

Collimator ML03

Operator Manual

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.

Table of Contents

Table of Contents

| | |
|--|-----------|
| <u>TABLE OF CONTENTS</u> | 4 |
| <u>INTRODUCTION</u> | 8 |
| INTENDED USE | 8 |
| PRODUCT MODEL | 8 |
| COLLIMATOR ML03 OPTIONAL PARTS | 8 |
| FEATURES AND BENEFITS | 10 |
| STANDARDS COMPLIANCE | 10 |
| CHINESE STANDARDS: | 11 |
| <u>SAFETY</u> | 13 |
| INFORMATION ABOUT THIS MANUAL | 13 |
| GENERAL INFORMATION | 13 |
| STRUCTURE | 16 |
| STRUCTURE OF SAFETY INFORMATION | 16 |
| PICTOGRAMS | 17 |
| WARNING SIGNS | 17 |
| PROPER USAGE OF THE PRODUCT | 18 |
| SAFETY PRECAUTIONS | 18 |
| IMPROPER USAGE | 19 |
| STAFF QUALIFICATION | 19 |
| OPERATING SAFETY | 20 |
| RADIATION PROTECTION | 20 |
| PROTECTIVE MEASURES | 21 |
| VISUAL CONTACT TO PATIENT | 21 |
| PROTECTION AGAINST ELECTRIC SHOCK | 21 |
| PRECAUTIONS FOR EMC | 22 |
| COMBINATION WITH OTHER PRODUCTS/COMPONENTS | 27 |
| ACCESSORY SPECIFICATIONS | 27 |

Table of Contents

| | |
|--|------------------|
| GENERAL HAZARDS | 28 |
| X-RAY RADIATION HAZARD | 28 |
| HAZARDS DUE TO HEAT DISSIPATION | 28 |
| MECHANICAL HAZARD | 28 |
| HAZARD DUE TO LIQUIDS | 29 |
| HAZARD DUE TO INCORRECT DISPOSAL | 29 |
| HAZARD DUE TO OPTICAL | 29 |
| COMPLIANCE WITH REGULATIONS AND STANDARDS | 30 |
| <i>TECHNICAL SPECIFICATIONS</i> | <i>31</i> |
| DIMENSIONS OF COLLIMATOR ML03 | 31 |
| BASIC PARAMETERS OF THE COLLIMATOR | 32 |
| FIELD SIZE SCALE DESCRIPTION | 33 |
| CLIMATIC CONDITIONS | 34 |
| MATERIALS USED | 35 |
| INHERENT FILTRATION | 35 |
| <i>OVERVIEW</i> | <i>36</i> |
| PARTS OF THE COLLIMATOR | 36 |
| FRONT OPERATING PANEL | 36 |
| TABLE OF FUNCTIONS AND DISPLAYS | 36 |
| PCB OF THE COLLIMATOR | 37 |
| DESCRIPTION OF THE PCBs | 37 |
| <i>INSTALLATION</i> | <i>38</i> |
| SAFETY INFORMATION | 38 |
| SETUP HAZARDS | 38 |
| DELIVERY CONTENTS | 39 |
| REQUIRED TOOLS AND MEASUREMENT DEVICES | 39 |

Table of Contents

| | |
|--|-----------|
| TRANSPORTATION TO THE INSTALLATION SITE | 39 |
| UNPACKING | 39 |
| INSTALLING THE COLLIMATOR | 40 |
| SETTING UP THE COLLIMATOR | 41 |
| FASTENING INSTRUCTIONS FOR COLLIMATOR WITH A ROTATING FLANGE | 42 |
| INSTRUCTIONS | 42 |
| FASTENING INSTRUCTIONS FOR MOUNTING OF THE FIXED COLLIMATOR | 43 |
| ELECTRICAL INSTALLATION | 44 |
| ELECTRICAL WIRING AND CONNECTIONS | 44 |
| LASER PARAMETER | 45 |
| <i>OPERATION</i> | 46 |
| SAFETY INFORMATION | 46 |
| FEATURES OF THE COLLIMATOR | 46 |
| LIGHT LOCALIZER WITH CENTERING CROSSHAIRS | 46 |
| ROTATION FLANGE | 47 |
| ROTATING THE COLLIMATOR TO THE 0° DETENT POSITION | 47 |
| LOCKING SPRING | 48 |
| PREFILTER SELECTION | 48 |
| THE DEFINITION OF PREFILTER BY COMBINATIONS OF TWO LEVERS | 48 |
| CENTERING CROSS (OUTPUT WINDOW) | 49 |
| <i>ADJUSTMENT</i> | 50 |
| ADJUSTMENT OF THE LIGHT FIELD | 50 |
| ADJUSTMENT OF THE LASER LOCALIZER | 52 |
| <i>MAINTENANCE</i> | 54 |
| GENERAL INFORMATION | 54 |
| CLEANING AND DISINFECTION | 54 |

Table of Contents

| | |
|---|-----------|
| CLEANING HAZARDS | 54 |
| REQUIRED TOOLS AND CLEANING AGENTS | 55 |
| REQUIRED TOOLS AND DISINFECTANTS | 55 |
| PROCEDURE | 55 |
| REPLACE LED MODULE ON THE COLLIMATOR | 56 |
| | |
| <i>DISASSEMBLY AND DISPOSAL</i> | 59 |
| <hr/> | |
| DISASSEMBLY | 59 |
| GENERAL SAFETY INFORMATION | 59 |
| DISASSEMBLING THE COLLIMATOR | 59 |
| DISPOSAL | 61 |
| LIST OF HAZARDOUS MATERIALS | 61 |
| | |
| <i>LABELING</i> | 63 |
| <hr/> | |
| LOCATION OF LABELS | 63 |
| LOCATION OF LABELS OUTSIDE | 63 |
| TABLE OF LABELS | 64 |

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

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

- Parts** This manual comprises of different parts. The part title is stated in the first header line.
- Chapters** Each part may contain one or more chapters. The chapter title is stated in the second header line.
- Page numbers** 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.



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.

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.

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.

Safety

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 Test level | Compliance level | Electromagnetic environment - guidance |
|---------------|-------------------------|------------------|--|
|---------------|-------------------------|------------------|--|

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,^a should be less than the compliance level in each frequency range.^b

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

| | | |
|---|-------|--------------------------|
| Maximum weight: | | 7 kg |
| Mounting dimensions: | width | 177.5 _{-0.5} mm |
| | depth | 177.5 _{-0.5} mm |
| Maximum torque from accessories: | | 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

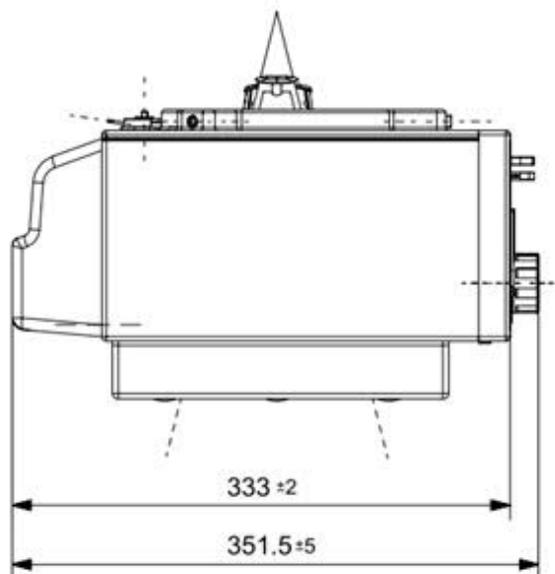
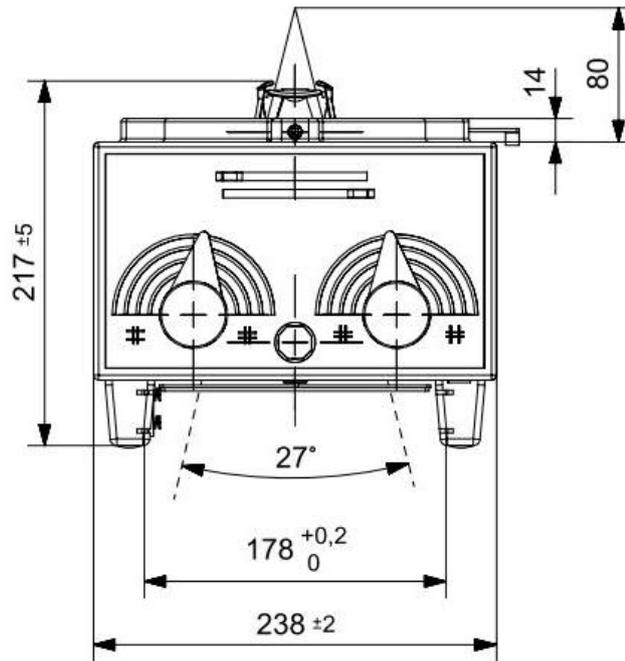
- Local Regulations** The installer and operator are responsible for complying with all local regulations regarding installation and operation of this collimator.
- National Regulations** In all countries, the legally established regulations are to be observed.
- Legally Required Tests** All legally 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.

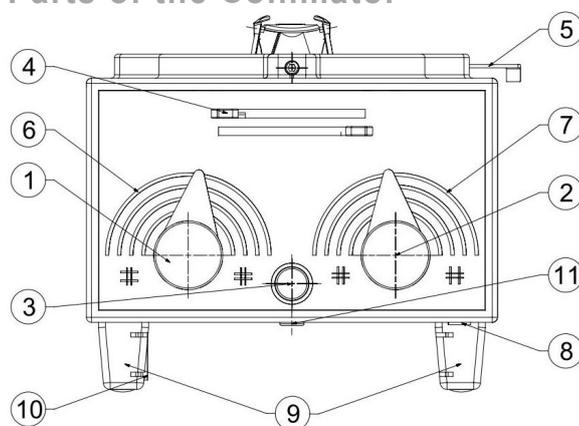
Materials Used

| 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

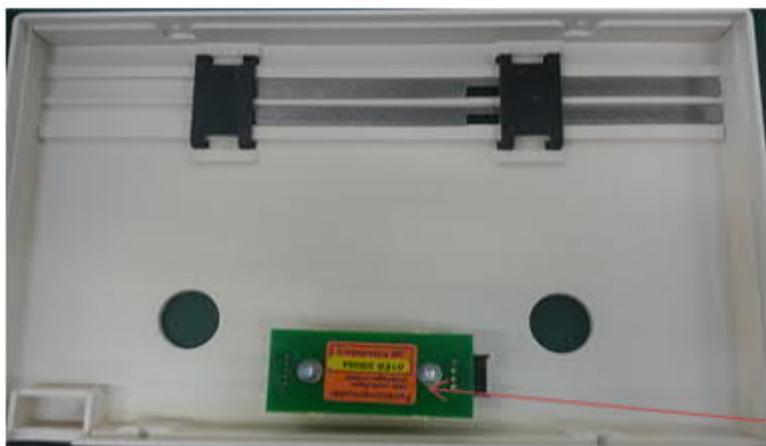
| No | Description |
|------|--|
| (1) | Knobs for height format collimation (Rotating counterclockwise to open the collimator, rotating clockwise closes the collimator). |
| (2) | Knobs for width format collimation (Rotating clockwise to open the collimator, rotating counterclockwise closes the collimator). |
| (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° 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.

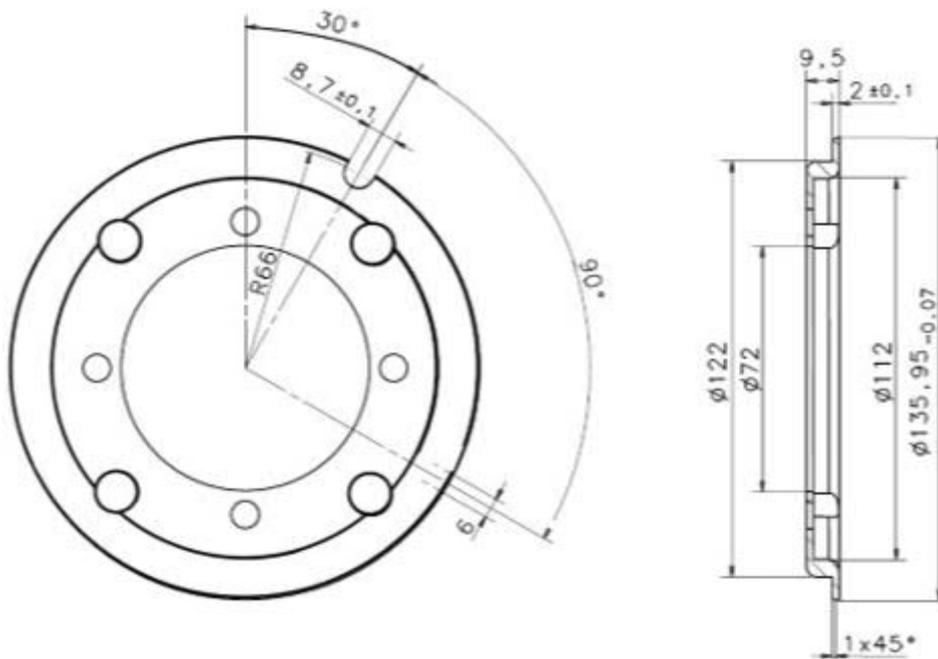
Keep the cover on the input window until the final installation of the collimator on the tube to protect the focal blades against damage.

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° 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.

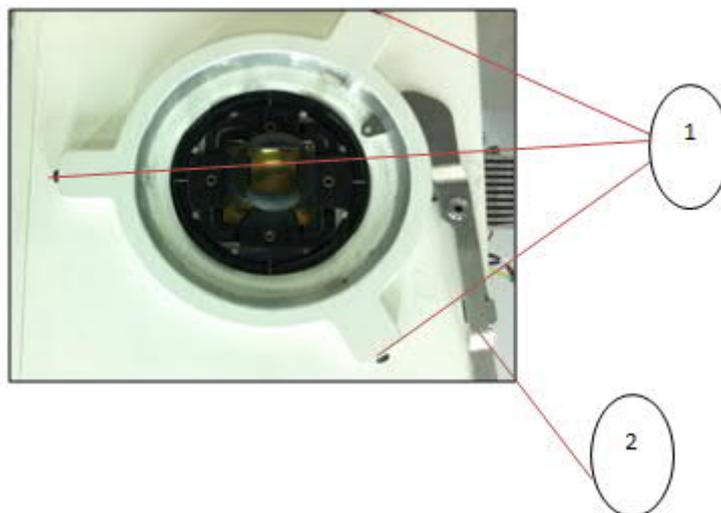
Patient/operator injured due to down falling collimator.

- ◆ 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

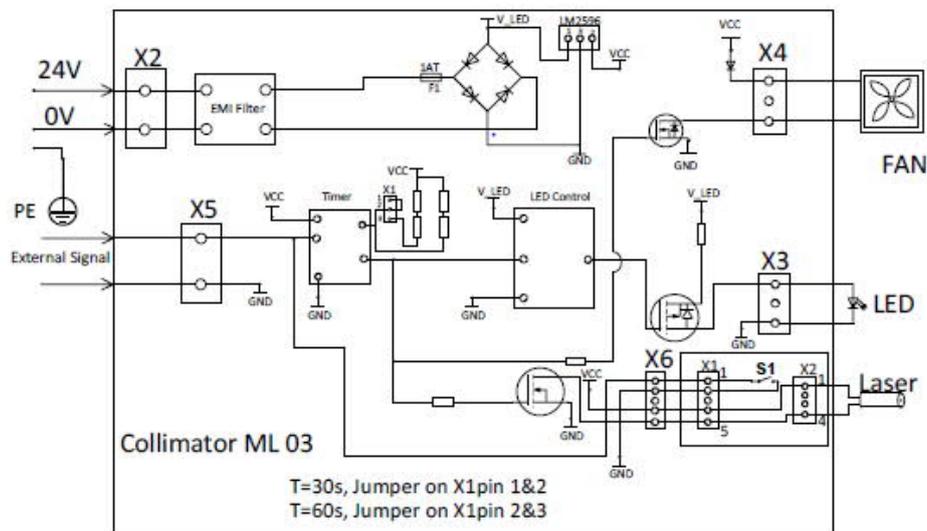
Electrical Installation

The collimator requires a power supply of:

- 24V DC/AC (50/60Hz±1Hz) ± 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 mm²

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 4mm² 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.

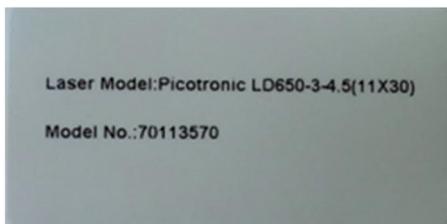
With an additional adapter the electrical interface of the Collimator ML03 is compatible with the Siemens Collimator ML02.

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

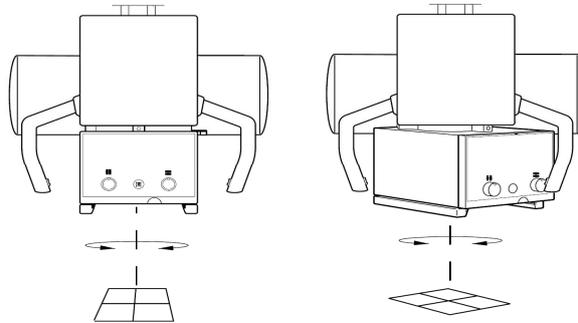
Light Localizer with Centering Crosshairs

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

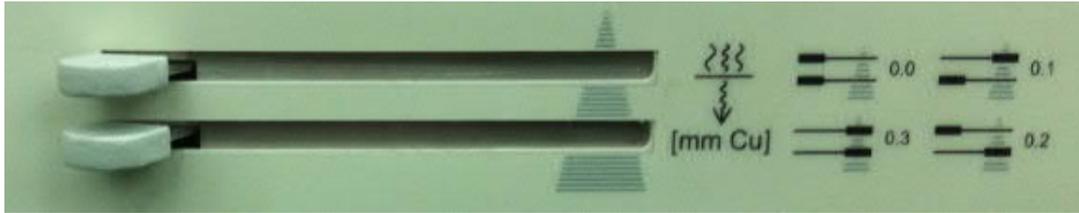
Risk of increased radiation dose for the patient

- ◆ 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 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.

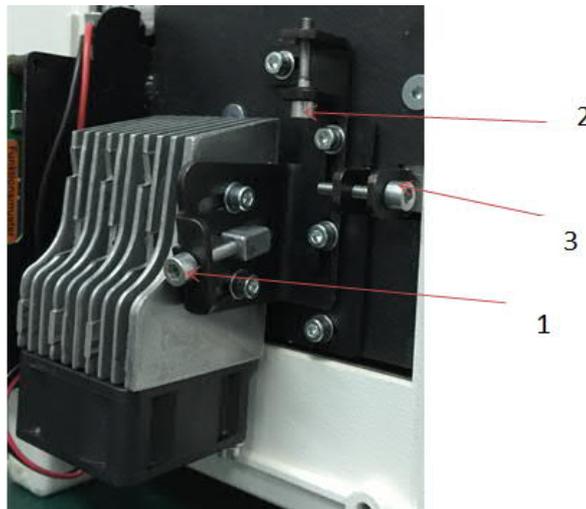
- ◆ Switch off the system.
- ◆ Unscrew the Allen screws on the heatsink rear cover.



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.



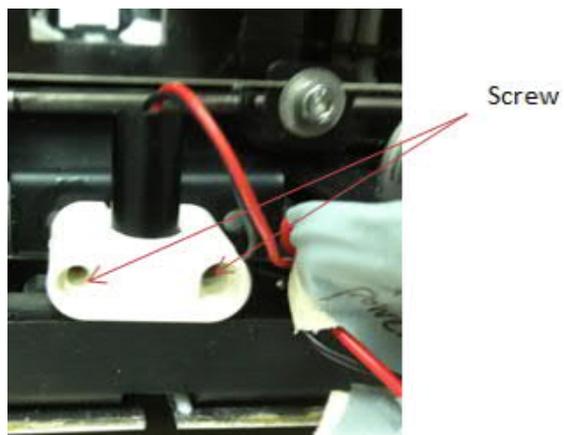
Knob

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.

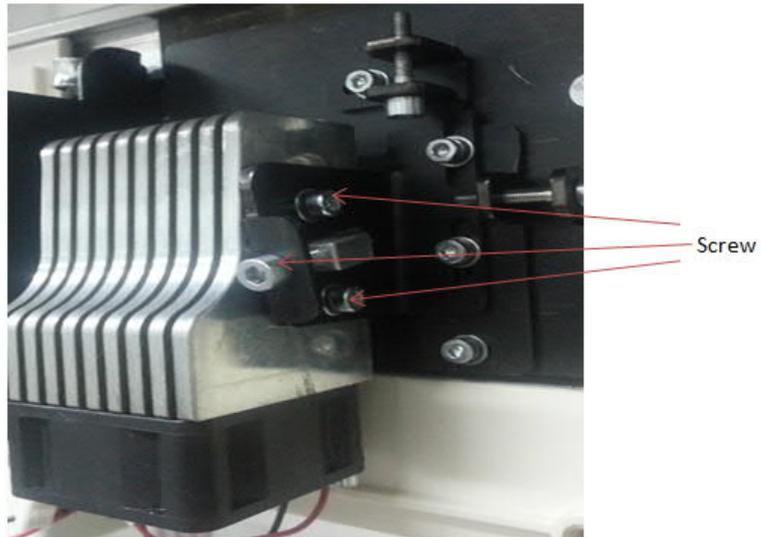
- ◆ Avoid contact with the heatsink to avoid burns.

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

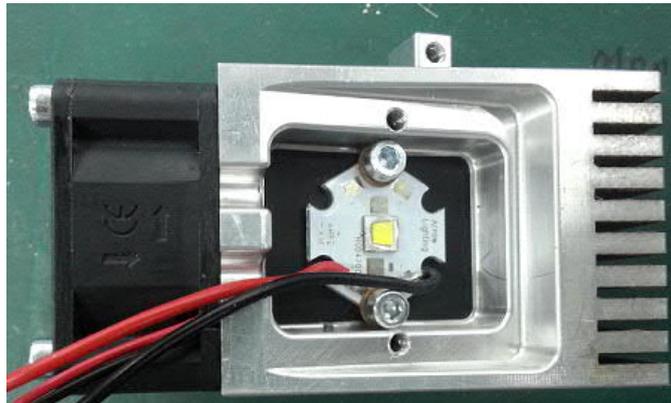


Maintenance

- ◆ 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

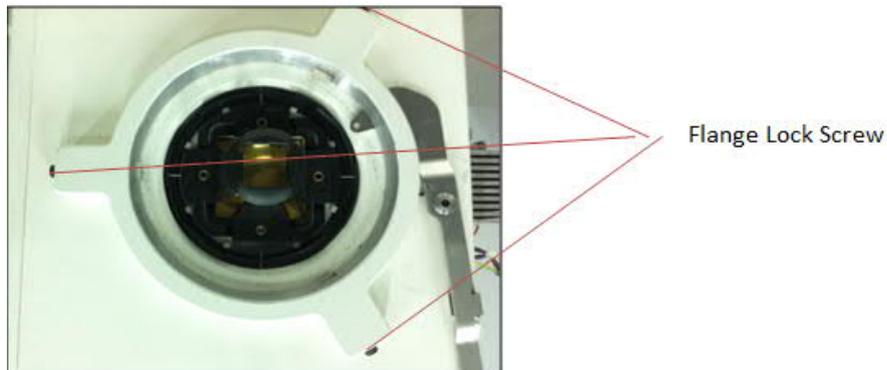


Protect the collimator against damage (e.g. from falling) during removal.

- ◆ 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.



EPRC Laser Label Indicating Label Laser label Laser Warning label

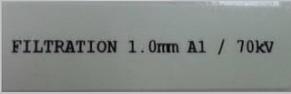
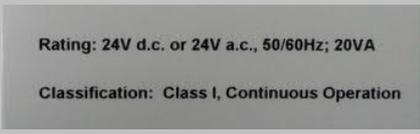
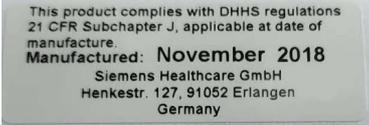
Location of Labels outside



User Manual Label logistic number label Revision label Inherent Filtration label Laser supplier nameplate UL Classified E347424 Manual Label EPRC label RoHS Compliant Label Production site label Nameplate-Collimator ML03 Identification label

Labeling

Table of Labels

| Number | Label | Description |
|--------|--|------------------------|
| (1) |  <p>Collimator ML03 (01) 04056869004280 GTIN (240) 10911200 MODEL (422) 156 ORIGIN CN (21) 10100 SERIAL IVK Siemens Healthcare GmbH, Henkestr. 127 91052 Erlangen, Germany Made in P.R. China</p> | Identification label |
| (2) |  <p>生产场所地址 Address of Production Site / Factory 上海西门子医疗器械有限公司 上海市浦东新区周祝公路278号 邮政编码: 201318 Siemens Shanghai Medical Equipment Ltd., 278 Zhouzhu Road, 201318 Shanghai, China Produced for Siemens Healthcare GmbH, Henkestr. 127, DE-91052 Erlangen 为德国西门子医疗股份有限公司生产 中国制造 Made in China</p> | Production site label |
| (3) |  | Laser label |
| (4) |  <p>FILTRATION 1.0mm Al / 70kv</p> | Filtration label |
| (5) |  | Read User Manual label |
| (6) |  <p>Rating: 24V d.c. or 24V a.c., 50/60Hz; 20VA Classification: Class I, Continuous Operation</p> | Rating label |
| (7) |  <p>LASER RADIATION DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT RAYONEMENT LASER NE PAS REGARDER DANS LE FAISCEAU APPAREIL A LASER DE CLASSE 2 RADIAZIONE LASER NON GUARDARE FISSO NEL FASCIO PRODOTTO LASER DI CLASSE 2 EN 60825-1:2014 P_s ≤ 1 mW, λ = 650nm</p> | Laser warning labels |
| (8) |  <p>CAUTION LASER RADIATION DO NOT STARE INTO BEAM LASER APERTURE PEAK POWER < 1mW WAVE LENGTH 650 nm CLASS II LASER PRODUCT</p> | EPRC Laser label |
| (9) |  <p>This product complies with DHHS regulations 21 CFR Subchapter J, applicable at date of manufacture. Manufactured: November 2018 Siemens Healthcare GmbH Henkestr. 127, 91052 Erlangen Germany</p> | 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.

Global Business Unit

Siemens Healthcare GmbH
Technology Centers
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthcare

**Global Siemens
Healthcare Headquarters**
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Legal Manufacturer
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany

Service Agents of after-sales
Siemens Shanghai Medical Equipment
No.278 Zhou Zhu Rd Shanghai, China
Zip: 201318
Phone: +86 21 3889 5000
China REG. NO.: 沪械注准
20182060283