

# Collimator ML03

## Operator Manual

[www.siemens.com/healthcare](http://www.siemens.com/healthcare)



## Legend

- ✓ Prerequisites
- ◆ Instructions
- Text lists
- Cross reference



### **X-ray radiation**

Warning of ionizing radiation.

## General Note

Before using this product

This product should be used only by employees adequately trained in the use of this equipment.

Before using this product, the operator should be thoroughly acquainted with the instructions for use and safety recommendations provided in this manual.



Failure to follow the instructions for use and safety recommendations provided in this manual can cause serious injury to the patient, the operator or other persons.

## Disclaimer

The contents of this document may be published under a system integrator's/manufacturer's label, but it is the sole responsibility of the system integrator of the finished medical device that content and safety measures described within this document are maintained and clear to the end user.

The system integrator is responsible for translations of this document and to provide the language versions that might be required under country specific regulations.

These components and configurations are not finished medical devices. The system integrator is responsible for complying with all laws and regulations that are applicable to finished medical devices with respect to marketing, sales and installation.

- Electromagnetic compatibility (EMC)** This Collimator is intended for use by healthcare professionals only. This Collimator may cause radio interference or may disrupt the operation of nearby equipment.  
It may be necessary to take mitigation measures, such as re-orienting or relocating the Tube Stand or shielding the location.
- Original language** This Manual was originally written in English.

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# Introduction

## Introduction

### Intended Use

This/these collimator/s is a/are standard, diagnostic X-ray beam-limiting and shaping device/s which is/are intended to be integrated in diagnostic X-ray systems. An X-ray collimator is used to limit the effects of scattered radiation on image quality, and to provide patient protection by eliminating exposure to non-target body areas.

### Product model

10911200 Collimator ML03

### Collimator ML03 Optional Parts

Part number	Optional parts	Description
10911469	Front Panel_assm CM without prefilter	Format scale in cm on the front panel without prefilter, Color: C610
10911470	Front Panel_assm Inch without prefilter	Format scale in inch on the front panel without prefilter ,Color: C610
10911295	Pre-Filter Unit	0.1mm,0.2mm , 0.3mm Cu combination filtration tablets
10911268	Front Panel_assm CM with prefilter	Format scale in cm on the front panel with prefilter, Color: C610
10911468	Front Panel_assm Inch with prefilter	Format scale in Inch on the front panel with prefilter, Color: C610
10911546	additional 1 mm Al filtration for in total 2 mm inherent filtration of the collimator	to reach the minimum required filtration at system level depending on the tube filtration
3099892	Laser Unit	Assistance Center positioning line
7736759	Focal blade unit	Reduction of extrafocal radiation
10911591	Lead Cone	Reduction of extrafocal radiation
10911300	Tape Ruler	For measuring the distance of SID
10911472	Siemens/Kailong/Toshiba 53 Tube Flange	Adapt for Siemens/Kailong/Toshiba Tube with 53 mm focal spot to tube port distance
10911471	Varian Tube Flange	Adapt for VarianTube
10645089	IAE Tube Flange	Adapt for IAE Tube
10911473	Toshiba 56 Tube Flange	Adapt for Toshiba Tube with 56 mm focal spot to tube port distance
10911547	Toshiba 60 Tube Flange	Adapt for Toshiba Tube with 60 mm focal spot to tube port distance
10911517	RAL9003 Cover Unit	Cover unit, Color: RAL9003
10911518	C610 Cover Unit	Cover uni,t Color: C610



# Introduction

10911519	RAL 9003 Front Panel_assm CM without prefilter	Format scale in cm on the front panel without prefilter, Color: RAL 9003
10911520	RAL 9003 Front Panel_assm Inch without prefilter	Format scale in inch on the front panel without prefilter, Color: RAL 9003
10911521	RAL 9003 Front Panel_assm CM with prefilter	Format scale in cm on the front panel with prefilter, Color: RAL 9003
10911522	RAL 9003 Front Panel_assm Inch with prefilter	Format scale in inch on the front panel with prefilter, Color: RAL 9003

# Introduction

## Features and Benefits

- ◆ Simple mounting on the tube flange.
- ◆ Comfortable operation by means of all controls on the front side.
- ◆ Simple rotating of the collimator at the tube (45°) by means of a swiveling flange with stop in 0° position.
- ◆ Integrated pre-filter assembly engineered to reduce the dose.(optional)
- ◆ Source image distance control in a user friendly way by means of a measuring tape. (optional)
- ◆ Line light indicator (laser) for centering the film cassette. (optional)
- ◆ Light field powered by LED with very high brightness and lifetime.
- ◆ Accessory rails for additional filters.
- ◆ This product belongs to Class I according to IEC 60601-1:2012+C1:2012.

## Standards compliance

The following standards for product development apply:

- ◆ IEC 60601-1:2012+C1:2012, Medical electrical equipment – General requirements for basic safety and essential performance
- ◆ IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic disturbances-Requirements and tests
- ◆ ISO 14971:2007, Medical devices - Application of risk management to medical devices
- ◆ IEC 60601-1-3/A1:2013, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment
- ◆ IEC 60601-2-54:2015, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- ◆ IEC 60825-1:2014, Safety of laser products-Part 1: Equipment classification and requirements
- ◆ EN 980:2008 Symbols for use in the labelling of medical devices
- ◆ IEC 63000:2016 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

# Introduction

This component has been manufactured and developed in agreement with the applicable requirements according to the following laws, directives and design regulations:

- ◆ Council Directive RoHS directive 2011/65/EU with 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, following the requirement of standard EN IEC 63000:2016.
- ◆ WEEE Directive 2012/19/EU on waste electrical and electronic equipment

## Chinese Standards:

- ◆ GB 9706.1: 2007 (IEC 60601-1: 1988) Medical electrical equipment - Part 1: General requirements for safety
- ◆ GB 9706.12:1997 (IEC 60601-1-3: 1994) Medical electrical equipment-Part 1: General requirements for safety 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment.
- ◆ YY/T 0291: 2016 Environmental requirements and test methods for medical X-ray equipment
- ◆ GB/T 191: 2008 Packaging-Pictorial marking for handling of goods

# Introduction

## Acronyms and abbreviations

<b>DAP</b>	<b>Dose Area Product</b>
<b>DIN</b>	German Institute for Standardization (= Deutsches Institut für Normung e.v.)
<b>EN</b>	European Standard
<b>EPRC</b>	Electronic Product Radiation Control
<b>IEC</b>	International Electrotechnical Commission
<b>PCB</b>	Printed Circuit Board
<b>SID</b>	Source Image Distance
<b>OEM</b>	Original Equipment Manufacturer
<b>RöV</b>	X-ray Ordinance (Roentgenverordnung)
<b>VDE</b>	Association for Electrical, Electronic & Information Technologies (= Verband der Elektrotechnik Elektronik Informationstechnik e.V.)
<b>ISO</b>	International Standardization Organization
<b>GB</b>	Chinese National Standard
<b>YY</b>	Chinese Medical devices and Medicine Industrial Standard

### Information about This Manual

To ensure proper installation, maintenance, or repair of the product, carefully read and understand the instructions in this manual. In addition, comply with country specific regulations and keep this instruction for future reference.

### General Information

**Scope of applicability** This manual describes all product features.

#### Note

**The complete product is described with all options and accessories that have been released. Possible options have not been specially marked.**

**Particular options or accessories may not be available for specific products.**

The quotation text of your order is the sole reference for the functional scope of your product.

- ◆ Particular options or components may not be available for specific products.
- ◆ If a specific feature is missing in your product, please contact your local sales representative.

**Installed product components** When reading this manual please remember that some components described herein may not be installed in your configuration.

On the other hand, you will find further information in separate manuals for some components and options installed in your product, if they are not described in the following chapters.

**Third-party components** Please refer to the relevant documents from the supplier for a description and information on the operation, design and technical data of third-party components.

# Safety

**Conditions** The product must only be used by persons with the necessary specialist knowledge after training, e.g., Radiology Technician Assistants.

- Patient population: newborn to geriatric.
- Operator profile: Use of the product described in this manual requires specific technical and medical knowledge and skills, at least in radiation protection, safety procedures and patient safety. Clinical standards for hygienic topics must be followed. Persons using, moving or working with the product must have acquired such knowledge and skills during their curriculum.
- Language understanding: Users must understand the language of the manual before using the product.
- Manual and precautions: Read and understand all the instructions in the manual before using the product and request additional training from the manufacturer, if needed.

Keep the manual with the equipment at all times and periodically review the procedures and safety precautions.

**Failure to follow the operating instructions and safety precautions could result in serious injury to the patient, others or yourself.**

- Patient safety: Be sure all patient supply lines (IV, oxygen, etc.) are positioned so they will not be caught when moving the equipment. Never leave the patient unattended while in the room. An unattended patient could activate a motion control, or encounter other problems which could be hazardous.
- Radiation safety: Always use proper technique factors for each procedure to minimize X-ray exposure and to produce the best diagnostic results.
- Establish emergency procedures: It is not always possible to determine when some components, such as X-ray tubes, are nearing the end of their operating lives. These components could stop operating during a patient examination.

**Establish procedures for handling the patient in case of the loss of product functions during an examination.**

# Safety

**Safety** Always pay attention to the relevant safety information.  
Disregarding the information on safety is considered abnormal use.

**Statutory regulations** If legally binding regulations govern the installation and/or operation of the product, it is the responsibility of the installer and/or the operator to observe these regulations.

# Safety

## Structure

<b>Parts</b>	This manual comprises of different parts. The part title is stated in the first header line.
<b>Chapters</b>	Each part may contain one or more chapters. The chapter title is stated in the second header line.
<b>Page numbers</b>	The footer contains the page numbers and the overall number of pages. The page numbering is continuous throughout the entire manual.

### Note Example for Note

Note	A note emphasizes important information without there being direct danger and helps you to operate the product properly and to avoid errors. It also provides additional useful explanations about a subject.
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### Example



Refers to information that is important for the safe operation of the system without presence of any hazard to health or life.

## Structure of Safety Information



### Warning/ Caution

#### Warning/Caution

Cause/Source of danger

#### Possible consequences

Precautions or remedies

**Warning** indicates a hazardous situation which, if not avoided, could result in death or serious injury.

**Caution** indicates a hazardous situation which, if not avoided, may result in minor or moderate injury or property damage.



# Safety

## Pictograms

The following are pictograms and their meanings as they may apply to your product (IEC standard).



Alternating current



Equipotential bonding

## Warning Signs

Special danger points are marked on the unit with a warning signs.

**General danger** Follow instructions for use.



## Illustrations

All illustrations of the equipment and of the user interface in this manual are examples only.

Differences in detail may occur in your product due to the installed options, configuration and constant development of the product.

Reproduction of images can cause loss of detail. Pictures in this manual do not therefore provide any indication of image quality.

All names of patients in images or illustrations are purely fictional. Any similarities with existing persons are entirely coincidental.

## Value statements

All technical data are typical values unless specific tolerances are stated.

Values in pictures of the software user interface have no clinical meaning.

Only set the values preset in the exam sets provided or the values recommended by experienced application specialists.

## Proper Usage of the Product

### Safety Precautions

X-ray collimators are supplied with housing and are used under X-ray radiation. Collimators should be handled with care by engineers having sufficient technical knowledge and training.

- Handle the collimator with care at all times. Always use the original packaging for the transportation and the cover for the off focal blades.
- Do not scratch the output window.
- Only apply a power supply on the collimator according to the technical description.
- When power is connected to the unit, do not open the collimator and do not touch any connectors in the collimator.
- Before touching connectors switch the power supply OFF.
- Do not drill any additional holes in the collimator.
- Always seek advice from the manufacturer when operation or handling is assumed to be hazardous.
- Also refer to the sections on installation, operation and maintenance for additional safety precautions.

# Safety

## Improper Usage



**Improper installation, service operation and usage can lead to hazardous situations for the patient, operator or service engineer. Do not carry out any installation, maintenance work or adjustment procedure other than described in this manual.**

The manufacturer will not be held responsible for the safety features, reliability, and performance of the product in the following cases:

- The component is used in a manner other than specified in the operating manual.
- Personnel not authorized by the manufacturer performs installation, upgrades, modifications or repairs,
- Components affecting product safety are not replaced with original SIEMENS spare parts,
- Electrical wiring in the operating room does not meet the specifications of DIN-VDE 0100-107 or local regulations.

## Staff Qualification

### Operating Staff

Using this product in accordance with regulations is only possible if the operating staff has the required specialized knowledge and is familiar with the operating instructions. These must be studied thoroughly before startup. The operating staff should have practical training in the correct operation. The training should be repeated at appropriate intervals of time. It is recommended that emergencies are simulated and corresponding measures are trained.

### Installation Maintenance and Repair Staff

Only persons having expert knowledge of electrical systems and radiation protection are allowed to install, maintain and adjust the collimator, e.g. electrical engineers or technicians. Furthermore, the installation and maintenance staff must have practical training in the installation, maintenance, and repair of the system and be authorized by the distributor or manufacturer to perform this kind of work.

# Safety

## Operating Safety

As manufacturer, SIEMENS will not be held responsible for the safety features, reliability and performance of the component when:

- The component is used in a manner other than specified in the operating manual. In this context also refer to the chapter “Installation, Operation and Maintenance” in this manual.
- Components affecting product safety are not replaced with original SIEMENS spare parts,
- Electrical wiring in the rooms containing the system do not meet the specifications of VDE ordinance 107 or local regulations.

## Radiation Protection

The shielding of the collimator is designed for tube potentials up to 150kV. Do not use this collimator with a higher tube potential.

The X-ray cone from the tube has to be reduced to an angle of 28° before it enters the collimator.

## Protective Measures

### Visual Contact to Patient

When operating the X-ray product ensure that there is visual and acoustic contact with the patient. In this way, you remain informed about the condition of the patient at all times.

### Protection against Electric Shock

#### Power supply

For all products that are operated within an X-ray system, the power supply has to be set up with a contactor or other multipole circuit breaker installed on-site.

The room installation must comply with DIN VDE 0100-710 or the corresponding national regulations.

#### Covers

If socket covers (especially of the operating modules) are damaged, they must be replaced.

In the event of defects, for example, if a covering cap has broken off,

- ◆ Call the manufacturer's customer service.

#### Protection class

The product conforms to the requirements of the IEC 60601-1:2012 +C1:2012.

The protection against ingress of water is IPx0.

#### Equipotential bonding

Products for which equipotential bonding is recommended must only be operated in medical facilities where supplemental equipotential bonding has been installed and tested according to the specifications in DIN 57107/VDE 0107/6.81 section 5 (Federal Republic of Germany) or the relevant local and federal regulations.

#### Opening the units

Only authorized service personnel are permitted to open the units.

# Safety

## Precautions for EMC

Medical electrical equipment needs special precautions regarding EMC. EMC information provided in the accompanying documents must be followed where appropriate.

Portable and mobile RF communications equipment can affect medical electrical equipment.

The use of accessories and cables other than those specified, with the exception of accessories and cables sold by the manufacturer of the product as replacement parts for internal components, may result in increased emission or decreased immunity of the product.



This equipment/system is intended for use by healthcare professionals only.

**This equipment/system may cause radio interference or may discontinue the operation of nearby equipment.**

It may be necessary to take mitigation measures, such as re-orienting or relocating the Tube Stand or shielding the location.

# Safety

## Guidance and manufacturer's declaration – electromagnetic emissions

The Collimator ML03 is intended for use in the electromagnetic environment specified below.

The customer or the user of the Collimator ML03 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Collimator ML03 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 B	
Harmonic emissions IEC 61000-3-2	Not applicable	The Collimator ML03 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

# Safety

## Guidance and manufacturer's declaration – electromagnetic immunity

**The Collimator ML03 is intended for use in the electromagnetic environment specified below. The customer or the user of the Collimator ML03 should assure that it is used in such an environment.**

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	Not applicable for power supply line ±1kV for input / output lines	±1kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Not applicable	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



# Safety

## Guidance and manufacturer's declaration – electromagnetic immunity

The Collimator ML03 is intended for use in the electromagnetic environment specified below. The customer or the user of the Collimator ML03 should assure that it is used in such an environment.

Immunity test	IEC 60601	Compliance level	Electromagnetic environment - guidance
	Test level		

Portable and mobile RF communications equipment should be used no closer to any part of the [Collimator ML03], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Conducted RF 3Vrms

IEC 61000-4-6 150kHz – 80MHz 3V

Radiated RF 3V/m

IEC 61000-4-3 80MHz – 2.5GHz 3V/m

### Recommended separation distance

$$d = 1.2 \sqrt{P}$$

$$d = 1.2 \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$$

$$d = 2.3 \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup>

Interference may occur in the vicinity of equipment marked with the following symbol:



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

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

A. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Collimator ML03 is used exceeds the applicable RF compliance level above, the Collimator ML03 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [Collimator ML03].

B. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

# Safety

## Recommended separation distances between portable and mobile RF communications equipment and the [Collimator ML03]

The Collimator ML03 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Collimator ML03 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Collimator ML03 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
W	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.79	3.79	7.27
100	12	2	23

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

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

# Safety

## Combination with other Products/Components

- ◆ To ensure the necessary safety, only products/components expressly approved by the manufacturer may be used in combination with the product.
- ◆ To find out about the current state of the equipment and the combinations and upgrades currently approved:
- ◆ Please contact your authorized local sales representative.

To ensure product safety use only accessories with the following specifications:

## Accessory Specifications

<b>Maximum weight:</b>		7 kg
<b>Mounting dimensions:</b>	width	177.5 <sub>-0.5</sub> mm
	depth	177.5 <sub>-0.5</sub> mm
<b>Maximum torque from accessories:</b>		15 Nm

Always slide the accessories into the rails until the lock spring prevents the accessory from falling out.

**Recommendation: Don't use more than 3 Kg accessories, when Collimator ML03 need be rotated.**

# Safety

## General Hazards

### X-ray Radiation Hazard



Caution

Incorrect filter selection

**Risk of increased radiation dose for the patient**

- ◆ Select the filter carefully.

### Hazards due to Heat Dissipation



Caution

If the LED of the light localizer burns for a long time, the heatsink can heat up

**Danger of burns.**

- ◆ Avoid contact with the lamp housing.

### Mechanical Hazard



Warning

Screws fastening the collimator to the tube assembly become loose.

**Patient/operator injured due to down falling collimator.**

- ◆ Follow the fastening instructions for the collimator and mount the collimator backlash-free.



Caution

Manual rotation of the collimator.

**Minor injury of the hands or fingers.**

- ◆ Always pay attention to your hands to ensure that they are not pinched or crushed between the collimator and other parts of the system.

# Safety

## Hazard due to Liquids



Caution

Use of harsh cleaning agents, liquids or sprays.

**When cleaning the collimator, liquids can seep into the openings of the system and cause electric shock, short circuits, or corrosion of electrical parts. Risk of electrical hazard or damage to the system.**

- ◆ Use only substances for cleaning and disinfection, which are recommended, but no sprays.
- ◆ Do not let cleaning liquids seep into the openings of the system (e.g. air openings, gaps between covers).
- ◆ Observe the following cleaning and disinfection instructions

## Hazard due to incorrect disposal



Caution

Incorrect disposal

### Pollution of the environment

- ◆ Dispose of waste material according to the national industry standards, Take account of local regulations governing the disposal of the product

## Hazard due to optical



Caution

Laser light

### Eye injury

- ◆ Do not look into the beam! Take care that neither you nor any other person look directly into the light beam. Close the Laser radiation exit of the Laser light localizer with the sliding cover to protect the eyes of the patient or any other person.



Caution

Photobiological effect of ultraviolet radiation

### Eye injury

- ◆ Do not look into the light beam for longer than 15 seconds. Always keep enough distance to the collimator.

# Safety

## Compliance with Regulations and Standards

**Local Regulations** The installer and operator are responsible for complying with all local regulations regarding installation and operation of this collimator.

**National Regulations** In all countries, the legally established regulations are to be observed.

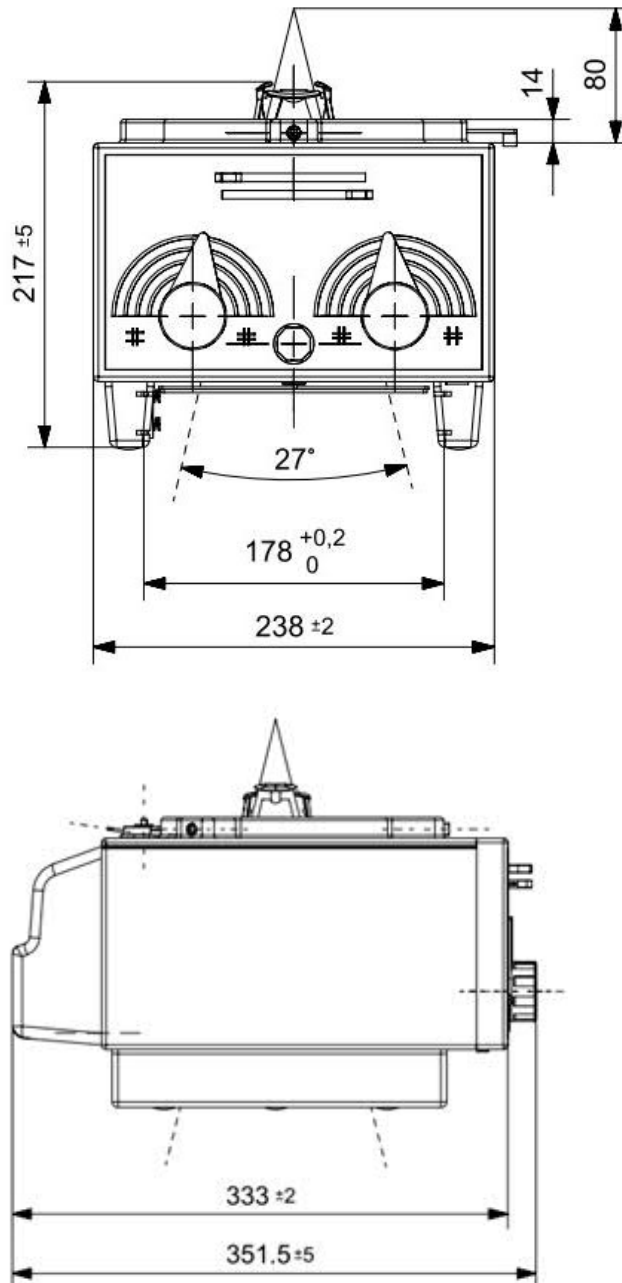
**Legally Required Tests** All legally required tests must be performed at the prescribed time intervals, e.g. constancy test according to the X-ray ordinance (§16 RöV) in the Federal Republic of Germany, e.g. tests based on EPRC guidelines (U.S. Code of Federal Regulations Title 21 Subchapter J).

# Technical Specifications

## *Technical Specifications*

### Dimensions of Collimator ML03

All dimension sizes in millimeter (mm)



# Technical Specifications

## Basic parameters of the collimator

Basic parameters	
Dimensions (L×W×H)	351.5mm×238mm×217mm
Weight of unit	8.8kg±0.5kg
Aperture angle [°]	27°/27° *
Angle of rotation around central beam axis	>45° (Two directions)
Maximum field size [cm]	48cm×48cm (SID=100cm) *
Minimum field size [cm]	3cm×3cm (SID=100cm) *
Power supply:	
Input voltage AC / DC [V]	24V±10% DC or AC
Max. input current [A]	1A
Light source	DC 3.3V /10W LED
Inherent filtration	1.0mmAl/70kV optional 2.0 mm Al/70kV
Leakage radiation	<0.5mGy/h

“\*”: Values are related to a focus flange distance of 80 mm.



# Technical Specifications

## Field size scale description

SID	Field size scale	
100	13/15/18/20/24/30/35/40/43	Metric(cm)
115	13/15/18/20/24/30/35/40/43	Metric(cm)
150	13/15/18/20/24/30/35/40/43	Metric(cm)
180	13/15/18/20/24/30/35/40/43	Metric(cm)
40	5/7/8/9.5/10/12/14/16/17	Inch(in)
45	5/7/8/9.5/10/12/14/16/17	Inch(in)
60	5/7/8/9.5/10/12/14/16/17	Inch(in)
72	5/7/8/9.5/10/12/14/16/17	Inch(in)

# Technical Specifications

## Climatic Conditions

	Transportation and storage	Operation
Admissible ambient temperature [°C]	-40 to +70	+10 to +40
Admissible relative humidity noncondensing [%]	≤95%	20% to 75%
Admissible barometric pressure [kPa]	500hPa~1060hPa	700hPa~1060hPa
Degree of protection	According to EN 60529 is IPX0	

# Technical Specifications



The collimator should not be subjected to extreme and fast temperature changes (both in cold and hot environments), excessive dust or high humidity. For further precautions during transportation, please refer to the sections on installation, operation and maintenance in this manual.

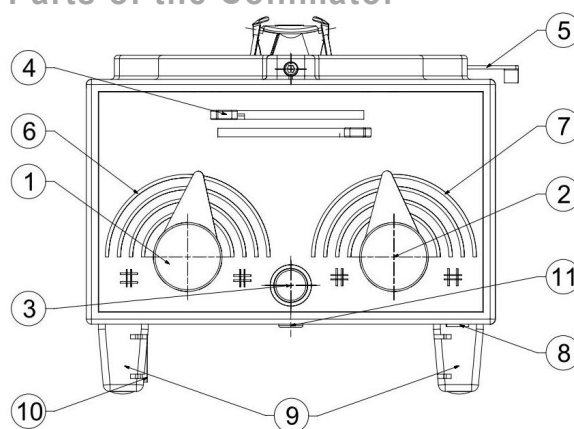
## Materials Used

Part	Material
Focus near collimator	Pb 2.5 mm
Filters	Cu 0.1 mm and Cu 0.2 mm
Collimation	Pb 3 mm

## Inherent Filtration

Part	Inherent Filtration
Reflector	Al equivalent 1.0 mm/70 kV
Additional Al Filter (optional)	Al equivalent 1.0 mm/70 kV
Output window	Al equivalent 0.1 mm/70 kV

**Parts of the Collimator**



**Front Operating Panel**

**Table of Functions and Displays**

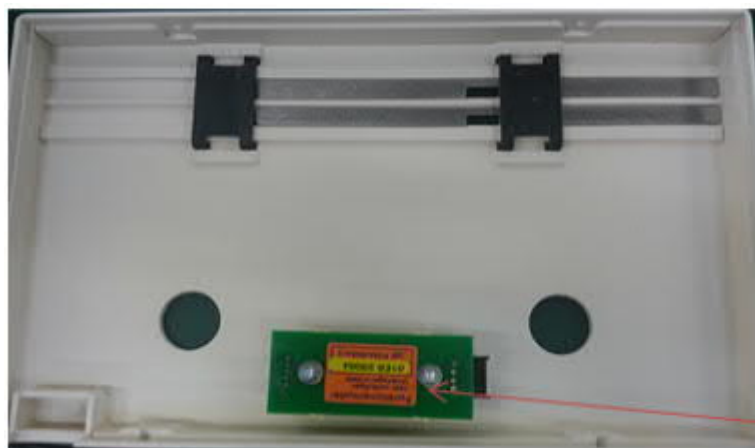
No	Description
(1)	Knobs for height format collimation (Rotating counterclockwise to open the collimator, rotating clockwise closes the collimator).
(2)	Knobs for width format collimation (Rotating clockwise to open the collimator, rotating counterclockwise closes the collimator).
(3)	Switching the radiation field and line light (laser) localizer lighting on. The lighting is switched off automatically by a timer.
(4)	Slides for setting the pre-filtration(optional)
(5)	Detent lever for $\pm 45^\circ$ rotation of the collimator about the vertical axis. The collimator only stops in the $0^\circ$ position.
(6)	Format width scales.
(7)	Format height scales.
(8)	Tape measure for SID measurement. Read off the measurement on the bottom edge of the collimator. (optional)
(9)	Two accessory rails.
(10)	Locking spring to fix accessories in the rails.
(11)	Slide for laser light

# Overview

## PCB of the Collimator

### Description of the PCBs

No	Description
(1)	PCB D312
(2)	PCB D314



### Safety Information



Only qualified staff is permitted to unpack, install and operate the collimator unit. Only the chapters “Operation” and “Maintenance” of the following instructions are intended as information for the end user. All other instructions are intended for installation and service personnel only.

### Setup Hazards



Drilling holes into the collimator housing can damage electrical components on the inside.

- ◆ Do not drill additional holes in the cover of the collimator.

# Installation

Standard

## Delivery Contents

- Documentation
- Factory test certificate
- Product status list

## Required Tools and Measurement Devices

- Set of Allen keys
- Slot screwdriver
- Hexagon wrench 5.5
- Ground wire test meter
- Digital multimeter
- Torque wrench, <5Nm

## Transportation to the Installation Site



To protect the collimator against damage, transport it in its packing as supplied by the manufacturer. Transportation is recommended with the exit window of the collimator facing down. Be careful not to damage or displace the focal blades at the inlet aperture.

## Unpacking



Remove all additional papers which are attached to the packaging and keep them with the system documents.

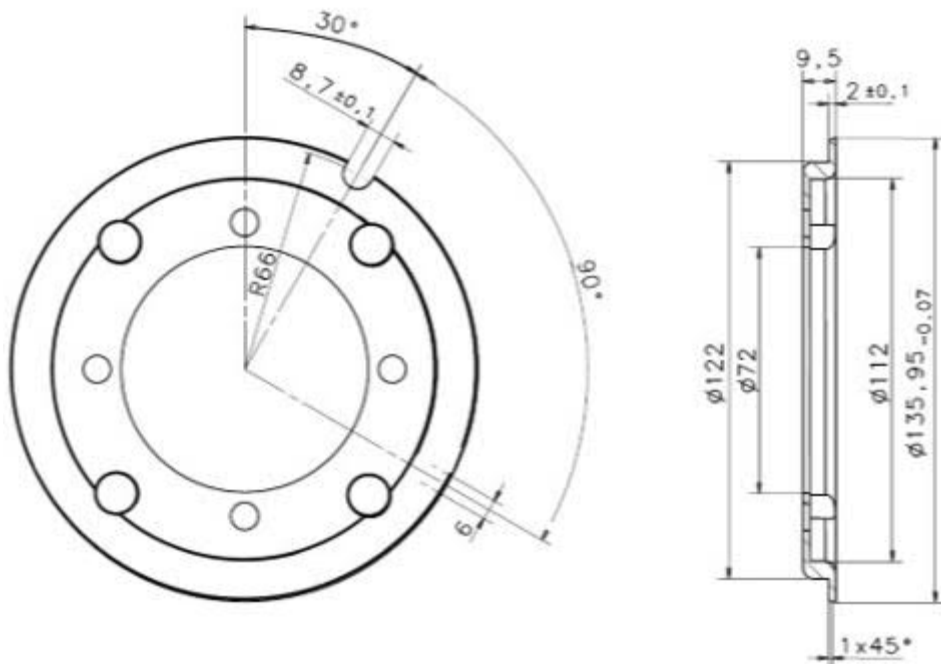
Keep the cover on the input window until the final installation of the collimator on the tube to protect the focal blades against damage.

# Installation

## Installing the Collimator

### Note

The collimator is designed for a focus to flange distance of 80mm.  
Please refer to specifications below, showing the mechanical interface (SIEMENS tube flange, part no.: 8440786 X1122).



For mechanical mounting of the collimator to the tube flange, please refer to the drawing for details.  
The three screws spaced at  $120^\circ$  for mounting on the tube flange have to be used.



**The mounting means of the unit supporting this product, must be able to support a load of 24 kg (7 kg accessories included).**



# Installation

## Setting Up the Collimator

### Note

Before installation of the collimator check the adjustment of the off focal blades. Each of the off focal blades should have a distance of 0.0 mm up to 1.0 mm to the pin of the adjustment gauge, when the rectangular blades are manual totally closed.

Off focal blades may extend into the beam path due to deviations of the focus within the tube unit. In this case the respective leaf has to be carefully bent towards the outside.

**Recommendation:** First of all grease the flange of the tube with Longtime PD2 a little.

# Installation

## Fastening Instructions for Collimator with a rotating flange

### Instructions



#### Warning

Screws fastening the collimator to the tube assembly become loose.

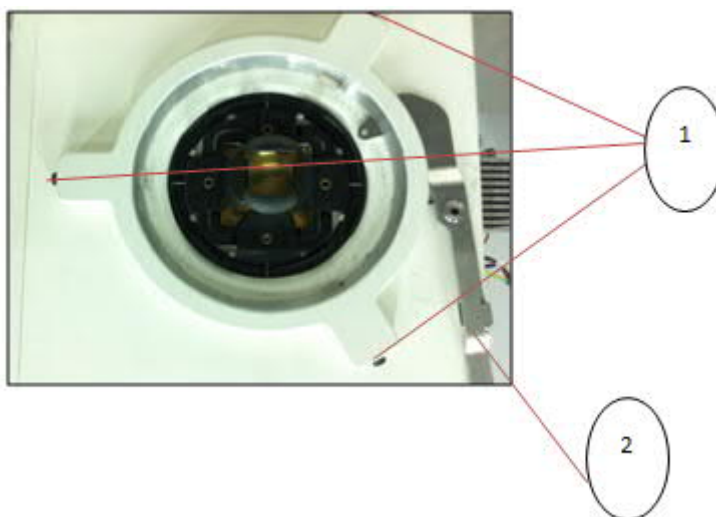
**Patient/operator injured due to down falling collimator.**

- ◆ Follow the fastening instructions for the collimator and mount the collimator backlash-free.



**Carefully place the collimator on the tube unit. The collimator blades are extremely sensitive and can be damaged very easily.**

- Tighten one of the three screws (1) so that the collimator just cannot be turned any more.
- Hook a spring balance (100N) (2) to the lever of the rotating flange.
- Loosen this screw again so that the collimator can turn when a force of 20 – 30 N is applied to the spring balance.
- Tighten one of the other two screws to 40 – 50 N as described previously and tighten the 3rd screw to 60 – 70 N using the spring balance.



# Installation

## Fastening Instructions for Mounting of the Fixed Collimator



### Warning

Screws fastening the collimator to the tube assembly become loose.

**Patient/operator injured due to down falling collimator.**

- ◆ Follow the fastening instructions for the collimator and mount the collimator backlash-free.

### Note

**Maximum torque to fasten the screws: 3 Nm.**

### Note

**Carefully place the collimator on the tube unit. The collimator blades are extremely sensitive and can be damaged very easily.**

- Tighten one of the three screws (1) so that the collimator just cannot be turned any more.
- Loosen this screw again by a half turn.
- Repeat this procedure with another screw.
- Tighten the third screw so that the collimator just cannot be turned any more.
- Tighten the first and the second screw the half turn back again.
- Maximum fastening torque of the screws: 3 Nm.

### Note

**The supplier of the system has to ensure that the tube flange is able to support the weight of the collimator and his accessories.**

# Installation

## Electrical Installation

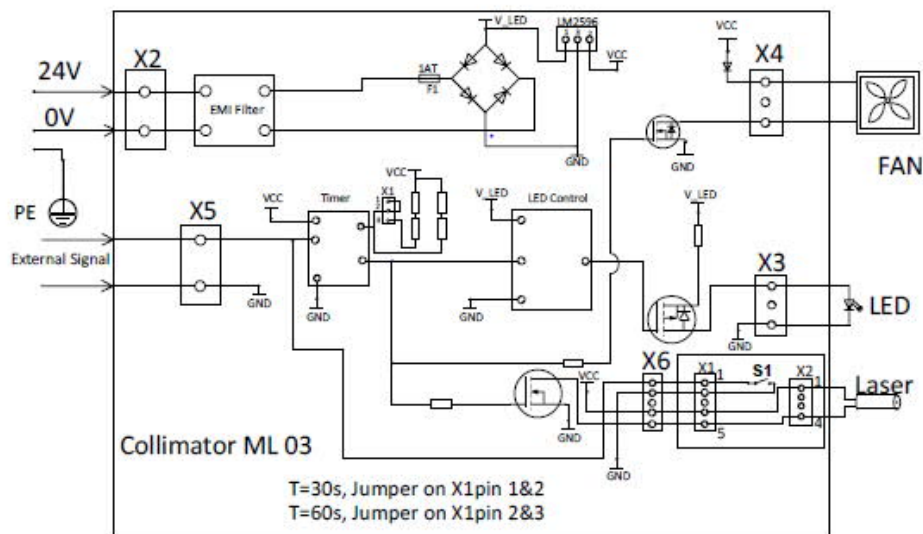
The collimator requires a power supply of:

- 24V DC/AC (50/60Hz $\pm$ 1Hz)  $\pm$  10% input with a maximum current of 1A and input power 20VA for the light indicator.
- The supply voltage shall be separated from supply mains by double or reinforced insulation, according to IEC 60601-1.
- The suitable LV power supply has to be provided by the system.
- The maximum tightening torque of the screws which are used for assemble PCBA: 3Nm

### Note

According to IEC 60601-1 the supply voltage shall be separated from the mains supply by double or reinforced insulation. The power supplies have to be provided by the system.

## Electrical Wiring and Connections



No	Description
X2-1	24VDC+/24VAC
X2-2	0VDC-/0VAC

External Signal means external switch signal for light button.  
The users may use the interface for remote control for light and laser.  
Power cord cross-sectional area: 0.75 mm<sup>2</sup>

# Installation



## Maximum temperature:

To prevent the cables from damaging by high temperature in case of malfunction of the light switch, we recommend using cables designed for 80°C.

The grounding point, located near the collimator timer board, is suitable for a grounding wire with 4mm<sup>2</sup> cable lug.

This Product is installation class I. Before taking the equipment into operation with the X-ray unit perform a ground continuity test according to IEC 60601-1 - to avoid electric hazard. In addition, to prevent electrical shock and personal injury, ensure there is no damage on the insulation of the input cables.

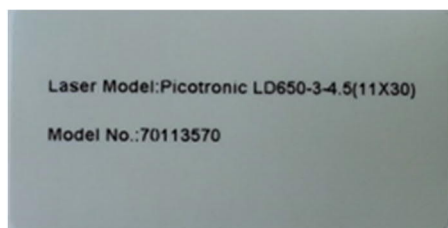
With an additional adapter the electrical interface of the Collimator ML03 is compatible with the Siemens Collimator ML02.

## Laser Parameter

Characteristic parameters	Least	Typical	Maximum	Unit
Voltage	4	4.5	6	V DC
Electric current	20	40	60	mA
Optics Output Power	2.4	3	4	mW
Wavelength @ 25 °C	640	650	660	nm

Laser class: 2, IEC 60825-1 : 2014

Optical parameters: divergence angle 85°±5°



### Safety Information



**During operation of the collimator ensure that the collimator can be operated safely.**



**Caution**

If the LED of the light localizer burns for a long time, the heatsink can heat up.

#### **Danger of burns.**

- ◆ Avoid contact with the heatsink to avoid burns.

### Features of the Collimator

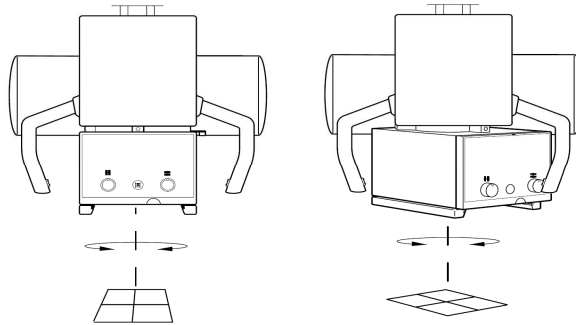
#### Light Localizer with Centering Crosshairs

The light localizer can be switched on or off by the light button on the front operating panel. The centering crosshairs of the full-field light localizer show the center lines of the field of view. An internal timer limits the illumination time. The timer for illumination time can be set up using jumper X1 on D312 PCBA.

# Operation

## Rotation Flange

The collimator can be rotated out of the stop position 0° by pulling the stop lever towards the front operating panel. The maximum rotation in both directions is 45° by using the Siemens tube flange. Ensure that the rotation is not limited by the wiring harness.



- ◆ Move the detent lever on the collimator toward front panel, i.e. toward the operator.
- ◆ The max. rotation of collimator up to clockwise stop or counter clockwise stop: >45°.
- ◆ The 0° lock-in position of the collimator is released by actuating the locking lever.
- ◆ Grasp the collimator with both hands and rotate it by the desired angle in the required direction.

## Rotating the Collimator to the 0° Detent Position

Grasp collimator with both hands and turn it to the lock-in position at 0°



### Caution

Manual rotation of the collimator.

### Minor injury of the hands or fingers.

- ◆ Always pay attention to your hands to ensure that they are not pinched or crushed between the collimator and other parts of the system.

# Operation

## Locking Spring

The locking spring prevents inserted accessories from slipping out of the accessory rails.

## Prefilter Selection



Caution

Incorrect filter selection

**Risk of increased radiation dose for the patient**

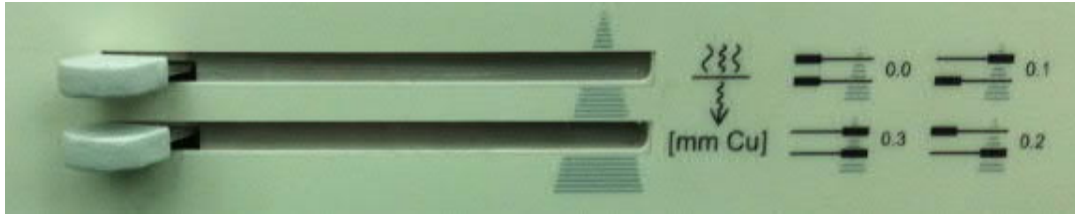
◆ Select the filter carefully.

## The definition of prefilter by combinations of two levers

Cu prefilter	Upper lever	Lower lever
0.0mm	Left	Left
0.1mm	Right	Left
0.2mm	Left	Right
0.3mm	Right	Right



# Operation



An indicator is placed on the right side of the collimator for proper positioning of the levers.

During operation of the collimator unit ensure that it is not damaged due to collision and adhere to the temperature range according to the specifications in this manual. Also refer to the safety section in this manual for additional information regarding the operation of this product.

## Centering Cross (Output Window)



The centering cross is used to display the longitudinal and transverse axis of the exposure field on the cassette or directly on the patient.

The full-field light localizer for projecting the centering cross is switched on with the push button on the control panel.

The light field and line light (laser) localizer cannot be switched separately.

# Adjustment

## Adjustment

### Adjustment of the light field

If the light field does not sufficiently match the radiation field (e.g. focus point tolerances), then the light field can be centered in the width, depth and height direction with three nuts using a 3 mm Allen wrench.



**Do not look into the focus of the lamp.**



**Use insulated tools to avoid short circuit.**



Caution

If the LED of the light localizer burns for a long time, the heatsink can heat up.

**Danger of burns.**

◆ Avoid contact with the heatsink to avoid burns.

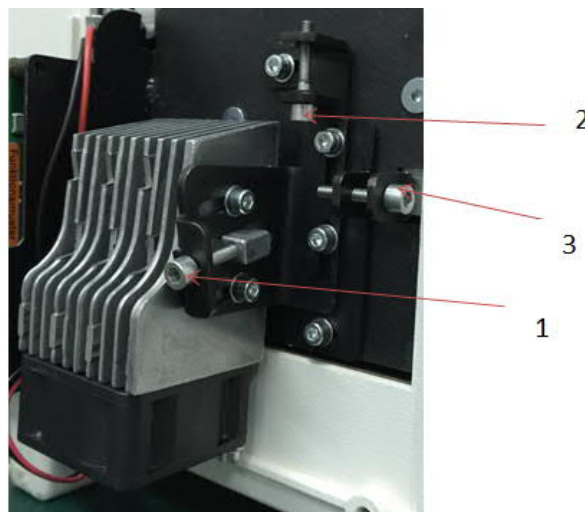
- ◆ Switch off the system.
- ◆ Unscrew the Allen screws on the heatsink rear cover.



Screw

# Adjustment

- ◆ Switch on the system.
- ◆ Adjustment of direction x (height): By turning the screw (2) the light field moves in height direction.
- ◆ Adjustment of direction y (width): By turning the screw (3) the light field moves in width direction.
- ◆ Adjustment of direction z (scale): By turning the screw (1) the light field moves in scale direction.



The setting screws can only be turned as long as the resistance of the compression springs can be felt. The screws should not be loose.

Subsequent to adjusting the light field, the crosshairs window is to be readjusted by loosening the four fastening screws in the holder frame and the line light (laser) is to be adjusted accordingly.

# Adjustment

## Adjustment of the Laser localizer

If the Laser light does not sufficiently match the center of the x-ray field, the line light (laser) localizer can be centered with two nuts using a M3 nut wrench.



**Do not look into the focus of the lamp.**



**Use insulated tools to avoid short circuit.**



Caution

If the LED of the light localizer burns for a long time, the heatsink can heat up.

**Danger of burns.**

- ◆ Avoid contact with the heatsink to avoid burns.
- ◆ Switch off the system
- ◆ First remove the knob covers and indicators of position, and then remove the two knobs by unlocking the nuts with a 10mm hexagonal wrench.



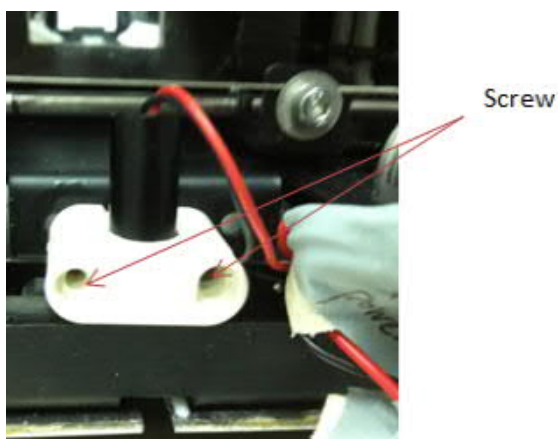
Knob

# Adjustment

- ◆ By unscrewing the screws on both sides of the front panel remove the front panel.



- ◆ Switch on the system.
- ◆ Loosen the two screws on the laser holder, rotating laser light until the laser positioning line coincides with the center line of the light field.



- ◆ Tighten the two screws

### General Information

#### Note

**No maintenance is necessary for this product.**

### Cleaning and Disinfection



**Before cleaning shut down the system properly.**

### Cleaning Hazards



#### Caution

Use of harsh cleaning agents, liquids or sprays.

**When cleaning the collimator, liquids can seep into the openings of the system and cause electric shock, short circuits, or corrosion of electrical parts.**

**Risk of electrical hazard or damage to the system.**

◆ Use only substances for cleaning and disinfection, which are recommended, but no sprays. Do not let cleaning liquids seep into the openings of the system (e.g. air openings, gaps between covers). Observe the following cleaning and disinfection instructions



**Harsh cleaning agents (e.g. acetone or alcohol) can damage the enameled surface of the collimator housing.**

◆ Use special enamel cleaning agents.

# Maintenance

## Required Tools and Cleaning Agents

- Lint-free cleaning cloths.
- Brush to remove dust.
- Only use water or a lukewarm diluted household cleaning agent solution.
- For plastics, use only special plexiglass cleaning agents, dishwashing detergent, soapy water or laundry detergent.
- For enameled surfaces, a special cleaning agent is recommended.



**Do not use scouring cleaning agents, organic solvents or solvent-based cleaning agents (e.g. benzine, alcohol, spot remover) because of potential incompatibility with the materials of the collimator!**

## Required Tools and Disinfectants

- Lint-free cleaning cloths.
- Solutions of common surface disinfectants (e.g. aldehyde based and/or amphoteric based surfactants) are recommended for disinfection.



**Phenol-based or chlorine-releasing agents can harm the surfaces or cause corrosion and therefore are not recommended for cleaning. The same applies to undiluted solutions with a high content of alcohol (e.g. cleaning agents to disinfect hands).**



**The concentration of disinfectants in the air must not exceed the statutorily defined limit. Observe the instructions given by the manufacturer of the disinfectants.**

## Procedure

- Clean and disinfect all contaminated parts.
- Clean and sanitize all parts which have (or had) contact with the patient.
- Wipe the collimator with a damp cloth or cotton pad.

# Maintenance

## Replace LED module on the Collimator

The LED cannot be changed by the user.



Caution

If the LED of the light localizer burns for a long time, the heatsink can heat up.

**Danger of burns.**

- ◆ Avoid contact with the heatsink to avoid burns.

- ◆ Switch off the system.
- ◆ Unscrew the Allen screws on the radiator on the collimator

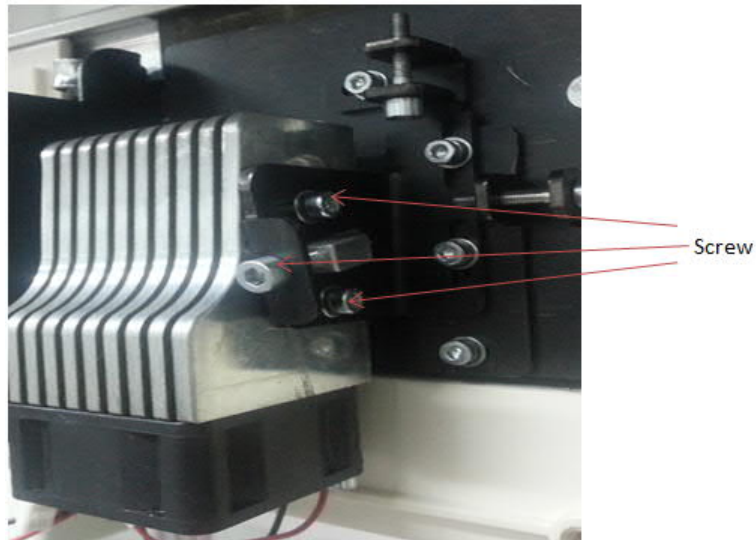


Screw

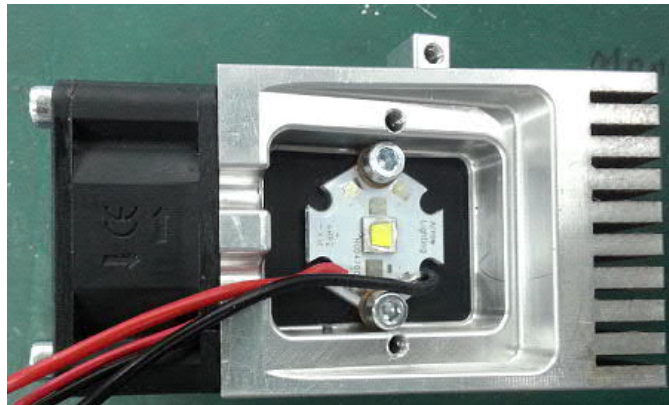


# Maintenance

- ◆ Disassemble defective LED module by loosening 3 screws.



- ◆ Remove the LED mounting plate screws, replace the faulty LED lights.



# Maintenance



**Do not touch the new lamp with your bare fingers.**

# Disassembly and Disposal

## *Disassembly and Disposal*

### Disassembly

#### General Safety Information

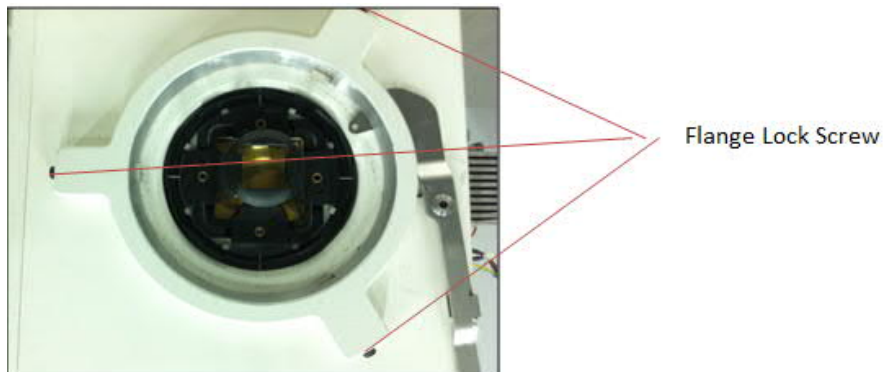


**Protect the collimator against damage (e.g. from falling) during removal.**

- ◆ e.g. place a table or a cart with a foam plastic cushion under it.

#### Disassembling the Collimator

- ◆ Move the collimator into an appropriate working position.
- ◆ Switch the system OFF.
- ◆ Disconnect all cables and connectors. To do this, the cover on the back must be removed.
- ◆ Evenly loosen the three Allen screws (1) on the top edge of the collimator and remove the collimator from the system.



# Disassembly and Disposal

**Note**

While loosening the screws, make sure to support the collimator and secure it against damage!

**Note**

Please note that any attachments (such as DAP chambers) must be removed from the collimator.

# Disassembly and Disposal

## Disposal

The “Recycling Management and Waste Management Act“ assigns responsibility for product disposal to the manufacturer/distributor. Therefore, perform disposal according to environmental guidelines. This manual can be used to determine types, quantities, and locations of hazardous waste materials.



Caution

Incorrect disposal

### Pollution of the environment

◆ Dispose of waste material according to the national industry standards, Take account of local regulations governing the disposal of the product

## List of Hazardous Materials

Hazardous Material	Quantity
Lead (Pb)	up to 3 kg

The following parts of the collimator consist of (or at least contain) lead:

- Covers
- Rectangular leaves
- Top frame
- Off focal blades
- Shielding plate
- Lead cone

# Disassembly and Disposal



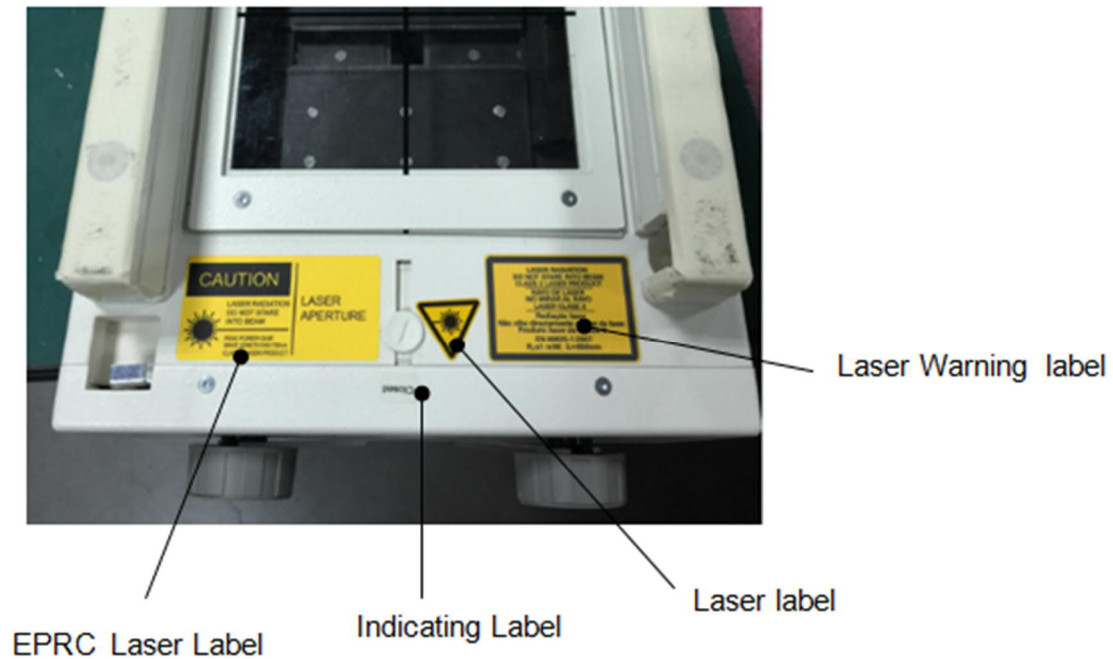
In order to comply with legal requirements concerning the environmental compatibility of our products (protection of natural resources and waste prevention) we endeavor to reuse parts and return them to the production cycle. By taking extensive quality assurance measures we guarantee the functional efficiency, quality and durability of reconditioned parts as well as for factory-new components.

# Labeling

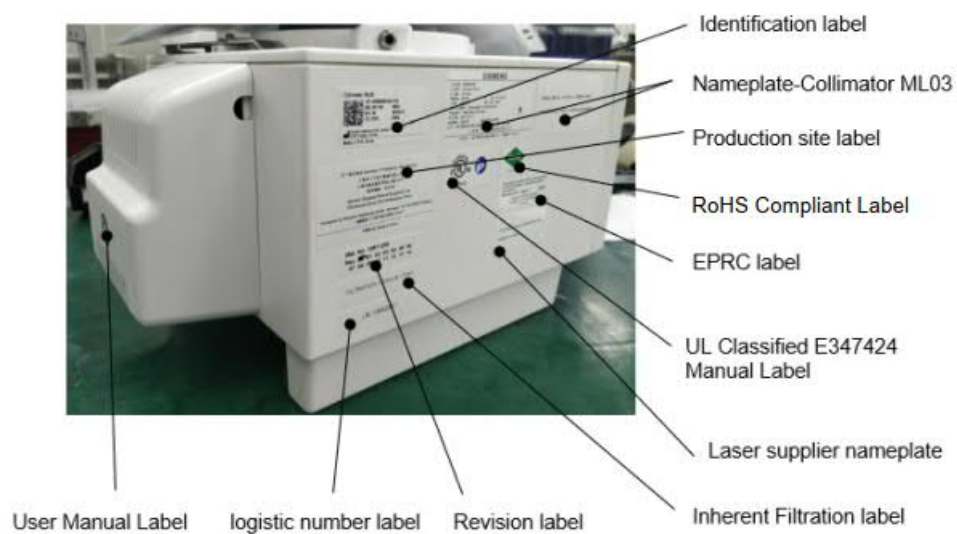
## Labeling

### Location of Labels

**Note** The labels are subject to change. Therefore the labels shown in this chapter should only serve as examples. The order of the labels may vary.




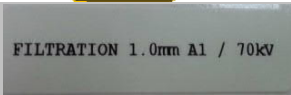

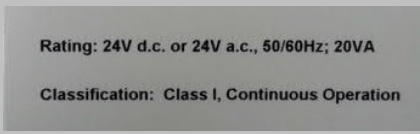





### Location of Labels outside



# Labeling

Table of Labels

Number	Label	Description
(1)		Identification label
(2)		Production site label
(3)		Laser label
(4)		Filtration label
(5)		Read User Manual label
(6)		Rating label
(7)		Laser warning labels
(8)		EPRC Laser label
(9)		EPRC label



# Labeling

(10)



MEDICAL APPLIED ELECTROMAGNETIC RADIATION EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005+AMD1(2012), CAN/CSA-C22.2No.60601-1(2014), IEC60601-1-3(2013), CAN/CSA-C22.2 No.60601-1-3-09(2014)+AMD1(2015), IEC 60601-1-6(2013), CSA CAN/CSA-C22.2 NO.60601-1-6:11+AMD1(2015) IEC60601-2-54(2014), CAN/CSA-C22.2NO.60601-2-54:11(2014)



(11)



RoHS label

The information in this document contains general descriptions of specifications and options as well as standard and optional features which do not always have to be present in individual cases.

Siemens reserves the right to modify the design, packaging, specifications and options described herein without prior notice. Please contact your local Siemens sales representative for the most current information.

Note: Any technical data contained in this document vary within defined tolerances.

Original images always lose a certain amount of detail when reproduced.

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