mounting flange by applying static loads. RALCO is not in a position to know the dynamic forces of all end-user systems. It is the responsibility of the end-user to ensure dynamic forces of the system to not create a dangerous condition.
	It is the responsibility of the system manufacturer to mitigate any dangerous conditions which may occur due to the dynamic forces created by the system. The end-user must perform a systematic and structural analysis during the installation and usual maintenance of the system.
	Should any damage to the collimator or mounting flange occur, a risk analysis and damage assessment must be conducted immediately. In the event of such a circumstance, please contact RALCO immediately. RALCO is not liable for any resulting damage and/or injuries arising as a consequence of an unreported incident.
	RALCO has designed and tested the collimator for a lifetime of 10 years. After this time period, it is the responsibility of the end-user to ensure the proper functioning of the collimator and mounting flange. Liability for any dangerous conditions which may arise after the 10-year lifetime of the collimator and mounting flange rests with the end-user.
	To ensure the safety of the collimator and mounting flange after 10 years of use, RALCO has instituted a program to assess the safety of the collimator and mounting flange. After applying a check list of quality controls and refurbishment activities (at end-user expense), RALCO may certify the collimator and mounting flange for additional years of use.

1. Prepare the collimator for installation by unscrewing the 4 hexagonal socket mounting screws until the four tabs are completely withdrawn from the collimator top mounting plane, see Fig. **"Location of Hex Socket Screws"**.
2. If installing a manual collimator, adjust the collimator shutters to the fully open position using the knobs.

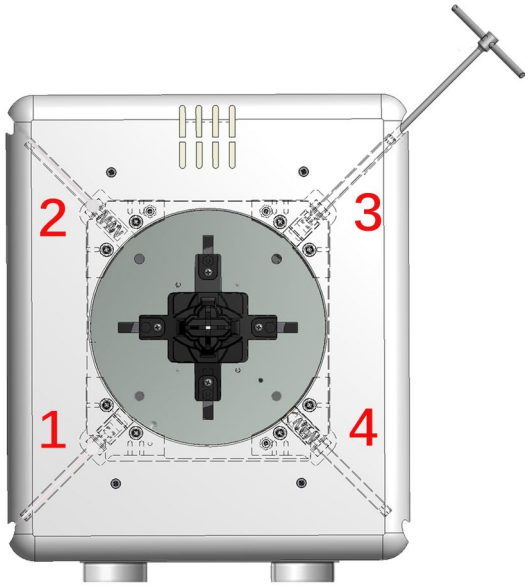
CAUTION

When unscrewing the hexagonal socket screw which control the tabs, do not use force exceeding 0,45 Nm.
Unscrew with care so as not to damage the hexagonal screw head and tabs.



Location of Hex Socket Screws

3. With the tabs fully retracted, the hexagonal socket screws of the mounting bracket must be tightened equally up to the end of their stroke with 0.45 Nm torque (at least 7 turns), see Fig. **"Mounting Bracket"**.
4. The 4 tabs of the hexagonal socket screws overlap on the flange outer ring in the same manner.
5. The collimator tabs adhere to the flange outer ring. Depending on the optional flange purchased, the collimator may rotate or be fixed (no rotation).
6. Once the collimator has been coupled to the flange according to the procedure described above, verify the distance between the collimator housing and the mounting flange is equal in all directions and the collimator face is parallel to the axis of the table. Loosen the screws and adjust as necessary.
7. The collimator must be coupled to the flange firmly. If the collimator is loose, please repeat the above mounting instructions, and if issues persist, please contact RALCO.



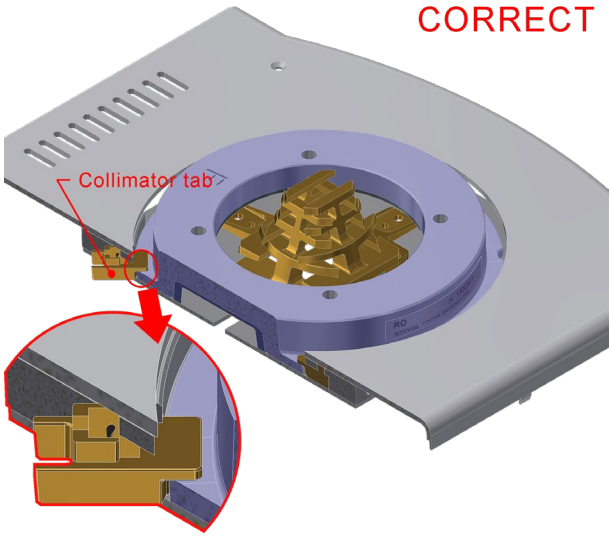
Mounting Bracket
(illustrative purpose only)

VERIFICATION OF CORRECT INSTALLATION

WARNING

It is the duty of the installer to ensure there is no risk of the collimator falling.
Each of the below must be ensured, as there is serious risk or injury and/or property damage due to non-adherence.

1. The 4 tabs must overlap the mounting flange outer ring, see Fig. **"Correct Overlap"** (illustrative purpose - valid to show correct position of tab only).
2. The mounting flange must be flat against the collimator mounting plane, see Fig. **"Correct Overlap"**.
3. The 4 tabs must not be in contact with only the mounting flange edge, see Fig. **"Incorrect Overlap"** (illustrative purpose - valid to show incorrect position of tab only).
4. Once the collimator is mounted, (unless this has already been done), return the collimator/tube head to the intended use position. Rotate and/or gently pull the collimator to ensure correct coupling.
5. If the collimator is loose, something is incorrect. Repeat the above, **"MOUNTING THE COLLIMATOR TO THE FLANGE"** instructions, and if the issues persist, please contact RALCO.



Correct Overlap

Incorrect Overlap

ELECTRICAL CONNECTION

IMPORTANT	
	The wiring diagram included in this document refers to the standard product. It is the responsibility of the customer who has requested an electrical customization, to ensure that an electric diagram relating to the customization has been provided with the documentation
	The device is intended to operate with a permanent power supply present, so the procedure of switching off the collimator is not foreseen. No risk or device damage will occur if the collimator is accidently switched off.

WARNING	
	The device must be exclusively connected to power network, with earth protection, in order to avoid a risk of electric shock.
	Supply and signals to the collimator must be to 2007/47/CE standards. Devices that supply the collimator must therefore feature double or reinforced insulation as provided by the general standard on electromedical equipment CEI62-5 +A2 (EN 60601-1). The device is electrostatic sensitive, consequently all the relating safety standards must be complied with
	Collimator must be supplied as specified, see Chapter *"SPECIFICATIONS"*. The supply must come from a separate source from the power network through double insulation or reinforced insulation and with limited current. Transformer characteristics must conform to the requirements of standard IEC 60601-1.
	Cables and terminals used for the internal connection of the collimator must be suitable for operation at temperatures of 80°C and collimator current absorption.
	To ensure the safe use of the collimator, it is MANDATORY to securely and firmly insert the power supply/data cable between the collimator and the radiological system. It is also MANDATORY the power supply/data cable is correctly secured to the strain relief. If the strain relief is missing it is MANDATORY one be correctly and securely installed. RALCO is not liable for damages in the event of missing or incorrect cable installation.

Power Supply Connection

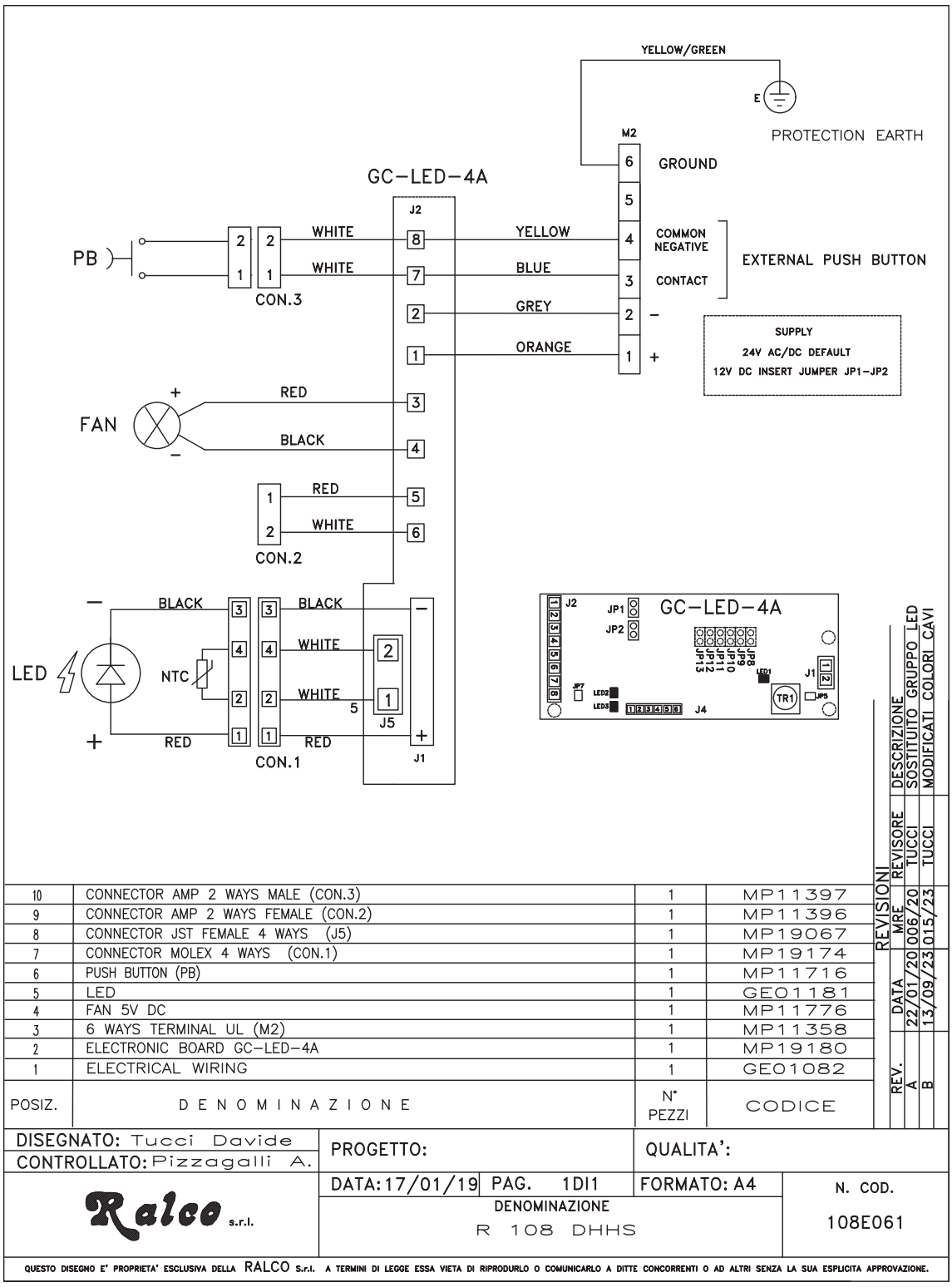
- Remove the part of cover to access the terminal, see Chapter *"COVER REMOVAL"*.
- Connect supply cables to the relative collimator terminals and earth on the screw marked with the relating symbol (see Fig. **"Earth Symbol"**). Use the protective earth cable with green/yellow insulation.
- In collimators with a free cable stop, remove the cable stop, connect the supply cables, remount and then secure the cable stop.
- Remount the cover.

Earth Symbol

WARNING

Incorrect power supply could damage the electronic boards and/or the light source.
Supply may be either in alternate or direct current.
Make certain that polarity is respected.

Wiring Diagram



POSIZ.	DENOMINAZIONE	N° PEZZI	CODICE
10	CONNECTOR AMP 2 WAYS MALE (CON.3)	1	MP11397
9	CONNECTOR AMP 2 WAYS FEMALE (CON.2)	1	MP11396
8	CONNECTOR JST FEMALE 4 WAYS (J5)	1	MP19067
7	CONNECTOR MOLEX 4 WAYS (CON.1)	1	MP19174
6	PUSH BUTTON (PB)	1	MP11716
5	LED	1	GE01181
4	FAN 5V DC	1	MP11776
3	6 WAYS TERMINAL UL (M2)	1	MP11358
2	ELECTRONIC BOARD GC–LED–4A	1	MP19180
1	ELECTRICAL WIRING	1	GE01082

REVISIONI			
REV.	DATA	REVISORE	DESCRIZIONE
A	22/01/20	MRE	SOSTITUITO GRUPPO LED
B	13/09/23	006/20 TUCCI	015/23 MODIFICATI COLORI CAVI

DISEGNATO: Tucci Davide
CONTROLLATO: Pizzagalli A.
PROGETTO:
QUALITA':
Ralco s.r.l.
DATA: 17/01/19 PAG. 1DI1
FORMATO: A4
DENOMINAZIONE
R 108 DHHS
N. COD.
108E061

OPERATION INSTRUCTIONS

LIGHT/X-RAY FIELD SETTING

- Set the collimator at 100 cm SID.
- By rotating the knobs and with the knob index on the front panel, follow the tags of the scale.
- Do not force the knobs.
- Activate the light field by pressing the related push-button on the collimator front panel.
- The collimator is ready to operate

WARNING

Prolonged use of the light source without allowing proper cooling time will result in the collimator overheating.
We advise you not to operate the light source for more than 5 times consecutively, which should be limited to emergency situations only. In such an event, always allow enough time for the collimator to cool down (about 10 mins.).
Operators must prevent the collimator from overheating, so as to not cause burns to the patient or themselves.

CAUTION

By increasing the consecutive "ON" times, the subsequent cooling down times must be extended accordingly. It is imprudent to perform two consecutive cycles of 5 ON times.

The collimator has been designed to operate as follows:

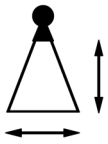
- Supply constantly connected during operation of the equipment.
- Lamp ON time: ON time is pre-set in factory to 30s (tol.20%).
- A normal lamp ON / OFF cycle is established at 1 minute followed by 4 minutes to allow for cooling (i.e. 1 minute ON / 4 minutes OFF).
- The field is set by the two knobs on the front panel by following the indications of the scale with the knob index or visually with the light field.

FRONT PANEL

The X-Ray field is set through the knobs that control the shutter movement. The table provides the readout of the values which must be set with the knobs. The exact value to be set is obtained by crossing the SID in use (the value indicated by vertical axis), with the cassette size value in cm or inches (horizontal axis).

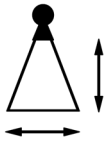
Example:

To obtain a 24 cm (LONG) x 35 cm (CROSS) X-Ray field at SID 150 cm, with reference to the chart, set the Long knob indicator to 16.5 cm and the Cross knob indicator to 24 cm. See Fig. **"Long Aperture"** and Fig. **"Cross Aperture"**.



cm	13	18	24	30	35	40	43	
90	15	20	27	33.5	39	44	47	36"
100	13	18	24	30	35	40	43	40"
120	11.5	15.5	20	25	29.5	34	36	48"
150	8	12	16.5	20	24	27	29	60"
180	7	10	13.5	17	20	22.5	24	72"
200	6	9	12.5	15.5	18	20	22	78"
	5"	7"	9.5"	12"	14"	16"	17"	Inch

Long Aperture

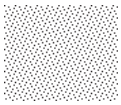


cm	13	18	24	30	35	40	43	
90	15	20	27	33.5	39	44	47	36"
100	13	18	24	30	35	40	43	40"
120	11.5	15.5	20	25	29.5	34	36	48"
150	8	12	16.5	20	24	27	29	60"
180	7	10	13.5	17	20	22.5	24	72"
200	6	9	12.5	15.5	18	20	22	78"
	5"	7"	9.5"	12"	14"	16"	17"	Inch

CrossAperture

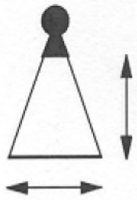
SID in use

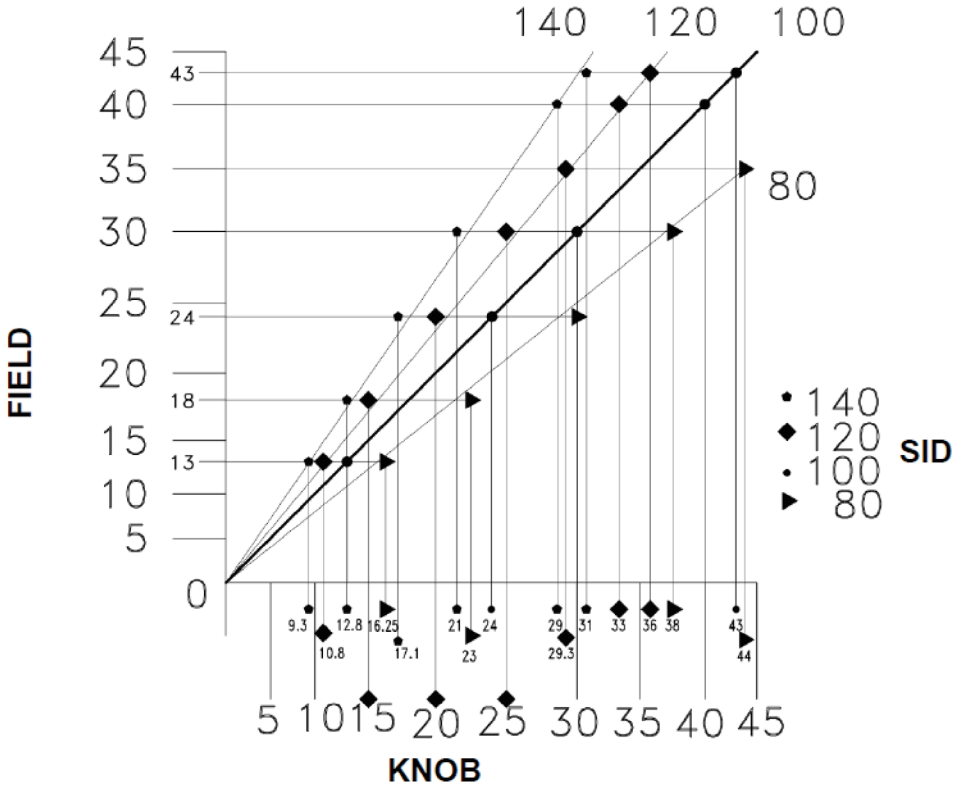
Format Required



Knob Index setting

Cm	13	18	24	30	35	40	43	Inch
100	13	18	24	30	35	40	43	40"
150	10	12	16	20	23.5	26.5	28	60"
200	6.5	9	12	15	17.8	20	21.6	78"
	5"	7"	9.5"	12"	14"	16"	17"	





Knobs for Field-Size Adjustment

RETRACTABLE TAPE MEASURE

IMPORTANT

The type of tape measure used is a standard tape mounted on a radiological unit.

The tape starts with values that correspond to the focus/collimator lower edge distance; maximum radiological measurement with the tape is 2 m max even though, for purely mechanical reasons, maximum tape extension is 3 m max. STOP is evident immediately after the maximum mechanical value.

Forcing and/or extending the tape beyond this point will cause the following inconveniences:

- breakage of the tape or,
- distortion of the tape or,

impossibility of retracting the tape into its lodging because the grip of the spring has been forced and hook-up is consequently distorted.

NOTE: do not extend the tape beyond the indication of stop.

IMPORTANT

To ensure correct measurement: extend the measuring tape perpendicularly to the collimator plane, until reaching the image receptor and / or the patient surface.

NOTICE

Upon completion of measurement and/or of functional check, retract the measuring tape into the initial position by holding the tab.
Do not let the tape fly back quickly: this might result in damage to the tape measure and/or to other collimator components (e.g. anti-dust panel, cover...)!

CALIBRATION

WARNING	
	**The following procedures require that X-Ray radiation be produced Take adequate precautions to make certain that no part of the human body is exposed to X-Ray radiation, direct or indirect.**
	**The information provided in this Section is meant only as an aid to the End-User. RALCO is not liable for any damages resulting from alteration of factory settings. Adjustments are preset at the factory prior to the shipment of the collimator. Should any problems arise requiring the collimator to be recalibrated, please contact RALCO for assistance before proceeding with the adjustment.**

CHECKING LIGHT FIELD TO X-RAY FIELD ALIGNMENT

Pre-condition:

The collimator has been installed and aligned with the X-Ray tube (see Section *"ALIGNMENT OF X-RAY TUBE FOCUS AND COLLIMATOR"* in Chapter *"INSTALLATION"*).

Regulatory requirement:

The light field/ X-Ray field misalignment in either the X (cross axis) or Y (long axis) direction must not exceed 2% of the Source-to-Image distance (SID).

Execution:

- Select large focus, 60 kV and 5 mAs (or equivalent for digital receptor).
- Place a loaded cassette 24 x 30 cm (9.5"x 12") on the table top and prepare exposure (this format is only an example. You may perform this check with any format).
- Using the retractable measure tape, or other instruments (e.g. a ruler), set SID = 100 cm (40").

Notes on the use of the retractable tape measure:

IMPORTANT

To ensure correct measurement: extend the measuring tape perpendicularly to the collimator plane, until reaching the image receptor and / or the patient surface.

NOTICE

Upon completion of measurement and/or of functional check, retract the measuring tape into the initial position by holding the tab.
Do not let the tape fly back quickly: this might result in damage to the tape measure and/or to other collimator components (e.g. anti-dust panel, cover...)!

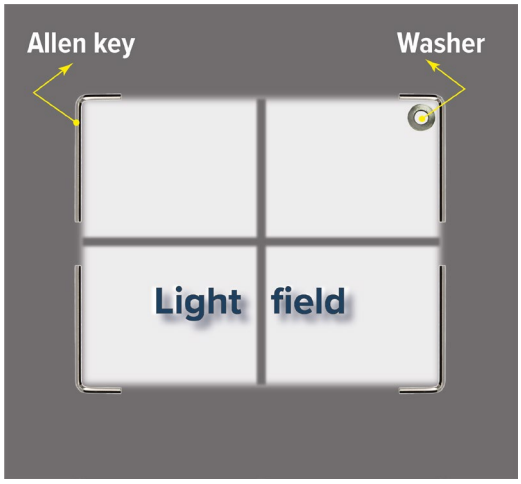
IMPORTANT

If the 100 cm (40") SID distance cannot be determined, use the SID value closest to 100 cm (40") and calculate the measurement tolerances as the appropriate percentages of the distance.

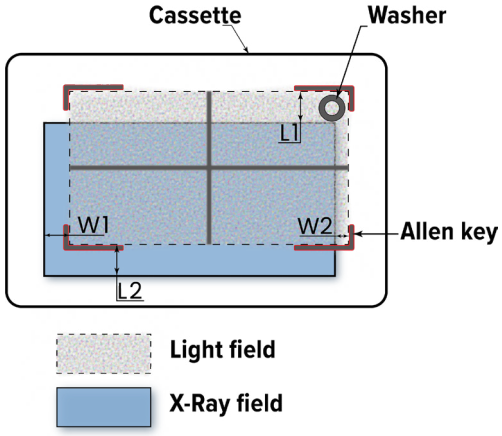
If the X-Ray beam cannot be positioned vertically use clamps, masking tape, or other material as required to position the X-ray tube and image receptor. The X-Ray tube and the image receptor must be set out at the specified SID distance perpendicularly to the X-Ray tube as described in the following procedure.

- Turn the knobs to set the light field corresponding to the chosen format (here: 24 x 30 cm).
- Centre the X-Ray tube on the cassette.
- Push the Light pushbutton to activate the collimator light.

- Place 4 Allen keys on the corners of the light field: the inside edge of the Allen key must be flush with the border of the light field. (Allen keys are a convenient way to delineate the edges of the light field. Other radiopaque objects may be used in substitution).
- Place a washer on the right-hand top of light field, to indicate the orientation of the light field, see Fig. **"Light Field Verification Preparation"**.



Light Field Verification Preparation



Light Field Verification

- Make an exposure.
- Develop the film or print the exposure scale 1:1.
- Measure the differences **L1**, **L2**, **W1** and **W2** between the inner edge of each Allen key image and the corresponding edge of the X-Ray Field - see Fig. **"Light Field Verification"** (the figure shows an example with film cassette. The same principle can be used for a digital system.
- For required values, please refer to the System Reference Manual.
  However, the values "**L1** + **L2**" and "**W1** + **W2**" shall NEVER exceed 2 cm (2% of the SID), i.e.:
  (L1+L2): max. 1 cm /
  (W1+W2): max. 1 cm
  (max. 1 cm along each axis).
- Note the measured values in the table here below.
- Select small focus and repeat the preceding steps.

Source-to-Image Distance (SID): Max. deviation (tot. 2% of SID):			❒ 100 cm (40") ❒ 2 cm (0.8")			❒ Other: ..... ❒ Other:	
	L1	L2	W1	W2	(L1+L2)	(W1+W2)	Pass/Fail
LARGE FOCUS							
SMALL FOCUS							

If misalignment is detected (deviation > 2% of SID) proceed as follows:

- Make sure the spacing from the focus to the collimator mounting surface is equal to 80 mm (3.14") +/- 1 mm (check: see Section *"X-RAY TUBE COMPATIBILITY"* in Chapter *"INSTALLATION"*). If needed, adjust spacing and repeat test film exposure.
- Make sure the collimator mounting flange is correctly aligned to the X-Ray beam (check: see Section *"ALIGNMENT OF X-RAY TUBE FOCUS AND COLLIMATOR"* in Chapter *"INSTALLATION"*). Reference also the tolerance for the placement of X-Ray tube focus provided by the X-Ray tube manufacturer.
- If misalignment is still present, adjust the light field (see Section *"LIGHT FIELD ADJUSTMENT"* in this Chapter).

Collimator to Focal Spot Alignment (Primary Shutter Cut-Off)

Inspect the four images of the four collimator shutters which form the edges of the X-Ray field.
A definitely indistinct edge indicates that the primary shutter, close to the focal spot, is the one forming the line, rather than the outermost shutter.
To correct the condition, use the four mounting/centering adjustment screws to shift the collimator in the direction of the indistinct line. Repeat the test film exposure after making the adjustment.

IMPORTANT

Due to the anode heel effect, the light field border on the anode-cathode axis of the X-Ray tube will have slightly less contrast than the other three sides. This is normal and cannot be corrected by adjustment.
In addition, an X-Ray tube of 12° or less target angle will produce an asymmetrically shaped field when a large field size is used at short SID, because of the anode cut-off effect. This is also normal and cannot be corrected by adjustment.

LIGHT FIELD ADJUSTMENT

The X-Ray field and the light field are aligned from the factory (tolerance between X-Ray and light field: +/-3mm per side).

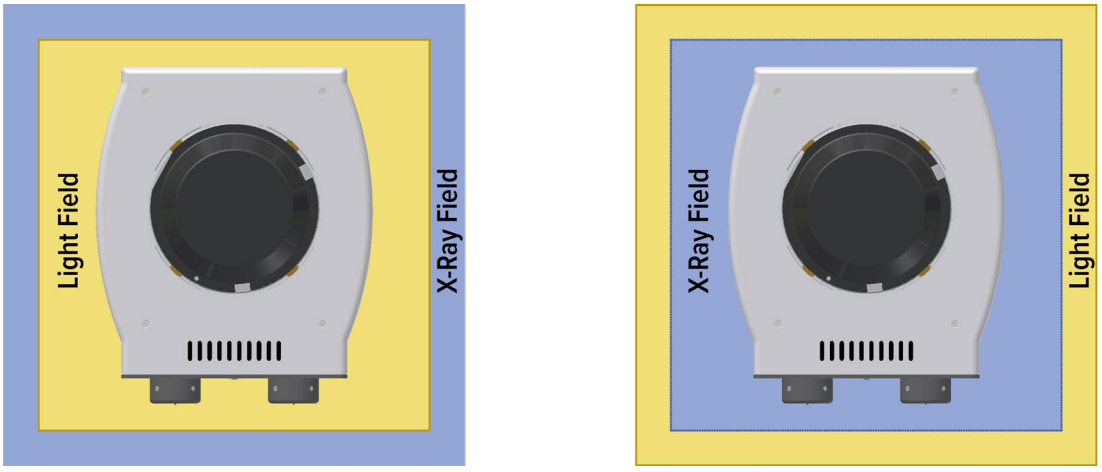
If, after carrying out the check described in Section *"LIGHT FIELD ADJUSTMENT"* of this Chapter, the misalignment between the light field and the X-Ray field in either the **X** (cross table) or **Y** (long table) exceeds **2%** of the SID (with SID = 100 cm, it would be less than 20 mm / 0.80"), the X-Ray field and the light field need to be aligned further. If this is the case, you can proceed as described below.

LEGEND

X-Ray field

Light field

Scenario A - X-Ray or light field uniformly smaller or larger



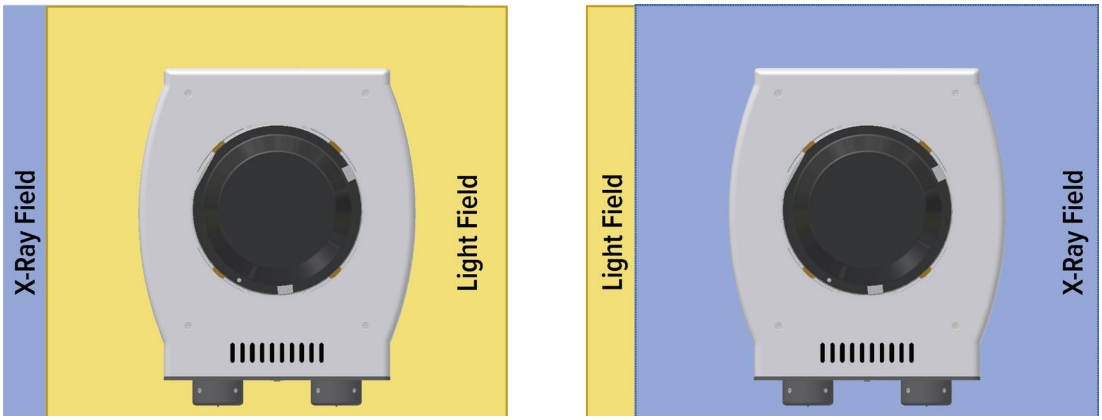
Scenario "A"

The X-Ray field and the light field are aligned (concentric), yet they differ in size (see figure **"Scenario A"**).

Make sure the collimator is mounted at the correct distance from the X-Ray tube focus (see Chapter *"SPECIFICATIONS"* and Section *"X-RAY TUBE COMPATIBILITY"* in Chapter *"INSTALLATION"*).

If situation persists: light source needs to be adjusted, see Section *"Field Size Adjustment (Scenario "A": X-Ray or Light Field Uniformly Smaller or Larger)"*.

Scenario B - Longitudinal misalignment between X-Ray and light fields (direction: LONG shutters)



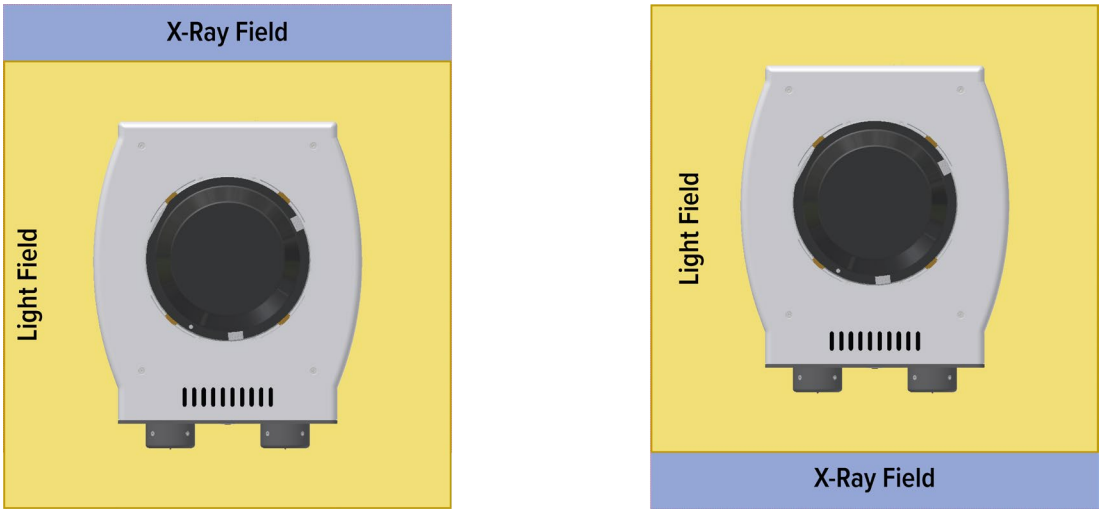
Scenario "B"

The X-Ray field and the light field are longitudinally misaligned, shifted either to the left or to the right, as depicted in the Figure **"Scenario B"** above.

Ensure the X-Ray focus has not shifted, and that the system/collimator/detector are all correctly aligned.

If situation persists: light source needs to be shifted longitudinally, see Section *"Longitudinal Adjustment (Scenario B: Longitudinal Misalignment between X-Ray and Light Fields)"*.

Scenario C - Transversal (cross) misalignment between X-Ray and light fields (direction: CROSS shutters)



Scenario "C"

The X-Ray field and the light field are transversally misaligned, shifted either to the front or to the rear, as depicted in the Figure **"Scenario C"** above

Ensure the X-Ray focus has not shifted, and that the system/collimator/detector are all correctly aligned.

If problem persists, the mirror needs a traversal adjustment, see Section *"Mirror Adjustment (Scenario C: Transversal (Cross) Misalignment between X-Ray and Light Fields)"*.

Light Source Adjustments:

Preliminary warning:

WARNING

When adjusting the light source (LED), never touch the heat sink of the LED support, as it might be hot and cause severe burns.

Field Size Adjustment (Scenario "A": X-Ray or Light Field Uniformly Smaller or Larger)

NOTE: positions are referred to Fig. "LED Support"

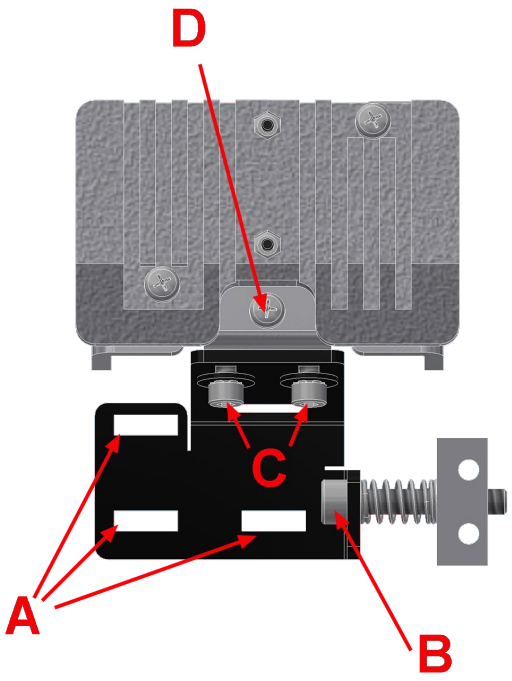
1. Remove the part of the cover necessary to access the LED support screws (see Chapter *"COVER REMOVAL"*).
2. Loosen the screws **"C"** holding the light support.

NOTICE

Do not remove the screws, keep them tensioned, so that the support can move transversally, yet it does not fall.

3. If the light field is *smaller* than the X-Ray field (see Figure **"Scenario A"**, picture on the left):
   Loosen screw **"D"** and move the light source closer to the mirror (the light field will become larger).

   If the light field is *larger* than the X-Ray field (see Figure **"Scenario A"**, picture on the right):
   Tighten screw **"D"** to move the light source away from the mirror (the light field will become smaller).
4. Once correct alignment has been achieved, tighten the screws **"C"** back again and remount the cover, see Chapter *"COVER REMOVAL"*.



LED Support

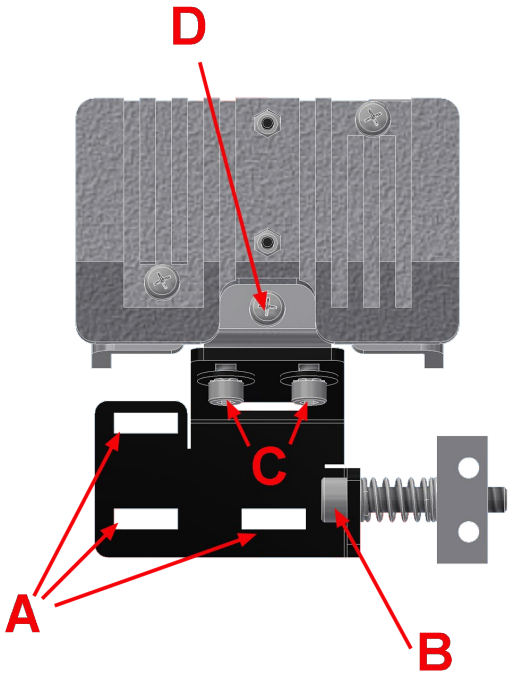
Longitudinal Adjustment (Scenario B: Longitudinal Misalignment between X-Ray and Light Fields)

NOTE: positions are referred to Fig. "LED Support"

1. Remove the part of the cover necessary to access the LED support screws (see Chapter *"COVER REMOVAL"*).
2. Loosen the fixing screws "**A**".

NOTICE	
	**Do not remove the screws, keep them tensioned, so that the support can move transversally, yet it does not fall.**

3. Turn the screw **"B"** clockwise (or resp. counterclockwise) to shift the light field transversally as needed.
4. Once correct alignment has been achieved, tighten the fixing screws **"A"** back again and remount the cover, see Chapter *"COVER REMOVAL"*.



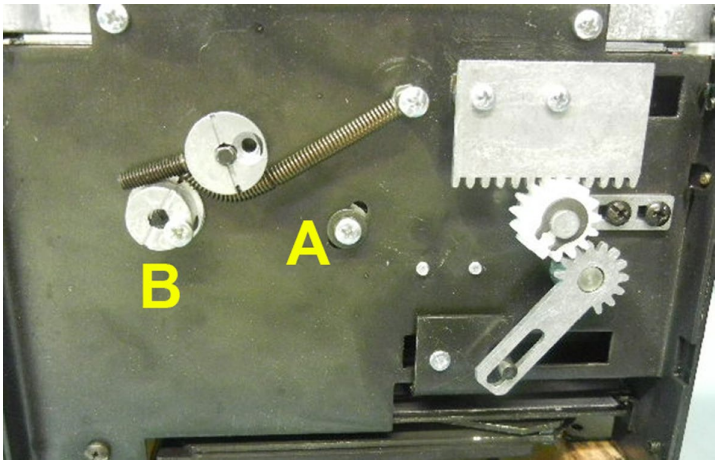
LED Support

IMPORTANT
 **Due to the anode heel effect, the light field border on the anode-cathode axis of the X-Ray tube will have slightly less contrast than the other three sides. This is normal and cannot be corrected by adjustment.** **In addition, an X-Ray tube of 12° or less target angle will produce an asymmetrically shaped field when a large field size is used at short SID, because of the anode cut-off effect. This is also normal and cannot be corrected by adjustment.**

Mirror Adjustment (Scenario C: Transversal (Cross) Misalignment between X-Ray and Light Fields)

NOTE: positions are referred to Fig. "Transversal Calibration (CROSS)"

1. Remove the part of the cover necessary to access the LED support screws (see Chapter *"COVER REMOVAL"*).
2. Loosen (do not remove) the mirror fixing screw **"A"** and rotate the cam **"B"** to to adjust the inclination of the mirror and shift the light field as needed, see Fig. **"Transversal Calibration (CROSS)"**.
3. Once correct alignment has been achieved, tighten the fixing screw **"A"** back again and remount the cover, see Chapter *"COVER REMOVAL"*.



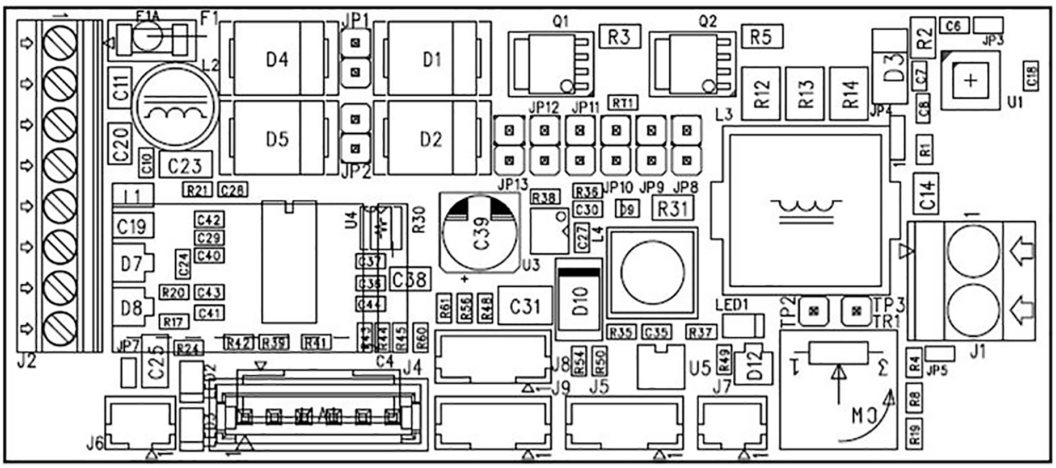
Transversal Calibration (CROSS)

ELECTRONIC SYSTEM

This section describes the electronic components of the collimator which include:

- **"GC-LED-4A"** - Timer board for light source supply and operation.

GC-LED-4A TIMER BOARD

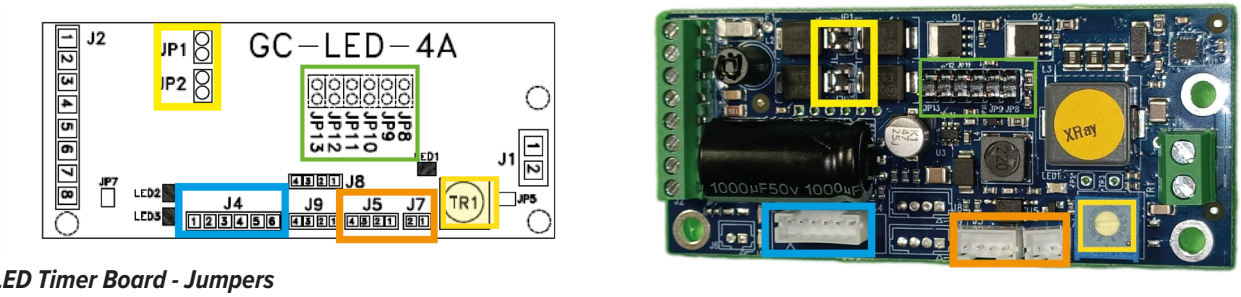


Connectors
(see topographic diagram above. Reference also wiring diagram)

J2 - Supply and outputs	1. 24 V AC/DC or 12 V DC 2. 24 V AC/DC or 12 V DC 3. +5 V Fan 4. GND Fan 5. +5 V Laser 6. GND Laser 7. + external light push-button 8. GND external light push-button
J1 - LED Output	1. + GC-LED-4A positive output 2. - GND GC-LED-4AS
J3 - Programming connectors	1. Vpp 2. +5 V 3. GND 4. PGD 5. PGC 6. NC
J4 - Home sensor input + external LED	1. + External LED 2. - External LED 3. - Photosensor LED Cathode 4. + Photosensor LED Anode 5. Input signal (Photosensor output collector) 6. GND (Photosensor output emitter)

J5 - Pushbutton input + NTC external LED	1. NTC LED input 2. NTC LED input 3. Laser input, pin 1 4. Laser input, pin 2
J7 - Open-collector (abnormal operation management)	1. + 2. -
J8 - J9 - Encoder (By connecting an opto-switch it is possible to switch ON the light when the shutter move) **The encoder reading is available for s.w. 2.00 and 5.00	1. +LED 2. IN 3. GND 4. GND

JUMPERS (see Figure "LED Timer Board - Jumpers"): OFF = no jumper / ON = with jumper



LED Timer Board - Jumpers

JP1, JP2 - Alternate/Direct Power Supply	**OFF:** **ON:**	AC power supply DC power supply (pay attention to polarity!)
JP5 - LED power supply up to 6.2 A (standard setting: 4 A)	**OFF:** **ON:**	LED power supply is adjustable through trimmer to max. 4.8 A LED power supply is adjustable through trimmer to max. 6.2 A
JP14 - Additional resistance	**OFF:** **ON:**	standard input used to power a retro-reflective photocell
JP8 - Operation mode selection - Lighting time extension mode	**OFF:** **ON:**	standard timer will operate in "time extension" mode, i.e.: if the LED light is ON, at each pressing of the LED pushbutton, the light will remain "ON" and the "ON" time will be extended.

JP9 - Laser controlled independently	**OFF:**	Standard
	ON:	When the laser button, connected to connector J5, is pressed, the laser will switch ON independently from the LED light. Same timing concept as LED light.
JP10 & JP11 - Lighting time setting	**OFF / OFF:**	Lighting time: 30 seconds.
	ON / OFF	Lighting time: 45 seconds
	OFF / ON	Lighting time: 60 seconds
	ON / ON	Continuous lighting ***(max. ON time set at 15 mins. for safety reasons)***.
For LED timer boards with SW version 4.00 only: **JP10 - Auto-OFF exclusion**	**ON**	Exclusion of LED AUTO-OFF.
JP12 & JP13 - SW version configuration	**OFF / OFF:**	***SW version 2.00:*** laser and LED can be switched ON/OFF via pushbuttons
	ON / OFF:	***SW version 3.01:*** continuous power supply without safety/OFF time
	OFF / ON	***SW version 5.00:*** when LED is off, pressing the button will only turn on LED and fan. If the button is pressed again within 5 seconds, the laser will also light up. Further pressing of the button within 5 seconds will switch everything OFF. However, the LED and the laser will switch OFF according to JP10 and JP 11 settings (laser and LED can be switched ON/OFF via pushbuttons).
	ON / ON	***SW version 4.00:*** board switching ON and OFF is controlled by closing the contact. If JP8 setting = OFF (standard): OFF: status will change by pressing the button. (if light ON, pressing the button will turn it off and vice versa) ON: The LED timer board will operate in “lighting time extension mode”, i.e. at each pressing of the LED pushbutton, the light will remain “ON” and the “ON” time will be extended

IMPORTANT

For GC-LED-4A software version and position of jumpers, please see wiring diagram in Chapter "Installation", Section "Electrical Connection"

FAN

The fan switches ON together with the LED, and operates 15 seconds longer after the LED turns OFF.

TRIMMERS (see Figure "LED Timer Board - Jumpers" - component "TR1")

TR1- Current Control

Adjust the output current intensity to the LED. Default trimmer setting for LED timer boards supplied loose (spare part code: RS 2539): **4.1A approx.**

NOTICE

Customers are not allowed to alter trimmer default setting without prior authorization by RALCO. Failure to respect this condition may impair LED function and will result in voiding the warranty.

LEDs (see topographic diagram above)

LED 1 - Green LED	Power supply + 5 V	
LED 2 - Yellow LED	Indicates software version: LED 2 will stop blinking if LED 3 is ON.	**1 blink** = **standard** software **2 blinks** = SW version: **3.01** **3 blinks** = SW version: **5.00** **4 blinks** = SW version: **4.00**
LED 3 - Alarms	Indicates an alarm LED is **OFF** -> OK	**1 blink** = LED disconnected or faulty driver **2 blinks** = LED short-circuited **3 blinks** = Fan failure or disconnected **4 blinks** = Laser failure of disconnected **5 blinks** = Push button pressed longer than 5 seconds or short-circuited **6 blinks** = Timer temperature >105° **7 blinks** = LED temperature >110°

Alarm diagnostic

The timer identifies anomalies/errors/malfunctions. The outgoing messages from J7 are managed and interpreted by "intelligent board"

bit = 10 ms
byte:
1 bit sync (1)
8 bit data - transmission bit L....H
1 bit stop (0)

Output status:
0 = output disabled
1 = output enabled

BYTE 1: firmware version
BYTE 2: firmware mode + jumper status
bit7: firmware mode bit 1
bit6: firmware mode bit 0
bit5: JP13
bit4: JP12
bit3: JP11
bit2: JP10
bit1: JP9
bit0: JP8

BYTE 3: input/output status
bit7: 1 = LED push button pressed
bit6: 1 = Laser push button pressed
bit5: 1 = ENC1 input activated
bit4: 1 = ENC2 input activated
bit3: 1 = O.C. output activated
bit2: 1 = Laser ON
bit1: 1 = Fan ON
bit0: 1 = LED ON

BYTE 4: alarms:
bit7:
bit6: High LED temperature
bit5: High timer temperature
bit4: Push button pressed more than 5 seconds
bit3: Laser error
bit2: Fan error
bit1: LED short-circuited
bit0: LED disconnected or faulty driver

COMPLIANCE VERIFICATION

MINIMUM FILTRATION REQUIREMENT

To indicate compliance with 21 CFR, sub-chapter J, part 1020 of Performance Standard it is necessary for the assembler to perform a series of tests.

Description of test methods are illustrated in this chapter but factors, such as experience, availability of equipment and tolerance on compliance are referred directly to the Safety Standards covering Electro-medical equipment.

WARNING

The following procedures require that radiation be produced. Take adequate precautions to ensure no part of the human body is exposed to X-Ray radiation, direct or indirect.

The above HVL requirements can be met if it is demonstrated that the aluminium equivalent in the primary beam is not less than that shown in the following table:

Minimum Filtration Requirement - Beam Quality (HVL)				
X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of Aluminum*)		
Designed Operating Range (kVp)	Measured Operating Potential (kVp)	Specified Dental System[1]	I-Other X-Ray Systems[2]	II-Other X-Ray Systems[3]
Below 51	30 40 50	1.5 1.5 1.5	0.3 0.4 0.5	0.3 0.4 0.5
From 51 to 70	51 60 70	1.5 1.5 1.5	1.2 1.3 1.5	1.3 1.5 1.8
Above 70	71 80 90 100 110 120 130 140 150	2.1 2.3 2.5 2.7 3.0 3.2 3.5 3.8 4.1	2.1 2.3 2.5 2.7 3.0 3.2 3.5 3.8 4.1	2.5 2.9 3.2 3.6 3.9 4.3 4.7 5.0 5.4

[1] Dental X-Ray Systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[2] Dental X-Ray Systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other X-Ray systems subjected to this section and manufactured before June 10, 2006.

[3] All X-Ray systems, except dental X-Ray systems designed for use with intraoral image receptors subjected to this section and manufactured on or after June 10, 2006.

The information contained in the above table was extracted from the Code of Federal Regulations FDA 21 1020.30 (m)

Type 100 Aluminium Alloy (as given in "ALUMINUM STANDARDS AND DATA" verification of compliance).

VISUAL DETERMINATION OF HALF-VALUE LAYER (HVL)

The above HVL requirements can be met if it is demonstrated that the aluminium equivalent in the primary beam is not less than that shown in the following "Total Filtration" table:

Total Filtration Of Primary Beam In Aluminium Equivalence	
Operating Voltage (kVp)	**Total Filtration (mm Al Equivalent)**
Below 50	0.5
From 51 to 70	1.5
Over 70	2.2

The Aluminum equivalence of each component in the primary beam (X-Ray tube and housing, beam limiting device and any additional filtration in the system) is specified on the component, in the technical data attached to the component or can be measured. Determine the total aluminium equivalence in the primary beam and make sure that it is equal or greater than those specified in the above table **"Total Filtration of Primary Beam in Aluminium Equivalence"**.

QUICK-CHECK OF MINIMUM FILTRATION REQUIREMENT AT A PARTICULAR KVP

If the total inherent filtration cannot be seen, then the HVL must be obtained with the following procedures:
The HVL in millimetres of aluminium in the system under test must be compared with those specified in Table **"Minimum Filtration Requirement - Beam Quality (HVL)"** and must be greater than or equal to the values shown in the table.

a) Direct the central X-Ray beam perpendicular and in the center of a RAD-Check instrument. Determine the exact distance from the X-Ray tube focal spot to the window of the collimator (273 mm - 10.75"). Place the input area of the RAD-CHECK at an equal distance from the collimator window. Collimate the beam to an area slightly larger than the detector.

b) Make an exposure at a pre-selected technique factor of 90 kVp and appropriate mA and time values with no added filtration in the beam; record the reading.
Using the type 1100 Aluminium Alloy, tape a total of 2.5 mm of Aluminium to the window of the collimator. Make an exposure using the same technique factors; record the reading.

c) Verify that the radiation read with the 2.5 mm Al in the beam is greater or equal to 50% of the radiation read with no filtration in the beam.

STANDARD ABSORBER METHOD

The HVL determination obtained from the following procedures are to be compared with those illustrated in the Table **"Minimum Filtration Requirement - Beam Quality (HVL)"**. The HVL in millimeters of aluminum obtained during the test must be greater or equal than the values listed in the above mentioned table.

a) Direct the central X-Ray beam perpendicular and in the center of a RAD-Check instrument. Determine the exact distance from the X-Ray tube focal spot to the window of the collimator (273 mm - 10.75"). Place the input area of the RAD-CHECK at an equal distance from the collimator window. Collimate the beam to an area slightly larger than the detector.

b) Select a tube potential of 100 kVp and appropriate mA and seconds, with no added filtration in the beam make an exposure and record the reading. Using a set of several sheets of 1100 Aluminium Alloy, each having a thickness of 0.5 or 1.0 mm, tape the filtration to the window of the collimator. Make an exposure for each increments of filtration and record the reading.

c) Plot the exposure readings (log scale) versus the total added filtration thickness on semi-log paper; see the sample hereunder.

d) Verify that HLV values in the useful beam for the above specific tube potential is not less than the values shown in the Table **"Minimum Filtration Requirement - Beam Quality (HVL)"**

VISUAL DEFINITION OF X-RAY VERSUS LIGHT FIELD

See Chapter *"CALIBRATION"*, Section *"LIGHT FIELD ADJUSTMENT"*.

FIELD SIZE INDICATION

See Chapter *"ADJUSTMENTS"*, Section *"FIELD SIZE INDICATION ADJUSTMENT"*.

CROSSHAIR ALIGNMENT

See Chapter *"ADJUSTMENTS"*, section *"CROSSHAIR ADJUSTMENT"*.

LIGHT FIELD ILLUMINATION INTENSITY

a) When a light field simulating the X-Ray field is used the illumination provided at 100 cm. cannot be less than: 160 lux [(21 CFR 1020.31 (d) (2) (ii)].

b) Place the Focus of the X-Ray tube at 100 cm. from the table top were the light field as been projected. Open the collimator's shutters to assure that each quadrant of the light field is larger than the measuring area of the photometer.

c) Check that the voltage specified by the manufacturer is applied to the lamp, make certain that all surfaces in the light beam are clean and unobstructed.

d) Place a photometer capable of reading up to 160 lux in the centre of each of the four quadrants of the light field.

e) Turn on the light beam and read the light intensity, subtract to it the ambient lighting, previously determined.

f) Verify that the average illumination is higher than 160 lux.

g) Verify that the contrast ratio is performed between two points:

- The first point at 3 mm outside the edge of the light field.
- The second point at 3 mm inside the edge of the light field.

These measurements are to be performed with the probe of the lux metre set at 1 mm aperture.

h) Record the measured values including all data regarding the instrument and voltage employed.

EMC COMPLIANCE

The ME Equipment is intended to be used in PROFESSIONAL EM ENVIRONMENTS.

WARNING	
	**Ensure that accessories, transducers and cables that can affect the emissions or immunity of the ME EQUIPMENT, accessories, transducers and cables are chosen to allow the ME EQUIPMENT to continue to meet the emissions and immunity requirements of this collateral standard.**

ELECTROMAGNETIC EMISSIONS		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT- GUIDANCE**
The collimator "R 108 - R 108 DHHS" is suitable for use in the specified electromagnetic environment. The purchaser or user of the "R 108 - R 108 DHHS " collimator should assure that it is used in an electromagnetic environment as described below		
RF emissions CISPR 11	Group 1	The "R 108 - R 108 DHHS " collimator needs special precautions regarding EMC and needs to be installed and put into service according to the EMC report. Portable and mobile RF communications equipment can affect the "R 108 - R 108 DHHS " collimator.
RF emissions CISPR 11	Class [A]	The "R 108 - R 108 DHHS " collimator is suitable for use in all establishments other than domestic and those directly connected to the low voltage power supply network which supplies buildings used for domestic purposes. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	[Not applicable]	
Voltage fluctuations/flicker emissions IEC 61000-3-3	[Not applicable]	

ELECTROMAGNETIC IMMUNITY FOR ALL EQUIPMENT AND SYSTEMS			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT**
The collimator "R 108 - R 108 DHHS " is suitable for use in the specified electromagnetic environment. The purchaser or user of the "R 108 - R 108 DHHS " collimator should assure that it is used in an electromagnetic environment as described below.			
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2/4/8/15 kV air	EN 60601-1-2 test level	Floors should be wood. concrete or ceramic tile. If floors are covered with synthetic material. the relative humidity should be at least 30%.
Radiated electromagnetic field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the collimator R108F DHHS. including cables. Minimum distance 30 cm.

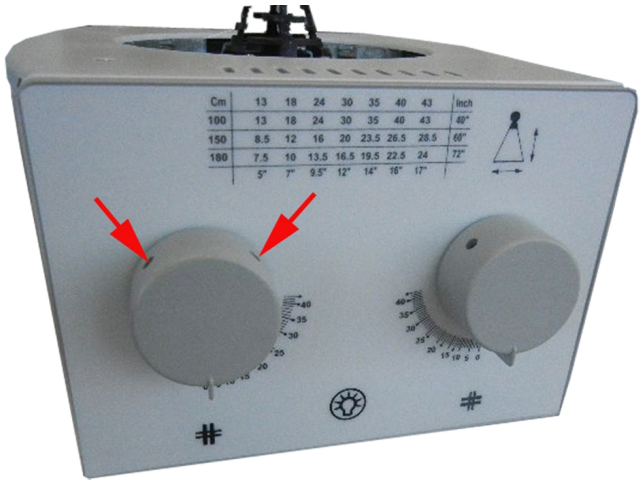
ELECTROMAGNETIC IMMUNITY FOR ALL EQUIPMENT AND SYSTEMS			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT**
Electronical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines >3m	EN 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	0.5/1 kV differential mode 0.5/1/2 kV common mode	EN 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 150 kHz to 80 MHz 6V ISM frequencies	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of the collimator R108F DHHS. including cables. Minimum distance 30 cm
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	10 ms – 0% a 0°, 45°, 90°, 135°, 180°. 225°, 270°, 315° 20 ms – 0% a 0° 500 ms – 70% a 0° 5 s – 0%	EN 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If the user of the collimator R 108 - R 108 DHHS requires continued operation during power mains interruptions. it is recommended that the collimator R 108 - R 108 DHHS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	EN 60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

FREQUENCY RANGE AND LEVEL: RF WIRELESS COMMUNICATION EQUIPMENT			
TEST FREQUENCY (MHZ)	**MODULATION**	**MINIMUM IMMUNITY LEVEL (V/M)**	**IMMUNITY LEVEL APPLIED (V/M)**
The collimator “R 108 - R 108 DHHS ” is suitable for use in the specified electromagnetic environment. The purchaser or user of the “R 108 - R 108 DHHS ” collimator should assure that it is used in an electromagnetic environment as described below.			
385	**Pulse Modulation: 18 Hz	27	27
450	*FM ± 5 Hz deviation: 1 kHz sine **Pulse Modulation: 18 Hz	28	28
710 745 780	**Pulse Modulation: 217 Hz	9	9
810 870 930	**Pulse Modulation: 18 Hz	28	28

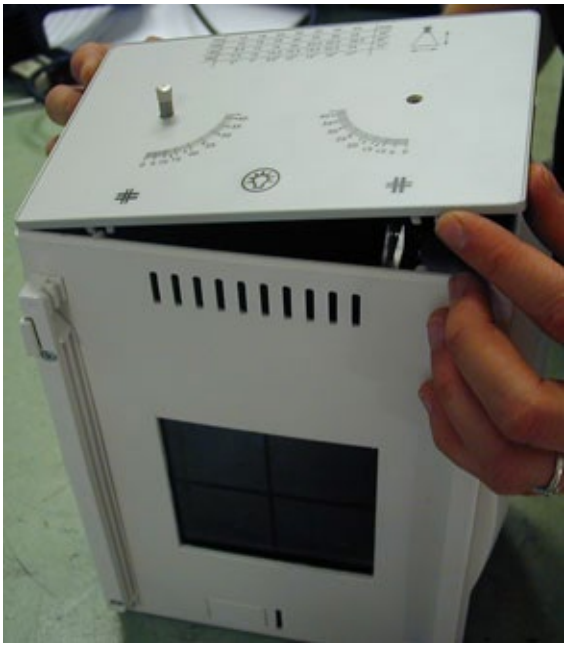
FREQUENCY RANGE AND LEVEL: RF WIRELESS COMMUNICATION EQUIPMENT			
TEST FREQUENCY (MHZ)	**MODULATION**	**MINIMUM IMMUNITY LEVEL (V/M)**	**IMMUNITY LEVEL APPLIED (V/M)**
1720 1845 1970	**Pulse Modulation: 217 Hz	28	28
2450	**Pulse Modulation: 217 Hz	28	28
5240 5500 5785	**Pulse Modulation: 217 Hz	9	9

COVER REMOVAL

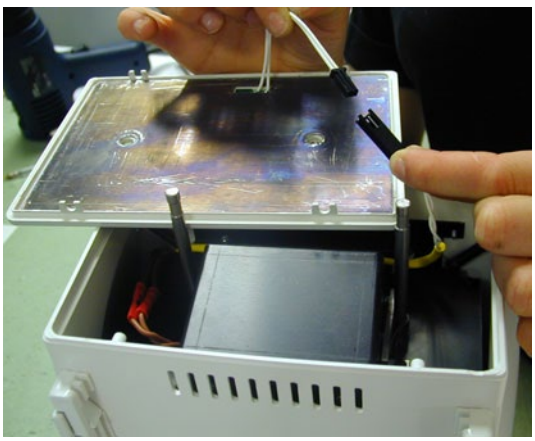
1. Remove the two knobs by unscrewing the two Allen screws per knob.



2. Remove the front panel.



3. Disconnect the connectors.



4. Turn the collimator over and unscrew the four screws on the two rails.

5. Gently ease the tape into the collimator

6. Remove the screw from the snap-fit plate. remove the plate and then lift the collimator cover off.

7. Remove the cover by lifting it off the collimator

Notes on the use of the retractable tape measure:

IMPORTANT

To ensure correct measurement: extend the tape measure perpendicularly to the collimator plane, until reaching the image receptor and / or the patient surface.

NOTICE

Upon completion of measurement and/or of functional check, retract the tape measure into the initial position while holding the tab.
Do not let the tape fly back quickly: this might result in damage to the tape measure and/or other collimator components (e.g. anti-dust panel, cover, etc.).

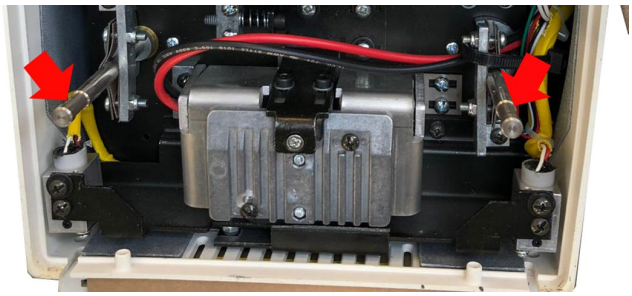
ACCESS TO DIFFERENT COLLIMATOR COMPONENTS

Power Supply

Access the collimator power supply by removing the screw and the rear panel.

Frictions

Access the clutches by removing the knobs and the front panel.



ADJUSTMENTS

WARNING

The information provided in this Chapter is meant only as an aid to the End-User. Ralco is not liable for any damages resulting from the alteration of factory settings. Adjustments are preset at the factory prior to the shipment of the collimator. Should any problems arise requiring the collimator to be recalibrated, please contact RALCO for assistance before proceeding with the adjustment.

FIELD SIZE INDICATION ADJUSTMENT

EN60601-1-3- par. 29.201.8

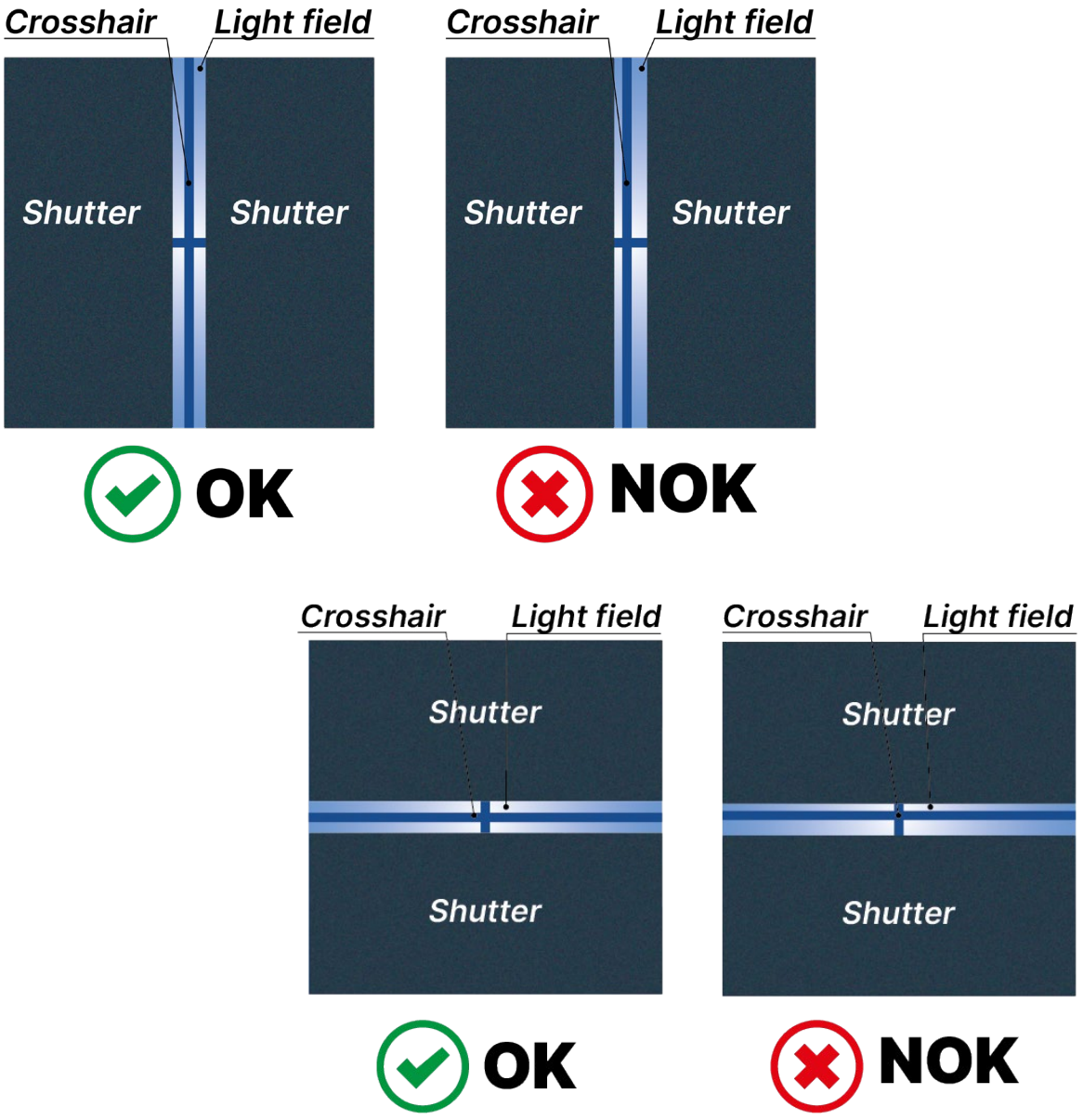
Regulations state that collimators must indicate the size of the X-Ray field at the SID in use to within 2% of that SID.

Shutter Dial Adjustment

1. Rotate the two control knobs to completely close both sets of shutters. Use the field light to check that the shutters are in fact closed.
2. Rotate the knobs and make the knob index coincide exactly with the scale reading that corresponds to size 30x30 cm at 1 m SID.
3. Measure the X-ray field of the test image.
4. If the reading is not correct, adjust the indicator using the screws on the sides of each knob.

CROSSHAIR ADJUSTMENT

- Activate the light field.
- Adjust the light field to a narrow line for each pair of shutters by turning the two knobs alternately.
- Check that the project cross line is exact halfway between the edges of the shutters, see Fig. **"Cross Line"**.
- If adjustment is required, remove the cover from the sides and bottom of the collimator, see Chapter *"COVER REMOVAL"*.
- Loosen the four screws securing the plastic panel and adjust the cross lines to coincide with the light lines, see Chapter *"COVER REMOVAL"*.
- Tighten the screws.

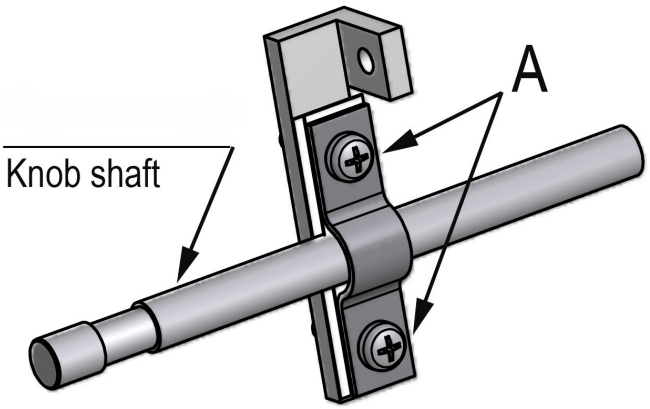


Cross line

FRICTION BRAKE ADJUSTMENT

If the shutter movement is too loose or too tight, proceed as follows:

1. Remove the parts of the cover to access the adjustment point, see Chapter *"COVER REMOVAL"*.
2. If a shutter control is *too loose* and does not hold position, tighten one of the two screws **"A"** on the U-bolt that frictions the shaft, see Fig. **"Friction Brake"**.
3. If a shutter control is *too tight*, loosen one of the two screws **"A"** on the U-bolt that frictions the shaft, see Fig. **"Friction Brake"**.
4. Before replacing the knobs, close both shutters and mount/fix the knobs so that the field index is set at "0" (completely closed), see paragraph *"Shutter Dial Adjustment"* in this Chapter.



Friction Brake

TROUBLESHOOTING

A faulty collimator must not be used until it is repaired and checked.

WARNING

The use of a faulty collimator might impair the safety of operator and patients!

Before returning the collimator to RALCO for repair, please make sure that the fault is not caused by one of the problems listed below. If the indications provided fail to solve your fault, please make sure that you obtain a Return number (RMA) from RALCO for the collimator, see Chapter *"GENERAL"*, section *"REPAIRS"*.

GENERAL FAULT FINDING

FUNCTION	FAULT DESCRIPTION	FAULT FINDING AND SOLUTIONS
Light	Faulty light source	• Check if power supply is OK • (see Chapter *"SPECIFICATIONS"*) • Check if LED power supply is + 3 V • If still NOK, replace LED (see Chapter *"SUBSTITUTIONS"*)
	Faulty timer	• Check if power supply is OK (see chapter *"SPECIFICATIONS"*) • Check if timer board is supplied • Check if fan operates when pressing the push button on the front panel • Check if the green diode placed on the timer is ON when pressing the push button on the front panel. • If NOK, replace the timer board (see Chapter *"SUBSTITUTIONS"*)
	Area defined by light field not (completely) on film	• Check if source flange distance is correct (see Chapter *"INSTALLATION"*) • Check if mirror or light source are positioned correctly (see chapter*"CALIBRATION"*)) • If still NOK, exchange the collimator.
	Faulty ON/OFF pushbutton	• Check contact • If NOK, replace the front panel

FUNCTION	FAULT DESCRIPTION	FAULT FINDING AND SOLUTIONS
Collimator calibration	Light field of collimator not centered	• Check if mirror or light source are correctly positioned (see Chapter *"CALIBRATION"*) • If still NOK, replace collimator.

FUNCTION	FAULT DESCRIPTION	FAULT FINDING AND SOLUTIONS
Shutters	Shutter movements not as expected	• Check if friction is loose (see Chapter *"ADJUSTMENTS"*) • If still NOK, replace friction.

GC-LED-4A INDICATORS

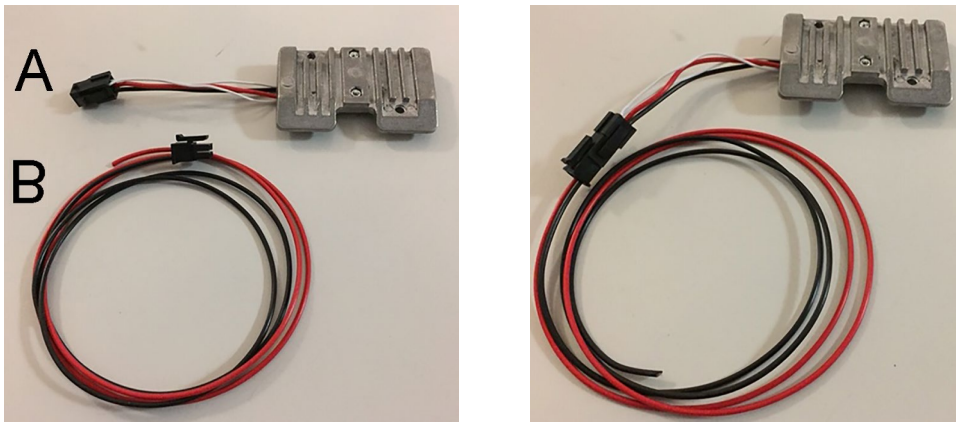
NUMBER	COLOR	DESCRIPTION	FAULT FINDING AND SOLUTIONS
LED 1	Green	+12 V DC or +24 V DC	In case LED1 is OFF: • check if +12/+24 V is present; LED1 should be ON • if still NOK, check if system cables are connected correctly to GC-LED-4A • if still NOK, replace GC-LED-4A (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace collimator.
LED 2	Yellow	Software version	• check if LED2 blinks 4 times • if NOT, wrong software version, replace collimator • (see Chapter *"SUBSTITUTIONS"*)
LED 3	Red	Alarms	**1 blink: Disconnected LED or Driver failure** • check if LED is connected correctly • if still NOK, replace LED • if still NOK, replace GC-LED-4A (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace collimator. **2 blinks: LED short circuit** • remove the short circuit • if still NOK, replace LED • if still NOK, replace GC-LED-4A (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace collimator. **3 blinks: Fan failure or disconnected** • check if fan is connected correctly • if still NOK, replace fan (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace GC-LED-4A (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace collimator. **4 blinks: Laser failure or disconnected** • check if laser is connected correctly • if still NOK, replace laser (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace GC-LED-4A (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace collimator. **5 blinks: push button pressed longer than 5 seconds or short-circuited** • check if push button works properly • remove short circuit if present • if still NOK, replace GC-LED-4A (see Chapter *"SUBSTITUTIONS"*) • if still NOK, replace collimator. **6 blinks: PCB temperature > 105°** • switch OFF the collimator for 10 minutes

SUBSTITUTIONS

LED SUBSTITUTION

WARNING	
	**Do not touch the heat sink: it might be hot and cause severe burns!**
	**Do not touch the light source, the socket or the light bracket: they might be hot and cause severe burns!**
	**Do not touch the LED lens, even if cold, to avoid contamination by natural skin grease, sweat or dirt, what might impair the LED performance.** **If you have touched the LED, wipe the LED surface with a soft cloth!**

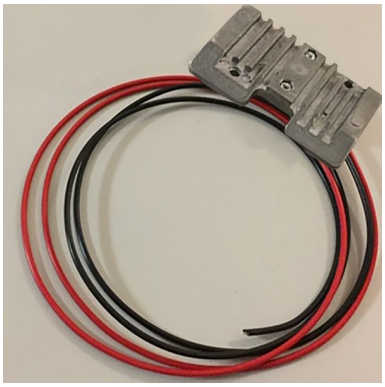
The LED Substitution Kit is composed of the following components: the LED (A), and an extension cable (B), pictured in Fig. **"LED Substitution Kit"**. This kit is designed to substitute any LED RALCO provides.



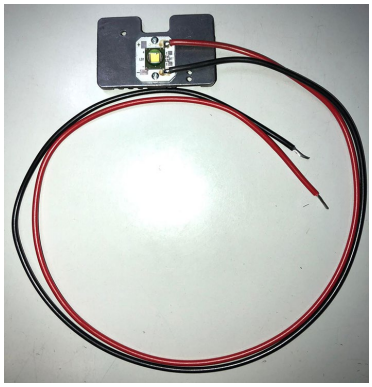
LED Kit

To ensure that the substitution is performed correctly, prior to replacing the LED, confirm which version of LED is installed on your collimator:

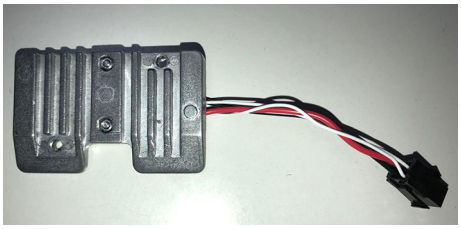
- The previous version LED is connected to the board via 2 cables (red and black), see Fig. **"Previous Version LED"** below.



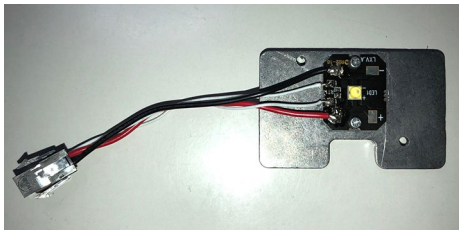
Previous Version LED



- The new LED is connected to the board via the connector, see Fig. **"New Version LED"** below.



New Version LED



Replacing the Previous Version LED

To replace the previous version of LED, both components of the LED Substitution Kit (**"A"** - LED - and **"B"** - extension cable) must be used.

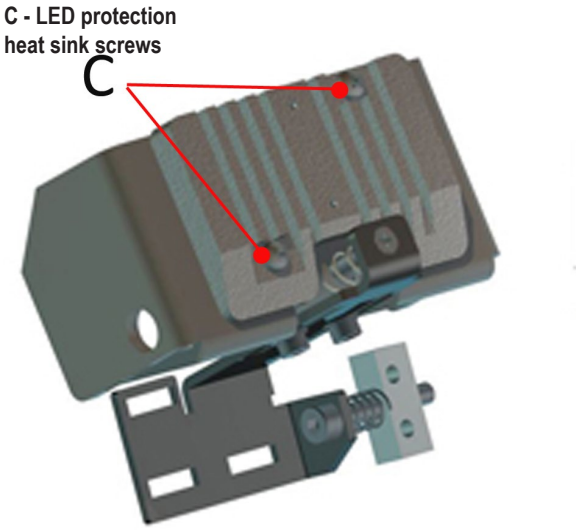
To substitute the LED, proceed as follows:

- Disconnect collimator supply.
- Remove cover, see Chapter *"COVER REMOVAL"*.
- Remove the LED heat sink protection by unscrewing the 2 screws **"C"**, see Fig. **"LED Substitution"** .
- Prior to disconnecting the LED cables from the board, identify the cables and their position on the terminal board, see Chapter **"Installation"**, paragraph **"Wiring Diagram"** in the Instruction Manual for your specific model.
- Carefully remove the LED and the extension cable from their packaging.
- Make sure that the extension cable (**"B"**) is firmly connected to the LED (**"A"**), see Fig. **"LED Kit"**.
- Adjust the length of the extension cable (**"B"**) by cutting the 2 cables (red/black).
- Connect both cables to the board.
- Remount the heat sink protection by tightening the two fixing screws (**"C"**), see Fig. **"LED Substitution"**.
- Remount the covers in reverse order, see Chapter *"COVER REMOVAL"*.
- Verify Light/X-Ray Field correspondence, see Chapter *"CALIBRATION"*.

Replacing the New Version LED

To replace the new version LED, only part **"A"** (LED) of the LED substitution kit is needed.

- To substitute the LED, proceed as follows:
- Disconnect supply.
- Remove the cover, see Chapter *"COVER REMOVAL"*.
- Remove the LED heat sink protection by unscrewing the 2 screws **"C"**, see Fig. **"LED Substitution"**.
- Detach the connector of the faulty LED from the collimator wiring.
- Substitute the LED with an identical item by using part **"A"** of the LED Substitution Kit.
- Remount heat sink protection by tightening the 2 fixing screws **"C"**, see Fig. **"LED Substitution"**.
- Remount the covers in reverse order, see Chapter *"COVER REMOVAL"*.
- Verify Light/X-Ray Field correspondence, see Chapter *"CALIBRATION"*.



LED Substitution

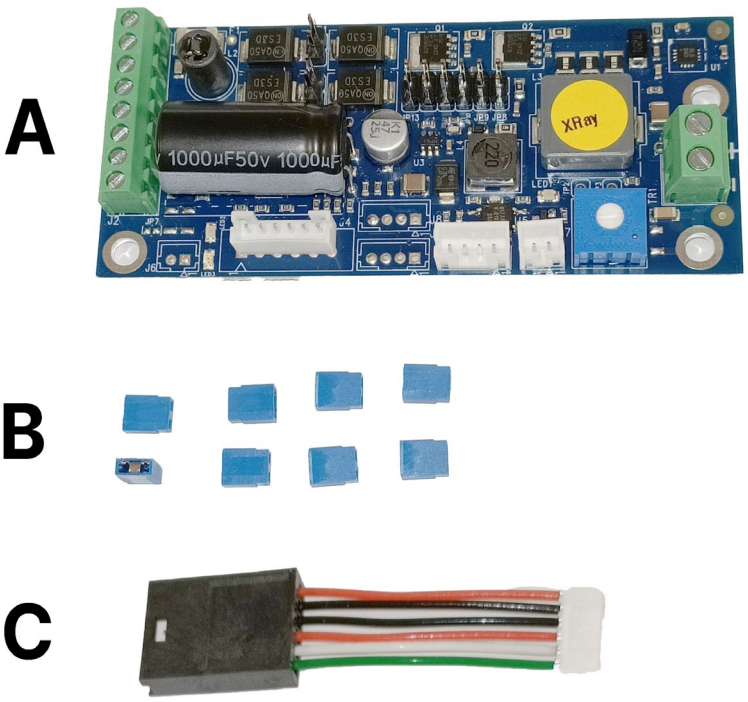
SUBSTITUTION OF THE ELECTRONIC BOARD FOR LED

The LED Timer Board Substitution Kit consists of following components (positions are referred to Fig. **"LED Substitution Kit"**):

(A) GC-LED-4A Timer Board (1 pce.)
(B) jumpers (8 pcs.)
(C) extension cable (1 pce.).

This Kit is designed to substitute any LED timer board installed on RALCO collimators.

The extension cable **"C"** is included in the kit in case of need, but it is to be used only for collimators with additional filtration and LED indicator on the front panel.



LED Substitution Kit

IMPORTANT

When replacing the LED timer board, it is not necessary to replace also the LED.

CAUTION

LED Timer boards are ESD (electrostatic sensitive devices).
Please take all necessary safety measures when handling them.

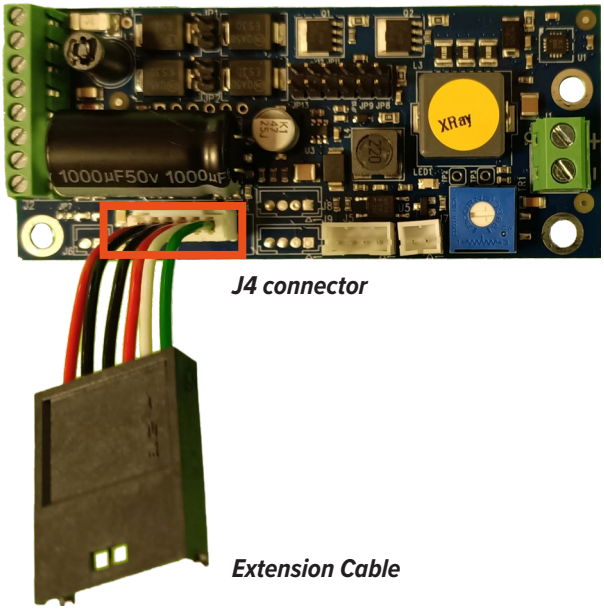
To substitute the timer board, proceed as follows:

1. Disconnect collimator supply.
2. Remove collimator cover, see Chapter *"COVER REMOVAL"*.
3. Prior to disconnecting the cables from the board, identify the cables and their position on the terminal board, see Chapter **"Installation"**, section **"Wiring Diagram"** in the Instruction Manual for your specific model (personalization pages).

4. Carefully remove the timer board, extension cable and jumpers from their packaging. Observe ESD protection measures!

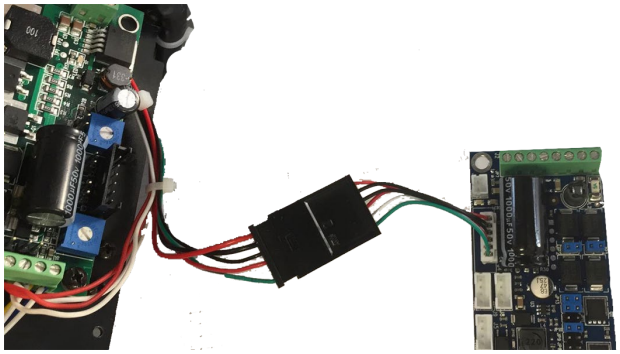
For collimators with extension cable only:

5. Insert the extension cable (**"C"**) in the **J4** connector of the new timer board, see Fig. **"Extension Cable"**.
6. Detach the connector from the faulty timer board, see Fig. **"Connector Removal"**.
7. Connect the unplugged connector to the extension cable (**"C"**), see Fig. **"Extension Cable Connection"**.

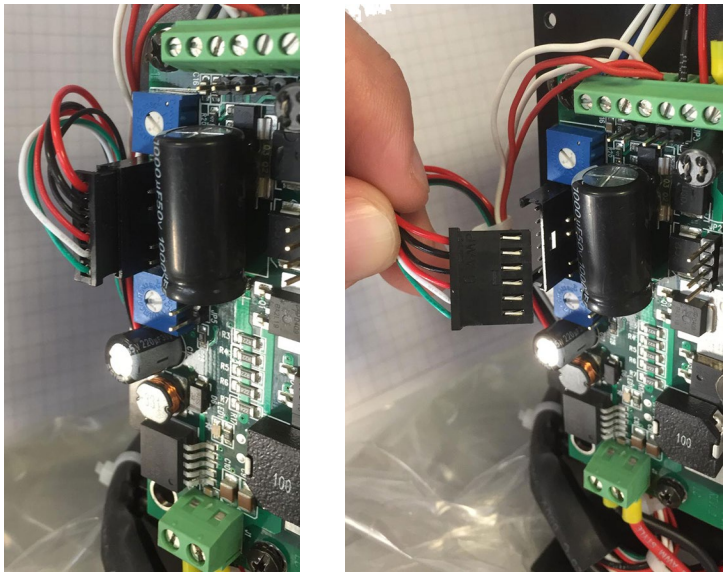


J4 connector

Extension Cable



Extension Cable Connection



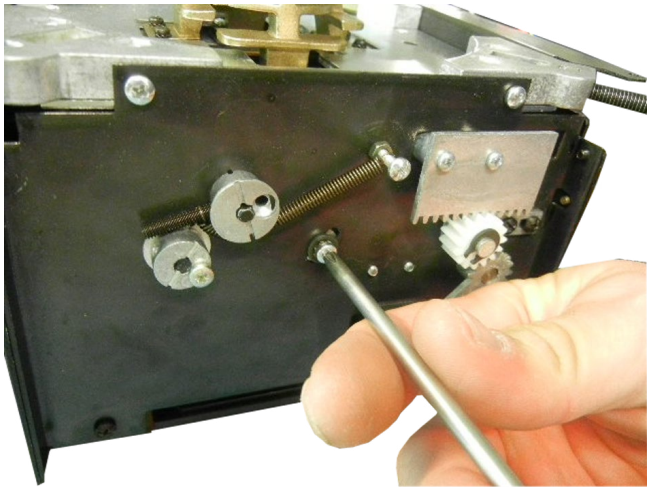
Connector Removal

For all collimators:

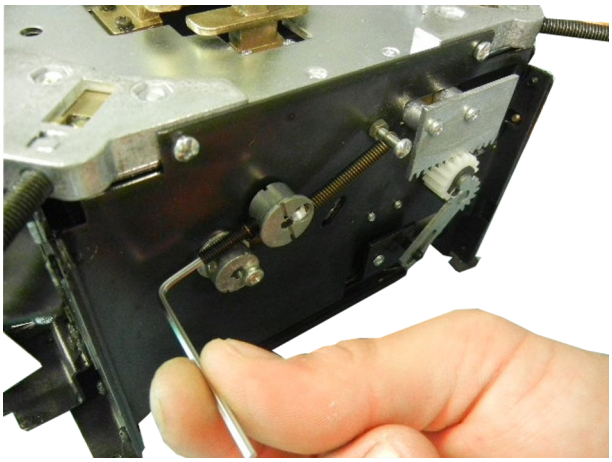
8. Remove the 2 screws holding the timer board.
9. Install the new timer board by proceeding in a reverse order; pay particular attention to the connection of the cables on the 2- or 8-way electric terminal.
10. Correctly set up the board by using the 8 jumpers (pos **"B"** of Fig. **"LED Substitution Kit"**). The function of the jumpers is explained in Chapter **"Electronic System"**, Section **"GC-LED-4A Timer board"**. For the actual setting of the jumpers applying to your collimator, please see Chapter **"Installation"**, Section **"Wiring Diagram"** of the Instruction Manual for your specific model (personalization pages).
11. Remount collimator covers, following in reverse order the procedure described in Chapter *"COVER REMOVAL"*.
12. Make sure that the light field ist still correctly set, see Chapter *"CALIBRATION"*.

SUBSTITUTION OF MIRROR

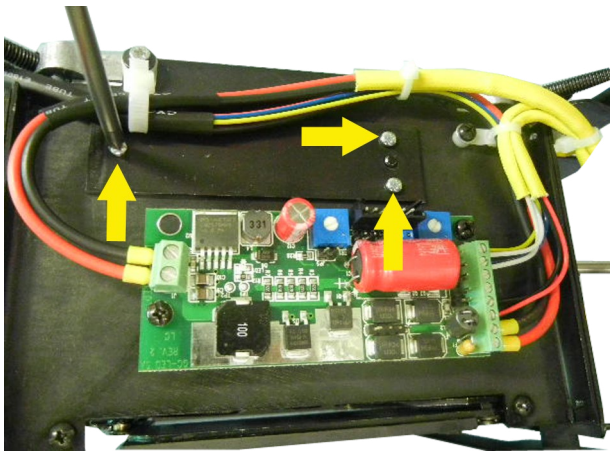
1. Right side:
Remove the mirror fixing screw.

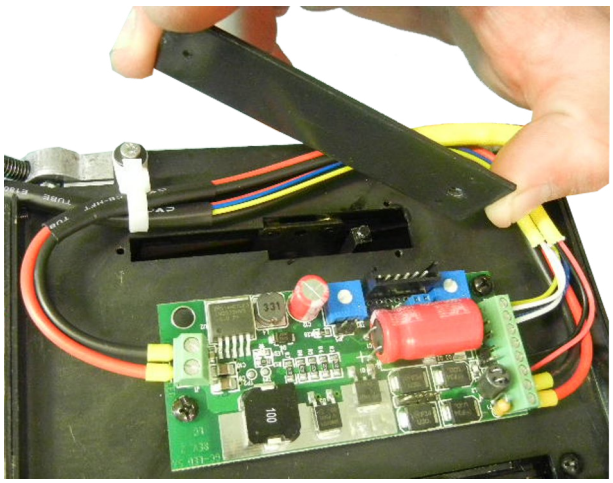


2. Right side:
Remove the mirror rotation cylinder.

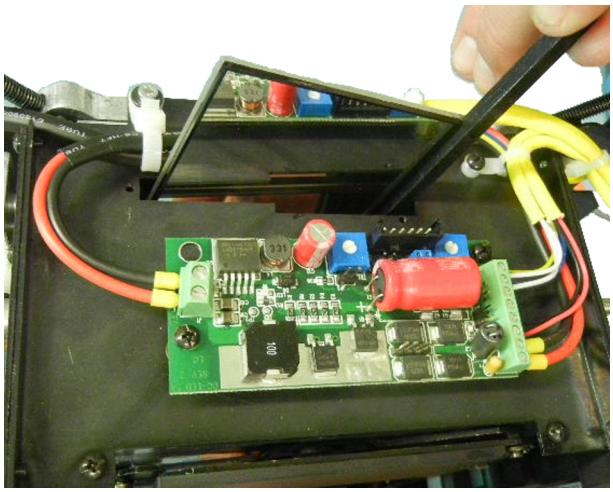


3. Left side:
Unscrew the mirror-group panel fixing screws (3x) and remove the panel.





4. Left side:
Slide the mirror group out.



SPARE PARTS

IMPORTANT

When ordering spare parts, customers are requested to specify collimator model and serial number.

The spare parts listed below refers to the standard model only.
Please consult your personalization page to identify the spare parts for your customized model.

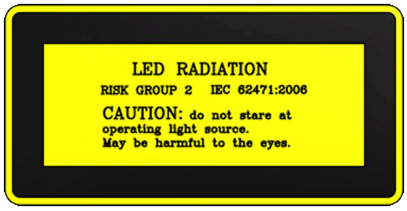
LABELS

Label 1A

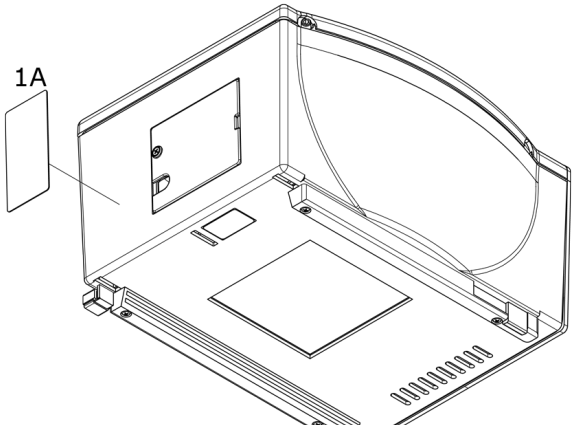
Label 1B

Label 2

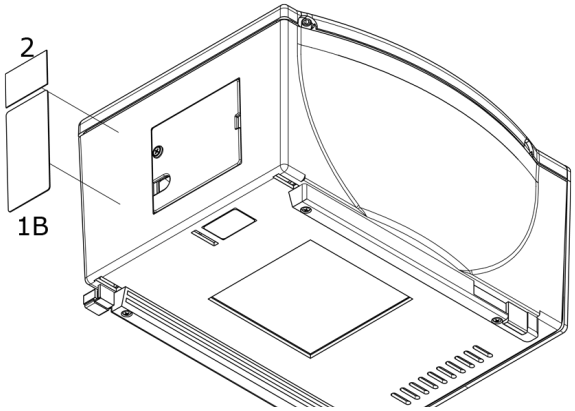
Label 7



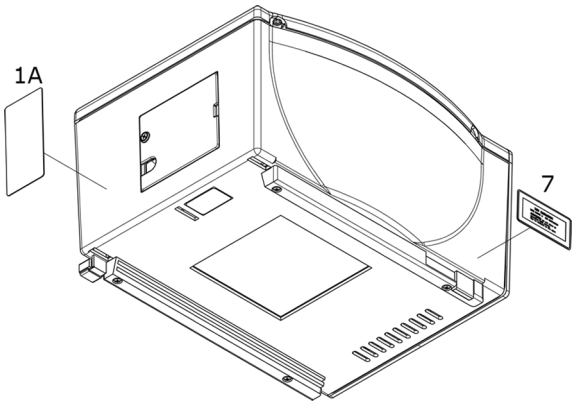
R 108 - R 108 DHHS - LABEL LOCATION DIAGRAM



Standard Model Label



DHHS Model Label

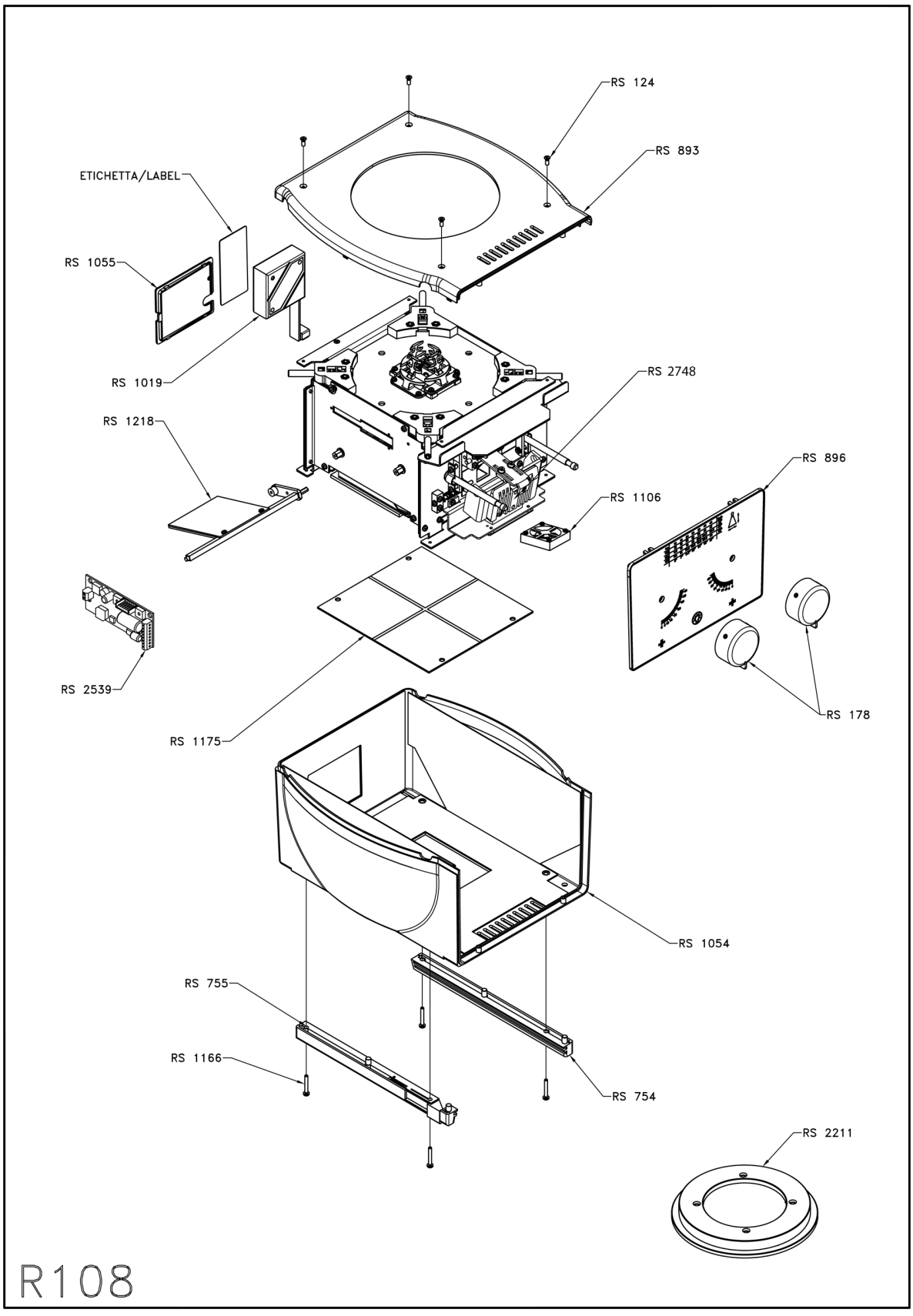


Standard Model, LED Label

R 108 - R 108 DHHS - SPARE PARTS LIST

PN	DESCRIPTION
RS 124	Screw, TS M3x8mm
RS 178	Knob
RS 754	Right accessory guide
RS 755	Left accessory guide
RS 893	Upper cover
RS 896	Front panel
RS 1019	Retractable tape measure
RS 1054	Lower cover
RS 1055	Rear panel
RS 1106	Fan
RS 1166	Screw, TC M3x20mm
RS 1175	Antidust panel
RS 1218	Mirror
RS 2211	Mounting flange
RS 2539	LED board
RS 2748	LED

PARTS BREAKDOWN

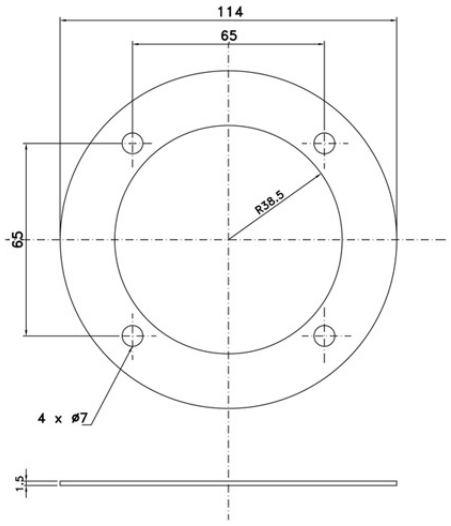


OPTIONAL ITEMS

This Chapter provides a detailed description of the optional items the collimator may be equipped with.

RO 002 IRON MOUNTING FLANGE SPACER

Iron spacer, 1.5 mm thickness, used for mounting flanges.



RO 051 METAL ROTATING MOUNTING FLANGE

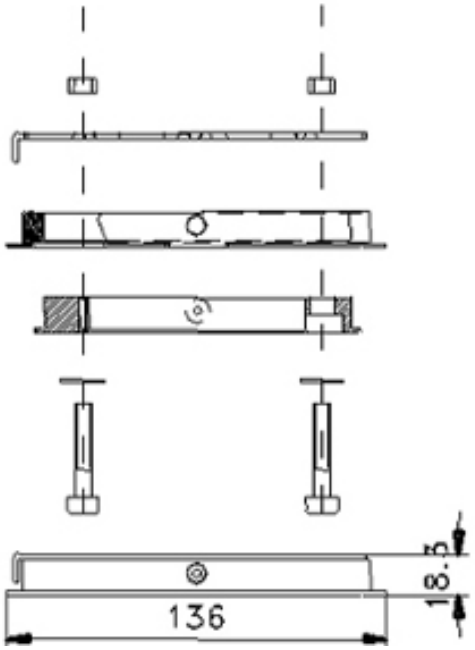
Metal rotating mounting flange:

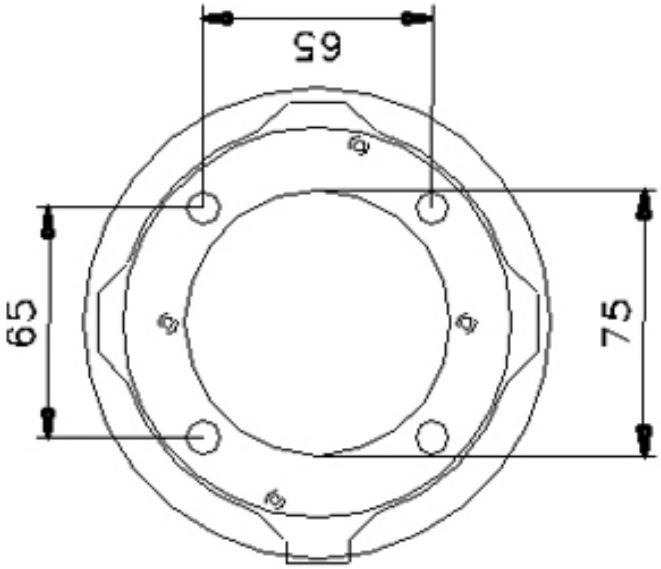
- 18 mm thickness
- +/- 90° with mechanical stop
- 136 mm diameter

Please refer to the chapter INSTALLATION in this Instruction Manual for the correct flange/collimator mounting instructions.*

*

- flange release force: 5.5 kg (+/- 1 kg)
- flange rotation force: 2.8 kg (+/- 1 kg)





When the collimator is assembled check the collimator to Focal Spot Alignment (Primary Shutter Cut-Off).

Inspect the four images of the four collimator shutters which form the edges of the X-ray field. A definitely indistinct edge indicates that the primary shutter, close to the focal spot, is the one forming the line, rather than the outermost shutter.

To correct the condition, use the four mounting/centering adjustment screws to shift the collimator in the direction of the indistinct line. Repeat the test film exposure after making the adjustment.

IMPORTANT

Due to the anode heel effect, the light field border on the anode-cathode axis of the X-Ray tube will have slightly less contrast than the other three sides. This is normal and cannot be corrected by adjustment.

In addition, an X-Ray tube of 12° or less target angle will produce an asymmetrically shaped field when a large field size is used at short SID, because of the anode cut-off effect. This is also normal and cannot be corrected by adjustment.

RO 063 FINAL QUALITY TEST REPORT DOCUMENTATION

This test provides higher control to check 100% of the production lot to verify product quality from the beginning to the end of the production cycle.

Final tests include:

- Light field illumination intensity (if applicable),
- Light field to X-Ray field alignment (if applicable),
- X-Ray leakage test,
- Edge contrast (if applicable),
- Operation and electronic check up.

RO 074 EXTERNAL HOUSING AND GUIDE RAILS IN CUSTOMIZED COLOR

Customers can specify the color for the collimator cover. Ralco's standard color is: **RAL9003**.

RO 082 GLASS MIRROR

Glass mirror, 0.8 mm thickness, inherent filtration 1 mm Al equivalent.

With this mirror, the collimator equivalent filtration value of 2 mm Al is reduced to 1 mm Al.

RO 096 WIRING CUSTOMIZATION

Customized electrical wiring. If ordered, please refer to the "PERSONALIZATION", annex included with this Instruction Manual, Chapter **"Installation"**, Section **"Wiring Diagram"**.

RO 107 KNOB COLOR CUSTOMIZATION

The customer can specify the required knob color.

RO 109 FRONT PANEL FRAME COLOR CUSTOMIZATION

The customer can specify the required frame color.

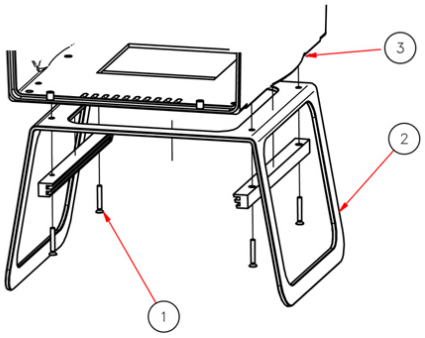
RO 111 FRONT PANEL CUSTOMIZATION

The customer can customize the front panel adding, for example, the Company Logo and/or the Company colors.

RO 240 FOCAL-SPOT-TO-SKIN SPACER

This accessory ensures a minimum safety distance (309.5 mm) between the X-Ray focus and the patient.

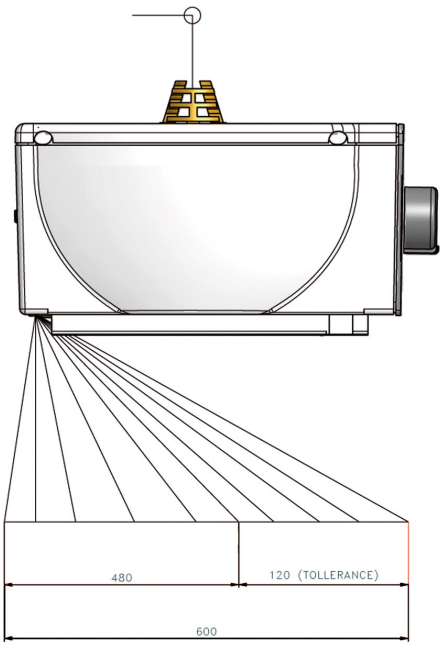
This accessory is meant to prevent the use of inappropriate small focus/skin distances, in order that the dose equivalent to the patient be kept as low as reasonably possible



1. Countersunk screws
2. Focus-Skin Distance Spacers
3. Collimator cover

RO 242/1 SINGLE LASER LINE TO ALIGN COLLIMATOR AND DETECTOR CENTER: CLASS 2

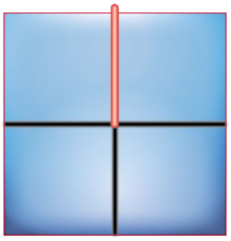
The collimator laser is classified as Class 2 (1 mW- wavelength = 645 nm, +/- 10 nm); used for collimator/image receptor center alignment, see Fig. **"Laser Line"**.



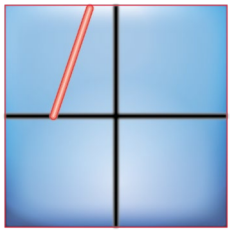
Laser Line

WARNING

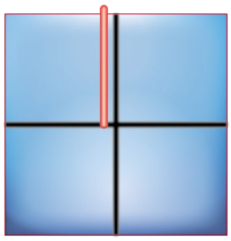
Class 2 laser system:
do not stare into the beam!



Correct alignment



Angular Misalignment

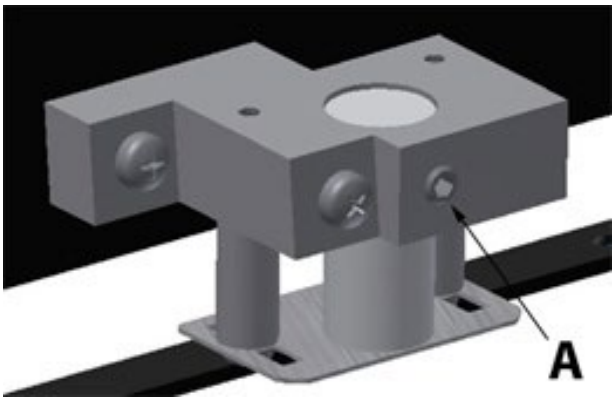


Lateral Misalignment

Laser Alignment

Adjustment

- Remove part of the cover to access the point of adjustment, see Chapter **"Cover Removal"**.
- The line is to fall on a perpendicular cross-line on the plastic anti-dust panel near the collimator controls, see Fig. **"Laser Line"** and **"Laser Alignment"** (images not in scale - illustrative purposes only).
- If necessary, you can adjust the position of the line as follows:
  - Loosen the Allen screw **"A"** (see Fig. **"Laser System - Detail"**) and adjust the position of the line by rotating or moving the base of the laser system until the laser beam falls on or is parallel to the bisector line drawn on the anti-dust panel.
  - Once the correct adjustment has been achieved, tighten the Allen screw **"A"** again.



Laser System - Detail

WARNING

Do not apply excessive force when tightening the screws!
The laser shell is in plastic: an excessive pressure could crack the plastic and possibly short-circuit the laser!

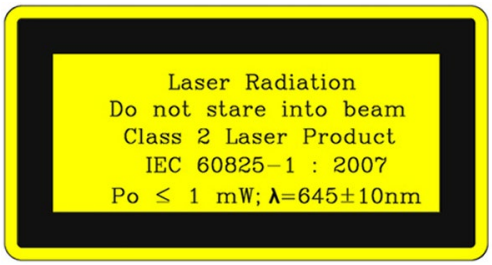
Substitution

- Disconnect supply.
- Remove the cover, see Chapter **"Cover Removal"**.
- Unscrew the fixing Allen screws "A", see Fig. **"Laser System - Detail"**.
- Disconnect the timer cables from the terminal board - white 0 V, red 5 V.
- Remove the laser and substitute with an identical item.
- Tighten the screws.
- Check the laser alignment, see Chapter **"Adjustments"**.
- Remount the cover, see Chapter **"Cover Removal"**.

Classification according to EN 60825-1 par. 1 -5: Class 2 laser product => Red laser line

Labels

Label 3A



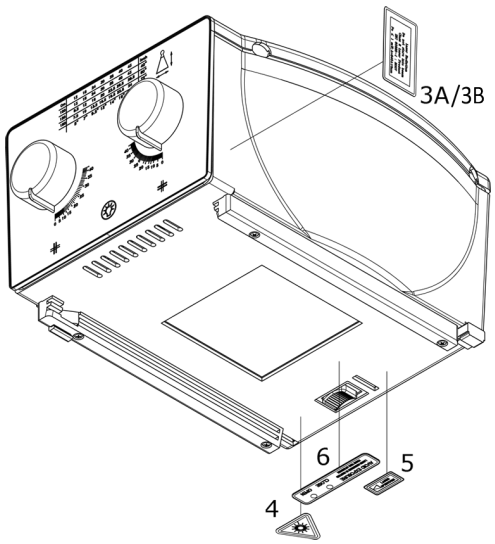
Label 3B

Label 4

Label 5

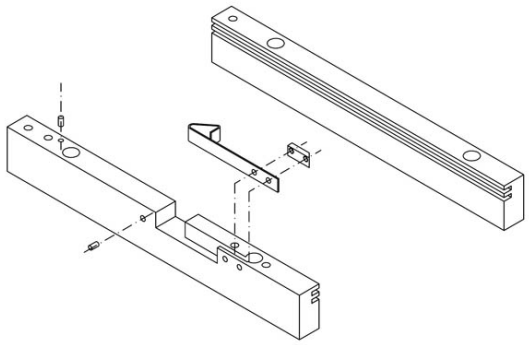
Label 6

Label location diagram



RO 253 PLASTIC SPACER GUIDES

Pair of plastic rail guides complete with support designed to accommodate the ionization chamber and ensure its lateral protection.



RO 258 ADDITIONAL VARIABLE FILTRATION - MANUAL SELECTION

Additional variable filtration with manual settings may be optionally added to the minimum collimator filtration in the form of a disk, 1 mm thickness, controlled manually from the front panel. The disk features a hole for the passage of X-Rays and accommodates the following three filters:

- 0: no filtration
- 0,1 mm Cu + 1 mm Al. (Al eq. 3.5 mm)
- 0,2 mm Cu + 1 mm Al (Al eq. 6.0 mm)
- 1 mm Al + 1 mm Al support (Al eq. 2.0 mm).

RO 258

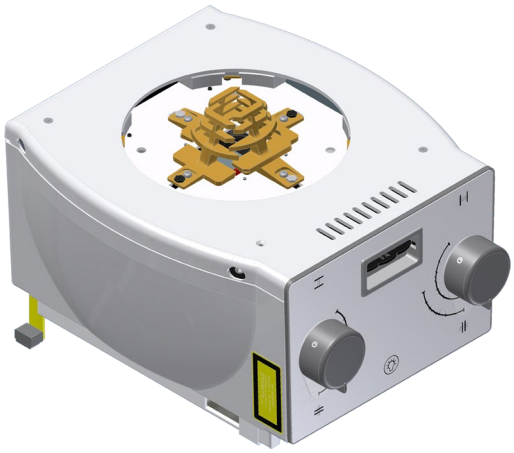
Setup of Filters

- Rotate the aluminium disc that protrudes from the filter opening on the front panel.
- Indication of the filtration value is provided on the upper part and lower rim of the disc; this value refers to the additional filtration in the X-Ray beam.

Substitution of Filter group

- Disconnect supply.
- Remove the front panel. See Chapter **"Cover Removal"**.
- Remove the filter support by unscrewing the 2 screw A, see Fig. **"Filter substitution"**.
- Substitute the support with an identical part.
- Remount the support with a new filter - do not tighten the screws.
- Check that disc rotation is uniform: play must be reduced to a minimum.
- Tighten the 2 screws **"A"**.
- Remount the front panel.

Filter Substitution



RO 258/1 ADDITIONAL VARIABLE FILTRATION - MANUAL SELECTION

Additional variable filtration with manual settings may be optionally added to the minimum collimator filtration in the form of a disk, 1 mm thickness, controlled manually from the front panel. The disk features a hole for the passage of X-rays and accommodates the following three filters:

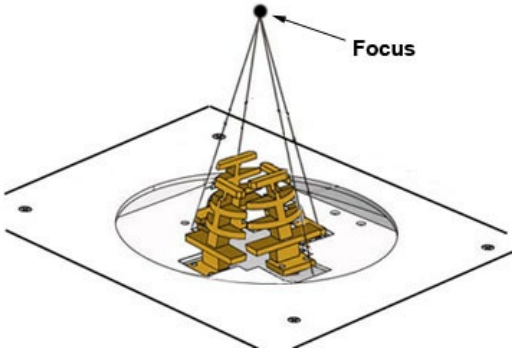
- 0: no filtration
- 0,1 mm Cu (Al eq. 2,5 mm)
- 0,2 mm Cu (Al eq. 5 mm)
- 0,3 mm Cu (Al eq. 7.5 mm)

RO 258/1

To adjust and/or to change the filter see RO 258 Additional Variable Filtration description in this Chapter.

RO 278 NEAR FOCUS SHUTTERS

Upper cover with extra-focal shutters (also called near-port shutters) to allow the use of the collimator with rotating anode X-Ray tubes; brass extra-focal.



RO 318 SELF-CENTERING TOP-COVER BRACKET

This mounting bracket allows for the coupling of a flange with a diameter of 140mm. Included in this optional item is a resin rotating mounting flange:

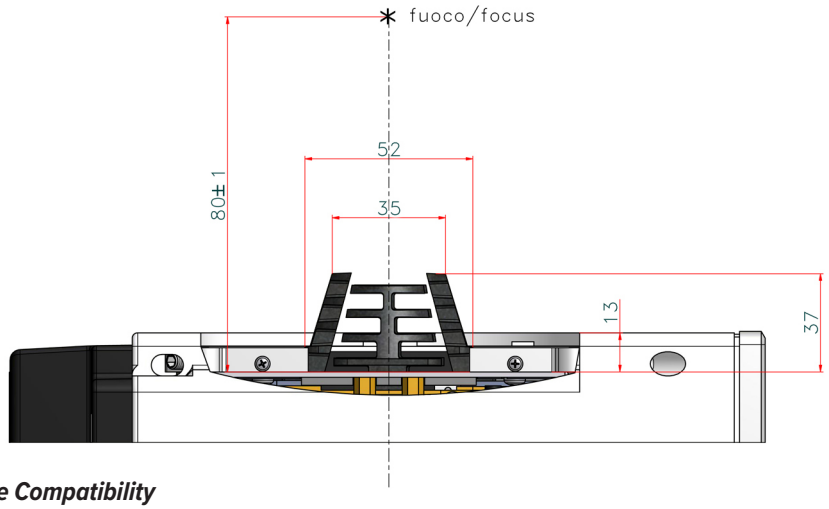
- 20mm thickness,
- +/- 0° detent,
- 140mm diameter (unless substituted with another compatible optional item flange).

Installation

WARNING	
	**The collimator must be installed to the X-Ray tube through a mounting flange.** **RALCO provides various flange options which may not be interchangeable.** **Only the flanges provided with the collimator may be used.** **End-users may install their own flanges; however, RALCO cannot guarantee compatibility.** **Any preexisting flange on the end-user system must not be used**
	**When a flange is provided with the collimator bearing a matching serial number, ensure they always remain coupled.** **It is mandatory they remain together and the correct flange part number is used.**
	**The contents of the instructions below should be strictly adhered to.** **RALCO is not liable for any property damage or resulting harm if non-RALCO components or non-compatible RALCO components are used during the installation process.**

Tube Compatibility

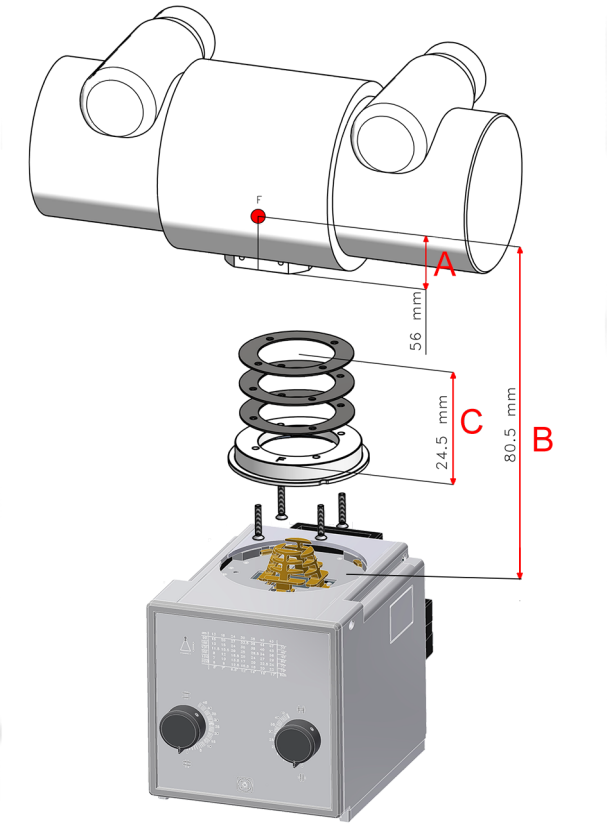
1. Consulting the dimensions in Fig. **"Tube Compatibility"** below, ensure the near port shutters of the collimator may be placed in the X-Ray tube port without interference.
2. The distance between the X-Ray tube focus and the flange mounting plane (collimator upper plate) must be: 80 mm (3.15"), tolerance +/- 1 mm (0.04 ").



Tube Compatibility

3. Carefully remove the collimator and the mounting flange from their packaging.
4. Consult the X-Ray tube housing datasheet to determine the distance from the focal spot to the X-Ray tube port, see Pos. **"A"** in Figure **"Collimator installation"**.
5. Subtract the resulting distance from the source flange distance **"B"** and determine the number of spacers (1.5 mm) which, combined with the thickness of the mounting flange, will make up the difference **"C"**. Allowable tolerance is 1 mm. (0.04"), see Fig. **"Collimator Installation"**.
6. Once the mounting plane distance has been confirmed, proceed with the installation of the mounting flange to the X-Ray tube.

Note: **the flange fixing screws and the spacers of the previous flange may be reused if the flange thickness is the same.**



Collimator Installation

Mounting the flange to the X-Ray tube

IMPORTANT

The following mounting instructions are only applicable for compatible flanges.
If you are unsure whether the mounting flange your collimator is equipped with is compatible, please consult your personalization page provided with this manual to locate the flange part number (RO reference). Follow the mounting instructions set forth under the specific RO reference in this manual.

WARNING

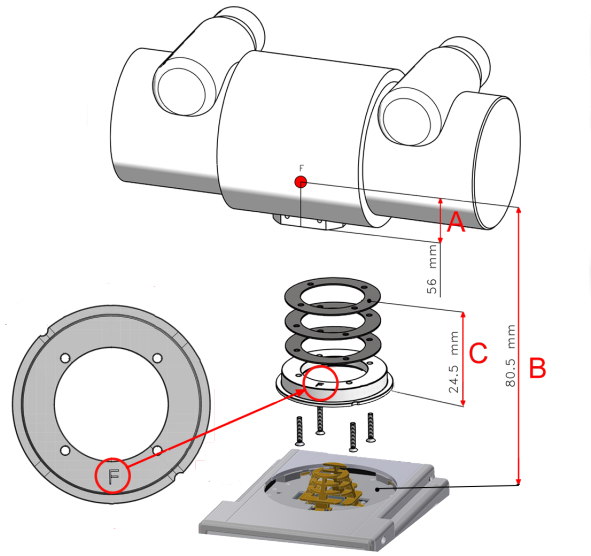
Flanges may be provided by RALCO or by the system manufacturer. Flanges may not be interchangeable. Only the flange provided with the collimator being installed with a specific part code may be utilized. Any pre-existing flanges may not be used. If there are any questions regarding compatibility, please contact RALCO.

CAUTION

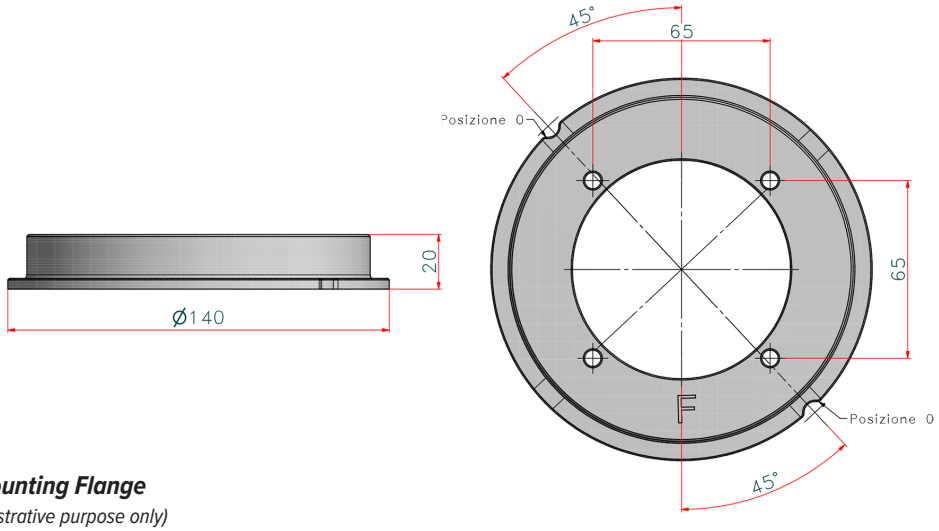
RALCO cannot guarantee compliance with radiation standards concerning safety if this control has been omitted.

1. Place the flange on the X-Ray tube port, see Fig. **Flange Installation**.
2. Mount the mounting flange and spacers (optional) to the X-Ray tube port using 4 screws.**

** ***Please ensure no conflicting information nor dangerous conditions exist due to adhering to these instructions or those provided by the X-Ray tube manufacturer. When in doubt please contact the X-Ray tube manufacturer and/or RALCO.***



Flange Installation
(illustrative purpose only)



Mounting Flange
(illustrative purpose only)

CAUTION	
	**The flange must be placed with the letter "F" facing toward the X-Ray tube port. Incorrect position may cause the collimator and flange to malfunction.**
	**Ensure to select the correct screw type for the mounting flange provided. It is the responsibility of the End-User to guarantee all safety measures are implemented to ensure the screws are appropriately tightened, including the use of any necessary threadlocker ("Loctite®").**
	**The 4 screws must be tightened to the X-Ray tube head securely, strictly adhering to the instructions of the X-Ray tube manufacturer, and with a max. tightening force of 0.45 Nm.**

ALIGNMENT OF X-RAY TUBE FOCUS AND COLLIMATOR

RALCO guarantees the correct collimator functionality, format compliance and light/X-Ray field alignment only if the mounting flange and the collimator have been installed exactly in the center of the X-Ray beam.

All RALCO collimators are aligned on our test bench utilizing specific references/values for our X-Ray tube focus, detector and Source to Image Detector Distance (SID). The customer must know and verify all known variables which may influence the X-Ray tube focus and collimator alignment. These may include, the X-Ray tube focus position tolerance, distance from X-Ray tube focus to collimator mounting plane, or the SID.

Alignment Device

X-Ray tube manufacturers provide tolerance ranges for the positioning of X-Ray tube focuses, therefore it is very important to make sure that the collimator mounting flange is correctly aligned to the X-Ray beam.
To verify that the flange is correctly aligned with the center of the X-Ray beam, RALCO recommends the use of a focal alignment device (see Fig. **"Focal Alignment Device"**), which - upon request - may also be supplied by RALCO.

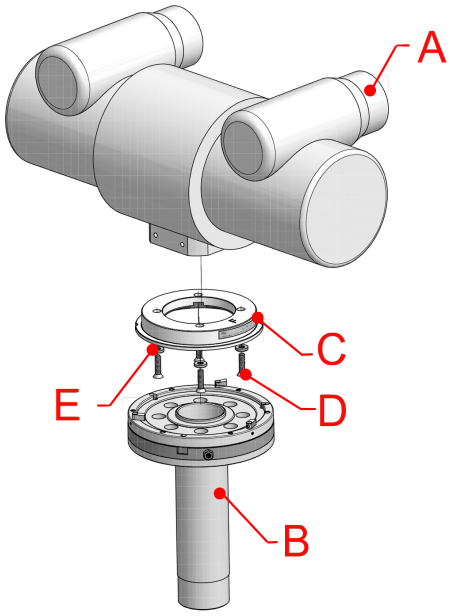
By mounting the alignment device to the flange and making an exposure, it is possible to verify perpendicularity and concentricity using the fixed references on the X-Ray image.

Once the mounting flange is aligned the collimator light/X-Ray field should also be aligned (within specific tolerances).

Please consult the technical specifications of your X-Ray tube to find the maximum tolerance for the position of the focus.

Should the use of an alignment device not be possible, RALCO collimators allow for the regulation of the light field.

Legend
A - X-Ray tube - B - Focal Adjustment Device
C - Mounting Flange
D - Screw - E - Washer



Focal Alignment Device

MOUNTING THE COLLIMATOR TO THE FLANGE

IMPORTANT	
	All mounting flanges supplied by RALCO (if applicable) are subjected to testing pursuant to all applicable standards.
	Mounting bracket tabs conform to EN60601.

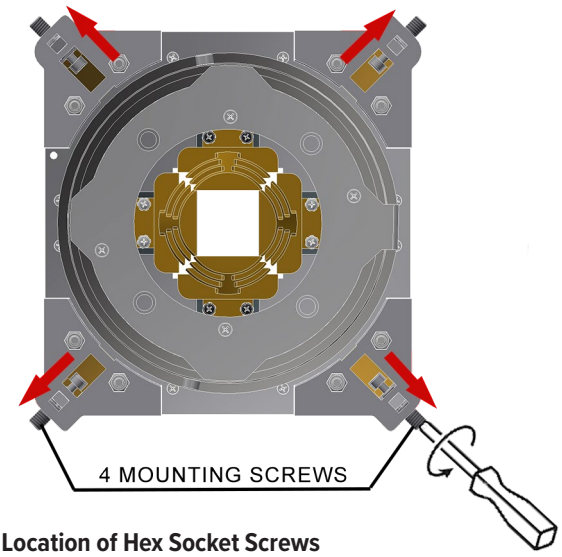
WARNING	
	Pursuant to applicable standards, RALCO has tested the collimator and the mounting flange by applying static loads. RALCO is not in a position to know the dynamic forces of all end-user systems. It is the responsibility of the end-user to ensure dynamic forces of the system to not create a dangerous condition.
	It is the responsibility of the system manufacturer to mitigate any dangerous conditions which may occur due to the dynamic forces created by the system. The end-user must perform a systematic and structural analysis during the installation and usual maintenance of the system.
	Should any damage to the collimator or mounting flange occur, a risk analysis and damage assessment must be conducted immediately. In the event of such a circumstance, please contact RALCO immediately. RALCO is not liable for any resulting damage and/or injuries arising as a consequence of an unreported incident.
	RALCO has designed and tested the collimator for a lifetime of 10 years. After this time period, it is the responsibility of the end-user to ensure the proper functioning of the collimator and mounting flange. Liability for any dangerous conditions which may arise after the 10-year lifetime of the collimator and mounting flange rests with the end-user.
	To ensure the safety of the collimator and mounting flange after 10 years of use, RALCO has instituted a program to assess the safety of the collimator and mounting flange. After applying a check list of quality controls and refurbishment activities (at end-user expense), RALCO may certify the collimator and mounting flange for additional years of use.

The mounting bracket has 2 tabs with springs in positions 2 and 4, while the 2 tabs in position 1 and 3 cover the surface of the outer ring of the flange, see Fig. **"Mounting Bracket"**.

1. Prepare the collimator for installation by unscrewing the 4 hexagonal socket mounting screws until the four tabs are completely withdrawn from the collimator top mounting plane, see Fig. **"Location of Hex Socket Screws"**.
2. If installing a manual collimator, adjust the collimator shutters to the fully open position using the knobs.

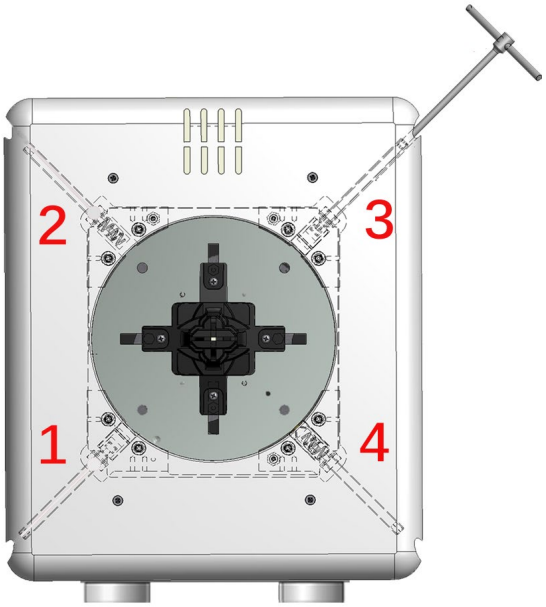
CAUTION

When unscrewing the hexagonal socket screw which control the tabs, do not use force exceeding 0,45 Nm.
Unscrew with care so as not to damage the hexagonal screw head and tabs.



Location of Hex Socket Screws

3. When the tabs are fully retracted (see point "**1**" above).
   - The hexagonal socket screws that control tabs in position **"1"** and **"3"** (see Fig. **Mounting Bracket***)*, overlapping the outer ring, must be tightened equally up to the end of their stroke (at least 7 turns). Torque: 0.45 Nm.
   - The tabs in position **"2"** and **"4"** (see Fig. **Mounting Bracket***)* have an integrated adjustable spring and can be tightened in two different ways allowing the flange to be fixed (see section **"Fixed - No Rotation"**) or to rotate (see section **"With rotation"**).



Mounting Bracket (illustrative purpose only)

FIXED (NO ROTATION)

With the tabs fully retracted, tighten all of the 4 the hexagonal socket screws up to the end stroke with 0.45Nm torque (at least 7 turns), see Fig. **"Mounting Bracket (FIXED flange)"**.
If you are not able to respect the turns something is incorrect, repeat the above instructions.
if issues persist, please contact RALCO.

WITH ROTATION

With the tabs fully retracted, tighten the hexagonal socket screws in the following sequence (if you are not able to respect the turns something is incorrect, repeat above instructions, if issues persist, please contact RALCO):

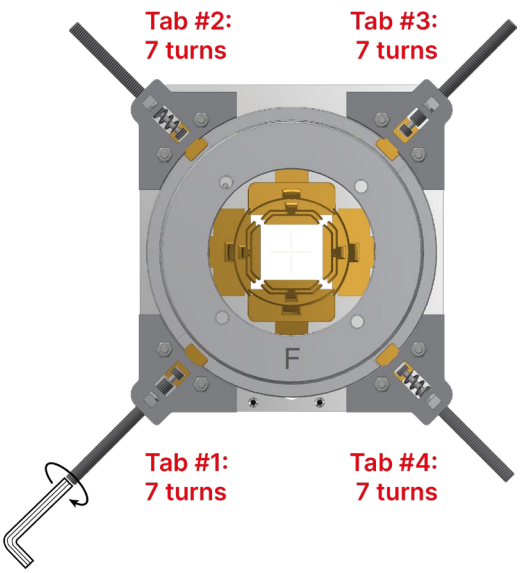
- Tabs **1** and **3** - minimum of 7 turns
- Tabs **2** and **4** – exactly 5 ½ turns.

Please see also Fig. **"Mounting Bracket (ROTATING flange)"**.

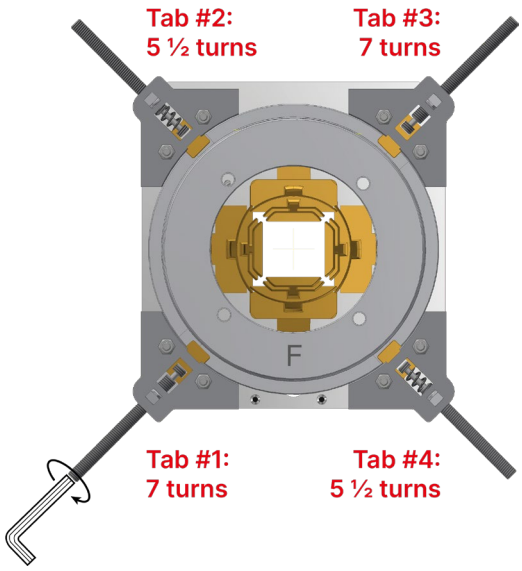
The collimator tabs glide on the flange outer ring and the collimator rotates towards the X- Ray tube axis.

If, however:

- The release force from the position 0° and the collimator rotation is too low, the two tabs of the tab **2** and **4** need to be tightened by ½ turn.
- The release force from the position 0° and the collimator rotation is too high, the two tabs of the tab **2** and **4** need to be loosened by ½ turn.



Mounting Bracket (FIXED flange)



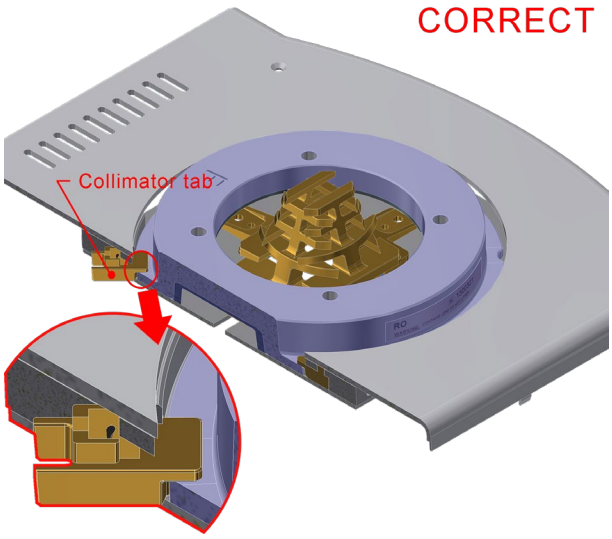
Mounting Bracket (ROTATING flange)

VERIFICATION OF CORRECT INSTALLATION

WARNING

It is the duty of the installer to ensure there is no risk of the collimator falling.
Each of the below must be ensured, as there is serious risk or injury and/or property damage due to non-adherence.

4. The 4 tabs must overlap the mounting flange outer ring, see Fig. **"Correct Overlap"** (illustrative purpose - valid to show correct position of tab only).
5. The mounting flange must be flat against the collimator mounting plane, see Fig. **"Correct Overlap"**.
6. The 4 tabs must not be in contact with only the mounting flange edge, see Fig. **"Incorrect Overlap"** (illustrative purpose - valid to show incorrect position of tab only).
7. Once the collimator is mounted, (unless this has already been done), return the collimator/tube head to the intended use position. Rotate and/or gently pull the collimator to ensure correct coupling.
8. If the collimator is loose, something is incorrect. Repeat the above, **"MOUNTING THE COLLIMATOR TO THE FLANGE"** instructions, and if the issues persist, please contact RALCO.



Correct Overlap

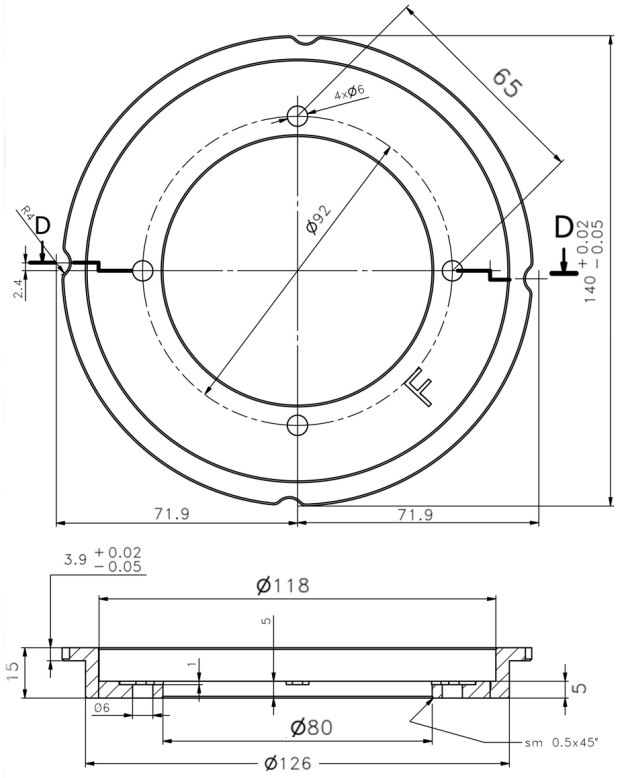
Incorrect Overlap

RO 332/A RESIN ROTATING MOUNTING FLANGE

Resin rotating mounting flange with fixing screws:

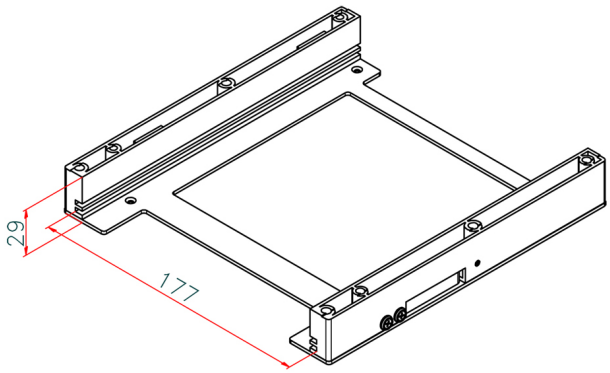
- 15 mm thickness
- +/- 90° detent
- 140 mm diameter

Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this chapter of the Instruction Manual for the correct flange/collimator mounting instructions.



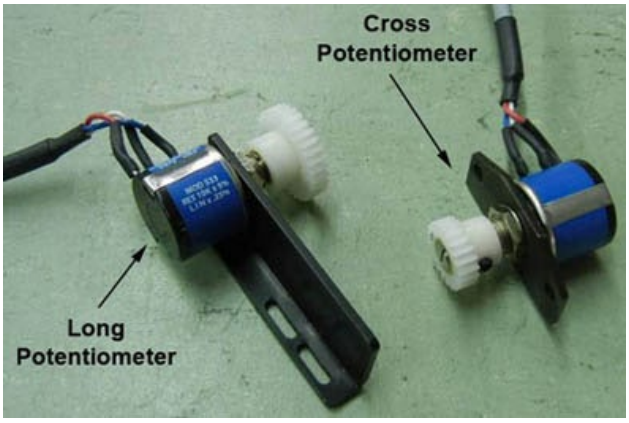
RO 344 PLASTIC SPACER GUIDES

Pair of plastic rail guides on metal support designed to accommodate the ionization chamber and allow the insertion of relative filter.



RO 356 SHUTTER POSITIONING CONTROL

Supplementary safety device to ensure correct positioning of shutters. It consists of two potentiometers mounted on the collimator: One is mounted on the back of the collimator to control the “LONG” shutters, and the other potentiometer is mounted on the side to control the “CROSS” shutters.

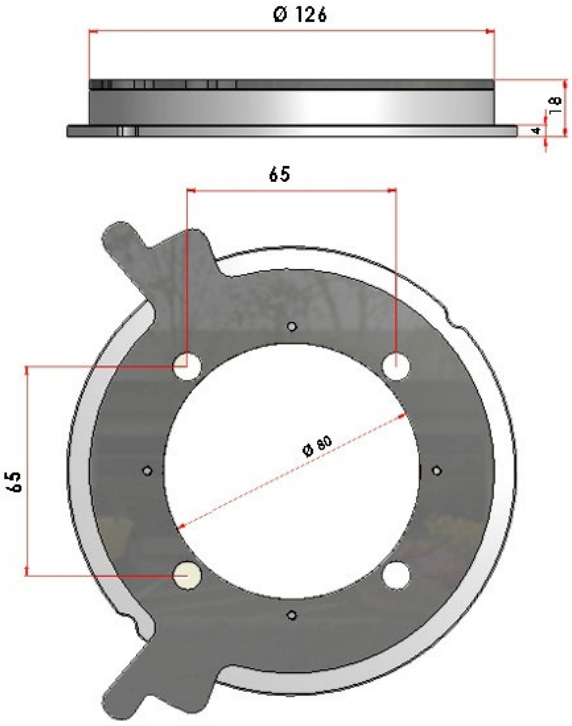


RO 367 RESIN ROTATING MOUNTING FLANGE

Resin rotating mounting flange:

- 18 mm thickness
- +/- 120° with mechanical stop
- 140 mm diameter

Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this Chapter of the Instruction Manual for the correct flange/collimator mounting instructions

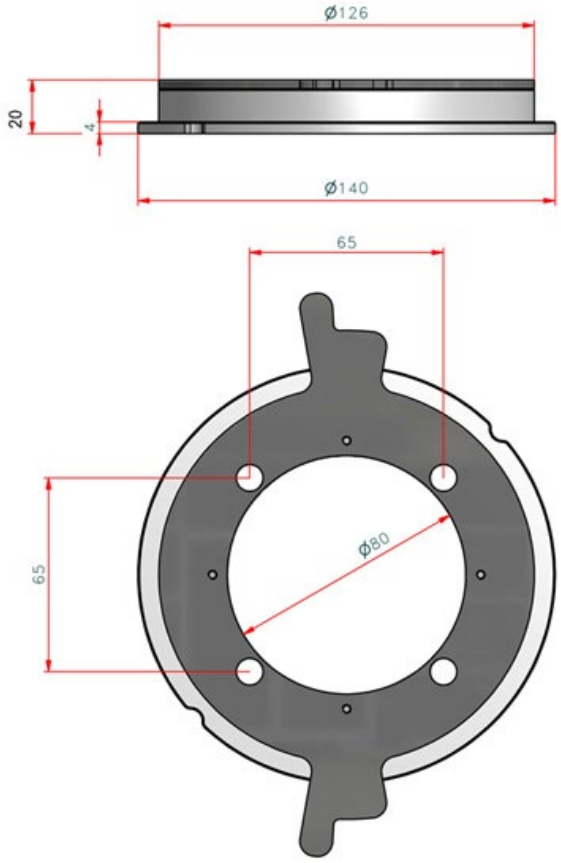


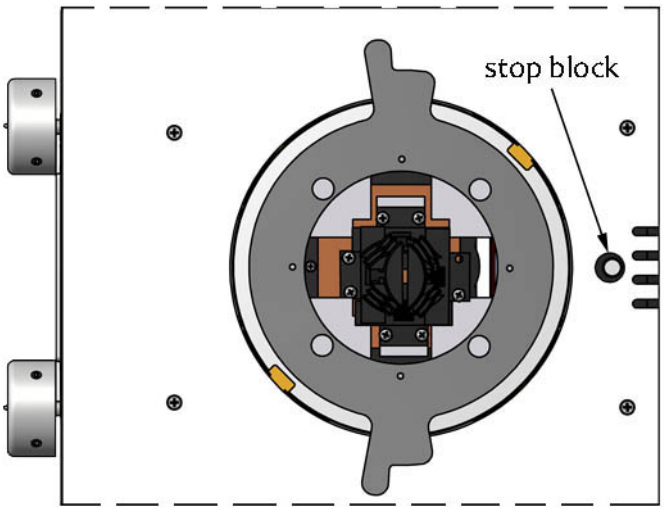
RO 369 RESIN ROTATING MOUNTING FLANGE

Resin rotating mounting flange:

- 20 mm thickness
- +/- 90° with mechanical stop
- 140 mm diameter

Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this Chapter of the Instruction Manual for the correct flange/collimator mounting instructions



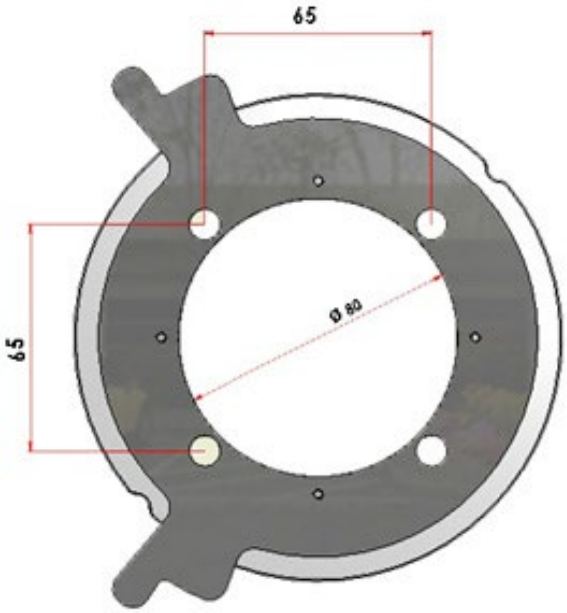


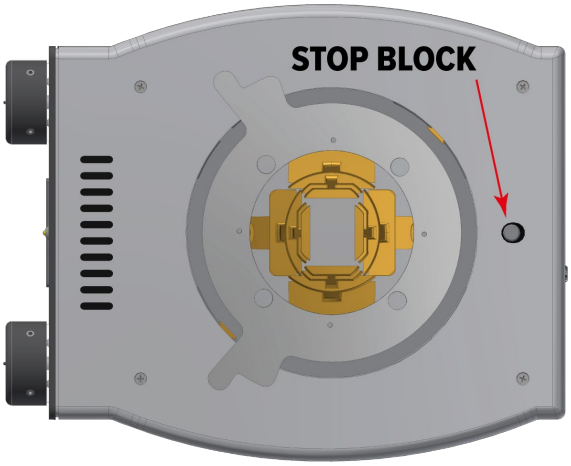
RO 370 RESIN ROTATING MOUNTING FLANGE

Resin rotating mounting flange:

- 20 mm thickness
- +/- 120° with mechanical stop
- 140 mm diameter

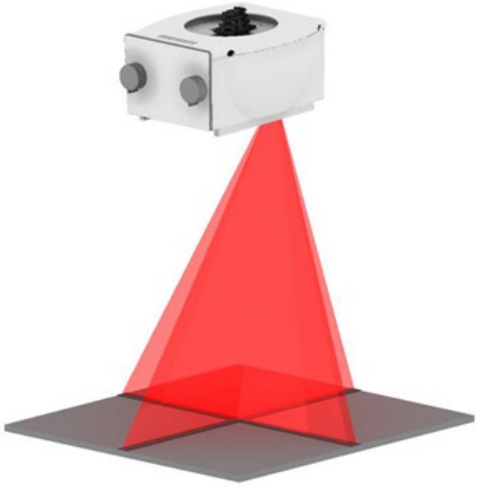
Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this Chapter of the Instruction Manual for the correct flange/collimator mounting instructions.





RO 395 SINGLE LASER FORMING A CROSSHAIR TO CENTER THE PATIENT TO THE DETECTOR AT A FIXED 1-METER SID: CLASS 2

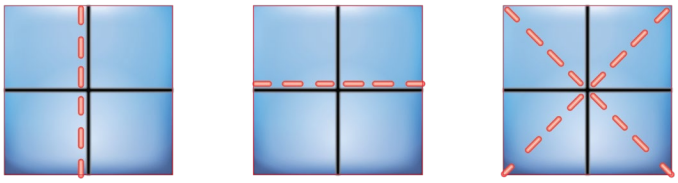
The collimator laser is classified as Class 2 (1 mW- wavelength = 645 nm, · receptor center alignment, see Fig. **"Laser Line"**.



Laser Line

WARNING

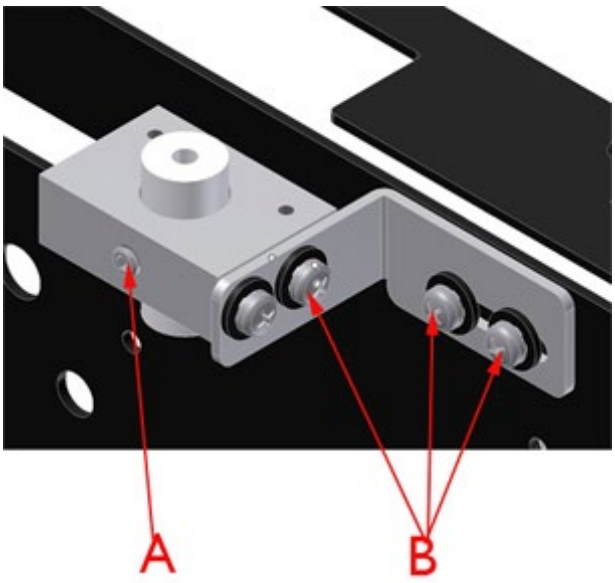
Class 2 laser system:
do not stare into the beam!



Laser Adjustment

Adjustment

- Remove part of the cover to access the point of adjustment, see Chapter **"Cover Removal"**.
- The lines are to fall on a perpendicular cross-line on the plastic anti-dust panel near the collimator controls, see Fig. **"Laser Line"**.
- If necessary, you can adjust the position of the line as follows:
  - Loosen the Allen screw **"A"** (see Fig. **"Laser System - Detail"**) and adjust the position of the line by rotating or moving the base of the laser system until the laser beam falls on or is parallel to the bisector line drawn on the anti-dust panel.
  - Once the correct adjustment has been achieved, tighten the Allen screw **"A"** again.



Laser System - Detail

- If necessary, you can shift the laser system as follows:
  - Loosen the screws **"B"** holding the laser system base to the beam limiting device front plate.
  - Move the base until the laser beam falls over the perpendicular bisector line on the anti-dust panel, see Fig. **"Laser Alignment"**).
  - Once the correct adjustment has been achieved, tighten the screws **"B"** back again.

WARNING

Do not apply excessive force when tightening the screws!
The laser shell is in plastic: an excessive pressure could crack the plastic and possibly short-circuit the laser!

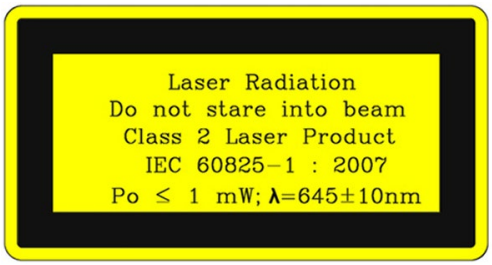
Substitution

- Disconnect supply.
- Remove the cover, see Chapter **"Cover Removal"**.
- Unscrew the fixing Allen screws "A", see Fig. **"Laser System - Detail"**.
- Disconnect the timer cables from the terminal board - white 0 V, red 5 V.
- Remove the laser and substitute with an identical item.
- Tighten the screws.
- Check the laser alignment, see Chapter **"Adjustments"**.
- Remount the cover, see Chapter **"Cover Removal"**.

Classification according to EN 60825-1 par. 1 -5: Class 2 laser product => Red laser line

Labels

Label 3A



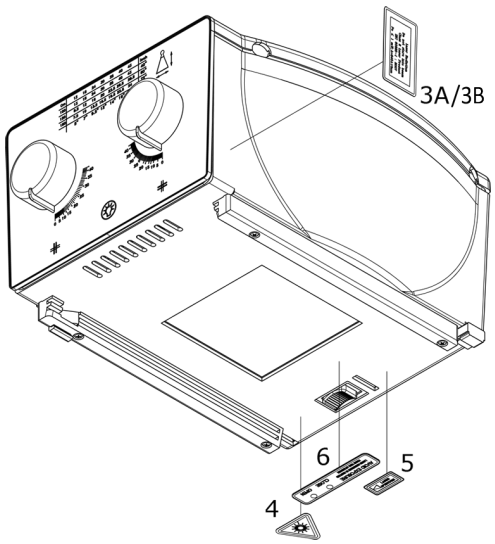
Label 3B

Label 4

Label 5

Label 6

Label location diagram



RO 405 CUSTOMIZED ALUMINIUM COVER

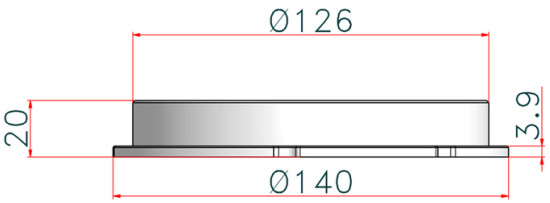
Customized covers in aluminium according to customer design.

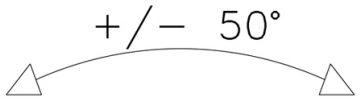
RO 441 RESIN ROTATING MOUNTING FLANGE

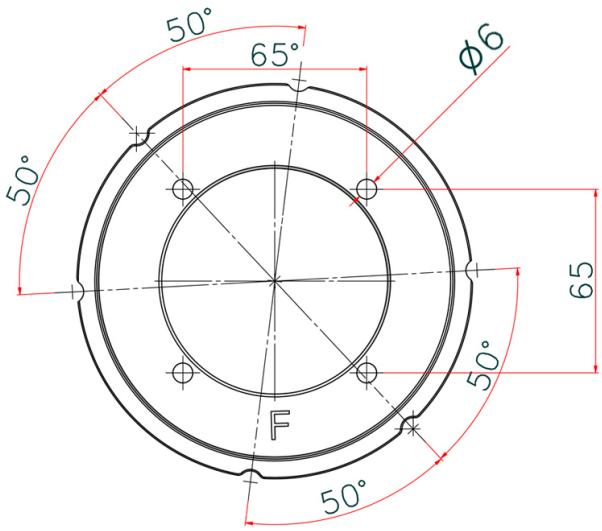
Resin rotating mounting flange:

- 20 mm thickness
- +/- 50° detent
- 140 mm diameter

Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this Chapter of the Instruction Manual for the correct flange/collimator mounting instructions.





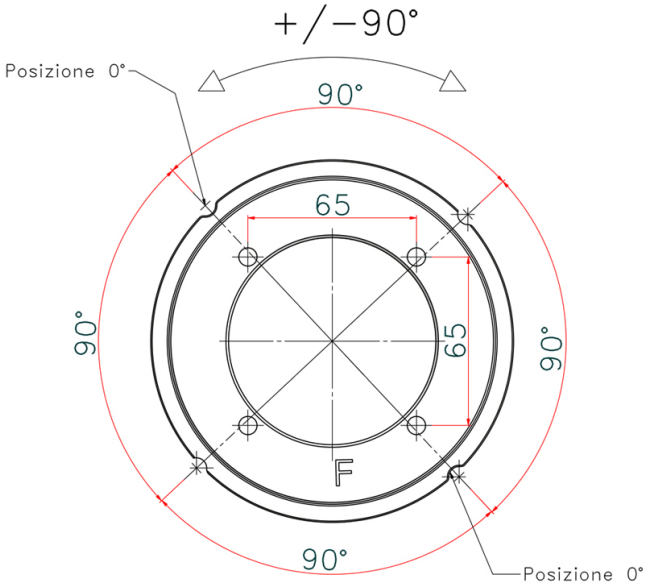


RO 442 RESIN ROTATING MOUNTING FLANGE

Resin rotating mounting flange:

- 20 mm thickness
- +/- 90° detent
- 140 mm diameter

Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this Chapter of the Instruction Manual for the correct flange/collimator mounting instructions.

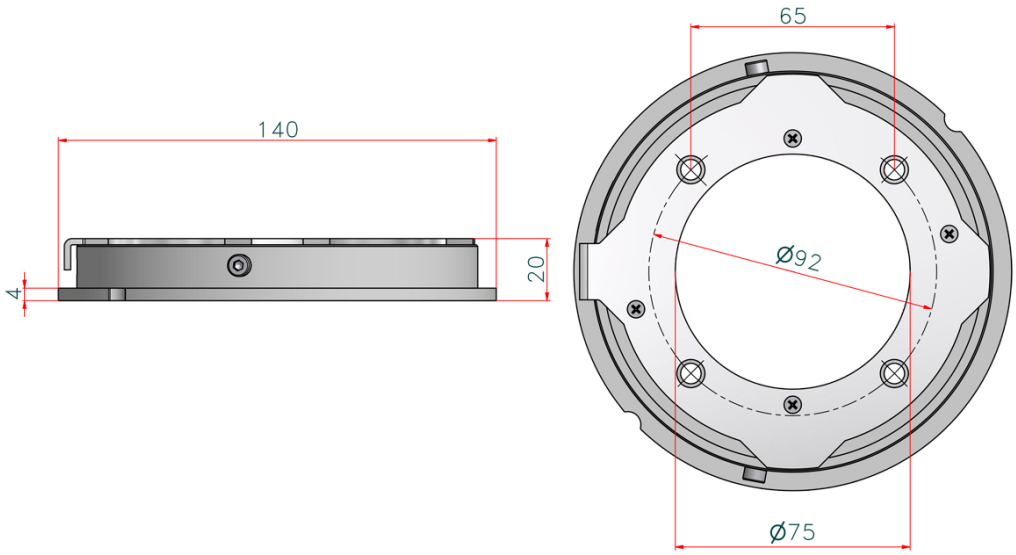


RO 445 METAL ROTATING MOUNTING FLANGE

Metal rotating mounting flange:

- 20 mm thickness
- +/- 90° mechanical stop
- 140 mm diameter

Please refer to section **"RO 318 Adjustable Top-Cover Bracket"** in this chapter of the Instruction Manual for the correct flange/collimator mounting instructions.



When the collimator is assembled, check the collimator to Focal Spot Alignment (Primary Shutter Cut-Off).

Inspect the four images of the four collimator shutters which form the edges of the X-ray field. A definitely indistinct edge indicates that the primary shutter, close to the focal spot, is the one forming the line, rather than the outermost shutter.

To correct the condition, use the four mounting/centering adjustment screws to shift the collimator in the direction of the indistinct line. Repeat the test film exposure after making the adjustment.

IMPORTANT

Due to the anode heel effect, the light field border on the anode-cathode axis of the X-Ray tube will have slightly less contrast than the other three sides. This is normal and cannot be corrected by adjustment.

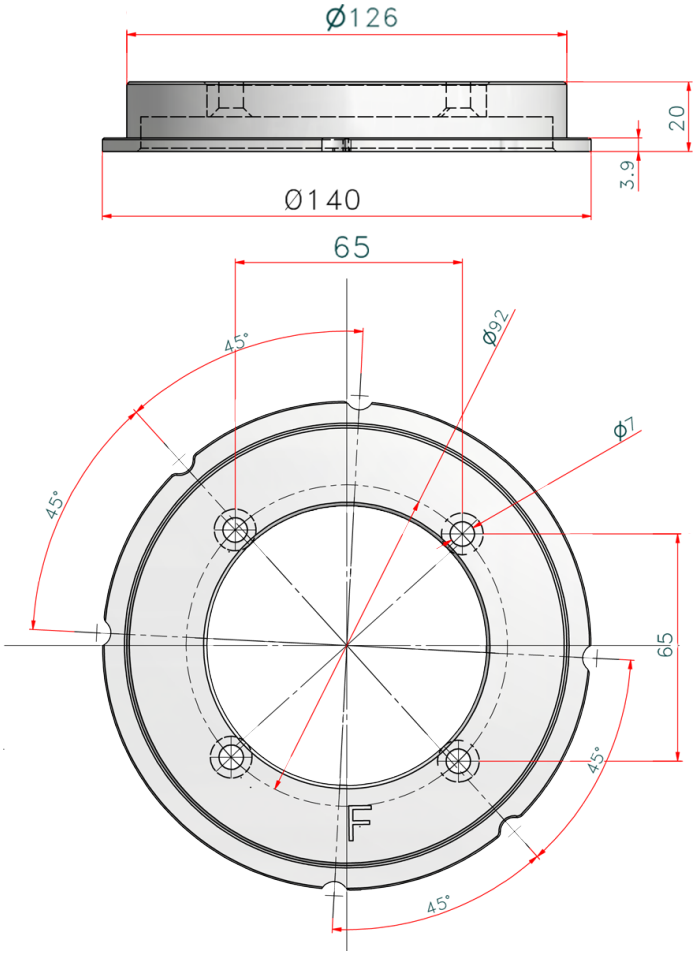
In addition, an X-Ray tube of 12° or less target angle will produce an asymmetrically shaped field when a large field size is used at short SID, because of the anode cut-off effect. This is also normal and cannot be corrected by adjustment.

RO 489 RESIN ROTATING MOUNTING FLANGE

Resin rotating mounting flange:

- 20 mm thickness
- +/- 45° detent
- 140 mm diameter

Please refer to section **RO 318 Adjustable Top-Cover Bracket** in this chapter of the Instruction Manual for the correct flange/collimator mounting instructions.



RO 524 GLASS MIRROR

Glass mirror, 1.7 mm thickness with the additional Aluminium filter, 0.5mm thickness, inherent filtration 2.5 mm aluminium equivalent.

RO 525 CUSTOMIZED KNOB DESIGN

The customer can specify the knob design.

RO 535 RUBBER CAPS

This accessory is used to close housing mounting access.

RO 553: MANUAL SHUTTER MOVEMENT FROM THE FRONT AND REAR OF THE COLLIMATOR

This option is available for all customers who want to customized the collimator shutter movement.

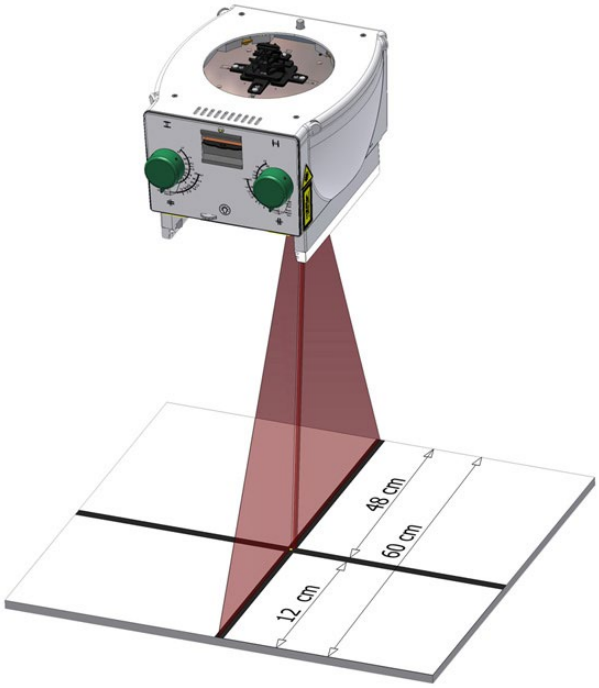
RO 586 SINGLE LASER LINE TO ALIGN COLLIMATOR AND DETECTOR CENTER: CLASS 1

The collimator laser is classified as Class 1 (1 mW - wavelength = 645 nm, +/- 10 nm) used for collimator/image receptor center alignment see Fig. **"Laser Line"**.

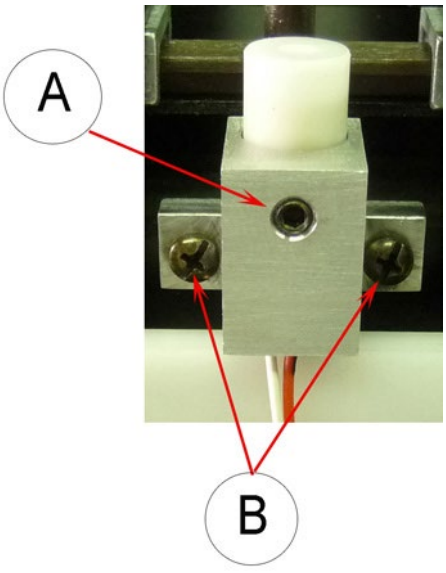
WARNING	
⚠	**Caution:** **Class 1 laser system.** **Do not stare into the beam.**

Laser Adjustment

- Remove part of the cover to access the point of adjustment, see Chapter **"Cover Removal"**.
- The line is to fall on a perpendicular cross-line on the plastic anti-dust panel near the collimator controls, see Fig. **"Laser Line"**.
- If necessary, you can adjust the position of the line as follows:
  - Loosen the Allen screw **"A"** (see Fig. **"Laser System - Detail"**) and adjust the position of the line by rotating or moving the base of the laser system until the laser beam falls on or is parallel to the bisector line drawn on the anti-dust panel.
- If necessary, you can shift the laser system as follows:
  - Loosen the screws **"B"** holding the laser system base to the beam limiting device front plate.
  - Move the base until the laser beam falls over the perpendicular bisector line on the anti-dust panel, see Fig. **"Laser Alignment"**).
  - Once the correct adjustment has been achieved, tighten the screws **"B"** back again.



Laser Line

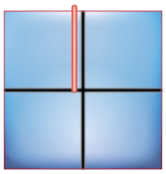


Laser Adjustment

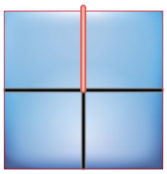
WARNING

Do not apply excessive force to the screws. The laser shell is in plastic: an excessive pressure could crack the plastic and possibly short circuit the laser.

Angular misal.



Lateral misal.

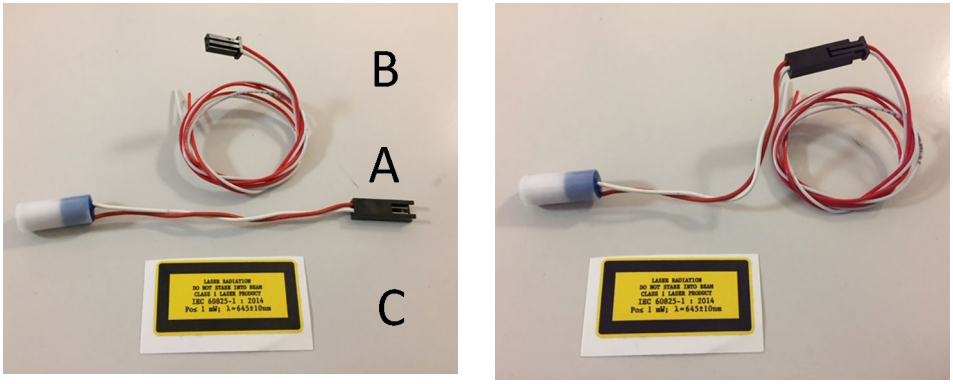


Correct align.

Laser Alignment

Substitution

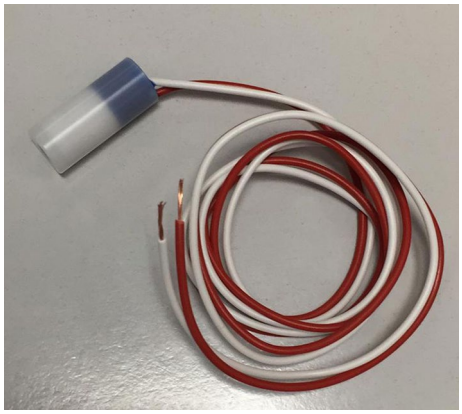
The Laser Substitution Kit is composed of the following components: the laser (**"A"**), the extension cable (**"B"**) and the laser label (**"C"**) pictured below in Fig. **"Laser Substitution Kit"**. This Kit is designed to substitute any laser Ralco provides.



Laser Substitution Kit

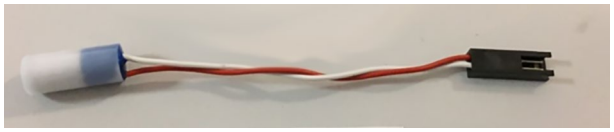
Prior to replacing the laser, confirm which version of laser is installed on your collimator which will ensure the substitution is performed correctly.

- The previous laser version is connected to the board via 2 cables (red and white), see Fig. **"Previous Laser Version"** below.



Previous Laser Version

- The new laser is connected to the board via the connector, see Fig. **"New Laser Version"** below.



New Laser Version

Replacing the Previous Laser Version

To replace the previous version of laser, all components of the Laser Substitution Kit (**"A"**, **"B"** and **"C"**) must be used.

To substitute the laser, proceed as follows:

1. Disconnect the collimator supply.
2. Remove the cover, see Chapter **"Cover Removal"**.
3. Prior to disconnecting the laser cables from the board, identify the cables and their position on the terminal board, see Chapter **"Installation"**, paragraph **"Wiring Diagram"** in the Instruction Manual for your specific model.
4. Carefully remove the laser, the extension cable and the label from their packaging.
5. Ensure the extension cable **"B"** is firmly connected to the laser **"A"**, see Fig. **"Laser Substitution Kit"** above.
6. Substitute the laser with the identical item using component **"A"** of the Laser Substitution Kit.
7. Adjust the length of the extension **"B"** cable by cutting the 2 cables (red/white).
8. Connect both cables to the board.
9. Apply the new laser label **"C"** to the collimator cover, see Chapter **"Spare Parts"** in the Instruction Manual for your specific model.
10. Verify laser alignment, see Chapter **"Adjustments"** or **"Optional Items"** in the Instruction Manual.

Replacing the New Laser Version

To replace the new laser version, only part **"A"** and **"C"** of the Kit must be used.

To substitute the laser, proceed as follows:

1. Disconnect the collimator supply.
2. Remove the cover, see Chapter Cover Removal in the Instruction Manual for your specific model.
3. Detach the connector of the faulty laser from the collimator wiring.
4. Carefully remove the laser, the extension cable and the label from their packaging.
5. Substitute the laser with the identical item using component **"A"** of the Laser Substitution Kit, see Fig. **"Laser Substitution Kit"** above.
6. Connect the new laser to the collimator wiring.
7. Apply the new laser label **"C"** to the collimator cover, see Chapter **"Spare Parts"** in the Instruction Manual for your specific model.
8. Verify laser alignment, see Chapter **"Adjustments"** or **"Optional Items"** in the Instruction Manual.

Classification EN 60825-1 par. 1 -5: **Class 1 laser product** => Red laser line

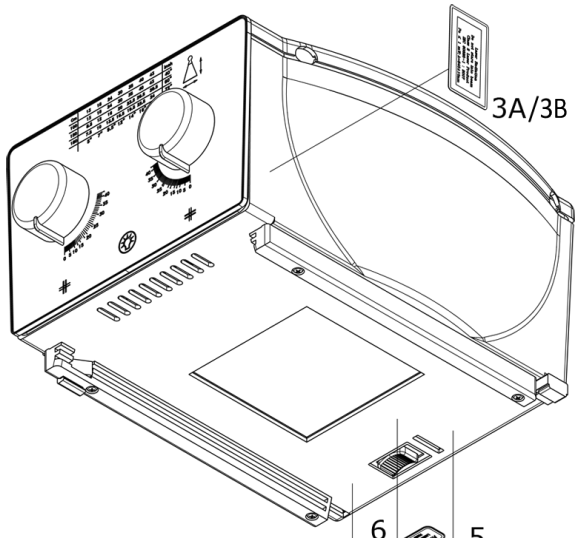
Label Location Diagram

Label 3A

Label 4

Label 5

Label 6



RO 602 SUBSTITUTION OF LED LIGHT FIELD WITH 24V 100 W HALOGEN LAMP

The light field is provided by 24V 100W halogen lamp with timer board GC338.

It is adjusted vertically, longitudinally and laterally.

IMPORTANT

This optional item is not available for post-sales collimators.

Light Field Calibration

Longitudinal Calibration (LONG)

WARNING

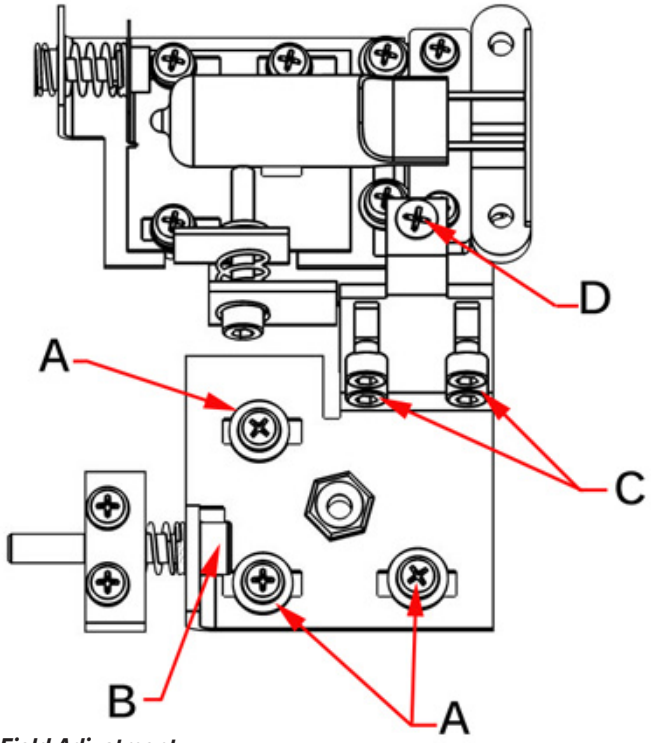
Do not touch the heat sink: it might be hot and cause severe burns!

1. Remove the part of the cover necessary to access the screws, see Chapter **"Cover Removal"**
2. Remove the light source protection heatsink by unscrewing the fixing screws . This allows you to access the light source.
3. If the light-field needs to be moved laterally, loosen (not remove) the fixing screws **"A"**.
4. Adjust through screw **"B"**.

5. When calibration is terminated, lock the screws **"A"**, See the following Fig. **"Light Field Adjustment"**.

Vertical Alignment

1. Remove the part of the cover necessary to access the screws, see Chapter - Cover Removal.
2. If adjustment is required loosen the two screws **"C"** holding the light support.
3. If the light-field is smaller than the X-ray field, move away the light source by adjusting screw **"D"**.
4. If the light-field is bigger than the X-ray field, move the light source closer by adjusting screws **"D"**.
5. Tighten the two screws **"C"**. See Fig. **"Light Field Adjustment"**.

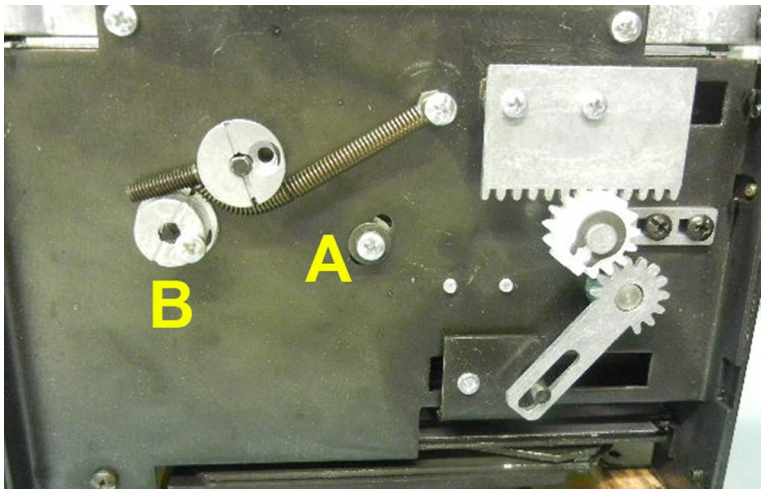


Light Field Adjustment

Transversal Calibration (CROSS)

If the light-field needs calibration, the mirror needs to be adjusted as follows:

1. Remove the part of the cover necessary to access the screws, see Chapter **"Cover Removal"**.
2. Loosen (do not remove!) the mirror fixing screw **"A"** and rotate the cam **"B"** to adjust the position of the mirror, see Fig. **"Transversal Calibration (CROSS)"**.
3. Once you have regulated the mirror tighten the screw **"A"** and remount the cover, see Chapter **"Cover Removal"**.



Transversal Calibration (CROSS)

IMPORTANT

Please consult your personalization page to perform correct transversal calibration if the mechanics differ from the standard collimator.

RO 606 SUBSTITUTION OF LED LIGHT FIELD WITH 12 V 100 W HALOGEN LAMP

The light field is provided by 12V 100W halogen lamp with timer board GC338.

It is adjusted vertically, longitudinally and laterally.

IMPORTANT

This optional item is not available for post-sales collimators.

Light Field Calibration

Longitudinal Calibration (LONG)

WARNING

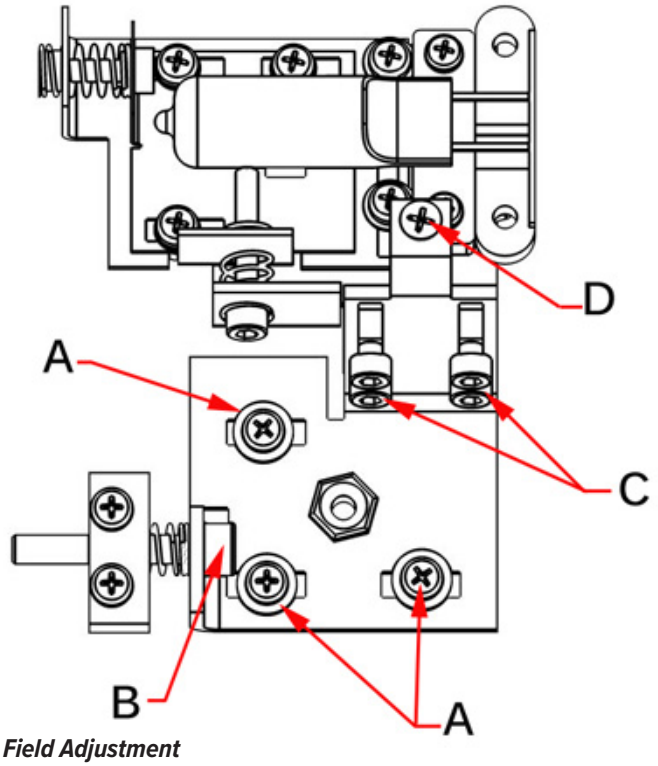
Do not touch the heat sink: it might be hot and cause severe burns!

1. Remove the part of the cover necessary to access the screws, see Chapter **"Cover Removal"**
2. Remove the light source protection heatsink by unscrewing the fixing screws . This allows you to access the light source.
3. If the light-field needs to be moved laterally, loosen (not remove) the fixing screws **"A"**.
4. Adjust through screw **"B"**.
5. When calibration is terminated, lock the screws **"A"**, See the following Fig. **"Light Field Adjustment"**.

Vertical Alignment

1. Remove the part of the cover necessary to access the screws, see Chapter - Cover Removal.
2. If adjustment is required loosen the two screws **"C"** holding the light support.
3. If the light-field is smaller than the X-ray field, move away the light source by adjusting screw **"D"**.
4. If the light-field is bigger than the X-ray field, move the light source closer by adjusting screws **"D"**.

5. Tighten the two screws **"C"**. See Fig. **"Light Field Adjustment"**.

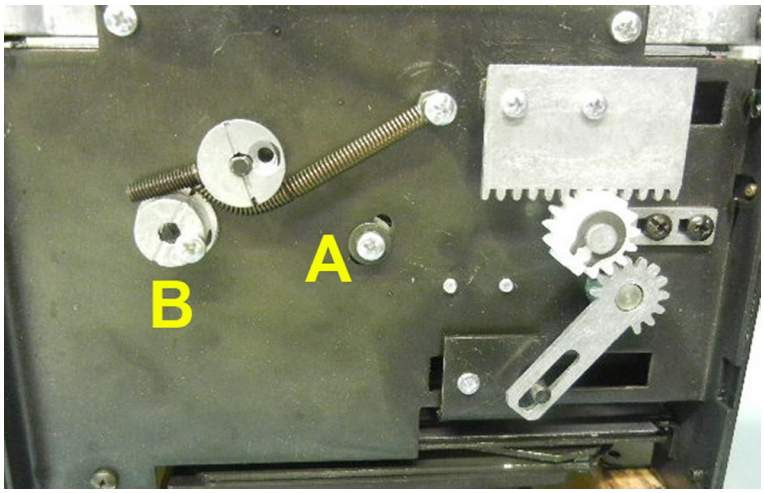


Light Field Adjustment

Transversal Calibration (CROSS)

If the light-field needs calibration, the mirror needs to be adjusted as follows:

1. Remove the part of the cover necessary to access the screws, see Chapter **"Cover Removal"**.
2. Loosen (do not remove!) the mirror fixing screw **"A"** and rotate the cam **"B"** to adjust the position of the mirror, see Fig. **"Transversal Calibration (CROSS)"**.
3. Once you have regulated the mirror tighten the screw **"A"** and remount the cover, see Chapter **"Cover Removal"**.



Transversal Calibration (CROSS)

IMPORTANT

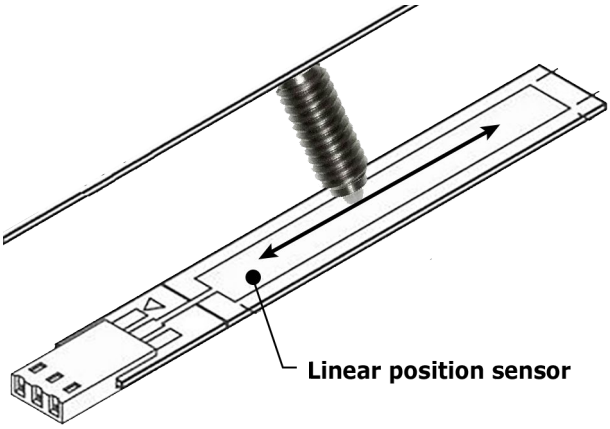
Please consult your personalization page to perform correct transversal calibration if the mechanics differ from the standard collimator.

RO 618 CUSTOMIZED MECHANICS TO ACCOMMODATE CUSTOMIZED COVERS

This option is available for all customers who have customized mechanics.

RO 651 SHUTTER POSITIONING CONTROL

It is a high quality linear position potentiometer that serves as a variable analog voltage divider to ensure correct positioning of shutters. The output signals can be managed by customer or by RALCO electronics.



MAINTENANCE

To ensure constantly safe performance of the collimator and its compliance with applicable regulations, a maintenance program is indispensable.

It is the Owner's responsibility to supply or arrange for this service.

CLEANING RECOMMENDATIONS

- The collimator housing must be cleaned as prescribed by the sanitary regulations followed by the operator.
- Disconnect supply.
- Use non abrasive cleaning products.
- Care must be taken to prevent liquid from entering the collimator.
  Please note: The collimator cover is not watertight.
- **Do not reapply power** if inflammable liquids have leaked into the collimator.
- See the following Maintenance Instructions.
- Clean the varnished and aluminium surfaces with a damp cloth only, using a neutral cleansing agent then dry the surfaces with a soft cloth.
- Clean chrome surfaces with a dry soft cloth.

CAUTION

Do not spray water or detergent directly over the collimator.
The unit's liquid protection level is IPx0!

DISINFECTION

The disinfection method use must conform with the currently applicable norms and directives covering disinfection and protection against explosion hazards.

CAUTION

Never use caustic substances, solvents or abrasive detergents.
If products that could form explosive gas mixtures are used, allow the gas to evaporate before starting the system.

- Disconnect supply.
- Disinfect the unit including accessories and cables with a dampened cloth.
- Do not spray the unit with the disinfectant because it could leak into the collimator

RECOMMENDED MAINTENANCE PROGRAM

RALCO suggests a yearly servicing program, however shorter intervals are advisable when the collimator is subject to heavy workloads.

- Re-calibration of the collimator will be necessary whenever the X-Ray tube is changed or at each substitution of the source light (lamp or LED, if assembled) used to simulate the light field.
- Calibration procedures (if provided) must be performed as described in this manual.
- Check once a week that the screws and tabs which serve to secure the collimator to the flange/tube adapter are correctly tightened.
- Remove the covers and panels from collimator. Inspect the moving parts for signs of wear or damage.
- Check the electric system and substitute parts that show wear.
- Check the plastic anti-dust window and substitute it if necessary.
- Clean the collimator with a soft cloth paying particular attention to the plastic anti-dust window. Do not use abrasive or inflammable cleaning products.
- Wipe away all excess oil and remount the cover

CAUTION

Make sure to tighten the Allen screws securing the collimator or the control tabs. Appropriate tightening of the 4 Allen screws ensures secure mounting of the collimator. Tightening force used must not exceed 0.50 Nm.

IMPORTANT

If the collimator is to be mounted on a rotating flange, use a tightening force between min. 0,50 Nm and max. 0.75 Nm.

GENERAL

WARRANTY

This product has been manufactured and tested by RALCO S.r.l. to the highest quality standards. RALCO undertakes to replace and repair any collimator during a period of 24 months for mechanical and 12 months for electrical parts (motors, potentiometers, electrical boards, lasers) from the date of invoice (shipment date from RALCO).

The warranty applies provided the product has been handled properly in accordance with its operating instructions and its intended use.

Warranty covers cost of all components and labor involved, unless:

- Product documents have been altered in any way or made illegible;
- The model or production number on the product has been altered, deleted, removed or made illegible;
- Repairs or product modifications and alterations have been performed by unauthorized and unqualified persons;
- Unauthorized repairs and/or modifications have been performed;
- Damage caused by misuse or neglect, incorrect installation or accidental damage;
- Damage occurred during transit due to shipping company, or incorrect packing by customer;
- Unoriginal spare parts and accessories have been used.

In-warranty spares will be available only upon return to RALCO, at the customer's expense, of the parts considered to be faulty to allow RALCO to assess the cause of the fault.

Components Not Covered by this Warranty:

- Consumable items such as lamp bulbs, lexan panels and mirrors (if applicable);
- Cosmetic damage such as scratches;
- Any missing components when product arrives for repair.

REPAIRS

In the event the customer finds any Non Conformity in the product, please contact RALCO via e-mail at the address: repairs@RALCO.it (RALCO Repair Assistance).

To successfully resolve any Non Conformity, the following information must be provided:

- The model and serial number of the collimator found on the label;
- A detailed description of the problem (in Italian or English);
- Whether you want a repair, refurbishment, or model upgrade of the product.

RALCO and the customer will work together to resolve the problem by either providing instructions, and/or field service or by sending replacement parts.

In the event the collimator needs to be repaired at RALCO, you will be provided with a RMA (Return Merchandise Authorization) number as our consent to the return. If a product is returned to RALCO without a RMA or without a description of the problem, the customer will incur a €100 processing fee.

If the product is returned under warranty and no defect is found, the customer incurs the cost of evaluation, testing and shipping.

The shipping of the unit is at the customer's expense if the unit is out of warranty.

The warranty period resets only on replaced parts once repairs are completed (shipment date from RALCO back to customer), see Section **"Warranty"**.

RALCO reserves the right to decide if the product is to be repaired or substituted.

Defective material is to be sent to following address:

RALCO SRL
VIA DEI TIGLI 13/G
20853 BIASSONO (MB) - ITALIA
FAX: ++39-039-2497.799
EMAIL: RALCO@RALCO.IT

END OF LIFE DISPOSAL

Your collimator contains materials which can be recycled and reused. Specialised companies can recycle your product to increase the amount of reusable materials and to minimize the amount of materials to be disposed of.

The product contains lead which can be highly contaminating if dispersed incorrectly. The following symbol signifies that the product conforms to the environmental requirements of directives 202/95/EC, 2002/96/EC, 2003/108/EC; it must be disposed of correctly at the end of its life-cycle.

The collimator does not contain polluting materials or products with the exception of the lead that composes the shutters - avoid direct contact with lead especially for prolonged periods.

It is required that you observe Local Laws regulating the disposal of the collimator using certified environmental management entities. Should this prove impossible, return the collimator to RALCO at the purchaser's expense and RALCO will undertake its correct disposal.

If you are replacing the unit with new equipment, you may return the old collimator to RALCO. Please contact us if you require further information.

DISASSEMBLY

WARNING

Care must be taken not to let the collimator fall.

- Disconnect supply to the collimator.
- Remove the cover and disconnect the supply cables.
- Loosen the fixing Allen screws on the upper part of the collimator connected to the flange mounted to the X-Ray tube.

TRANSPORT AND STORAGE

WARNING

Any damage to the collimator due to incorrect or unsuitable packaging is the responsibility of the customer. If possible, the use of original RALCO packaging is recommended. If this is not possible, please follow the instructions provided within the instruction manual.
If the collimator is not packaged correctly, all warranties will be voided.

In order to properly package the collimator for shipping the following materials are needed:

- Plastic bag;
- Sturdy cardboard box properly sized for the collimator;
- Protective packaging (bubble wrap, bubble bags, air pillows, polyfoam etc.) -
- Packaging tape;
- Strapping.

Procedure:

1. Ensure all covers are remounted properly on the collimator if previously removed.
2. Place the collimator in the plastic bag to avoid packing material from entering the collimator.
3. Place the collimator inside the cardboard box.
4. Use protective packaging to fill any empty spaces inside the cardboard box so that the collimator is stable during shipment.
5. Seal the cardboard box firmly so it will not open during shipping using high-quality packaging tape.
6. Use strapping to ensure proper closure.
7. It is strongly recommended to pallet the packaging (especially when single collimators are shipped) to ensure proper handling.
8. Ensure of the correct storage conditions:

   Ambient Temperature = from -40°C to +70°C
   Relative Humidity = from 10% to 95%
   Atm. Pressure = from 500 to 1060 hPa

SAFETY/RESPONSIBILITY

RALCO adheres to the directives governing manufacturers of electro-medical equipment:

Directive 2007/47/CE para.10 -Legislative Decree n° 46 para.10

RALCO shall not be held responsible when instructions provided in the present manual are not complied with.
RALCO shall not be held responsible if the collimator relates to one or several of the following instances:

- The unit is of RALCO construction, built to client specifications with no CE marking.
- The unit has been modified by the OEM or end user.
- The unit has been installed without respecting the instructions provided in this manual.
- The unit is used without respecting the instructions provided in this manual.
- The unit has not been subject to routine functional inspection.
- The unit has not been subject to routine maintenance.
- The unit has been repaired with unoriginal spare parts.
- RALCO shall decline all responsibility for any damage, direct or indirect, caused to persons or things by inappropriate accessories.

WARNING

Information regarding accidents that have occurred while using the radiological collimator must be reported immediately to RALCO srl

RESIDUAL RISKS

The collimator has been constructed to current standards to meet the safety requisites of directive 2007/47/CE. However, due to the presence of X-Rays, the type of application implies a residual risk derived from possible faults that could occur during operation of the unit.

The Instructions contained in the this Manual will ensure the correct use of the device and reduce the causes of possible hazards.

The residual risks of the device are reasonable; they have been assessed and approved in the related Risk Management Plan contained the Technical Report.

Information For The Manufacturer

The following form is provided for your comments and suggestions with regards to the collimator so that we may ensure and improve the quality of our production.

Please e-mail comments and/or suggestions to: repairs@ralco.it

Date:

Customer:

Information regarding possible accidents that may have occurred while using the collimator.

Directive 2007/47/CE states that accidents (such as death or grievous injury to a patient) that involve the collimator described herein, must be reported to the Ministry of Health and to the Manufacturer.

The present form is provided to report to Ralco srl post-free

Date:

Customer: