

Instruction Manual MTR 302/A - MTR 302/A DHHS

MANUAL RADIOLOGICAL COLLIMATOR

Confidential Information



Ralco s.r.l.

MADE IN ITALY



SERIES R 302/A DHHS

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LEGAL WARNING



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THE CONTENTS OF THIS MANUAL MUST ONLY BE USED FOR THE PROPER INTENDED USE, FUNCTION AND MAINTENANCE OF THE RALCO COLLIMATOR.

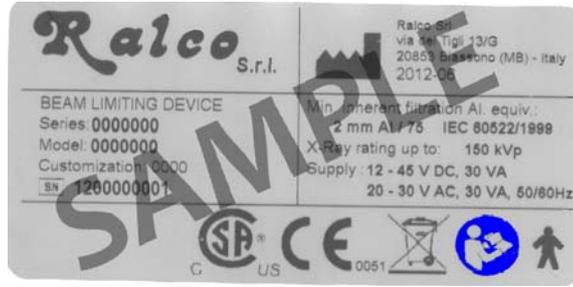
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Model		Certifications
R 302/A	STANDARD VERSION	
R 302/A DHHS	FDA CERTIFIED VERSION AVAILABLE ON REQUEST	 

Revision Level:

<i>The English version of this manual is a translation of the Italian text which prevails in case of doubts.</i>		
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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.

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ADVISORY

THE FOLLOWING INSTRUCTION MANUAL MUST BE READ AND UNDERSTOOD IN ITS ENTIRETY BY THE INSTALLER AND OPERATOR.

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 SAFE USE OF THIS COLLIMATOR MUST BE STRICTLY FOLLOWED.

REPORTING

INFORMATION REGARDING ACCIDENTS THAT HAVE OCCURRED WHILE USING THIS COLLIMATOR MUST BE REPORTED IMMEDIATELY TO RALCO, SRL.

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:

IF 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.

R302/A - R302/A DHHS - Advisory

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/CEE OF 14 JUNE 1993 AND SUCCESSIVE MODIFICATIONS APPLYING DIRECTIVE 2007/47/CE.

LIST APPLICABLE STANDARDS AND TO WHICH RALCO ADHERES TO:

- EN 60601-1:2006
- EN 60601-1-2:2007
- EN 60601-1-3:2008
- EN 60601-2-45:2012
- EN 60601-2-54:2009
- EN 60825-1:2007
- ISO 9001:2008
- UNI EN ISO 13485:2012
- 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/CE 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.

R302/A - R302/A DHHS - Advisory

SYMBOLS

IN THIS MANUAL THE FOLLOWING SYMBOLS ARE USED:

THE TRIANGLE EMPHASIZES WARNINGS AND CAUTIONARY MESSAGES WHICH ARE IMPORTANT FOR YOUR SAFETY AND/OR EFFICIENT OPERATION OF THE EQUIPMENT. THESE WARNINGS MUST BE STRICTLY COMPLIED WITH.



INFORMATION PROVIDED WITH THE LAMP IS ADDITIONAL ADVICE FOR THE PROPER CONTROL AND PRACTICAL USE OF THE UNIT.



RALCO INSTRUCTION MANUALS ARE AVAILABLE IN TWO VERSIONS: ITALIAN AND ENGLISH. THE ENGLISH VERSION OF THIS MANUAL IS A TRANSLATION OF THE ITALIAN TEXT WHICH PREVAILS IN CASE OF DOUBTS.

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SYMBOLS

	Description	No.	Ref. IEC
	<i>Alternating Current</i>	01-14	417-iec 503
	<i>Direct Current</i>	01-18	417-iec 5031
	<i>Continuous and Alternating Current</i>	01-19	417-iec 5033
	<i>Protective Ground</i>	01-20	417-iec 5019
	<i>Plus; Positive Polarity</i>	01-27	417-iec 5019
	<i>Minus; Negative Polarity</i>	01-28	417-iec 5006
	<i>Input</i>	01-36	417-iec 5006
	<i>Output</i>	01-37	417-iec 5034
	<i>Remote Control</i>	01-38	
	<i>Manual Control</i>	01-45	ISO 7000-096
	<i>Automatic Control (Closed Loop)</i>	01-46	iso 7000-0017
	<i>Iris Diaphragm: Open</i>	01-69	iso 7000-0017
	<i>Iris Diaphragm: Closed</i>	01-70	417-iec 5324
	<i>General Warning Sign</i>	03-02	iec 601-1
	<i>Radiation Filter or Filtration</i>	04-51	417-iec 5381
	<i>Light Indicator of Radiation Field</i>	04-51	417-iec 5381
	<i>Beam Limiting Device: Open</i>	04-55	417-iec 5385
	<i>Beam Limiting Device: Closed</i>	04-56	417-iec 5386
	<i>Beam Limiting Device: Closed with Separate Opening of the Shutters</i>	04-57	417-iec 5387
	<i>Beam Limiting Device with Separate Closing of the Shutters</i>	04-58	417-iec 5388
	<i>Type B Applied Part</i>	02-02	601-i-iec

R302/A - R302/A DHHS - Symbols

	Description	No.	Ref. IEC
	<i>Caution: Laser Radiation</i>		60825-1
	<i>Electrostatic-Sensitive Device</i>		
	<i>Cassette Size Sensing Device</i>		
	<i>Device Requiring Proper Disposal</i>	attch.4	2002/95/CE
	<i>Follow Instructions for Use</i>		ISO 7010-M002

DESCRIPTION

Multilayer, square field, manual collimation system intended for installation on stationary X-ray equipment. This device has been designed and manufactured for skeletal and thoracic investigations.

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, controlled by two knobs on the collimator front panel.

CHARACTERISTICS

Mounting Plane at 80 mm (3.14") from the focus.

Continuous Film Coverage from Min: 00 x 00 cm to Max: 48 x 48 cm at 100 cm (40") SID.

Maximum Radiation Leakage: 150 kVp - 4 mA.

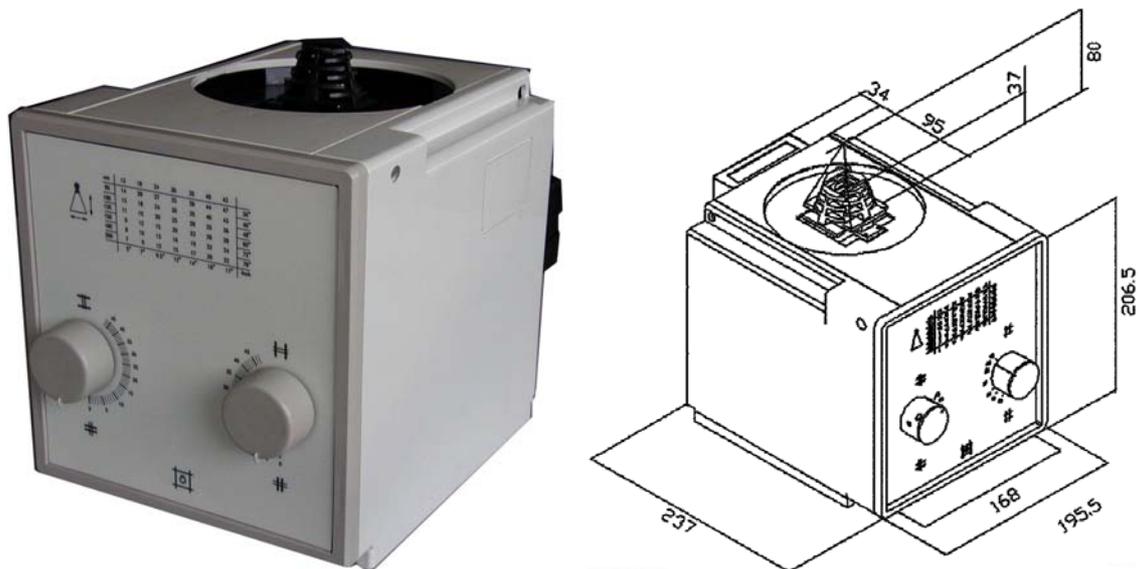
High Luminosity provided by a quartz iodide lamp simulating the X-ray field.

Minimum Inherent Filtration: 2 mm aluminium equivalent.

Accessory Guides are used for accessories and additional filtration.

GC 338 timer limiting projection lamp exposure time to 30 seconds thus extending lamp life by preventing overheating.

Fig. R302/A - R302/A DHHS with Exterior Dimensions



R302/A - R302/A DHHS - Description

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

RO 001/A	Fixed mounting flange, 20 mm thickness
RO 002	Spacers for mounting flange; 1.5 mm thickness
RO 012/B	Tape measure, retractable
RO 041	Mylar mirror, inherent filtration 0.3 mm Al equivalent
RO 051	Rotating mounting flange, 18 mm thickness, 136 mm diameter
RO 055/B	Fixed mounting flange, 18 mm thickness
RO 063	Final control testing (light intensity, light field/radiation field alignment, radiation leakage, light field border contrast ratio, general functionality and electronic)
RO 074	Customized external cover color
RO 077	Potter Bucky light centering device (BL)
RO 082	Mirror 0.8 mm thickness, filtration equivalent 1 mm Al
RO 096	Customized wiring
RO 107	Customized knobs
RO 109	Customized cover
RO 111	Personalized front panel
RO 161	Plastic spacer guides to accommodate the DAP
RO 185/A	Fixed mounting flange, 20 mm thickness
RO 202	Auto-centering top plate for fixed metal flange
RO 203	Auto-centering Siemens top plate
RO 222/A	Rotating mounting flange, 136 diameter, 18 mm thickness
RO 240	Focus-skin spacers, preventing X-ray exposure too close to the patient
RO 253	Plastic spacer guides to assemble DAP
RO 258	Additional variable filtration through three filters on rotating support 1 mm Al + (0.1 mm CU O 0.2 mm CU O 2 mm Al), manual selection (available only for collimators assembled with DHHS)
RO 271	Halogen lamp 150 W for high luminosity with cooling system
RO 318	Auto-centering top plate with coupling for plastic flange allowing rotation of the collimator, the plastic flange is included
RO 333	White LED
RO 339	Device equipped with 2 lasers for optical SID
RO 441	Plastic flange with a notch rotating +/- 50°, 20 mm thickness without stop (available only for collimators assembled with RO 318)

R302/A - R302/A DHHS - Description

RO 442	Plastic flange with a notch rotating +/- 90°, 20 mm thickness without stop (available only for collimators assembled with RO 318)
RO 452	Independent Long shutters

SPECIFICATIONS

Specifications of the basic version of the collimator are described here below.

Power Supply	24 V DC - 50/60 Hz - 6.5 A
Fuse for power supply protection collimator. Not supplied by Ralco.	T 10 A
Motor Supplied by Collimator Board	n.a.
Fuse for Power Supply Protection Collimator. Not supplied by Ralco.	n.a.

Software	n.a.
Power Supply, External PCB	n.a.
Fuse for External Board	n.a.

Inherent Filtration Al. Equivalent X-ray beam = 75 kV EN 60601-1-3 par. 7.3; 7.4	Min. Al 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 1 m EN 60601-2-54	< 150 mm
Square X-ray Field Selection 100 cm (40") SID - ($\pm 1\%$ SID) EN 60601-2-54	Min: 00 x 00 cm Max: 48 x 48 cm
Round X-ray Field Selection 1 m SID - ($\pm 1\%$ 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 lux

R302/A - R302/A DHHS - Specifications

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 60601-2-54	< 40 mRh

Potentiometers	n.a.
Square Field	n.a.
Round Field	n.a.
Maximum Load for Accessory Guides GUIDES FOR ACCESSORIES (IF ASSEMBLED): PRIOR TO INSERTING ACCESSORIES IN THE GUIDES CHECK ON THE PERFECT ATTACHMENT OF THE SUPPORT WITH THE MOUNTING SLOT ON THE COLLIMATOR (TOLERANCE MAX. $\pm 0,5$ MM). A FAULTY ATTACHMENT COULD BE DANGEROUS AND IT COULD CAUSE THE FALL OF ACCESSORIES	Static load: 70 N (about 7.1 Kg) Dynamic load: 15 Nm (approx. 3.06 Kg)
Operation Environment • Ambient Temperature • Relative Humidity • Atmospheric Pressure	10° - 40°C 0% - 75% 700 - 1060 hPa
Storage • Temperature • Humidity • Atmospheric Pressure	-40° - 70°C 10% - 95% 500 - 1060 hPa
Weight	9.4 Kg
Dimensions	L: 268 mm W: 195.5 mm H: 206.5 mm

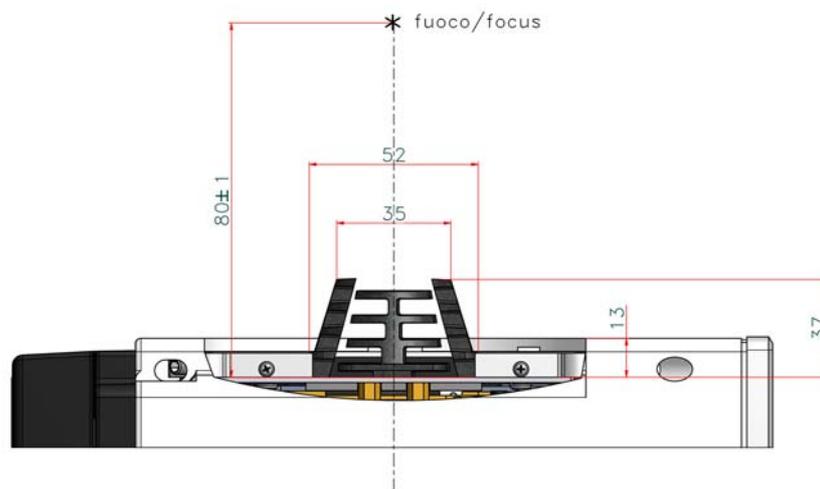
R302/A - R302/A DHHS - Specifications

INSTALLATION

X-RAY TUBE COMPATIBILITY

- Using the dimensions in **Fig. Tube Compatibility** below, ensure the near port limiter can be inserted in to the X-ray tube port.
- Check that the tube housing literature indicates congruent minimum inherent filtration (1 mm) and, that maximum radiation leakage is 30 mR/hour measured at 1 m from the source when operating at its leakage technique factors (150 kVp - 4 mA).
- Source values (tube housing-collimator) must not be less than 3 mm Al for filtration and must never exceed 100 mR/hr for radiation leakage [21 CFR sub-chapter J, part 1020.30 (m) (1)].
- The distance between the X-ray tube focus and the flange mounting plane (collimator upper plate) must be: 80 mm (3.14"), tolerance +/- (0.04").

Fig. Tube Compatibility



MOUNTING THE COLLIMATOR TO THE X-RAY TUBE



CAREFULLY FOLLOW THE MOUNTING INSTRUCTIONS AND MAKE SURE THAT THE COLLIMATOR IS CORRECTLY ASSEMBLED. INCORRECT MOUNTING COULD BE DANGEROUS: IT COULD CAUSE THE COLLIMATOR TO FALL OR TO OPERATE INACCURATELY.

- Use the X-ray tube housing literature to determine the distance from the focal spot to the tube port face.
- Subtract the resulting distance from 80 mm (3.14") and determine the number of 1.5 mm (0.06") spacers that, combined with the thickness of the mounting flange, will make up the difference: (20 mm for the fixed flange; 18 mm for the rotating flange) Allowable tolerance is 1 mm. (0.04").
- Different flange models with their dimensions are listed in the Chapter **DESCRIPTION**, paragraph **Optional Items**.
- Mount the flange and spacers to the tube port with 4 countersunk bolts and 4 countersunk washers, the bolts must be long enough to be driven into the tube port face for at least 5 threads.

- Tighten the bolts.



IMPORTANT
TO SAFEGUARD THE OPERATOR AND PATIENT AGAINST THE HAZARD OF
A FALLING COLLIMATOR, THE FOLLOWING INDICATIONS MUST BE RESPECTED.

- Unscrew the four mounting and centering adjustment Allen screws on the collimator until the four tabs are withdrawn from the collimator top opening, see **Fig. Mounting Flange**, in this Chapter.



WHEN UNSCREWING THE ALLEN SCREWS WHICH CONTROL THE TABS, DO
NOT USE FORCE EXCEEDING 0,55 NM.
UNSCREW WITH CARE SO AS NOT TO DAMAGE THE FIXING TABS.

- Manually adjust the collimator opening to their widest setting.
- Carefully couple the collimator with the tube to determine that the cone/extra focal shutters have enough clearance to move in the port opening and in the mounting flange, see **Fig. Tube Compatibility** in this Chapter.
- Place the collimator on the flange. Tighten the four mounting screws equally until the collimator holds firmly on the tube housing, see **Fig. Mounting Flange** in this Chapter.
- The collimator control tabs conform to **EN 60601-1**. Ralco recommends an appropriate force which ensures safe locking of the tabs min. 0.75 Nm (± 5 cNm)



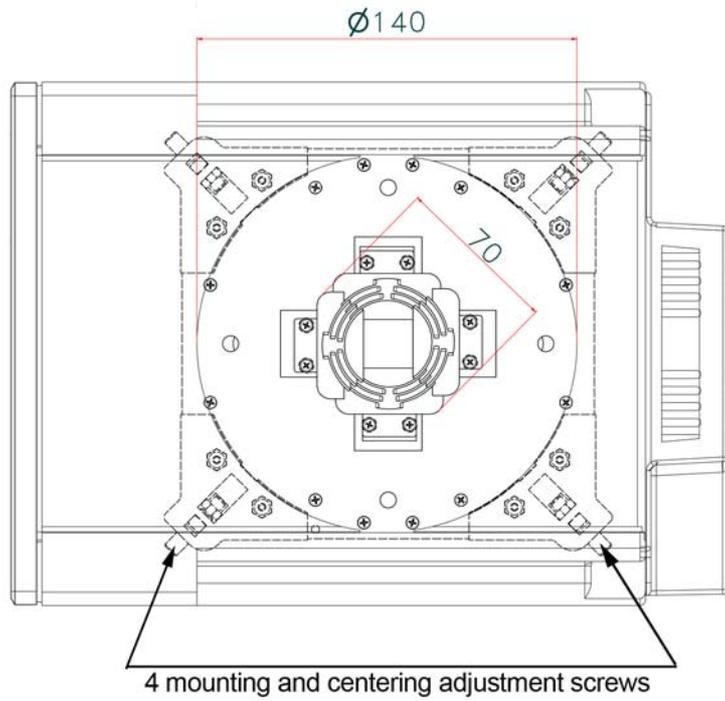
MAKE SURE TO TIGHTEN THE ALLEN SCREWS SECURING THE CONTROL TABS.
APPROPRIATE TIGHTENING OF THE 4 ALLEN SCREWS ENSURES SECURE MOUNTING
OF THE COLLIMATOR. TIGHTENING FORCE USED MUST BE GREATER THAN 0.50 NM.



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.

- Check to see that the distance between the collimator housing and the mounting flange is equal in all directions and that the collimator face is parallel to the axis of the table.
- Loosen the screws and adjust if required.

Fig. Mounting Flange



ELECTRICAL CONNECTION



THE WIRING DIAGRAM INCLUDED IN THIS CHAPTER REFERS TO THE STANDARD PRODUCT. IT IS THE RESPONSIBILITY OF THE CUSTOMER WHO HAS REQUESTED AN ELECTRIC CUSTOMIZATION, TO ENSURE THAT AN ELECTRIC DIAGRAM RELATING TO THE CUSTOMIZATION HAS BEEN PROVIDED WITH THE DOCUMENTATION.



THE DEVICE MUST BE EXCLUSIVELY CONNECTED TO POWER NETWORK, WITH EARTH PROTECTION, IN ORDER TO AVOID A RISK OF ELECTRICAL SHOCK.



THE DEVICE IS PROJECTED 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 MACHINE IS ACCIDENTLY SWITCHED OFF.

Supply and signals to the collimator must be to 2007/47/CE standards. Devices that supply to the collimator must therefore feature double or reinforced insulation as provided by the General Standard on Electro-medical 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 70°C AND COLLIMATOR CURRENT ABSORPTION.

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:  . 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.

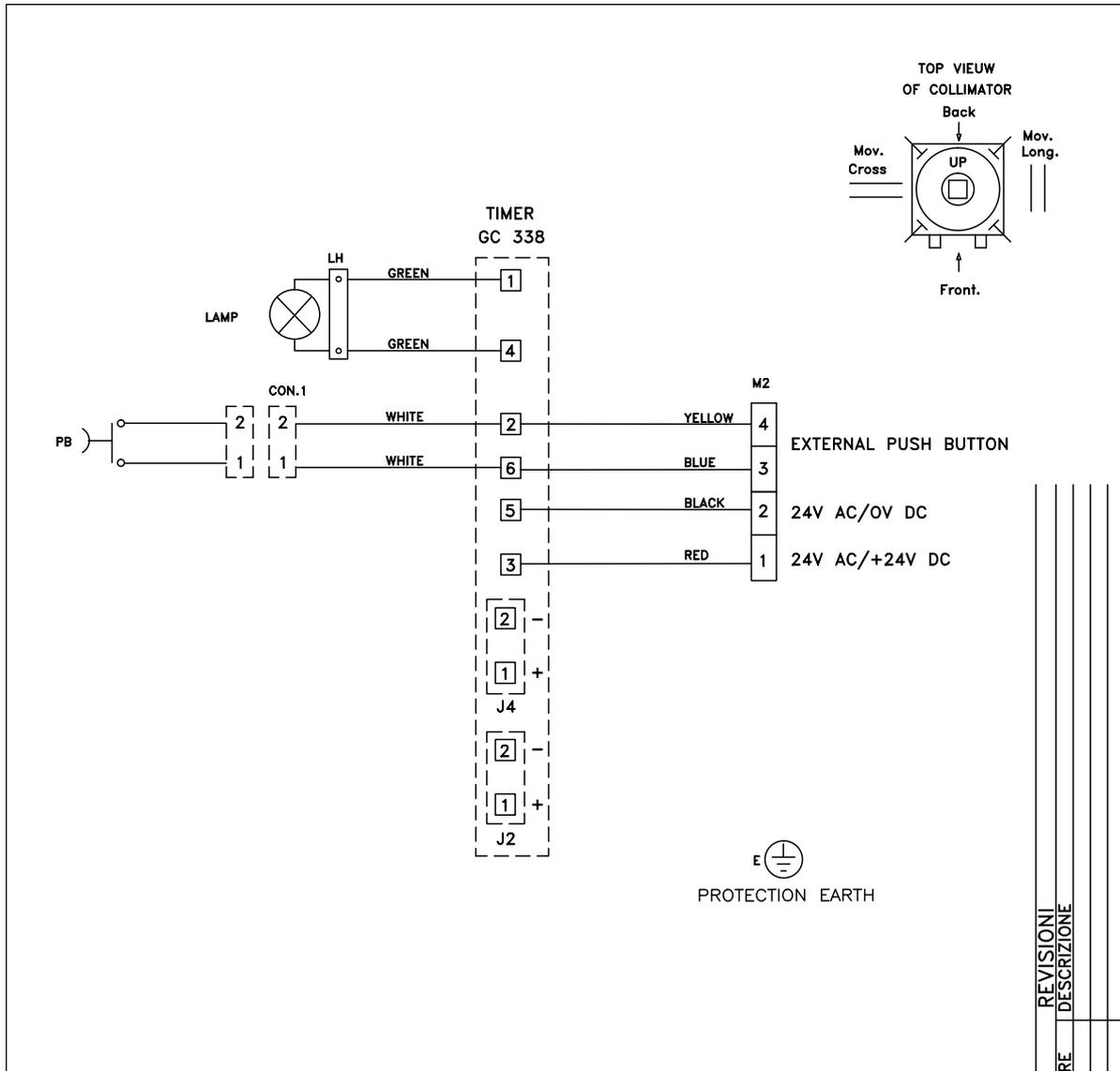
- Remount the cover.



INCORRECT POWER SUPPLY COULD DAMAGE THE ELECTRONIC TIMER 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
7	PUSH BUTTON (P.B.)	1	MP11716
6	4 WAYS TERMINAL (M2)	1	MP11357
5	AMP CONNECTOR MALE 2 WAYS (CON.1)	1	MP11397
4	LAMP HOLDER 905/1 (LH)	1	MP11721
3	HALOGEN LAMP 24V 100W	1	MP11737
2	TIMER BOARD GC 338	1	MP11845
1	ELECTRICAL WIRING	1	GE00717

DISEGNATO: Tucci Davide		PROGETTO:		QUALITA':	
CONTROLLATO: Alessandro Pizzagalli		DATA: 10/05/12		FORMATO: A4	
		PAG. 1 di 1		N. COD.	
		DENOMINAZIONE R 302/A DHHS		302E171	
QUESTO DISEGNO E' PROPRIETA' ESCLUSIVA DELLA RALCO S.r.l. A TERMINI DI LEGGE ESSA VIETA DI RIPRODURLO O COMUNICARLO A DITTE CONCORRENTI O AD ALTRI SENZA LA SUA ESPLICITA APPROVAZIONE.					

R302/A - R302/A DHHS - Installation

GC 338 Timer

Connectors

J1 POWER SUPPLY AND OUTPUTS	<ol style="list-style-type: none"> 1. Lamp output (max 9 A) 2. Push button input 3. Power Supply +12/24 V DC o 12-24 V AC/V DC A 4. Shared Lamp 5. Power Supply -12/24 V DC o 12-24 V AC/V DC B 6. Shared push button 	
J2 LASER POWER SUPPLY 5VDC	<ol style="list-style-type: none"> 1. +Laser Power Supply (5 V) 2. GND Laser 	
J3 PROGRAMING CONNECTOR	<ol style="list-style-type: none"> 1. V pp 2. +5 V 3. GND 4. PGD 5. PGC 6. NC 	
J4 – FAN POWER SUPPLY 12V DC	<ol style="list-style-type: none"> 1. +Fan Power Supply (max 200 mA) 2. – Fan Power Supply 	
JUMPERS	<p>OFF - no jumper ON - jumper</p>	
JP1, JP2 – LAMP TIME SELECTION	<p>JP1</p> <p>OFF - 30 s ON - 45 s OFF - 60 s ON - 120 s</p>	<p>JP2</p> <p>OFF - 30 s OFF - 45 s ON - 60 s ON - 120 s</p>
JP3, JP4 – OPERATION MODE SELECTION	<p>JP3</p> <p>OFF - Timer ON - Timer reset by pressing the button OFF - Power Supply ON - Fan ON for 90 seconds longer than the lamp</p>	<p>JP4</p> <p>OFF - Timer OFF - Timer reset by pressing the button ON - Power Supply ON - Fan ON for 90 seconds longer than the lamp</p>

R302/A - R302/A DHHS - Installation

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 LIGHTING WITHOUT ALLOWING LIGHT SOURCE TO COOL CAUSES THE COLLIMATOR TO OVERHEAT IN THE AREA NEAR THE LIGHT SOURCE.
 FOR EMERGENCIES: MAXIMUM LIMIT ADVISED IS 5 SUCCESSIVE LIGHT SOURCE OPERATIONS. ALLOW THE COLLIMATOR TO COOL (ABOUT 10 MIN).



BY INCREASING THE CONSECUTIVE "ON" TIMES, THE SUBSEQUENT REST PERIODS NEED TO BE EXTENDED ACCORDINGLY. IT IS IMPRUDENT TO PERFORM TWO CONSECUTIVE CYCLES OF 5 **ON** TIMES.

The collimator has been designed to operate as follows:

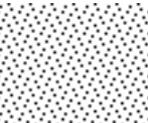
- Supply constantly connected during operation of the equipment.
- Light source ON time for the light field is factory set at 30 seconds (tol.20%). It is adjustable from 30 to 45 seconds via a trimmer on the timer board.
- The normal ON/OFF cycle is set at 1 minute followed by an idle time of 4 minutes to allow for cooling time (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.

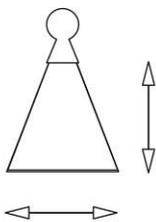
Front Panel

The table provides the readout of the numbers which must be set with the knobs. The exact number to be set is obtained by crossing the SID in use (the value indicated by vertical arrow), with the Cassette size value in cm or inches (horizontal arrow). If necessary see Chapter- **ADJUSTMENTS**.

SID in Use

Format Required

Knob Index Setting




cm	13	18	24	30	35	40	43	
90	14	20	27	33	39	44	47	36 ^{''}
100	13	18	24	30	35	40	43	40 ^{''}
150	10	12	16	20	23,5	26,5	28	60 ^{''}
180	8	10,5	13	16,5	19,5	22	24	72 ^{''}
	5 ^{''}	7 ^{''}	9,5 ^{''}	12 ^{''}	14 ^{''}	16 ^{''}	17 ^{''}	Inch

CALIBRATION



THE FOLLOWING PROCEDURES REQUIRE THAT X-RADIATION BE PRODUCED. TAKE ADEQUATE PRECAUTIONS TO MAKE CERTAIN THAT NO PART OF THE HUMAN BODY IS EXPOSED TO X-RADIATION, DIRECT OR INDIRECT.

CENTERING X-RAY BEAM WITH COLLIMATOR LIGHT

- Place a 35 x 43 cm. (14 x 17") cassette on the table top or other flat, horizontal surface.
- Position the X-ray tube/collimator assembly with the focal spot at 1 meter (40") over the cassette with the X-ray beam perpendicular to the cassette surface. Do not use measurement indicators on the system as reference values, but measure the distance from the focal spot to the cassette surface with a tape measure of similar device.

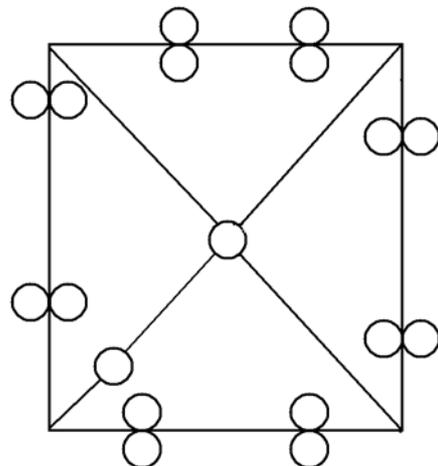


IF THE DISTANCE OF 1 M SID CANNOT BE DETERMINED, USE THE SID VALUE CLOSEST TO ONE METER AND CALCULATE THE MEASUREMENT TOLERANCES AS THE APPROPRIATE PERCENTAGES OF THE DISTANCE.



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.

- Use the collimator light to center the cassette in the field.
- Mark the location of the cassette with masking tape or other means so that it may be removed and replaced in the same position.
- Place white paper on top of the cassette to provide maximum contrast for the light field.
- Set the collimator to provide a field size of 30 x 30 cm. (12" x 12") at 1 meter (40").
- Activate the light field and use it to position 18 coins as shown in the diagram.
- Position each pair of coins touching one another so that the inner coin is lighted as much as possible and the outer coin is lighted as little as possible.
- The points where the coins contact will define the edges of the light field.
- The extra two coins are to be set:
 - One in a corner to ascertain film position.
 - The other at the intersection of the diagonals to define film center.



- Set the X-ray generator to produce a density of about 50 kVp, 5 mAs.
- Make an exposure.
- Remove the cassette and process the film.
- Use the test film to check the alignments described below.



THE HEEL EFFECT WILL CAUSE THE FIELD TOWARD THE CATHODE TO BE SLIGHTLY LESS SHARP THAN ON 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 ANODE CUT-OFF EFFECT. THIS IS NORMAL AND MAY NOT BE CORRECTED BY ADJUSTMENT.

LIGHT FIELD TO X-RAY FIELD ALIGNMENT

Misalignment of the light field/ X-ray field in either the X (cross table) or Y (long table) direction must not exceed 2% of the SID. In this case, it would be less than 20 mm (0.80"). If the test film shows that the light field (shadows of the markers) matches the X-ray field (shadow of the collimator shutters) to within the diameter of one marker and, if the diameter is less than 20 mm (1.80"), then alignment complies with the regulations.

Greater precision than this is possible. Recommended maximum deviation is one fourth. It is important the greatest degree of congruency possible is achieved.

If misalignment is detected in both X and Y directions, check the spacing from the focal spot to the collimator mounting surface is 80 mm (3.14") +/- 1 mm. If spacing needs to be adjusted, repeat the test film exposure after the adjustment.

If the collimator mount spacing is correct, but adjustment is still necessary proceed as follows:

- Place the test film on the face of the cassette over the white paper.
- Place the cassette in the position originally marked.
- Check the correct position of the film by the shadows cast by the markers.
- Using the images of the collimator shutters as the references for the shape and size of the X-ray field, adjust the light field to match.
- If adjustment is necessary, adjust the travel of the light source. All procedures can be found in **LIGHT FIELD ADJUSTMENTS** in this chapter.

LIGHT FIELD CALIBRATION

Longitudinal Calibration (LONG)



DO NOT TOUCH THE DISSIPATER WITH YOUR HANDS; IT COULD BE HOT AND CAUSE SEVERE BURNS.

- Remove the part of the cover necessary to access the screws, see Chapter - **COVER REMOVAL**
- Remove the light source protection heatsink by unscrewing the fixing screws . This allows you to access the light source.
- If the light-field needs to be moved laterally, loosen (not remove) the fixing screws **A**.
- Adjust through screw **B**.
- When calibration is terminated, lock the screws **A**.

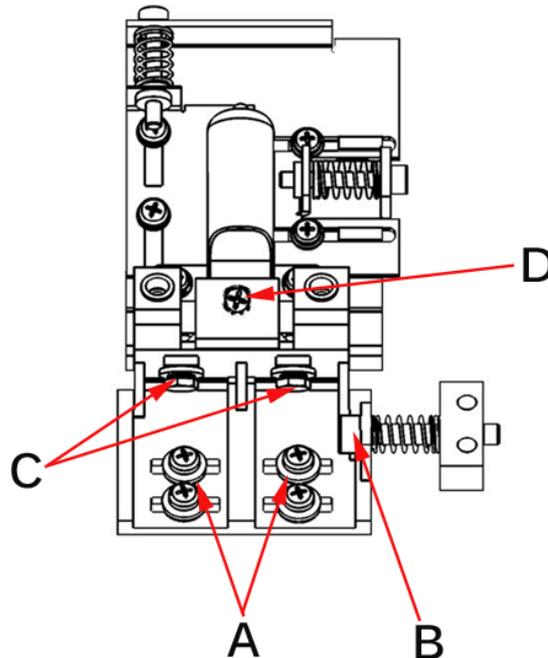
See the following **Fig. Light Field Adjustment**

Vertical Alignment

- If the light field is *smaller* than the X-ray field, lower the lamp by adjusting screw **C**.
- If the light field is *bigger* than the X-ray field, raise the lamp by adjusting screw **C**.

See **Fig. Light Field Adjustment**.

Fig. Light Field Adjustment



Transversal Calibration (CROSS)

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

- Remove the part of the cover necessary to access the screws, see Chapter - **COVER REMOVAL**.
- Loosen the mirror fixing screw **A** (not remove) and shift it to adjust the position of the mirror, see **Fig. Transversal Calibration (CROSS)**.
- Once you have regulated the mirror tighten the screw **A** and remount the cover, see Chapter - **COVER REMOVAL**.

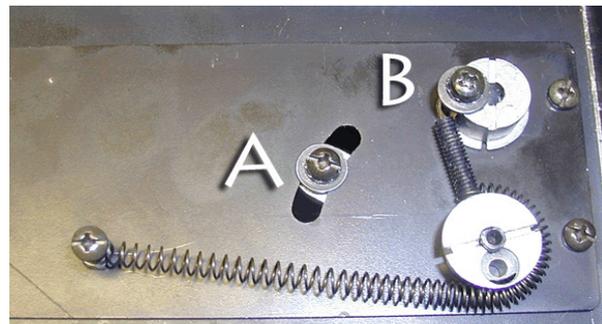


Fig. Transversal Calibration (CROSS)

R302/A - R302/A DHHS - Calibration

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.

	THE FOLLOWING PROCEDURES REQUIRE THAT X-RADIATION BE PRODUCED. TAKE ADEQUATE PRECAUTIONS THAT NO PART OF HUMAN BEING IS EXPOSED TO X-RADIATION, DIRECT OR INDIRECT.
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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)		
Designed Operating Range (kVp)	Measured Operating Potential (kVp)	Minimum HVL (mm. Of Al) X-ray System
Below 50	30	0.3
	40	0.4
	50	0.5
From 51 a70	51	1.2
	60	1.3
	70	1.5
Above 71	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

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:

R302/A - R302/A DHHS - Compliance Verification

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 Aluminium 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.

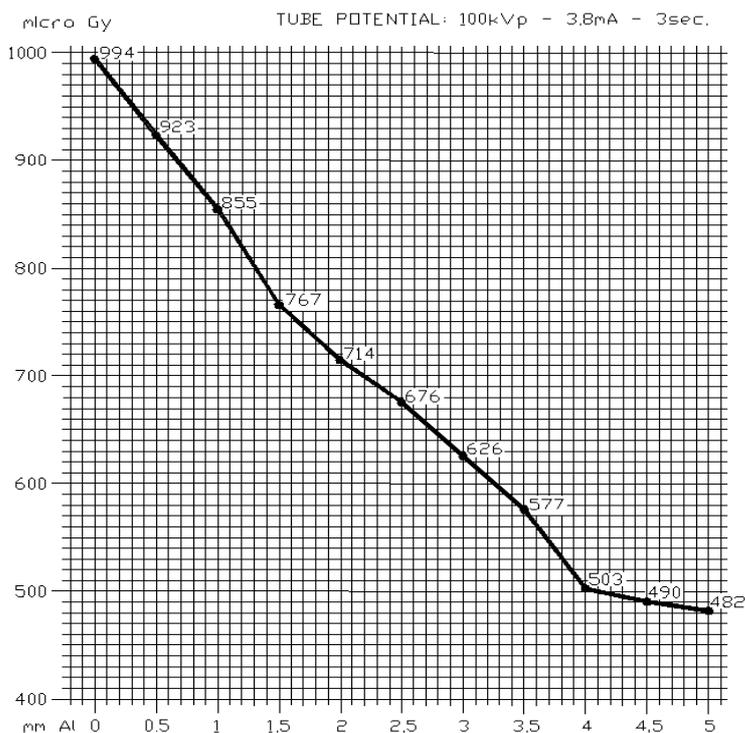
Standard Absorber Method

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 millimetres of aluminium 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.

R302/A - R302/A DHHS - Compliance Verification

- c) Plot the exposure readings (log scale) versus the total added filtration thickness on semi-log paper; see the sample hereunder.
- d) Verify that HVL values in the useful beam for the above specific tube potential is not less than the values shown in **Table - Minimum Filtration Requirement - Beam Quality (HVL)**.



generale\12_verif_conf_graph.gif

VISUAL DEFINITION OF X-RAY VERSUS LIGHT FIELD

Chapter - **COLLIMATOR CALIBRATION** - paragraph - **Light-Field to X-ray Field Alignment**.

FIELD SIZE INDICATION

Chapter- **ADJUSTMENTS**, paragraph **Field Size Indication**.

CROSSHAIR ALIGNMENT

CHAPTER- **ADJUSTMENTS**, PARAGRAPH **CROSSHAIR ALIGNMENT**.

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.

R302/A - R302/A DHHS - Compliance Verification

- 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

Electromagnetic Emissions

The R302/A - R302/A DHHS collimator is suitable for use in the specified electromagnetic environment. The purchaser or user of the R302/A - R302/A DHHS should assure that it is used in an electromagnetic environment as described below:

Emissions Test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	The Collimator R302/A - R302/A DHHS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class [A]	This R302/A - R302/A DHHS 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.
Harmonic emissions IEC 61000-3-2	[Not applicable]	
Voltage fluctuations/flicker emissions IEC 61000-3-3	[Not applicable]	
CISPR 14	N.A.	This Collimator is not suitable for interconnection with other equipment.
CISPR 15	N.A.	This Collimator is not suitable for interconnection with other equipment.

Electromagnetic Immunity for All Equipment and Systems

Collimator R302/A - R302/A DHHS is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic discharge (ESD) IEC 61000-4-2	6 kV contact 8 kV air	EN 60601-1-2 test level	Hospital
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	Hospital
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	EN 60601-1-2 test level	Hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_n for 0.5 cycles. 40% U_n for 5 cycles 70% U_n for 25 cycles 0% U_n for 5 s	EN 60601-1-2 test level	Hospital
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	EN 60601-1-2 test level	Hospital

R302/A - R302/A DHHS - Compliance Verification

Electromagnetic Immunity for Non Life-Supporting System

The R302/A - R302/A DHHS collimator is intended for use in the electromagnetic environment specified below. The customer or the user of the collimator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
			<p>Portable and mobile RF communications equipment should be used no closer to any part of the R302/A - R302/A DHHS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d=1.2 \sqrt{P}$ 80 MHz to 800MHz $d=2.3 \sqrt{P}$ 800 MHz to 2.5GHz
Conducted RF IEC 61000-4-6	3 V/m 150 kHz to 80 GHz	3 V	$d= 1.2 \times \sqrt{P}$
			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p>
			<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

R302/A - R302/A DHHS - Compliance Verification

Recommended Separation Distances for Non-Life Supporting Equipment

Collimator R302/A - R302/A DHHS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the collimator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the collimator as recommended below, according to the maximum output power of the communications equipment.

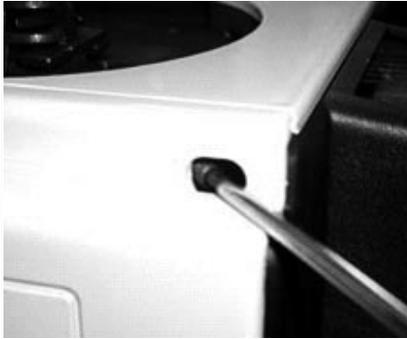
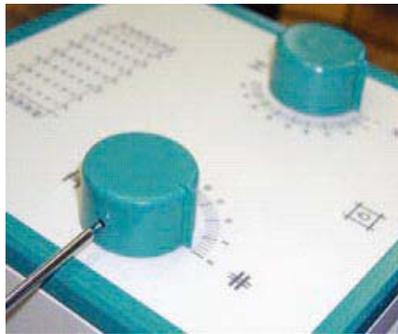
Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \times \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \times \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

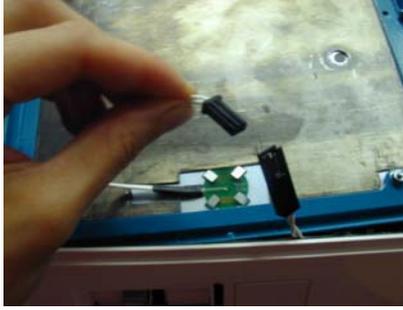
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter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

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

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

COVER REMOVAL

(1).	
<p>TIGHTEN THE FOUR ALLEN SCREWS TO ALLOW REMOVAL OF THE COVER.</p>	
(2).	
<p>REMOVE THE FRONT PANEL BY UNSCREWING THE TWO DOWELS PER KNOB.</p>	
(3).	
<p>REMOVE THE SNAP-FIT FRONT PANEL BY PRISING IT OFF AS SHOW IN THE PHOTOGRAPH.</p>	

(4).	
<p>DISCONNECT THE CONNECTOR.</p>	
(5).	
<p>IN COLLIMATORS WITH MEASURING TAPES, REMOVE THE TAPE STOP BY LIFTING IT OFF WITH A SCREW DRIVER. GENTLY EASE THE TAPE INTO ITS CONTAINER WITHIN THE COLLIMATOR.</p>	
(6).	
<p>TURN THE COLLIMATOR OVER AND UNSCREW THE FOUR SCREWS.</p>	

(7).

**REMOVE THE REAR COVER
BY UNSCREWING THE THREE
SCREWS.**



(8).

**PLACE THE COLLIMATOR
LOWER SIDE DOWN AND
SLIGHTLY RAISE.
SLIP THE SEMI-CIRCLE OUT.**



(9).

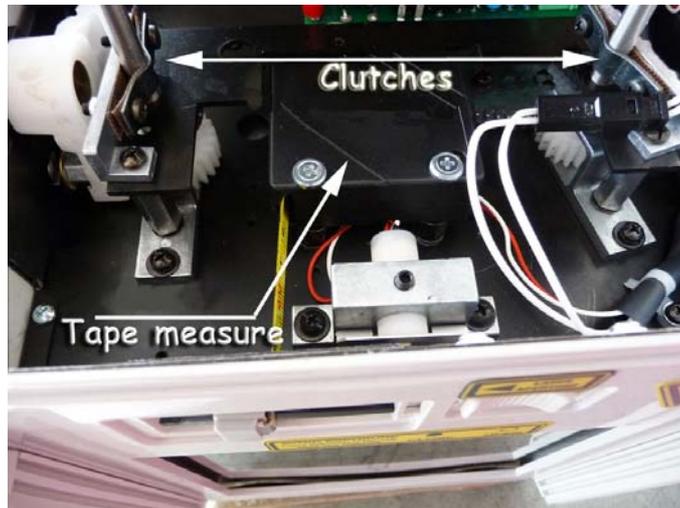
**EASE THE COVER UPWARDS
GENTLY.
THIS WILL ALSO RELEASE
THE SMALL PANEL.**



ACCESS TO COLLIMATOR COMPONENTS

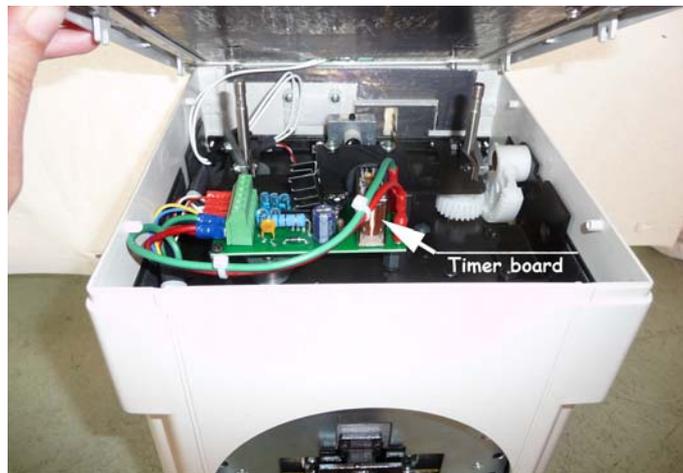
Friction

ACCESS THE CLUTCHES BY REMOVING THE TWO KNOBS AND/OR THE FRONT PANEL DEPENDING ON THE COLLIMATOR MODEL.



Timer Board

ACCESS THE TIMER BOARD BY REMOVING THE TWO KNOBS AND/OR THE FRONT PANEL DEPENDING ON THE COLLIMATOR MODEL.



Power Supply

ACCESS THE COLLIMATOR POWER SUPPLY BY REMOVING COLLIMATOR BACK PANEL.



Longitudinal Movement

ACCESS THE TRANSVERSAL ADJUSTMENT PARTS BY REMOVING THE LATERAL PLATE.



ADJUSTMENTS



WARNING:

THIS IS PROVIDED AS AN AID TO THE END USER. RALCO IS NOT LIABLE FOR ANY DAMAGES RESULTING FROM THE ALTERING OF PRESET FACTORY CONFIGURATIONS.

ADJUSTMENTS HAVE BEEN PRESET AT THE FACTORY PRIOR TO SHIPMENT OF THE COLLIMATOR. SHOULD ANY PROBLEM ARISE REQUIRING THE NEED TO RECALIBRATE, 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

- 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.
- Rotate the knobs and make the knob index coincide exactly with the scale reading that corresponds to size 30x30 cm at 1 m SID.
- Measure the X-ray field of the test image.
- 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.



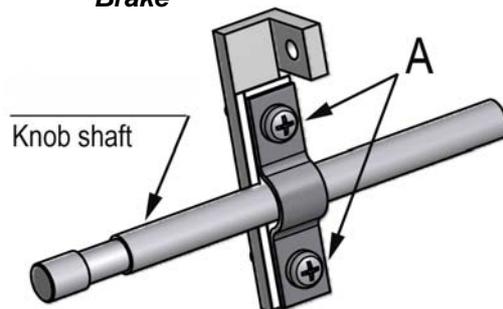
Fig. Cross Line

Friction Brake Adjustment

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

- Remove the parts of the cover to access the adjustment point, see Chapter- **COVER REMOVAL**.
- 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**.

Fig. Friction Brake



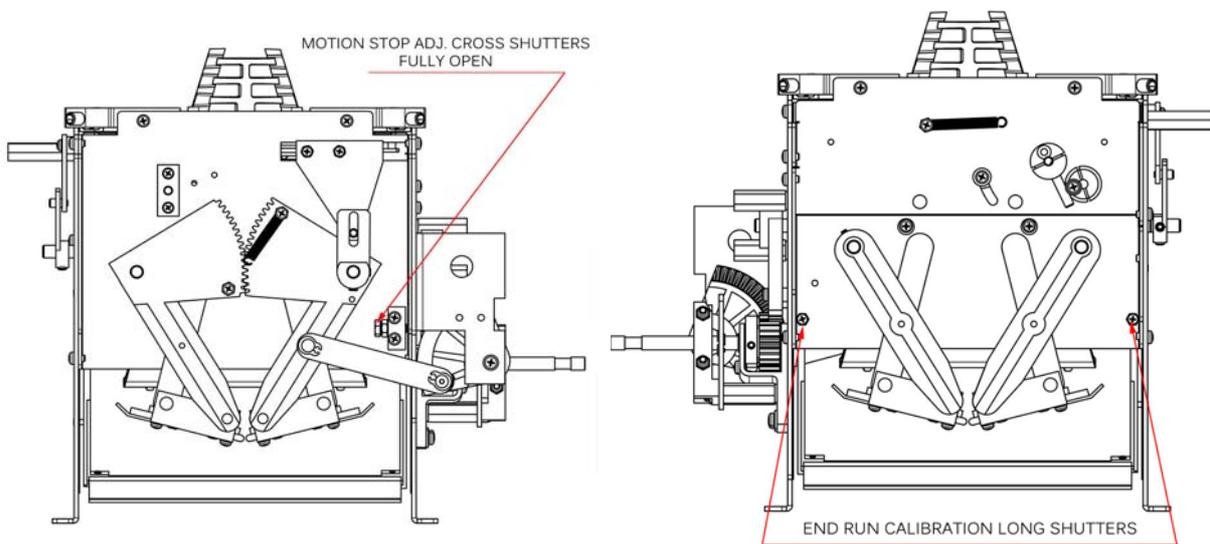
- If a shutter control is too tight, loosen one of the two screws **A** on the U bolt that frictions the shaft, see **Fig. Friction Brake**.
- Before replacing the knobs, close both shutters and mount/fix the knobs so that the field index is set at "0" (completely closed), see paragraph **Shutter Dial Adjustment** in this Chapter.

MECHANICAL MOTION STOP ADJUSTMENT

The purpose of these stops is to prevent stressing the control shafts of the shutters at the two limits of travel. This is done by limiting rotation of the control shafts.

- Adjustment of these stops will not be required unless:
 - The shutters can not be completely closed or opened to the largest size.
 - Torsion is felt at one or both ends of the travel.
 - The shutters themselves appear to limit the motion rather than the stops.

Fig. Long & Cross Shutters

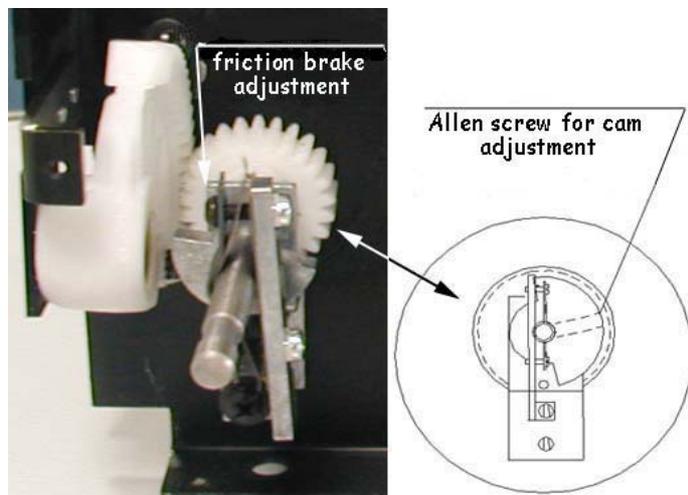


CLOSED Stop Long and Cross Shutters

The stop is effected by a cam

- Loosen the Allen screw placed on the side of the stop. See **Fig. Closed Stop**
- Use the knob to close the shutters. Take care not to apply excessive force to check that the shutters touch.
- Use the field light to check that shutters are closed.
- Rotate the cam stop to a stand still.
- Tighten the Allen screw.
- Open and close the shutters several times to check that they close/open fully and that, when they close, the cam touches the stop.

Fig. Closed Stop



R302/A - R302/A DHHS - Adjustments

TROUBLESHOOTING

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

The use of a faulty collimator might impair the safety of the operator and patient.

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**, paragraph **Repairs**.

Light Source

Problem	Cause	Solution
The light source fails to switch ON	Collimator supplied incorrectly	Check: Supply/Tension/Current/Polarity/Fuses
	Faulty light source	Check item Replace if necessary, see Chapter- SUBSTITUTIONS
	Faulty timer	Check timer supply Substitute if necessary, see Chapter- SUBSTITUTIONS
	Faulty ON/OFF push-button	Check contact Substitute if necessary
Light source fails to switch OFF	Faulty timer	Substitute timer
	Push-button is shorted	Substitute push-button

Centering

Problem	Cause	Solution
The light field of the collimator is not centered	The mirror or light source are not positioned correctly	See Chapter- CALIBRATION , paragraph Light Field to X-ray Field Alignment

Field Size

Problem	Cause	Solution
Faulty field size indication	Knobs are not regulated	Regulate, see Chapter- ADJUSTMENTS

Shutters

Problem	Cause	Solution
Shutters close	Friction is loose	Regulate, see Chapter- ADJUSTMENTS

SUBSTITUTIONS

SUBSTITUTION OF THE HALOGEN LAMP



WARNING: NOT IMMEDIATELY TOUCH THE DISSIPATER WITH YOUR FINGERS IT COULD BE HOT AND CAUSE SEVERE BURNS.



WARNING: DO NOT TOUCH THE LAMP, THE SOCKET, OR THE LAMP BRACKET WITH YOUR FINGER. THEY CAN BE VERY HOT AND CAUSE SEVERE BURNS.



WARNING: DO NOT TOUCH THE LAMP WITH YOUR FINGERS, EVEN WHEN IT IS COLD. OIL FROM YOUR SKIN WILL CAUSE THE LAMP TO CRACK AND POSSIBLY EXPLODE. IF YOU HAVE TOUCHED THE LAMP, WIPE THE SURFACE WITH ALCOHOL, THEN HANDLE THE LAMP WITH A PIECE OF PAPER.

- Disconnect power supply.
- Remove the part of the cover and/or the knobs to access the component, see Chapter- **COVER REMOVAL**.
- Remove the lamp protection heat sink.
- Carefully remove the faulty lamp.
- Substitute the lamp with an identical lamp.
- Make sure that the lamp pins are completely inserted in the lamp-holder.
- Check on light field/X-ray field correspondence, see Chapter- **ADJUSTMENTS**.
- If necessary remove the lamp, rotate it 180° axially and reinsert.

SUBSTITUTION OF THE ELECTRONIC TIMER

- Disconnect power supply.
- Remove part of the cover to access the component, see Chapter - **COVER REMOVAL**.
- Remove the two screws holding the electronic timer, see **Fig. Timer GC 338**.
- Identify the cables and their position on the terminal board, see Chapter- **INSTALLATION**, paragraph **Electrical Connection**.



Fig. Timer GC 338

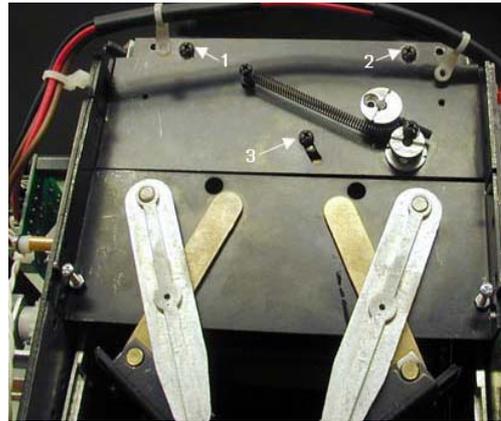
- Disconnect the cables from the terminal board.
- Install the new timer by proceeding in a reverse order; pay particular attention to the connection of the cables on the 4 or 6-way electric terminal depending in the model.

SUBSTITUTION OF THE MIRROR

- Remove the collimator cover, front panel and rear cover, see Chapter **COVER REMOVAL**.
- Remove the collimator lateral protection walls.
- Remove the mirror shaft stop on the left side of the collimator.



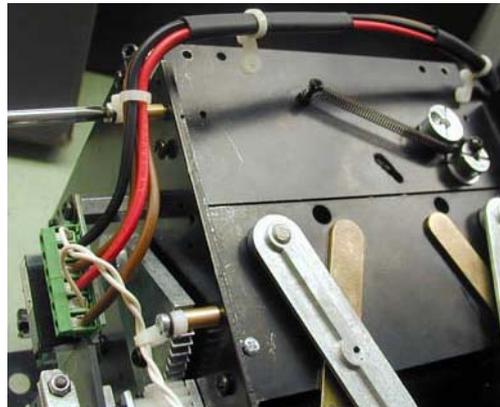
- Remove the three screws on the upper left partition.



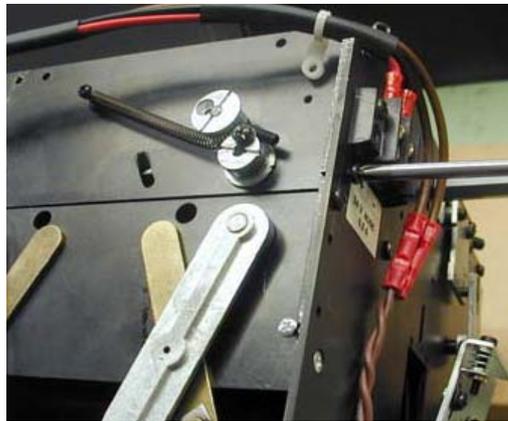
- Remove the two screws on the cable stops.



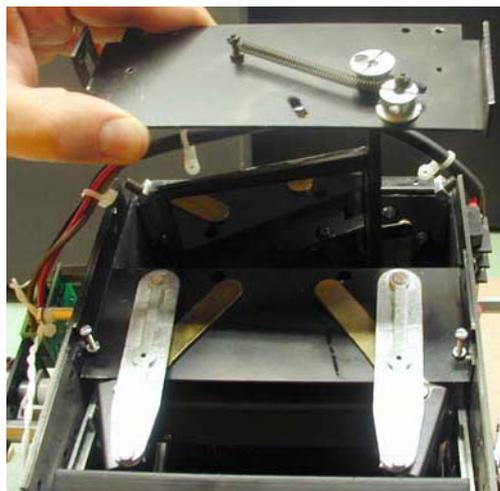
- Remove the cable stop located on the front partition of the collimator on the upper right hand side.



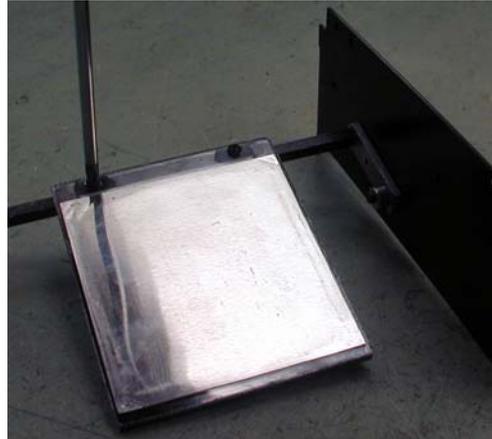
- Remove the screw on the rear partition of the collimator on the upper left hand side.



- Lift off the upper part of the right hand partition.



- Substitute the mirror and remount in reversed order.



SPARE PARTS

NOTE: When ordering spare parts, the customer is requested to specify the collimator model and serial number.

R302/A STANDARD

Cod.	Description
RS 006	Lamp, 24 V-100 W
RS 033	Lamp holder, ceramic R302/A
RS 047	Push-button
RS 063	Timer, electronic, GC 338-24V
RS 093	Mirror with support
RS 178	Knob
RS 390	Cover
RS 394	Guide for accessories, right
RS 395	Guide for accessories, left
RS 402	Panel, lateral, leaded
RS 403	Cover, upper, semicircular
RS 422	Panel, front, leaded up to s.n. 13771
RS 423	Cover, rear, leaded
RS 424	Frame, plastic
RS 578	Lamp holder support
RS 596	Screws, fixing for cover, T.C. M3x25
RS 797	Panel, front leaded from s.n. 13772
RS 1107	Panel, anti dust

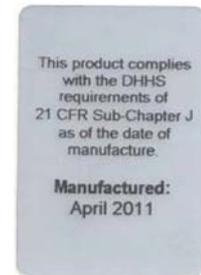
R302/A DHHS STANDARD

Cod.	Description
RS 006	Lamp, 24 V-100 W
RS 033	Lamp holder, ceramic
RS 047	Push-button
RS 063	Timer, electronic, GC 338-24V
RS 093	Mirror with support
RS 178	Knob
RS 265	Panel, anti dust - R302/A DHHS
RS 390	Cover
RS 394	Guide for accessories, right
RS 395	Guide for accessories, left
RS 402	Panel, lateral, leaded
RS 403	Cover, upper, semicircular
RS 421	Lamp holder, ceramic - R302/A DHHS
RS 423	Cover, rear, leaded
RS 424	Frame, plastic

R302/A - R302/A DHHS - Spare Parts

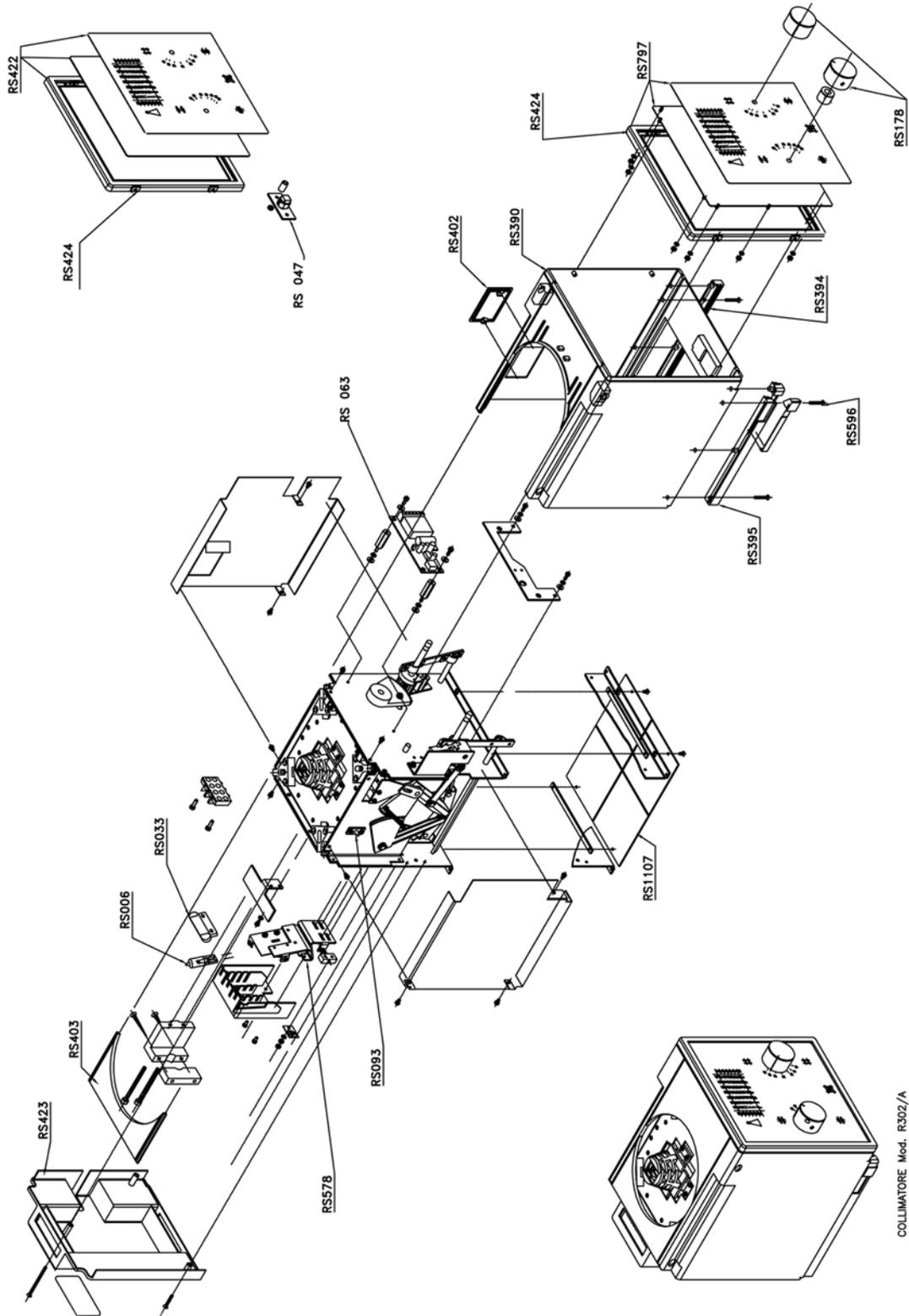
RS 578	Lamp holder support
RS 596	Screws, fixing for cover, T.C. M3x25
RS 796	Panel front, leaded - R302/A DHHS up to s.n.13771
RS 798	Panel front, leaded - R302/A DHHS from s.n.13772

LABELS



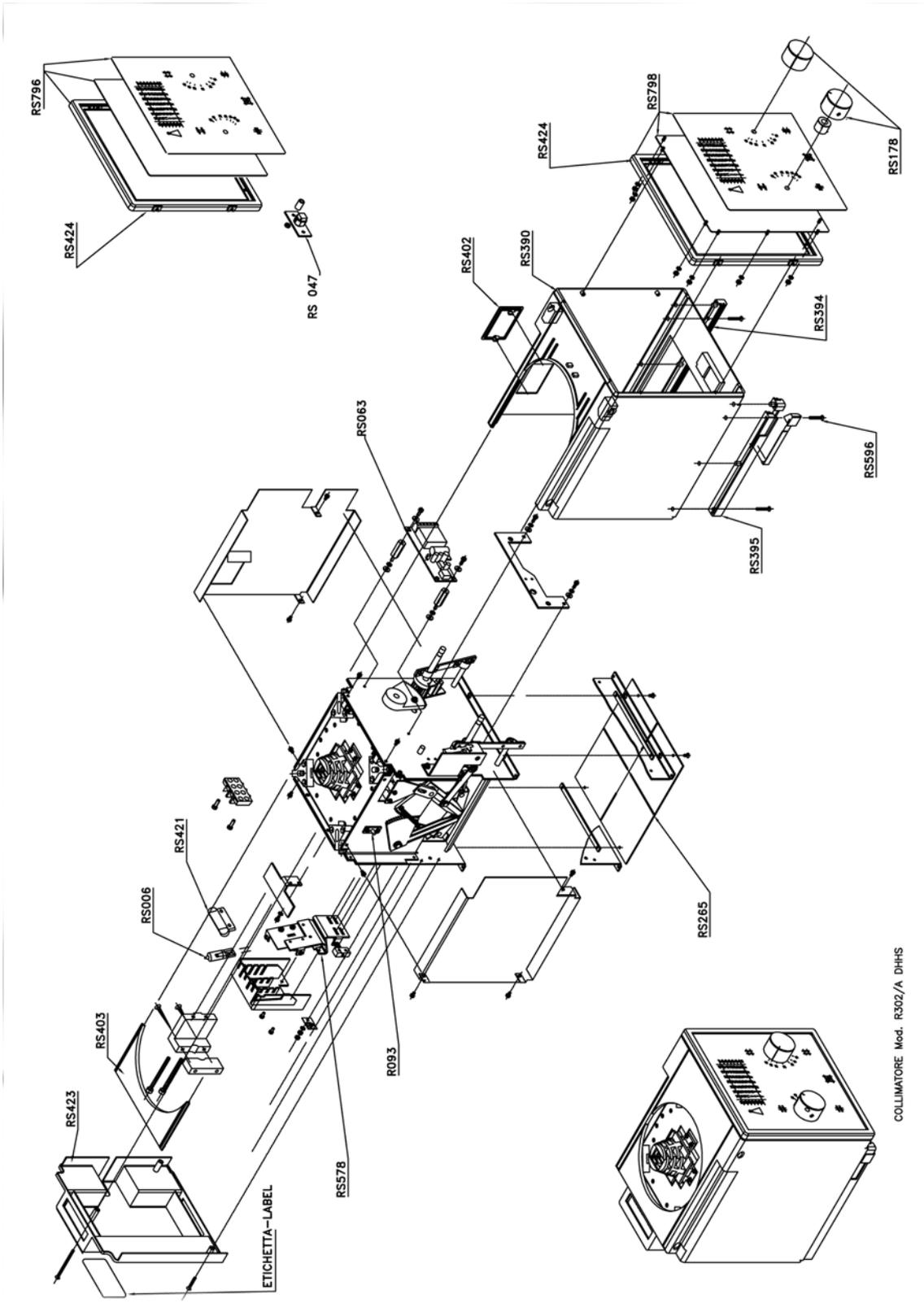
Parts Breakdown

R 302/A



R302/A - R302/A DHHS - Spare Parts

R302/A DHHS



R302/A - R302/A DHHS - Spare Parts

COLLIMATORE Mod. R302/A DHHS

OPTIONAL ITEMS

This collimator may have the following optional items; a detailed description is provided in this chapter.

RO 001/A Fixed Mounting Flange

Thickness of this mounting flange is 20 mm.

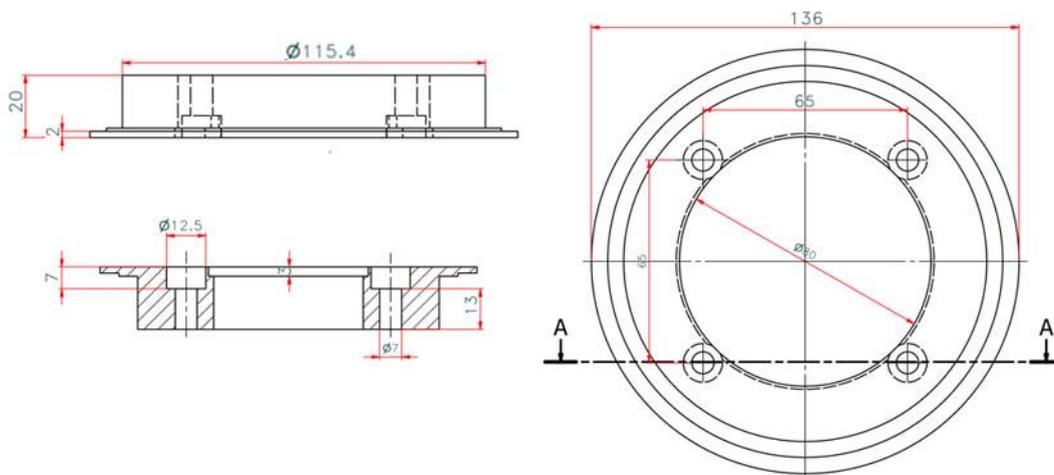
When the collimator is assembled check the collimator to Focal Spot Alignment (Primary Shutter Cut-Off).

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.



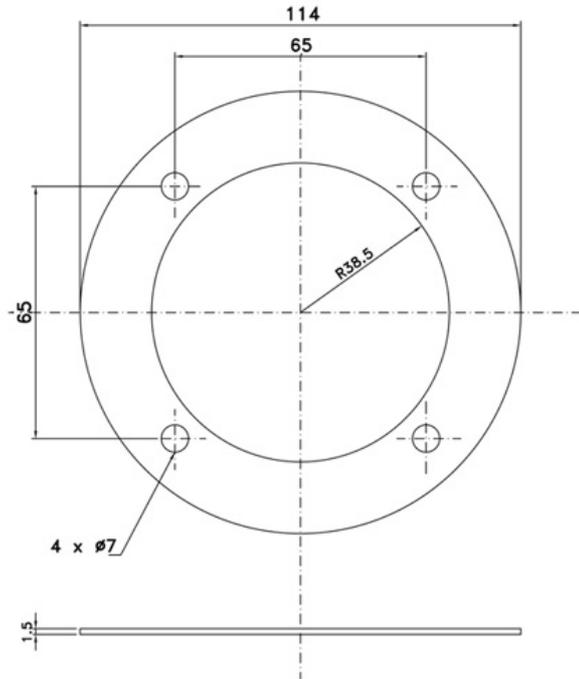
THE HEEL EFFECT WILL CAUSE THE FIELD TOWARD THE CATHODE TO BE SLIGHTLY LESS SHARP THAN ON THE OTHER THREE SIDES. THIS IS NORMAL AND CANNOT BE CORRECTED BY ADJUSTMENT. IN ADDITION, AN X-RAY TUBE OF 12° OR LESS TARGET ANGLE WILL PRODUCE AN ASYMMETRICALLY SHAPED FIELD WHEN A LARGE FIELD SIZE IS USED AT SHORT SID, BECAUSE OF ANODE CUT-OFF EFFECT. THIS IS NORMAL AND MAY NOT BE CORRECTED BY ADJUSTMENT.



R302/A - R302/A DHHS - Optional Items

RO 002 Iron Spacer

This accessory is used for the mounting flange; 1.5 mm thickness.



RO 012/B Retractable Tape

Mounted on a radiological unit, measures the distance between the focus and the patient.

	<p><i>Use of the retractable tape measure in collimators with this feature: 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:</i></p> <ul style="list-style-type: none"> • <i>Breakage of the tape or,</i> • <i>Distortion of the tape or,</i> • <i>Impossibility of retracting the tape into its lodging because the grip of the spring has been forced and hook-up is consequently distorted.</i> <p><u>NOTE:</u> DO NOT EXTEND THE TAPE BEYOND THE INDICATION OF STOP.</p>
---	---

RO 041 Mylar Mirror

Mylar mirror, internal filtration equivalent at minimum 0.3 mm Al.



R302/A - R302/A DHHS - Optional Items

RO 051 Rotating Mounting Flange

This accessory is used to rotate the collimator assembled to the X-ray tube.

- Flange thickness: 18 mm
- Flange diameter: 136 mm

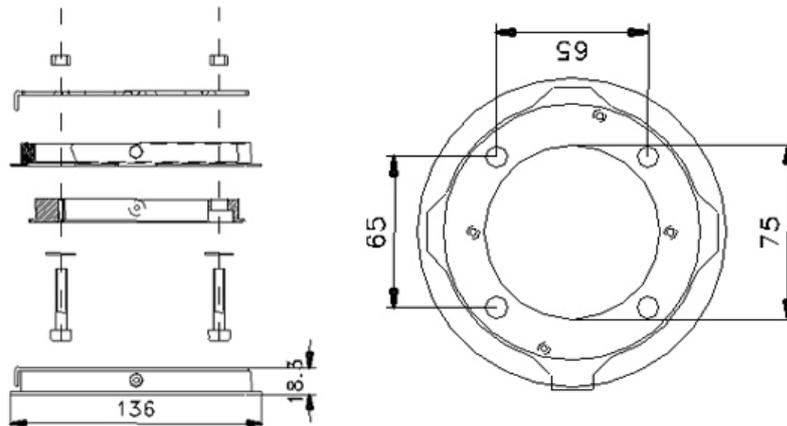
When the collimator is assembled check the collimator to Focal Spot Alignment (Primary Shutter Cut-Off).

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.

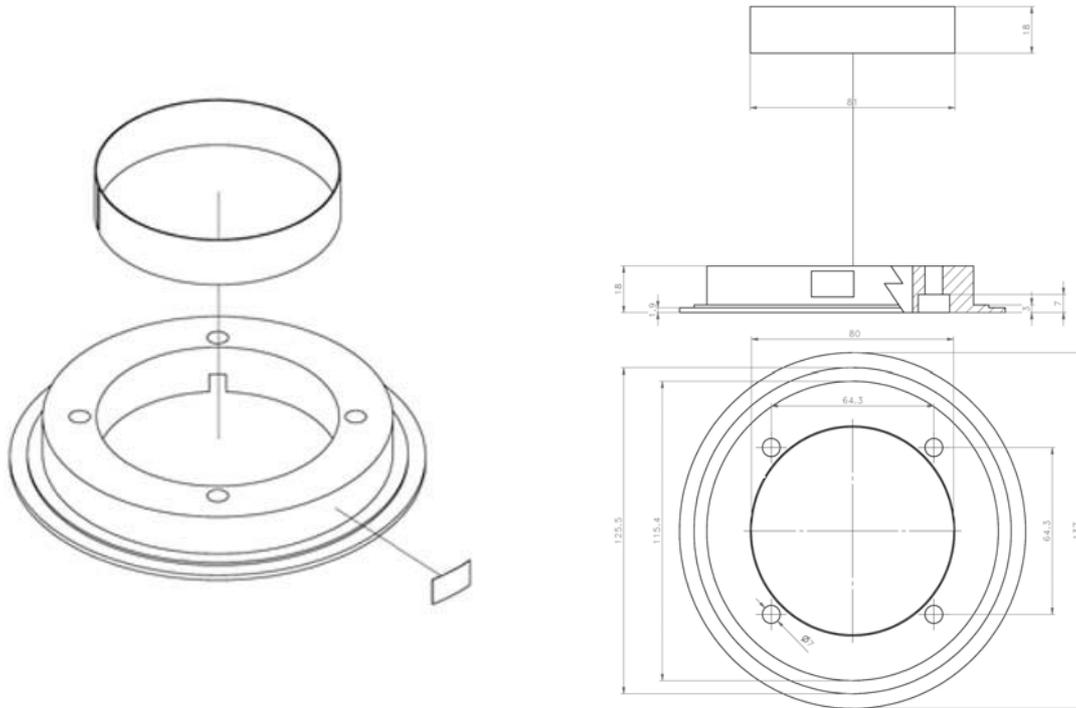


THE HEEL EFFECT WILL CAUSE THE FIELD TOWARD THE CATHODE TO BE SLIGHTLY LESS SHARP THAN ON THE OTHER THREE SIDES. THIS IS NORMAL AND CANNOT BE CORRECTED BY ADJUSTMENT. IN ADDITION, AN X-RAY TUBE OF 12° OR LESS TARGET ANGLE WILL PRODUCE AN ASYMMETRICALLY SHAPED FIELD WHEN A LARGE FIELD SIZE IS USED AT SHORT SID, BECAUSE OF ANODE CUT-OFF EFFECT. THIS IS NORMAL AND MAY NOT BE CORRECTED BY ADJUSTMENT.



RO 055/B Fixed Mounting Flange

Thickness of this mounting flange is 18 mm.



RO 063 Final Control Testing

This test provides higher control to check 100% of the production lot to verify product quality from beginning to 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 Customized Housing

The customer can specify a collimator housing color. Ralco's standard color is RAL9003.

R302/A - R302/A DHHS - Optional Items

RO 077 Centering Device

Centering device of the Potter Bucky (BL). Reflects the lamp light to form a bright line to align collimator to Potter Bucky.

Adjustment

- Remove the collimator rear cover to gain access to the point of adjustment, see Chapter **COVER REMOVAL**.
- The line is to fall on a perpendicular bisector line constructed against the anti-dust plastic panel toward the control face of the collimator.
- To adjust the position of the line, shift the light support group as required. Note that the support group and bracket are inside the collimator frame and cannot be seen, but may be controlled by the two securing screws **A**, see **Fig. Centering Device Adjustment**.

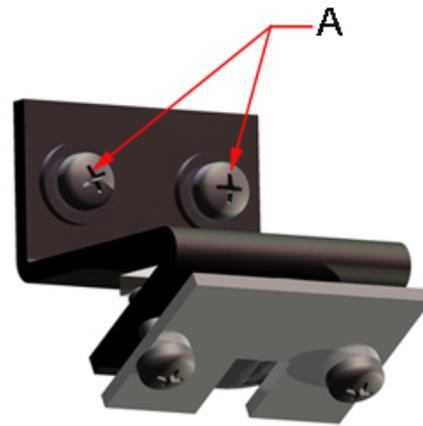


Fig. Centering Device Adjustment

RO 082 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 Customized Wiring

Customized electrical wiring, if ordered please see Chapter- **PERSONALIZATIONS**, paragraph **Wiring Diagram**.

RO 107 Customized Knobs

The customer can specify the required knob color.

RO 109 Customized Frame

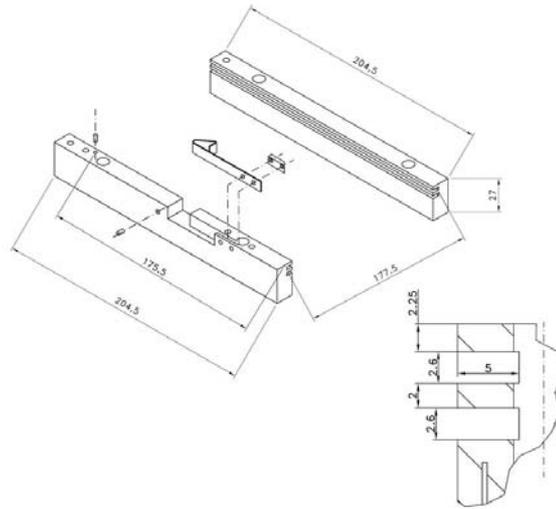
The customer can specify the required frame color.

RO 111 Customization of Front Panel

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

RO 161 Plastic Spacer Guides

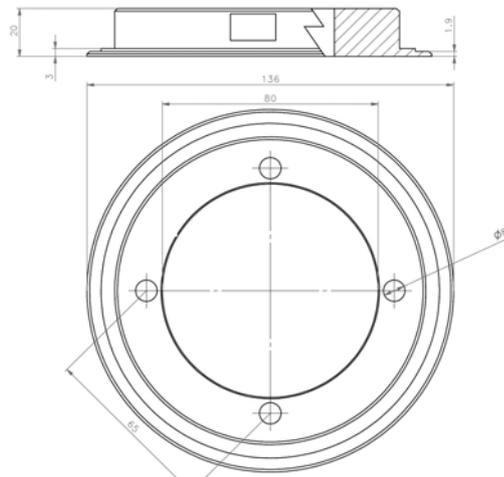
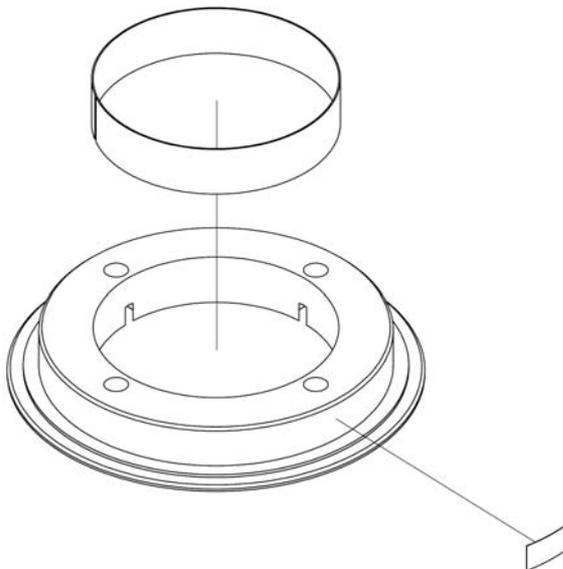
Pair of plastic rail guides designed to protect the ionization chamber and allow the insertion of other accessories.



RO 185/A Fixed Mounting Flange

This accessory is used to install the collimator to the X-ray tube.

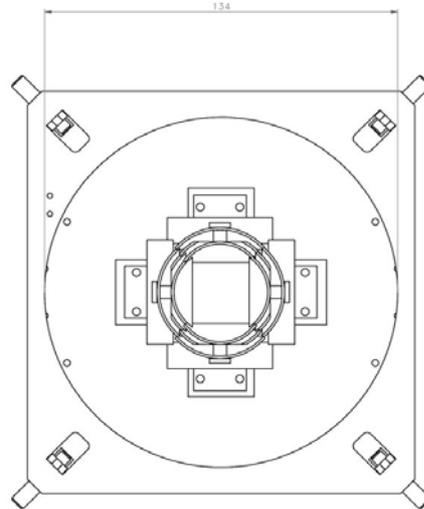
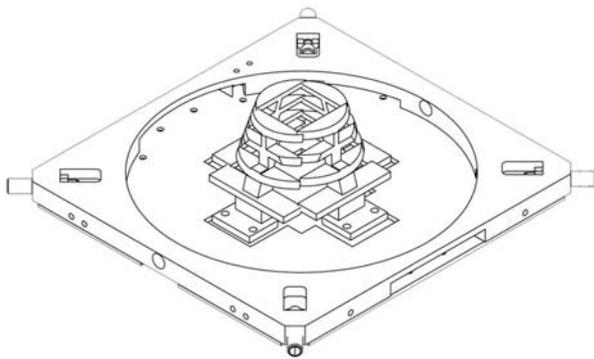
- 20 mm thickness



R302/A - R302/A DHHS - Optional Items

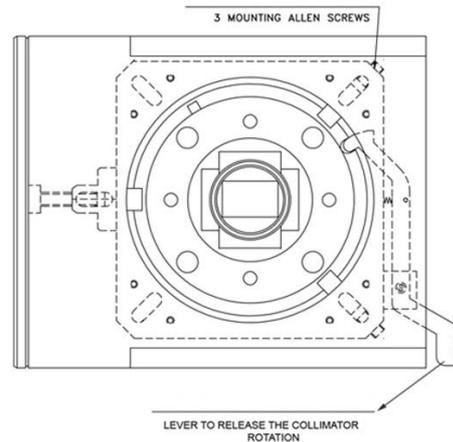
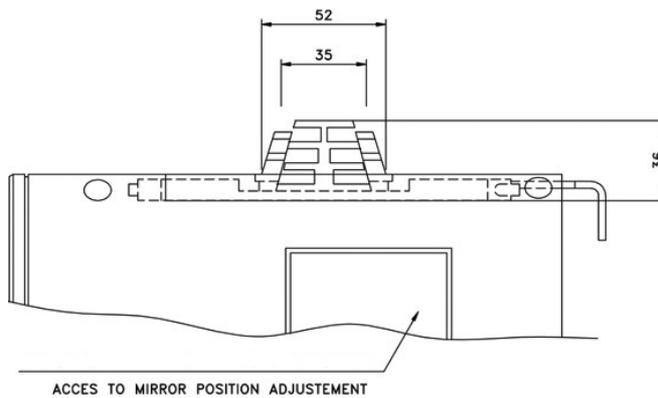
RO 202 Auto Centering Top Cover

This accessory is designed to precisely install the collimator to the X-ray tube with a metal flange and without any additional adjustment of light field to X-ray field.



RO 203 Auto-Centering Siemens Type Cover

This cover is designed to allow the attachment of the collimator to a Siemens X-ray tube.

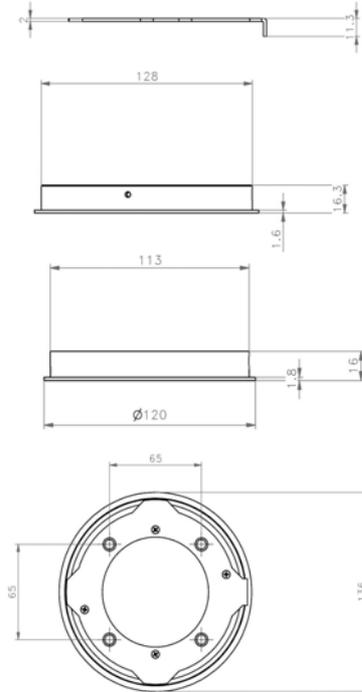
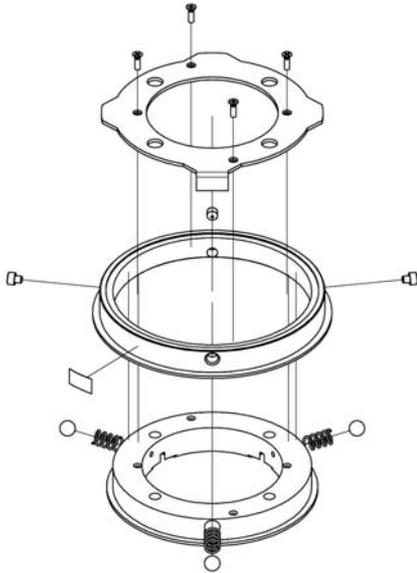


R302/A - R302/A DHHS - Optional Items

RO 222/A Rotating Mounting Flange

This customized accessory is used to rotate the collimator assembled to the X-ray tube.

- 136 mm diameter
- 18 mm thickness

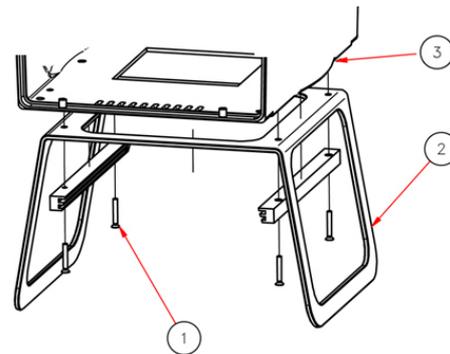


RO 240 Focus-Skin Distance Spacer

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



THIS ACCESSORY DEALS WITH PREVENTING THE USE OF INAPPROPRIATE SMALL FOCUS/SKIN DISTANCES IN ORDER THAT THE DOSE EQUIVALENT TO THE PATIENT BE KEPT AS LOW AS REASONABLY POSSIBLE.

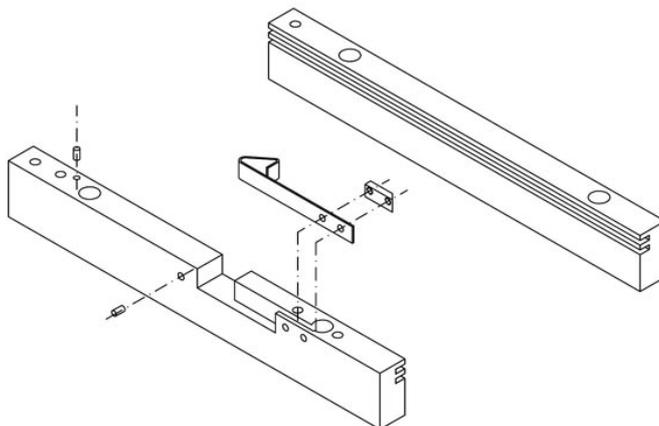


- 1 - Countersunk Screws, 2 - Focus-Skin Distance Spacers, 3 - Collimator Cover.

R302/A - R302/A DHHS - Optional Items

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 an aluminium 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 copper + 1 mm Al (Al eq. 2.8 mm)
- 0,2 mm copper + 1 mm Al (Al eq. 5.6 mm)
- 1 mm aluminum + 1 mm Al support.

Setup of Filters

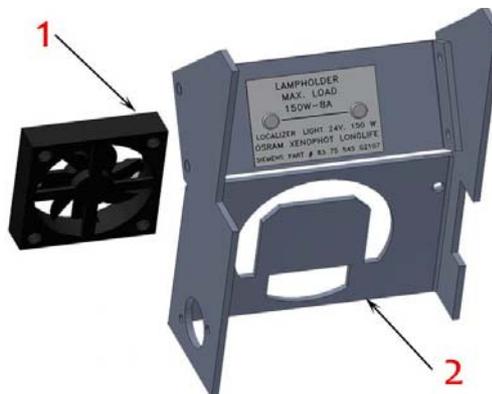
- Rotate the aluminium disc that protrudes from the filter opening on the front panel.
- Indication of the filtration value is provided on the upper part and lower rim of the disc; this value refers to the additional filtration in the X-ray beam.

RO 271 Lamp with Cooling

System lamp for high luminosity. This Lamp is complete with a cooler system kit which includes: fan, thermo probe, and timer board to limit lamp ON cycles.

Power Supply: 24 V 150 W - 8 A

Fuse for power supply protection collimator: T 10 A (not supplied by Ralco).



1 - Fan, 2 - Heat sink

R302/A - R302/A DHHS - Optional Items

RO 318 Auto Centering Cover with Plastic Flange

This accessory is designed to allow rotation and precisely install the collimator to the X-ray tube through the plastic flange.

The mounting flange is provided with the collimator top plate. Place the flange with the letter F (front/knob) turned toward the X-ray tube front using countersink screws.

For the collimator to rotate to position "Ø", two of the four tabs retract to allow to rotation. Adjust and tighten the four Allen screws as follows:

screws 1 and 3 = 7 turns until the tongue touches slightly the flange;

screws 2 and 4 = 5½ turns exactly;

See **Fig. Mounting Flange** in this chapter. Please Note: If Allen screws "2" and "4" are tightened more than 5 ½ turns, the collimator will not rotate.

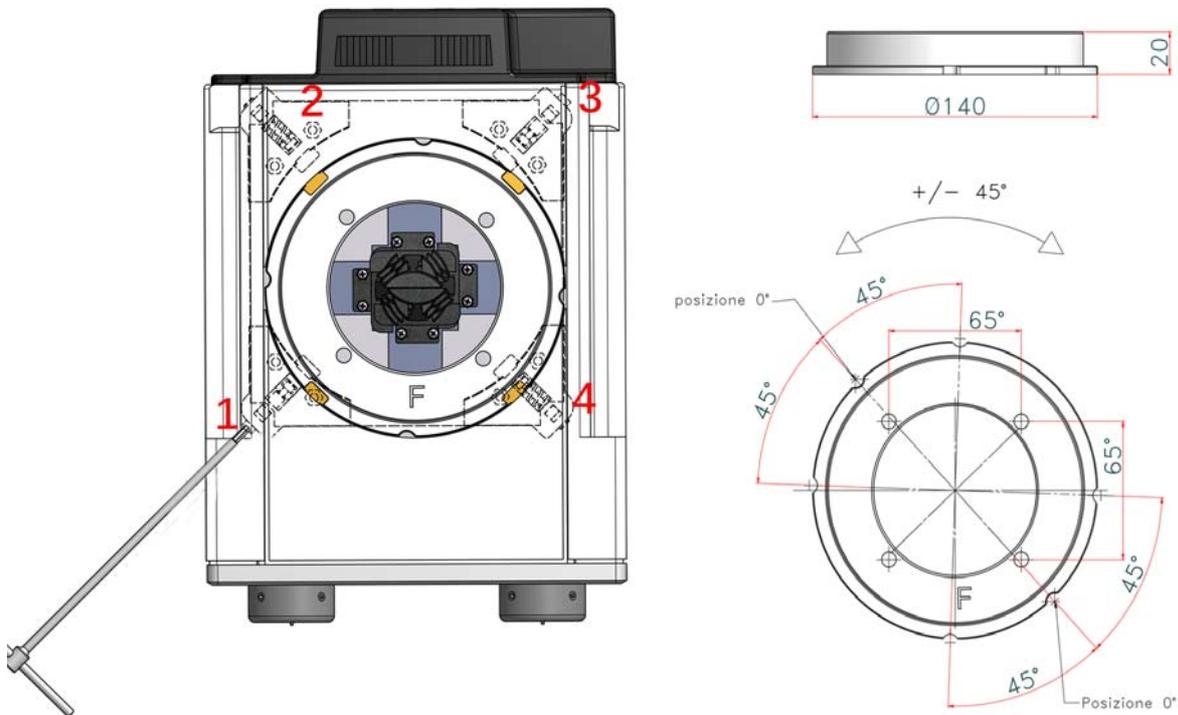
The collimator control tabs conform to **EN60601-1**. Secure the tabs along the edge of the mounting flange but do not lock them. Excessive tightening of the tabs prevents collimator rotation.



Check that the distance between the collimator housing and the mounting flange is equal in all directions and, that the collimator face is parallel to the table axis.

Loosen the screws and adjust if required.

Fig. Mounting Flange



Screws 1 e 3= Tighten fully.

Screws 2 e 4= from position completely open, tighten 5½ turns to ensure collimator rotation. Tighten these screws to stop collimator rotation.

RO 333 White LED

The white LED which substitutes the halogen lamp has a higher luminosity (>250 lux a SID of 1 m) and a longer life (60,000 hours). The board GC-Led-5A supplies the LED and a fan for cooling is supplied by a 12-45 V DC 30 CA/20 - 30 V AC 30 V A - 50/60 Hz.

The white LED can be adjusted vertically, longitudinally and laterally.



1 - Fan, 2 - LED, 3 - GC-LED-5A Board

Vertical Alignment

- Remove the part of the cover necessary to access the screws, see Chapter - **COVER REMOVAL**.
- If adjustment is required loosen the two screws **C** holding the light support.
- If the light-field is smaller than the X-ray field, lower the light source by adjusting screw **D**.
- If the light-field is bigger than the X-ray field, raise the light source by adjusting screws **D**.
- Tighten the two screws **C**.

See Fig. *Light Field Adjustment*

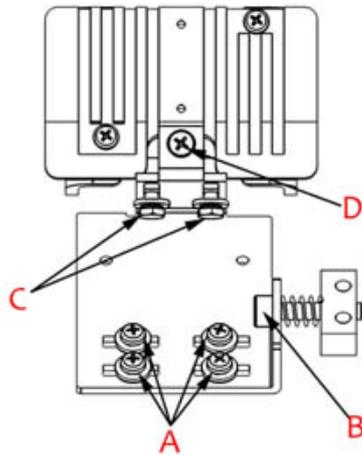
Longitudinal Alignment (Long)

	<p>DO NOT TOUCH THE DISSIPATER WITH YOUR HANDS; IT COULD BE HOT AND CAUSE SEVERE BURNS.</p>
---	---

- Remove part of the cover, see Chapter - **COVER REMOVAL**.
- If the light-field needs to be moved laterally, loosen (not remove) the fixing screws **A**.
- Use screw **B** to adjust transversely.
- When calibration is terminated, lock the screws **A**.

See **Fig. Light Field Adjustment**

Fig. Light Field Adjustment

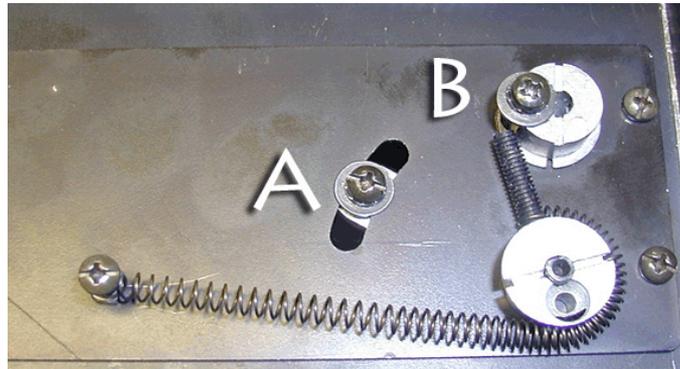


Transversal Calibration (CROSS)

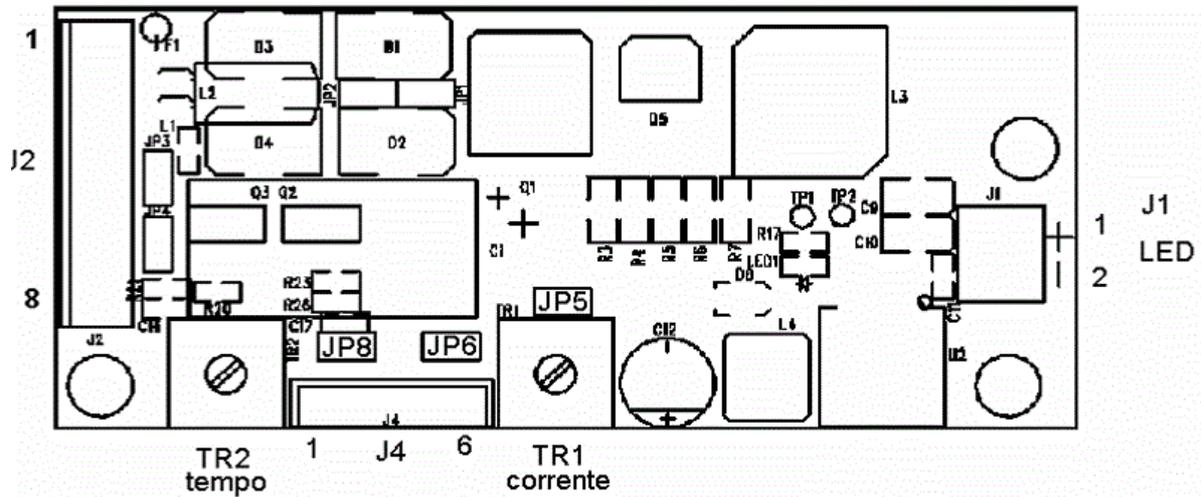
If the light-field needs calibration, the mirror needs to be adjusted as follows:

- Remove the part of the cover necessary to access the screws, see Chapter - **COVER REMOVAL**.
- Loosen the mirror fixing screw **A** (not remove) and shift it to adjust the position of the mirror, see **Fig. Transversal Calibration (CROSS)**.
- Once you have regulated the mirror tighten the screw **A** and remount the cover, see Chapter - **COVER REMOVAL**.

Fig. Calibrazione Trasversale (CROSS)



GC-LED-5A Board



CONNECTORS

<p>J2 - SUPPLY AND OUTPUTS</p>	<ol style="list-style-type: none"> 1. 20-30 V AC or 12-45 V DC 2. 20-30 V AC or 0 V DC 3. +5 V Fan 4. GND Fan 5. +5 V Laser 6. GND Laser 7. + Power-up/Power down external push-button 8. GND Power-up external push-button
<p>J1 - LED OUTPUT</p>	<p>+ LED 5 A positive output - GND Led 5A</p>

R302/A - R302/A DHHS - Optional Items

J3 - PROGRAMMING CONNECTORS	<ol style="list-style-type: none"> 1. Vpp 2. +5 V 3. GND 4. PGD 5. PGC 6. NC
J4 - HOME SENSOR INPUT + EXTERNAL LED	<ol style="list-style-type: none"> 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)
Jumpers	<p>OFF: without jumper ON: with jumper</p>
JP1, JP2 - ALTERNATE/DIRECT POWER SUPPLY	<p>OFF: alternate power supply ON: direct power supply (pay attention to polarity)</p>
JP3 - FAN POWER SUPPLY	<p>OFF: fan is operated by micro controller according to settings made with LED ON: fan is always supplied</p>
JP4 - LASER POWER SUPPLY	<p>OFF: Laser is micro controller operated ON: Laser is always supplied</p>
JP5 - CONFIGURATION OF PUSH-BUTTON NUMBER OUTPUT	<p>OFF: LED and laser are controlled by only push button (on J2) ON: LED is controlled by standard push button (on J2), laser is controlled independently by push button on JP6.</p>
JP6 - BUTTON INPUT FOR LASER ON TIME.	<ol style="list-style-type: none"> 1. Laser ON button pin 1 2. Laser OFF button pin 2
JP8 - CONFIGURATION OF LED ON TIME	<p>Laser is controlled independently by the timer, this configuration is applicable in the same manner for both push buttons.</p> <p>OFF: output status is changed by pressing button (if the light is OFF will be ON and vice versa).</p> <p>ON: the timer operates in the time renew mode. When the button is pressed the time is renewed without the LED OFF (if the LED is ON it will stay ON but with the time reset). The same is applicable for the laser if is independent.</p>
FAN	<p>The fan switches ON together with the LED, and operates 15 seconds longer after the LED OFF.</p>
IMPORTANT	
JP7 - PROGRAMMING OF MICROCONTROLLER PIC16F52	<p>OFF - Pic16F526 may be programmed by removing JP8 (thermistor input) from Pic ON - JP8 connected to Pic prevents reprogramming</p>

R302/A - R302/A DHHS - Optional Items

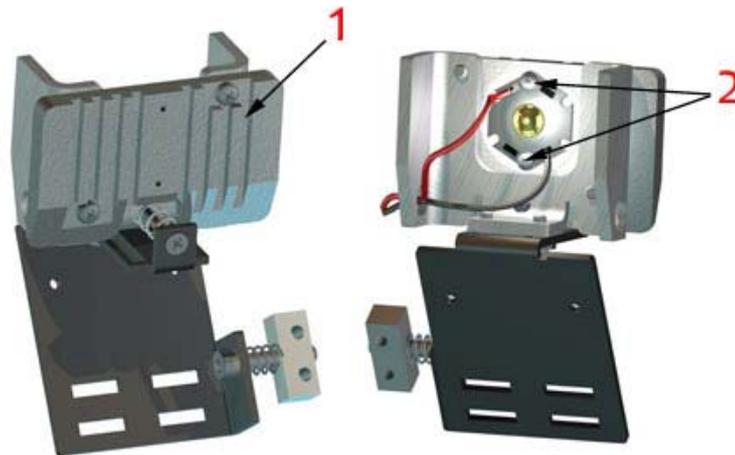
Trimmers

<p><i>TR1- CURRENT CONTROL</i></p>	<p>Adjust the output current intensity to the LED. Step-less current adjustment from 0 to 5.1 A. Adjusting current to approximately 3.4 A (+/- 5%) will increase LED life without a significant loss of luminosity.</p>
<p><i>TR2 - TIME ADJUSTMENT</i></p>	<p>Adjusts the time from 30s to 120s up to 90% of run, maximum light ON time is 15 min. for safety reasons. When the timer is regulated at over 120s (i.e. 100% of its adjustment), the timer performs as power supply: it starts by powering-up the LED and other features such as laser and fan. In this case, maximum light ON time is 15 min. for safety reasons.</p>

LED Substitution

- Disconnect supply.
- Remove the cover, see Chapter - **COVER REMOVAL**.
- Remove the LED protection heatsink.
- Unsolder two wires. See **Fig. LED Substitution**.
- Unscrew two fixing screws. See **Fig. LED Substitution**.
- Remove the faulty LED.
- Substitute the LED with an identical item; handle it gently and make sure it doesn't get dirty.
- Tighten the two fixing screws.
- Solder the two wires.
- Check on light field/X-ray field correspondence.

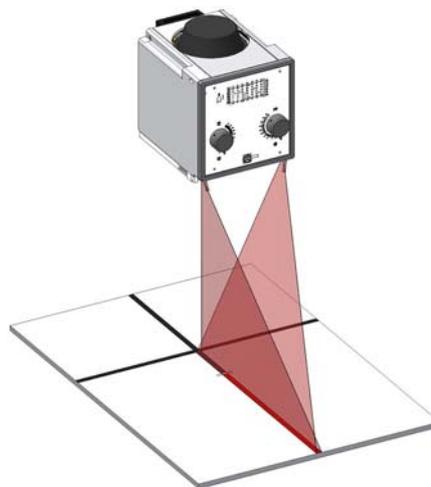
Fig. LED Substitution



1 - LED protection heatsink 2 - Fixing screws

RO 339 Double Laser for Optical SID

The collimator has two lasers which serve for the optical definition of the prefixed SID. The lasers are mounted behind the front panel. Two laser lines must measure 60 cm (+/-1) at 1 m (+/- 0.5cm) and projected at 10 cm (+/-1) from the centre of the light/X-ray field. The projection of a single line signifies that the two lines overlap and consequently the lasers are correctly focussed at the SID set. The projection of two laser lines signifies the SID value has not been entered correctly. See fig. **Laser Line**.



CAUTION: CLASS II 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**.
- Adjust the position of the line by rotating or moving the base of the laser system.
 - To rotate the laser system, loosen the Allen screw **A**, see **Fig. Laser Adjustment**.
 - Tighten the Allen screw when the laser beam falls on or is parallel to the bisector line drawn on the anti-dust panel.
- Shift the laser system by loosening the two **B** screws 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 Adjustment**.
 - Tighten the screws **B**.

Fig. Laser Line

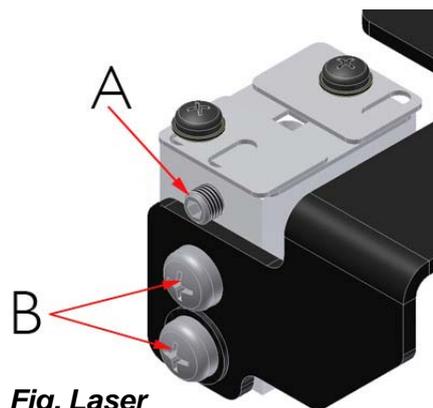


Fig. Laser Adjustment



DO NOT APPLY EXCESSIVE FORCE TO THE SCREW. THE LASER SHELL IS IN PLASTIC AND EXCESSIVE PRESSURE COULD CRACK THE PLASTIC AND POSSIBLY SHORT-CIRCUIT THE LASER.

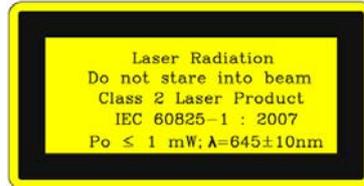
Substitution

- Disconnect supply.
- Remove the cover, see Chapter- **COVER REMOVAL**.
- Unscrew the fixing Allen screws **A**, see **Fig. Laser Adjustment**.
- 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.

R302/A - R302/A DHHS - Optional Items

- Check the laser alignment, see Chapter- **ADJUSTMENTS**.
- Remount the cover, see Chapter- **COVER REMOVAL**.

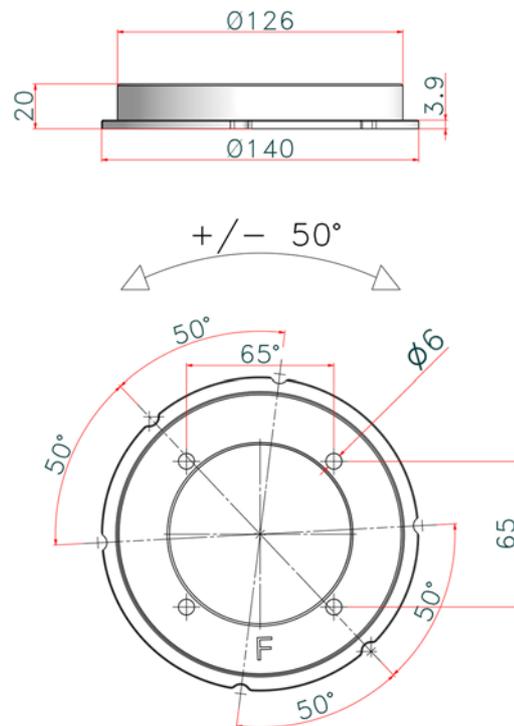
Classification EN 60825-1 par. 1 -5: Class 2 laser product => Red laser line.



RO 441 Plastic Flange, 50° Rotation

Plastic flange with notch allowing +/- 50° rotation of the collimator without stop, 20 mm thickness.

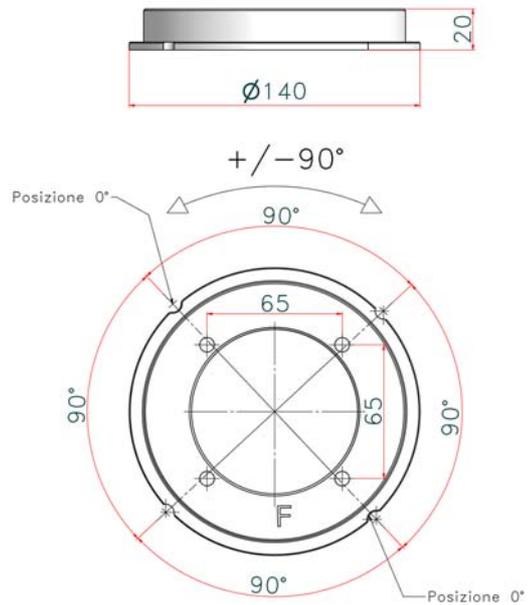
Available only if collimator is assembled with optional item RO 318.



RO 442 Plastic Flange, 90° Rotation

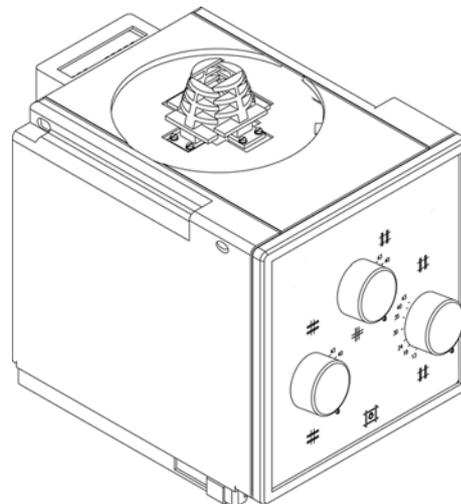
Plastic flange with notch allowing +/- 90° rotation of the collimator without stop, 20 mm thickness.

Available only if collimator is assembled with optional item RO 318.



RO 452 Independent Long Shutters

Each single Long shutter is moving through a knob on the front panel.



R302/A - R302/A DHHS - Optional Items

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.



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.



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 lamp used to simulate the light field.
- Calibration procedures 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.



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.



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 to the highest quality standards by Ralco, srl. 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;
- 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 your 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 paragraph, **WARRANTY**.

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

Please send defective material to the 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



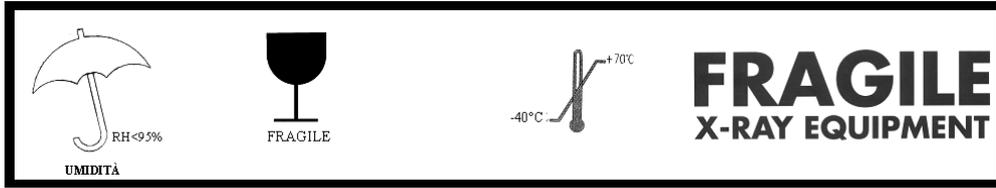
CARE MUST BE TAKEN NOT TO LET THE COLLIMATOR FALL.

- 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

- Suitable packing must be provided for the collimator.
- Place the collimator in a plastic bag to avoid packing material from entering the collimator.
- Use an appropriate packing for transport, shipment or storage; the collimator must be protected from rough handling. This will avoid damage to the collimator during transport, shipment or storage.
- Limit Storage conditions:
 - Ambient Temperature = from -40°C to +70°C
 - Relative Humidity = from 10% to 95%

- Atm. Pressure = from 500 a 1060 hPa.



images\collimator\fig

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.



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: p.vescera@ralco.it

Date:

Customer:

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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:

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