Optica 20 series

CE 1639

User Manual

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The Optica 20 series contains features which are model type specific, the appearance of the device depends on the configuration and may differ to the images in this document.

Warranty
The product has the warranty provisions of our general conditions.

The warranty on your equipment will be void if:

- Service and maintenance are not carried out according to the instructions and if repairs are not performed, or performed without proper validation.
- Changes or modifications made without our prior written consent.
- Non-original parts or other than the specified lubricants have been used.
- The equipment has been used improperly, carelessly or not in accordance with its nature and / or purpose.

All consumables (e.g. bolts, nuts, screws, etc.) are excluded from warranty.

1. Introduction

This document is accompanying the Optica 20 series (see also §1.7). Additional to this User Manual a Technical Manual is supplementary to the INSTRUCTIONS FOR USE.

1.1. Contact information

This manual provides all the technical information necessary for the correct installation, application, operation, maintenance and service of the device.

If you need additional information, need support or want to report a problem with the device, please contact your distributor or Varex Imaging Nederland B.V.:

	Manufacturer	Distributor
Name	Varex Imaging Nederland B.V.	
Address	Fabriekstraat 41 7005 AP Doetinchem The Netherlands	
Telephone	+31 (0)314 799 870	
E-mail	Netherlands.CNC@vareximaging.com	
Website	www.vareximaging.com	

1.2. Abbreviations, acronyms and definitions

Term	Definition
Collimator	X-ray Collimator Optica 20 series
Optica 20	X-ray Collimator Optica 20 series
SID	Source Image Distance The distance from the source of radiation (the focal spot of the x-ray tube) to the film or other image-receptor. Synonym: Focal Film Distance (FFD)
RF	Radio Frequency

1.3. Symbols used in this document

To ensure adequate and clear understanding of the information provided in this manual, the symbols listed below are used to indicate warnings, cautions, and notes that are important for correct and safe use of the device.

	**WARNING:** Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.
	**CAUTION:** Cautions are directions which, if they are not followed, can cause damage to the device described in this manual or any other equipment or goods or can cause environmental pollution.
	**NOTE:** Notes provide advice and highlight unusual points. A note is not intended as an instruction.

1.4. Advisory

This manual must be read and understood by the users as defined in the INTENDED USE (see section 2.1) and SERVICE PERSONNEL.

This manual must be made available to the users and SERVICE PERSONNEL.

The users must verify that all requirements according to the safety standards and regulatory legislation are met before use of the Optica 20 series.

Information regarding serious incidents that have occurred using the Optica 20 series must be reported to Varex Imaging Nederland B.V. and the competent authority.

Varex Imaging Nederland B.V. is not liable if the provided instructions are not complied with. Varex Imaging Nederland B.V. is not liable if one or more of the following cases apply:

- Modification or repairing of the Optica 20 series in any way other than described in this manual.
- Use of the Optica 20 series other than the INTENDED USE.
- The Optica 20 series is not subjected to regular inspection and maintenance.
- Use of the Optica 20 series in a way which could not be reasonable foreseen by Varex Imaging Nederland B.V..
- Direct or indirect damage which are caused by not following the procedures and instructions in this manual.

Radiation danger

The Optica 20 series is designed and manufactured according applicable standards to meet the safety legislation. However due to inherent radiation danger which cannot be eliminated it is crucial to follow all safety procedures and instructions. To minimize the inherent danger of radiation, all procedures and instructions must be followed by the users.

The user must ensure that all possible measures are taken to ensure health and safety of patient and user.

1.5. General warnings, cautions and notes

	**WARNING:** Possibly hazardous optical radiation emitted. The collimator contains field light power LED of Risk Group 2. Do not stare at operating lamp. May be harmful to the eyes.
	**WARNING:** The collimator contains a Class 2 laser. Do not stare into the laser beam.
	**WARNING:** Be extra careful with unconscious patients because they cannot blink their eyes to protect their eyes to the possible hazardous optical radiation (field light and laser).
	**WARNING:** When there is structural damage to the housing of the collimator or if the collimator is malfunctioning, label the collimator as “out of order” and have the collimator repaired prior to further use.
	**WARNING:** Strong mechanical vibrations of the collimator shall be avoided.
	**WARNING:** Do not modify this equipment without (written) authorization of the manufacturer. Any change or modification carried out by unauthorized personnel may introduce serious hazards. When changes or modification are carried out by unauthorized personnel, Varex Imaging Nederland B.V. cannot be held responsible for injuries or damage to equipment.
	**WARNING:** The collimator shall only be used with specified conditions listed in §6.
	**WARNING:** The temperature of the enclosure can become more then 41 °C.
	**WARNING:** Preventive checks (see TM50844) shall be carried on a regular basis. The interval of these checks shall be tailored to the application and frequency of use.
	**WARNING:** When there is any damage to the collimator or repair is needed, only original replacement parts shall be used. Contact your distributor or Varex Imaging Nederland B.V. for assistance.
	**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Optica 20 series, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
	**WARNING:** If the collimator is used in an X-ray system with an automatic exposure control, verify before operation if the selected measuring cell is within the diagnostic (collimated) area.
	**WARNING:** The shutter opening indication and selected filter indication as available on the USER INTERFACE of the device (see Figure 1) is defined as primary indication. Additional indication available on the device shall be verified to the primary indication during use of the device. Values on the primary indication are leading.

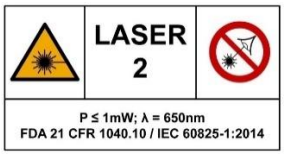
Requirements for SERVICE PERSONNEL

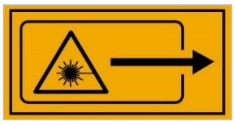
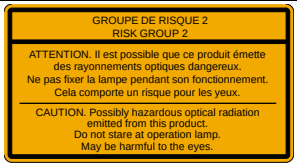
The device may only be installed, repaired or serviced by qualified SERVICE PERSONNEL, i.e.:

- Authorized by the RESPONSIBLE ORGANIZATION of the device;
- Authorized by the manufacturer;
- In possession of the diploma's / certificates required by national and local legislation.

	**WARNING:** Service, maintenance and adjustments may only be executed by qualified SERVICE PERSONNEL.

1.6. Labels and markings on the device

Symbol	Explanation
	Manufacturer
	Date of manufacture
	Serial number
	CE-mark directive 93/42/EC; conformity assessment by notified body 1639 (optional feature)
	SGS recognized component for US & Canada, registration number 710383 (optional feature)
	Identification of compliance with FCC 47 CFR Part 15 (optional feature)
	CAUTION: Federal law restricts this device to sale by or on the order of a physician. (optional feature)
	Identification of compliance with the provisions for EU WEEE directive
	DC supply voltage indication.
	AC supply voltage indication (optional feature).
	Follow the instructions for use Reading the instructions for use is crucial for a correct and safe use of the collimator
	Warning: Laser emission, possibly hazardous optical radiation emission. Explanatory warning for laser radiation (optional feature)

Symbol	Explanation
	Warning: Laser emission, possibly hazardous optical radiation emission Identifies the exit point of the laser beam (optional feature)
	Explanatory warning for hazardous optical radiation
	Indication cross shutters
	Indication long shutters
	Operate single line laser
	Operate field light indicator

1.7. Supplied components

The device that you have purchased is packed in a transport packaging appropriately designed to ensure the integrity of the device. Please ensure that the package you received is intact and that there are no traces of moisture or visual damages to the device. Otherwise, you should immediately contact your distributor or Varex Imaging Nederland B.V.. It is highly recommended to always use the original packaging during transport and for return shipments. See §6 for storage conditions if the device is not used directly.

The packaging contains the following components:

Amount	Description	Reference	
1	Optica 20 series	This **User Manual** is applicable for the below stated part number: Optica20-VV-XXX-YYY-LLL (where “VV” stands for the release version of the model) (where “XXX-YYY” stands for a sequel code to define the configuration) (where “LLL” implicates the regional version) This User Manual is applicable for devices with a VV value of 00, XXX value of 000 to 055 and any YYY and LLL value.	
1	Accessory Kit	Contains: • 1 User Manual • 1 Technical Manual • 1 EC Declaration of Conformity • 1 Terminal adapter OR • Leaflet referring to website for digital version of the Manuals and EC Declaration of Conformity • 1 Terminal adapter Content depends on the model as described above	50855

Be advised by your distributor or Varex Imaging Nederland B.V. for any accessories available. See also §6.3.

2. Device description

This chapter will describe the device in general and detail. The device is pointed out with features present in §2.4. Classifications of the device are listed in §2.11.

2.1. INTENDED USE

The device is intended to be used in medical diagnostic applications with restrictions to human diagnostics. The device is intended to be used as accessory of an X-ray system in a professional healthcare facility environment. The device is intended to restrict the dimensions of a diagnostic X-ray field by limiting the primary X-ray beam. The limitations of use are specified in §6. The device is not intended to be used in fluoroscopy applications; near active HF Surgical Equipment or in the RF shielded room of a system for magnetic resonance imaging, where the intensity of Electromagnetic Disturbances is high.

Use, other than above, is identified as abnormal use.

The intended user of the device is defined as the operator of an X-ray system. The operator shall be qualified and/or trained to operate the X-ray system.

2.2. Description of the device

The Optica 20 series is operated manually and consists of independent moveable shutter pairs. The shutters are limiting (collimating) the diagnostic X-ray field. The Optica 20 series projects a light field to indicate the size and position of the diagnostic X-ray field. A measuring tape is provided to measure the SID.

Additionally, the device can be configurated with:

- A single line laser for alignment of the X-ray image receptor.
- A filter module to provide additional filtration.
- Means for mounting additional accessories.
- Means for mounting a DAP-meter inside the enclosure.

For operation and usage see chapter 3 and chapter 4.

2.3. Principle of operation

The operable features to perform the INTENDED USE of the collimator are positioned on the front of the collimator. The following table shows symbols that are used to indicate the operable features:

Symbol	Definition	Description
	Cross shutters	The bold lines indicate the shutter pair seen from the top-side of the collimator.
	Long shutters	
	Operate light field	Symbol used to indicate the light button switch. Press the button to activate the light which will indicate the X-ray diagnostic area.
	Operate laser line(s) (optional)	Symbol used to indicate the laser button switch. Press the button to activate the single line laser.
n/a	Additional filtration (optional)	Additional filtration can be selected by rotation of the filter module (see Figure 1)

2.4. Overview of the device

This section gives an overview of the collimator.

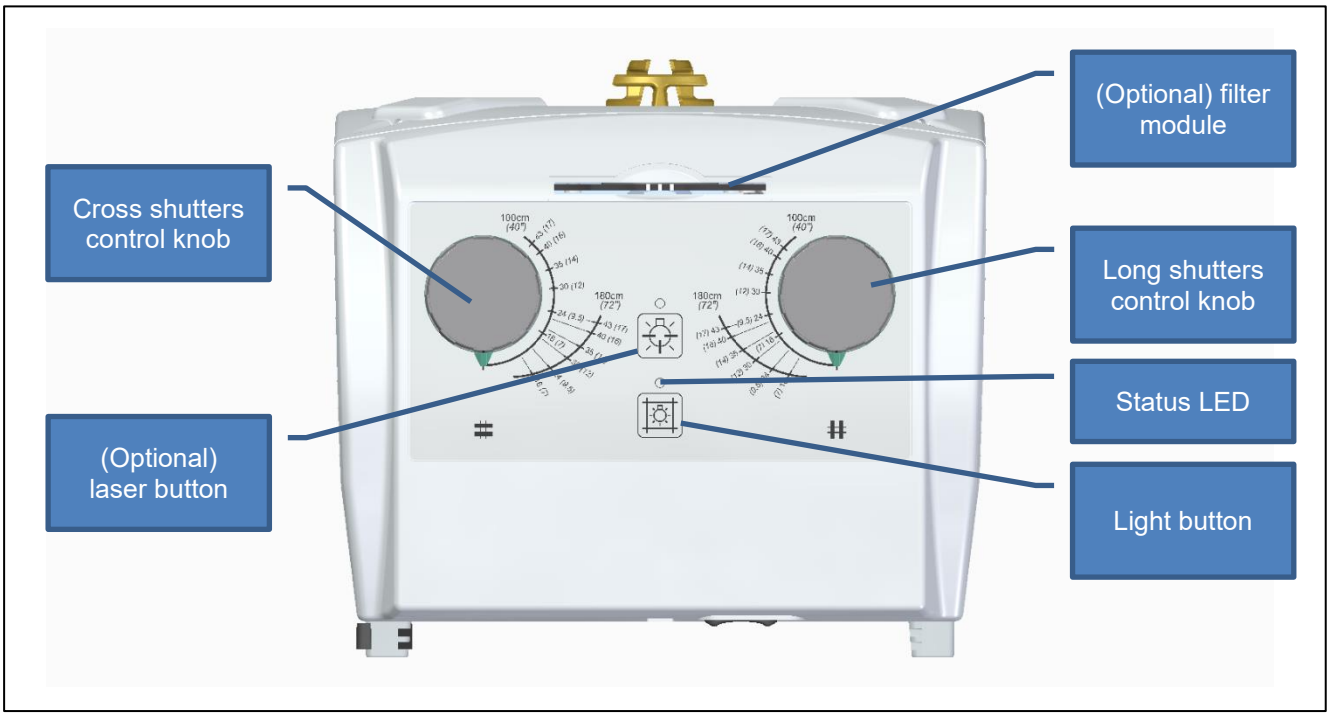


Figure 1: Device, Front view

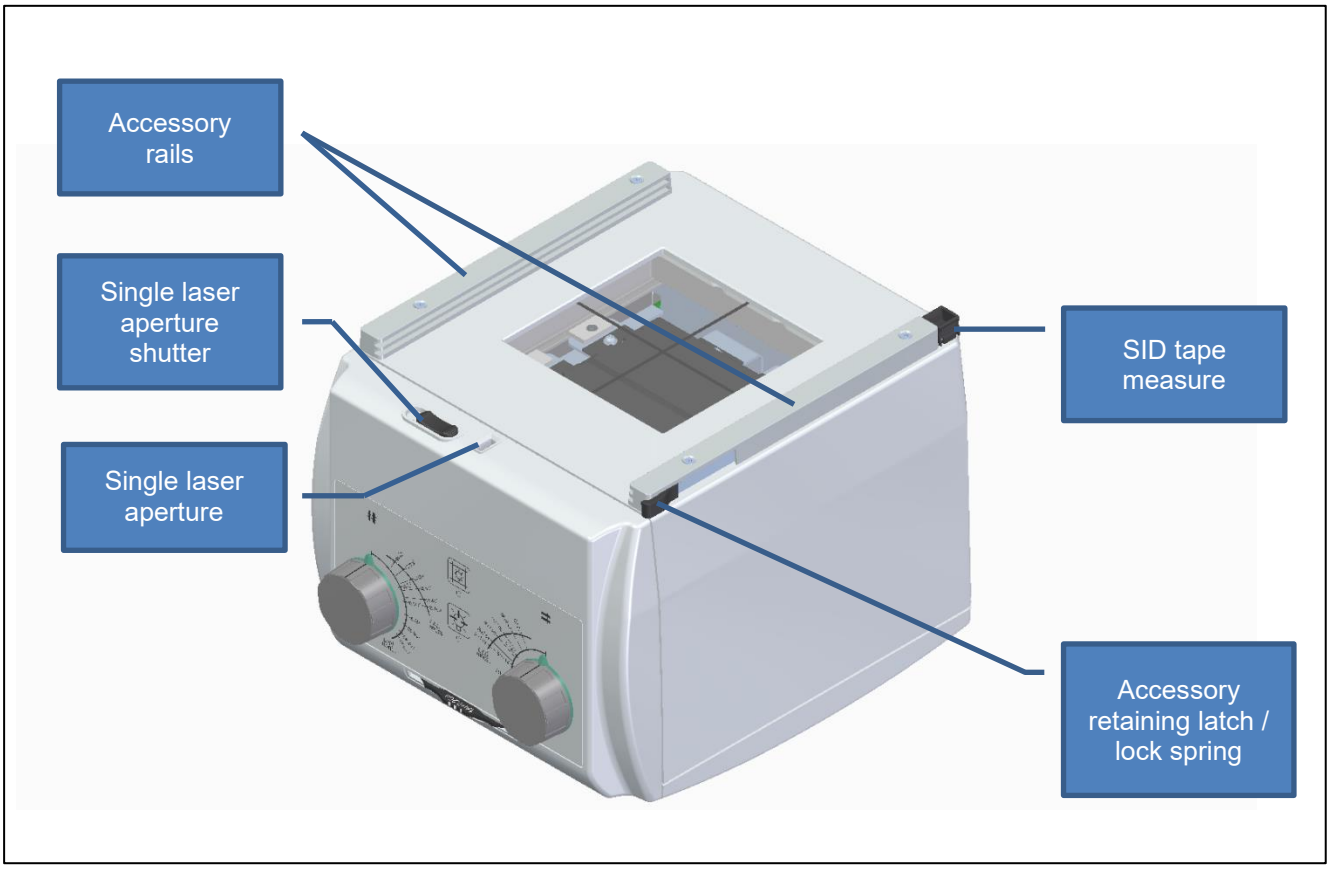


Figure 2: Device, Bottom view

Accessory rail specifications

Maximum accessories: 2

Maximum allowed total weight of accessories: 2 kg per Optica 20 series device.

Accessory rail interface dimensions, see also figure below

- Width (d1): 176 – 177 mm
- Thickness (d2): Max 2.3
- Pitch between slots (d3): 4.5 mm
- Length (d4): max. 177 mm
- Lock – collimator center distance (d5): 89 mm
- Slot to collimator housing (d6): 5 mm

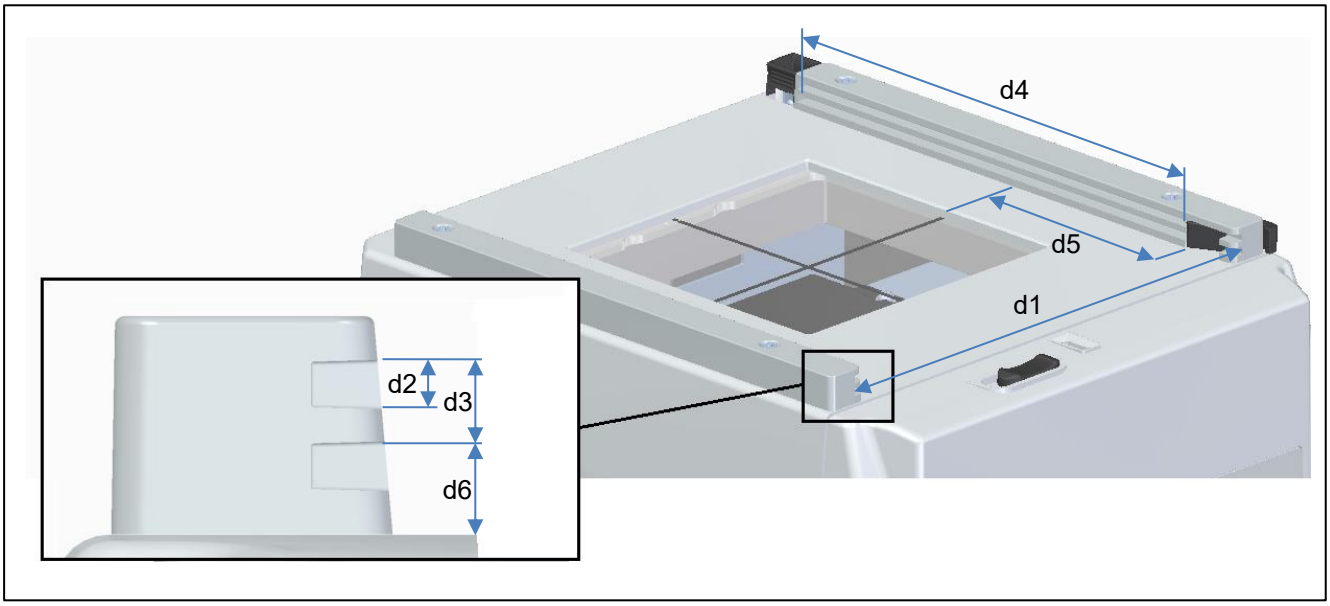


Figure 3: Accessory rail specification

⚠	**WARNING:** Check fit and locking of (inserted) accessory. The accessory must fit and be properly mounted to prevent it from falling.

2.5. Main dimensions

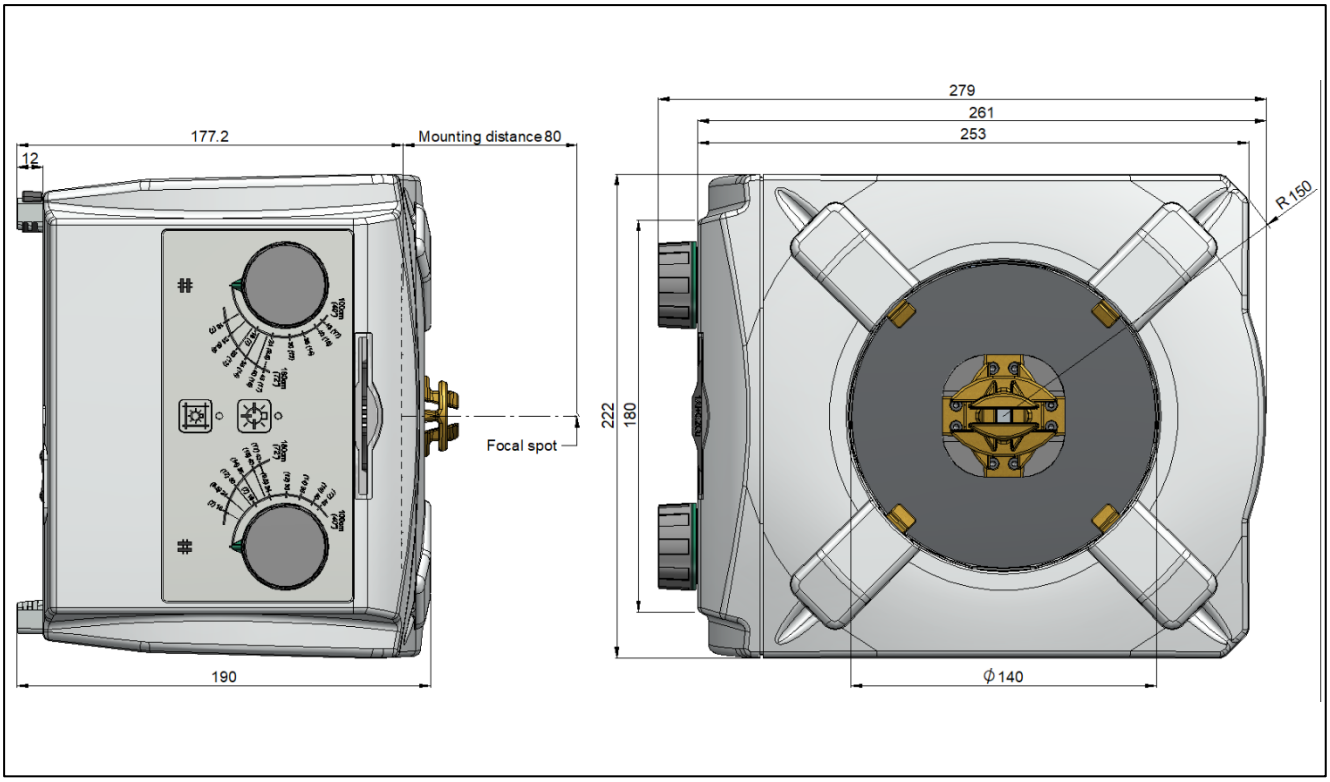


Figure 4: Main dimensions

2.6. Aluminum equivalent

The Aluminum equivalent (or ATTENUATION EQUIVALENT) can be found on the product label. The location of the product label can be found in §6.2. The ATTENUATION EQUIVALENT is expressed in [mm] aluminum.

2.7. Restriction on use

RF communication devices should be kept at a minimum distance of 30 cm. Otherwise the performance of the device can be negatively influenced.

2.8. ESSENTIAL PERFORMANCE

The Optica 20 series does not have essential performance.

2.9. APPLIED PARTS

No APPLIED PARTS are identified for the Optica 20 series.

2.10. Known contraindication(s)

Contraindications of the X-ray system continue to apply (see X-ray system documentation).

Additionally the Optica 20 series introduces matter in the primary X-ray beam which primarily results in additional X-ray scatter. Additional X-ray scatter causes a radiation risk. The Optica 20 series is mitigating the radiation risk by shielding the additional scatter and limiting the size of the primary X-ray beam and also confining the scatter generated from the X-ray tube (housing).

2.11. Classifications

Subject	Classification	Reference
Electrical safety	Class I	IEC 60601-1
Electromagnetic Compatibility intended environment	Professional healthcare facility environment	IEC 60601-1-2
Mode of operation	Continuous	IEC 60601-1
Ingress protection	IP20	IEC 60529
Laser	Class 2	IEC 60825-1
Field light	Risk Group 2	IEC 62471
Not intended for use in Oxygen Rich environment.		
Not suitable for Sterilization.		

2.12. Installation

The installation instructions for the device are available in the Technical Manual (see TM50844).

3. Operating instructions

This chapter describes the operating instructions. Powering ON and OFF are described in §3.1. The status LED colors are clarified in §3.2. A description of features to perform the INTENDED USE is given in §3.3.

3.1. Switching the device ON and OFF

The collimator does not have a switch to power on/off the device.

POWER-ON:

When the power supply to the collimator is switched ON, the collimator performs a power-ON self-test. During the power-ON self-test (which takes a few seconds), the status LEDs are flashing orange. The initialization cycle ends with a green status color for each status LED during 1 second. When the status LEDs are turned off, the collimator is ready for use. If the power-ON self-test is not successful, the status LED above the light button will be flashing red. See §3.2 for further information.

POWER-OFF:

There is no shutdown procedure for the collimator. The collimator can be switched OFF at any time without damaging the collimator. This is done by switching OFF the power supply to the collimator.

3.2. Status LED color

On the front panel status LEDs are present above the light- and laser button, indicating the ON/OFF status of the field light and the laser.
The status LED above the light button can show the colors green, orange and red.
The status LED above the laser button can only show the green color.

Color	Flashing	Meaning
No color	No	OFF state
Orange	Yes	Initializing
Green	No	ON state
Green	No	Just 1 second after orange flashing: End of initializing
Green	Yes	Short flashing after Laser switch-on: Laser does not function
Red	Yes	ERROR state

3.3. Device features

This section describes the features which can be present on the collimator. Depending on the configuration of the collimator some features may be unavailable. The following figures show a generic model, characteristics like layout, color and available features can be different.

A. The collimator is equipped with two control knobs. The knobs control the shutters to define the diagnostic area. Knob A_1 controls the shutters in the cross direction. Turning knob A_1 clockwise closes the shutters in cross direction. Knob A_2 controls the shutters in the long direction. Turning knob A_2 counterclockwise closes the shutters in long direction.

A_1. Knob for moving shutters in cross direction:

A_2. Knob for moving shutters in long direction:

Figure 5: Shutter control

	CAUTION: Striving the control knobs beyond the mechanical limits could result in damage to the collimator

B. Scale indication for field size is set out. The scale indicates the (X-ray) field size at two SID distances. An indication for SID 100[cm] (40”) and 180[cm] (72”) are available. The pointer of the shutter control knob points out the (X-ray) field size dimension. The field size dimension is given in centimeters and inches. The value between parentheses show the value in inches.

	NOTE: Take into account that a read inaccuracy can occur since it is an approximate and optical read-out.

C.  Push button for light field indicator, a green indication LED will light above the button. The light will be activated for a pre-defined time and will switch off automatically. Push the button again to switch off the light field.

D.  Push button for activating single line laser.
The laser will be activated for a pre-defined time and will switch off automatically. Push the button again to switch off the laser. A green indication LED will light above the button.

E. Additional to the single line laser, a laser shutter is present. The laser shutter is added to close the laser aperture. Slider E_1 shuts off or opens the laser aperture of the Bucky laser. The slider will snap-lock once in the correct position.

E_1. Laser shutter for single line laser

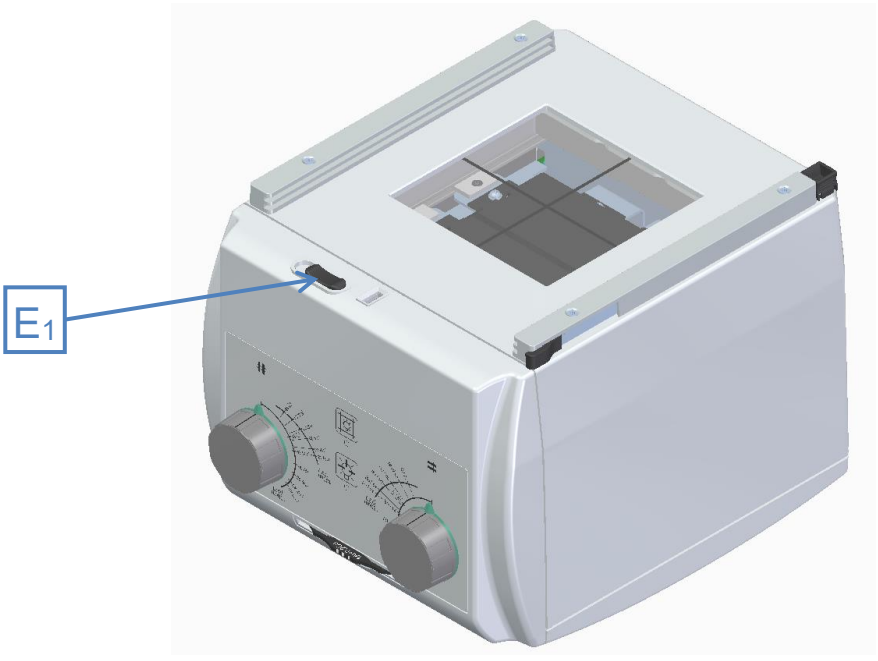


Figure 6: Laser shutter(s)

F. Measuring tape for determining SID. Pull out the lever and place it against the designated surface (e.g. table, wall stand, etc.). The SID value can be read on the measuring tape where it exits the collimator enclosure. The maximum value to be measured is 2m / 80”.

	**WARNING:** Incorrect readout of the measuring tape could result in under or overexposed x-ray image
	**CAUTION:** Pulling out the measuring tape beyond the maximum value can cause breakage and/or distortion of the tape. Always guide the measuring tape back to its start position.

G. Accessory rails, suitable for holding maximum of two accessories. See also §2.4.

H. Lock spring for accessories; slightly pull out the spring and remove the applicable accessory. See also §2.4.

☞	**NOTE:** Be careful when handling the lock spring, over-elongating the spring can cause permanent damage to the lock spring.

I. The filter module is an optional feature for the collimator.

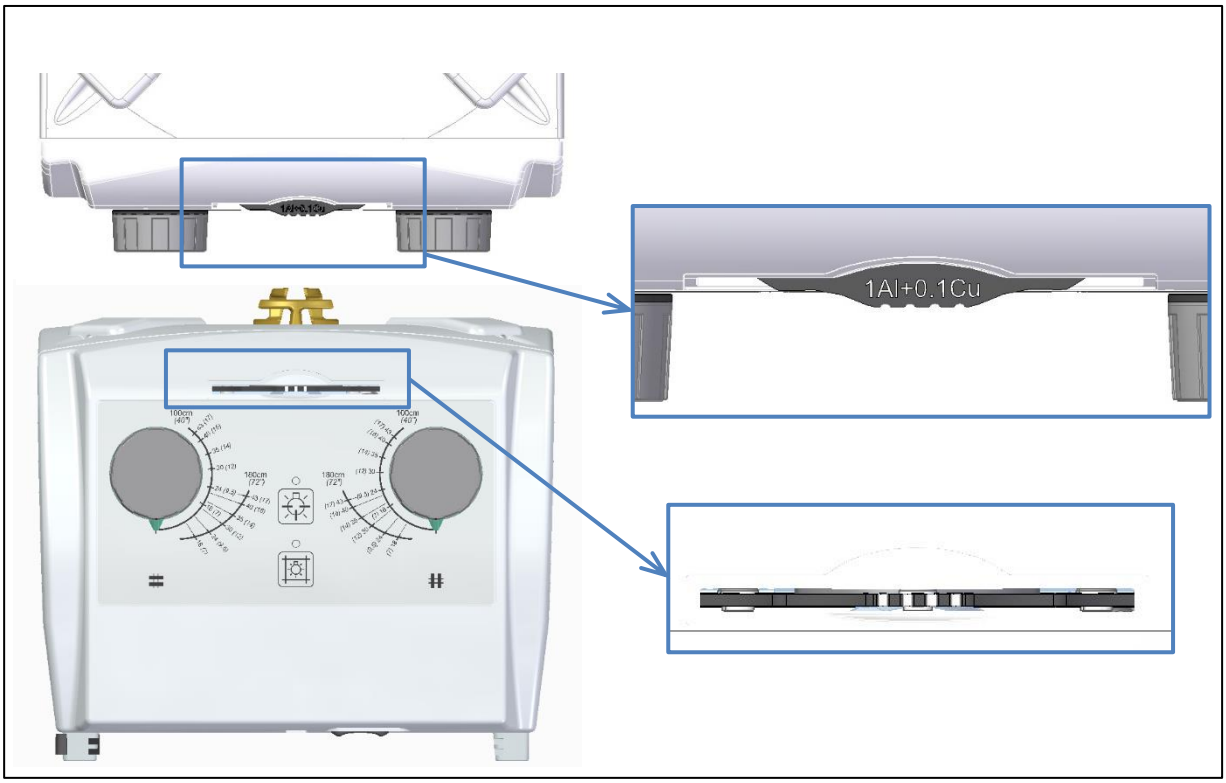


Figure 7: Filter module

Turn the disc clockwise or counterclockwise to select the required additional filter material, the disc will snap-lock once in the correct position. The filter material is written on top of the disc (for example see also print screen above) and at the bottom of the disc, the composition of the material is configured on request and can vary. Also, each position has an indication (from 1 up to 4 lines) at the perimeter of the disc. Position 1 (indicated as “0” on top and bottom of the disc) is always the no-filter position, the other three positions contain filters. Both indications (material marking and line(s)) also functions as a read-out for correctly positioning of the filter module.

⚠	**WARNING:** Incorrect setting of the filter module could result in under or overexposed x-ray image

3.4. Adjustments

Information about adjustment of the device can be found in the Technical Manual (see TM50844).

3.5. EMC compatibility

The device conforms to IEC60601-1-2:2014+AMD1:2020 for EMC compatibility and must be used according to the EMC information provided in this manual.

	**WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	**WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
	**NOTE:** The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

4. Troubleshooting, maintenance and service

This chapter describes troubleshooting, cleaning, maintenance and service.

4.1. Troubleshooting

Information about troubleshooting can be found in the Technical Manual (see TM50844).

4.2. Cleaning

Cleaning procedures and agents

Follow local, national and organizational procedures regarding cleaning. The following agents are safe to use:

Agents
Isopropanol
Ethyl alcohol

The cleaning agents above may be diluted with water for cleaning purposes.

WARNING:
Use of cleaning agents other than described to be save may result in damaging the collimator or possible injury to the user.

Cleaning recommendations

- Make sure the collimator is switched OFF (see §3.1 for instructions)

WARNING:
Use of abrasive cleaning could result in deterioration of the collimator. E.g. the crosshair window can be damaged which will result in reduction of light field illumination.

- Do not use abrasive cleaning products.

WARNING:
Do not spray, pour or soak the collimator with liquids.

- Use a damp soft cloth to clean the collimator, this will reduce the possibility for liquids to enter the collimator. Use a dry soft cloth to remove any residuals from the collimator.

4.3. Maintenance and service

Information about maintenance and service of the device can be found in the Technical Manual (see TM50844).

5. Disposal

This device contains substances that can be hazardous to the environment and care should be taken when disposed of.

The device is marked with the following symbol:

Follow national and local regulations regarding disposal of electronic equipment.

Packaging material shall be recycled according national and local regulations.

6. Specifications and accessories

This chapter gives specifications (technical and product label information) and information about available accessories.

6.1. Technical specifications

Classifications	See section 2.11
Application	Stationary equipment for radiography (see §2.1)
Materials	ABS/PC, PC, POM, stainless steel, aluminum, lead, glass, brass, (spring) steel
Power source	24 [VDC] ± 10% / 24 [VA]
Power source (optional feature)	12-45 [VDC] ± 10% / 24 [VA] 20-30 [VAC] ± 10% / 35 [VA] 50/60 [Hz]
CAN-bus	ISO 11898−2, ISO 11898−5 compatible (5V CAN-transceiver); Communication speed 125; 250; 500; 1000 kb/s configurable; (default 500 kb/s) Bus-termination 120 Ohm ON/OFF configurable (default OFF)
RS232-bus (optional feature)	TIA/EIA-232 and ITU v.28 Standards compatible Baud-rate 9600; 19200; 38400; 115200 bit/s configurable (default 115200 bit/s) 8 data bits; 1 stop bit; no parity; no flow control No hardware handshaking (Rx/Tx-only);
USB-bus (service only)	USB 1.0 compatible
Output switch (optional feature)	30V 100mA
Input switch	Inactive: floating (3.3V) Active: short to ground, OC-output compatible (0.5mA)
Field size	Min. 3x3[cm] @ 1[m] SID [1.2”x1.2” @ 39.4” SID] Max. 43x43[cm] @ 1[m] SID [16.9”x16.9” @ 39.4” SID]
Shutter feedback light field indication accuracy (optional feature)	+/- 1% of SID
Light field luminosity	Configurable between 160 [lux] and 220 [lux]
Light source and color	LED, nominal CCT light color 4500K – 6000K (natural - day white)
Light field / X-ray alignment	≤ 1% SID
Light field edge contrast ratio	≥4
SID tape measure range	90 – 200 [cm]
Weight	Configuration specific: approximately 7 [kg]
Size (accessory rails and knobs excluded)	(WxDxH) 222x261x178[mm] [8.7”x10.3”x7.0”]
Al eq.	Between 1.2[mm] – 3.0[mm] @ 75[kV], see § 2.6
Leakage	≤ 0.5 mGy/h
Filter module (added filtration) (optional feature)	1 mm Al + 0.1 mm Cu 1 mm Al + 0.2 mm Cu 2 mm Al None

Operation environment	Ambient temperature: +15 – +40 [°C] Relative humidity: 30 – 75 % RH, non-condensing Atm. Pressure: 750 – 1030 [hPa], <3000 [m]
Transport and storage	Ambient temperature: -20 – +60 [°C] Relative humidity: 30 – 95 % RH, non-condensing Atm. Pressure: 750 – 1030 [hPa]
Power and Communication Contra connector	Molex Micro-fit (3.0) series 43025-1600 receptacle housing to be used with Molex Female Terminal series 43030 or 46235
Maximum cable length	< 30 m (applies to all cables)
Cable type(s)	Unshielded or shielded; Can-bus H/L signals preferably twisted

6.2. Product label

The product label is located on the back-side of the collimator:

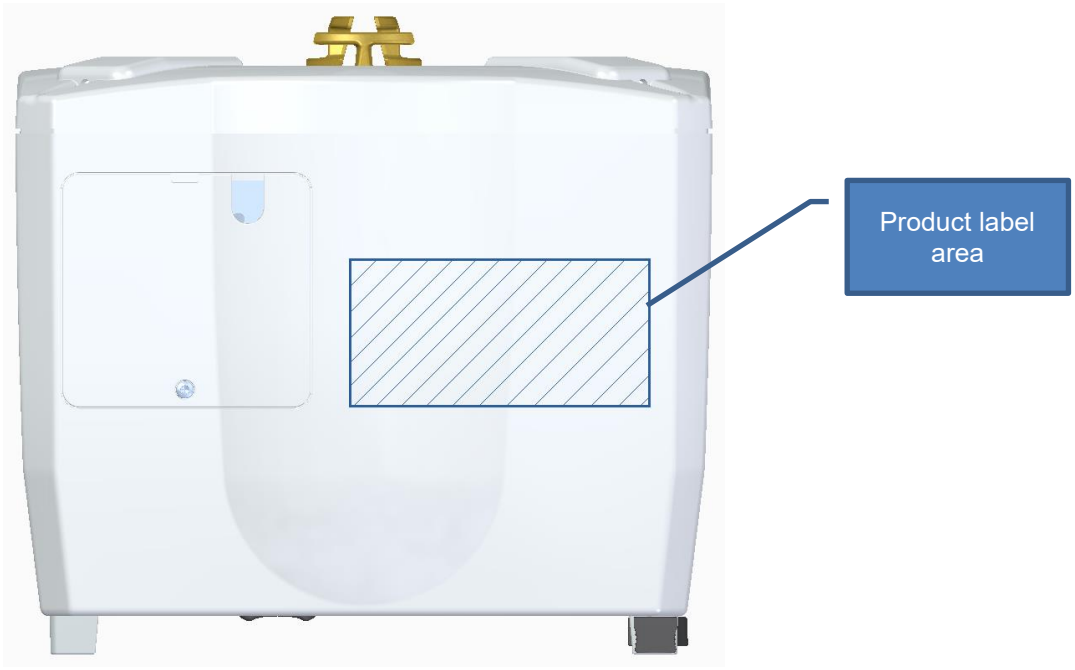


Figure 8: Back view (product label)

⚠	**WARNING:** If the product label is missing or not readable contact your distributor or Varex Imaging Nederland B.V.

The figure below shows the information provided on the product label.

Figure 9: Product label

☞	**NOTE:** The product label as shown in Figure 9 is representing the layout. The attached label on the collimator shows the specific information valid for your device.

6.3. Accessories

Be advised by your distributor or Varex Imaging Nederland B.V. for any accessories available. The following accessories are available (see TM50844):

1. Screw terminal adapter accessory
2. Double accessory rails

Contact details

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