OCULUS SDI® 4

INSTRUCTION MANUAL

Stereoscopic **D**iagonal **I**nverter

OCULUS®

Notes on this instruction manual

The SDI® 4 has been manufactured and tested according to strict quality criteria.
To ensure safe operation, it is essential that you use the device correctly. For this reason, you should thoroughly familiarize yourself with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

This operating manual describes the following SDI® 4 models:

- SDI® 4c
- SDI® 4cli
- SDI® 4e
- SDI® 4eli
- SDI® 4m

Due to ongoing development, the diagrams shown in the instruction manual may depict minor changes to the actual device delivered.
If you have any questions or would like additional information about your device, please do not hesitate to call us or to contact us by mail or fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

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1 Scope of Delivery

Product (versions)	
■ SDI® 4m with two protective dust covers and transportation lock	54302
■ SDI® 4m (Leica Version) with two protective dust covers and transporting lock	54312
■ SDI® 4m (Kaps version) with two protective dust covers and transportation lock	54305
■ SDI® 4e with two protective dust covers and transportation lock	54300
■ SDI® 4e (Leica Version) with two protective dust covers and transportation lock	54310
■ SDI® 4e (Kaps version) with two protective dust covers and transportation lock	54315
■ SDI® 4c with two protective dust covers and transportation lock	54320
■ SDI® 4c (Leica Version) with two protective dust covers and transportation lock	54330
■ SDI® 4cli (Leica CAN version) with two protective dust covers and transportation lock and CAN connection cable	54331
■ SDI® 4eli (Leica CAN Slave version) with two protective dust covers and transportation lock and CAN Slave connection cable	54332

Accessories for each SDI® 4	
■ Sterilisable rubber cap	54335
■ Hexagon screw driver	05490061
■ Instruction Manual	G/54320/EN
■ Conditioning Instructions	G/55185/EN

Accessories for each SDI® 4eli	
■ Connection cable CAN Slave	54341

Accessories for each SDI® 4cli	
■ Connection cable CAN	025433100004

Accessories for SDI® 4 c and SDI® 4 e	
■ Optional: Plug-in power supply GEM12I 09-P1J	54905
■ Optional: extension cable for voltage power supply plug (approx. 5 m)	54898
Required accessories:	
■ Combination foot switch SDI® 4c	10009585
■ Footswitch for SDI® 4e	10017270
■ Optional: extension cable to SDI® 4e foot switch (approx. 5 m)	54885
■ Leica M820/M822/M844 control cable for SDI® 4c/SDI® 4e	54873
■ Leica M820/M822/M844 supply cable for SDI® 4c/SDI® 4e	54876

We reserve the right to make changes to deliverables as a part of any technical improvements.

➔ If transport damage is discovered from the shipment, please file a complaint with the shipping company immediately.

➔ Have the damage confirmed on the bill of lading so that an orderly handling of the complaint for damages is possible.

2 Graphic Symbols SDI® 4

Pictographs device				Pictographs packaging	
	Manufacturer		Protection class		Keep dry
	Date of manufacture	IP XX	Level of protection		Transport upright
CE	Conformité européenne	REF	Article number		Fragile
	Follow instruction for use	SN	Serial number	Transpor	Permitted temperature range for transport
	Disposal in household trash is prohibited		Attention	Storage	Permitted temperature range for storage
	Applied part, type B		Do not reuse		Limit of humidity
		MD	Medical Device		Keep dry
(21) ABCDEFG123456789 Matrix (01) 04049584000040		Example: UDI number consisting of UDI-DI (device identification) UDI-PI (Product Identifier) machine-readable matrix code			

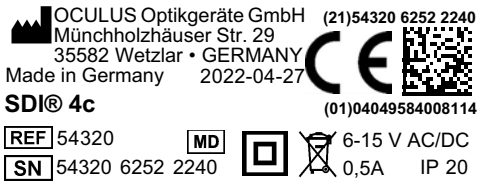


Fig. 2-1: Rating plate SDI® 4c

3 Safety Instructions

Attention

All safety-related instructions for use of the SDI® 4 are given in the Instruction Manual for the unit. It is therefore imperative that you read and understand the whole Instruction Manual before you use the SDI® 4.

3.1 About this Manual

➔ Carefully read through the Instruction Manual.
➔ Make sure to keep the instruction manual in a safe place and available to operating personnel at all times.
➔ Observe the legal regulations with regard to accident prevention.

3.1.1 Used Graphic Symbols

Attention

Denotes a potentially hazardous situation which can easily result in minor physical injury or property damage.

Note

Denotes situations which could result in incorrect findings, denotes user instructions and useful or other important information.

Denotes important information about the product and its use, which require special attention.

3.2 Safety Instructions for Use

Attention

Risk of personal injury or property damage due to improper operation

➔ Observe the following safety instructions.

Risk of personal injury or property damage due to equipment modifications that could jeopardize safety

➔ This equipment may not be modified without the permission of the manufacturer. Changes or modifications may only be made by OCULUS Service and authorized dealers.

Report any serious incidents occurred related to the product to the manufacturer at (vigilance@oculus.de) and to the relevant authorities of the member state in which you and/or your patient reside.

Instructions for operating personnel

➔ Ensure that the SDI® 4 is used only by duly trained physicians and operating theatre personnel, who, due to their training or their knowledge and practical experience, can guarantee proper handling of the device. Only OCULUS or an authorized dealer is allowed to train the personnel.

Transport and storage instructions

Refer to the notes in *sec. 10, page 16*.

Instructions for setup and connection

➔ Only OCULUS, an authorized dealer or trained personnel are allowed to setup and connect the SDI® 4.

➔ Comply with the legal provisions in force in your country, and with the hygiene and waste disposal regulations of the hospital or clinic.

➔ Set up the SDI® 4 so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

➔ Do not use excessive force to plug in the electrical plugs for the OCULUS BIOM® 5.
If you are unable to make a plug connection, check whether the plug fits the socket.
If you find damage to the plug connector, have the damage corrected by our service department.

➔ Heed unconditionally the operating instructions and safety advice of the operating microscope and of the additional equipment.

➔ Familiarize yourself with all safety features and devices before you put the unit into initial operation.

Operation and Maintenance Information

- ➔ Before initial operation: Let OCULUS or an authorized dealer train you in the operation of the SDI® 4.
- ➔ Never operate a damaged SDI® 4.
  Inform the supplier of any damage.
- ➔ Only operate the SDI® 4 with the original accessories supplied by us and only when the unit is in a technically perfect condition.
- ➔ Only operate the equipment after your have read and understood the Instruction Manual.
- ➔ Do not touch the patient and the device at the same time.
- ➔ If a malfunction occurs that you cannot rectify by following in the instructions in the troubleshooting table *(sec. 11, page 17)*, you must not use the device. Clearly mark the unit as non-operational and get in touch with our service personnel.
- ➔ The sterilisable rubber cap for the adjusting knob of the SDI® 4 must be sterilized before the first and before each subsequent use.
  It is imperative that you heed the cleaning, disinfection and sterilization instructions given in the Conditioning Manual.
  A sterilization of the SDI® 4 is not possible.

Instructions for disassembly and disposal

- ➔ When disconnecting electrical connections, pull on the respective plug and not on the cable itself. Take hold of the plug, do not pull on the cable.
- ➔ Dispose of the equipment in compliance with the corresponding legal requirements. Comply with the hygiene and disposal regulations of the hospital or clinic.

Patient environment information

Patient environment is the area where patients can come into contact with any part of a medical electrical equipment (ME equipment) or with another person being in contact with the ME equipment.

In the patient environment, use devices that conform to IEC 60601-1. If a multiple power socket is to be used, or if a device is to be used that does not meet the IEC 60601-1 standard, use an isolating transformer.

EMC and Electrical Safety Information

The SDI® 4c or SDI® 4cli, a connected BIOM® 5c/cl and a microscope constitute a Medical Electrical System (ME System) in accordance with DIN EN 60601-1. If you connect any more devices, they too become part of the ME System.

- ➔ Make sure that all devices of the ME System meet the provisions of IEC 60601-1 or of IEC 60950-1

Use the plug-in power supply unit included in the scope of delivery.

Attention

Use of a Multiple Socket Extension Cord

Risk of personal injury or material damage caused by unsafe multiple socket extension cord

If you use a multiple socket extension cord to connect the SDI® 4 to the power supply, you must heed the following information:

- ➔ Use a multiple socket extension cord that complies with the requirements of DIN EN 60601-1:2005 section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the SDI® 4 into this multiple socket extension cord.

If you use a multiple socket extension cord, it must be supplied with power via an isolating transformer.

Electromagnetic Compatibility (EMC / Cables)

Risk of personal injury or damage to property due to electromagnetic interference

Portable and mobile HF communications appliances (high frequency) can affect medical, electric equipment.

- ➔ Make sure that portable and mobile RF communications equipment do not cause interference.
- ➔ Recommendation: Maintain a minimum distance of 4 m. If the distance is shorter, you must ensure that the SDI® 4 functions correctly.

4 Proper Use

These stereoscopic diagonal inverters SDI® 4m/4e/4c/4eli/4cli reverse the picture of indirect monitoring systems (BIOM® 5, wide-angle contact lenses) true to side for the human eye during minimal invasive posterior segment surgery.

The SDI® 4 is designed for use in hospitals and clinics in conjunction with the appropriate operation microscopes.

These operation microscopes must have been designated as adaptable by the company OCULUS Optikgeräte GmbH.

➔ Make certain that the following connection types are used for the power supply.

Intended medical indication

The device is intended to support observation of the posterior segment of the eye during surgery (vitrectomy).

Contraindication

None known

Unwanted adverse effects

None known

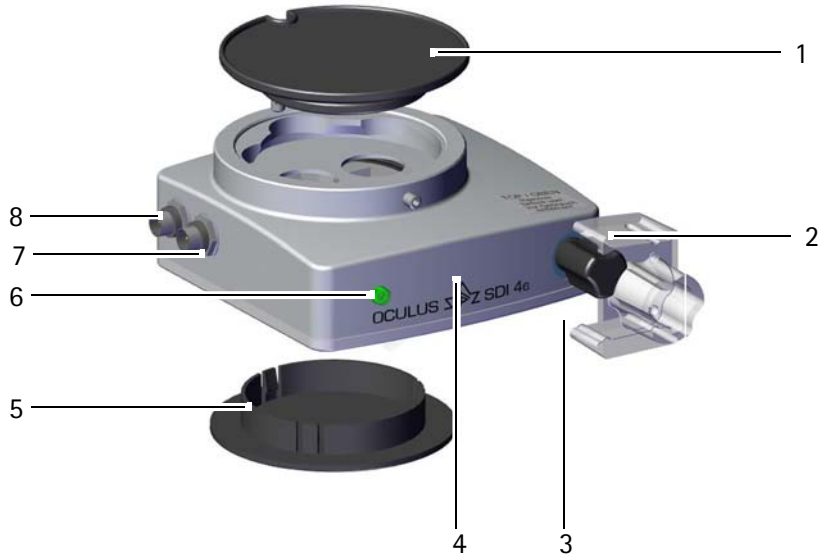
Intended users

The device must only be used by duly trained physicians and operating theatre personnel, who, due to their training or their knowledge and practical experience, can guarantee proper handling of the device. Only OCULUS or an authorized dealer is allowed to train the personnel.

Patient group

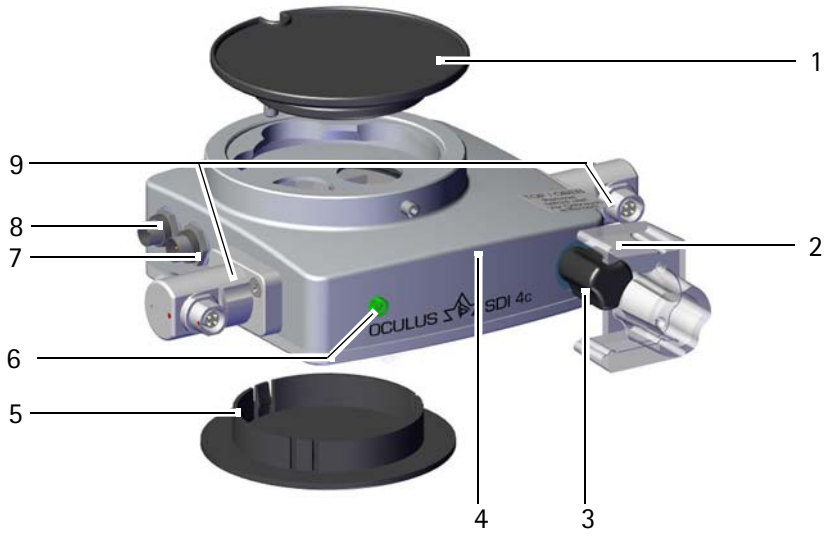
No limitations with regard to weight and health condition.

5 Description of the Unit



1 Top dust cover
2 Transporting lock for star knob
3 Star knob
4 SDI® 4e
5 Bottom dust cover
6 Indicator lamp
7 Connection for a foot switch (optional)
8 Power supply connection

Fig. 5-1: Unit Components SDI® 4e



1 Top dustcover
2 Transporting lock for star knob
3 Star knob
4 SDI® 4c
5 Bottom dust cover
6 Indicator lamp
7 Connection for a foot switch
8 Power supply connection
9 BIOM® 5c connection, pivotable

Fig. 5-2: Unit Components SDI® 4 c

6 Functional description

The SDI® 4 (Stereoscopic Diagonal Inverter) is used to reinvert images, e.g. that of a BIOM® 5 or a wide angle contact lens.

SDI® 4e/4c/4eli/4cli

On the SDI® 4e/4c/4eli/4cli, the image can be inverted by pressing an optional foot switch.

You can also operate the inverting optics manually with the star knob.

You can recognize the position of the optical system by the indicator light. If it is illuminated, the optic system and the image inversion feature are activated.

If adjusting mechanically by hand when the electric power switch is turned on, turn the star knob clockwise until you feel it click into position. The indicator lights up shortly before the final position is reached.

Only SDI® 4c/4cli

If you are using the SDI® 4c/4cli in conjunction with the BIOM® 5c/cl, the image inversion function is controlled by the position of the BIOM® 5c/cl.

When the BIOM® 5c/cl is swung into the vertical working position, a position switch on the BIOM® 5c/cl activates the SDI® 4c/4cli.

The SDI® 4c/4cli is automatically deactivated when the BIOM® 5c/cl is swung out of the beam path.

Respectively, you can control the SDI® 4c/4cli with the combination foot switch.

SDI® 4m

Image inversion with the SDI® 4m can take place only by mechanical adjustment with the star knob. You can recognize the position of the optical system by the indicator in the transparent glass. It is centrally located on the front of the SDI® 4m, just to the left of the star knob. If the sight glass is completely yellow, the image erection is not active.

7 Initial Operation

Attention

Risk of incorrect use due to improper training

➔ Before initial operation: Let OCULUS or an authorized dealer train you in the operation of the SDI® 4.

7.1 Preliminary Steps

➔ Remove the plastic carrying case from its packing and dispose of the packing properly.

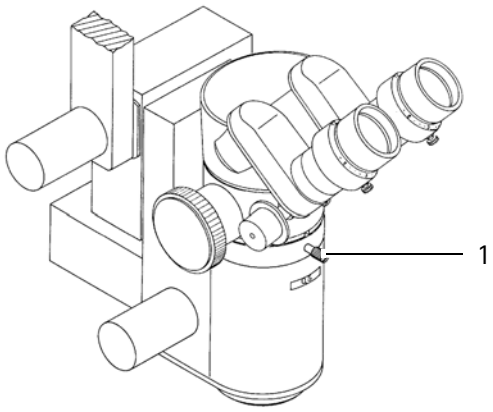
➔ Make sure that the sterilisable rubber cap has been cleaned, disinfected and sterilized before the first and every subsequent use.

➔ Keep the plastic case and the transport lock for the star knob.
If you want to store the SDI® 4 for a longer period of time or if you want to transport it, or if you have to return it for service or repair, this can only be optimally done in the plastic case with special insert and with the transport lock for the star knob.

➔ Like the operation microscope, the SDI® 4 is part of an optical unit. Handle the equipment with care. Do not expose the equipment to vibrations, knocks, soiling and high temperatures (above 35°C).

➔ Before assembling the unit, remove both protective dust covers and the transporting lock for star knob. Keep the two dust covers for proper dust protection later, in case you have to dismantle the SDI® 4 at some point.

7.2 Attach the SDI® 4 to an Operation Microscope



1 Locking screw

Fig. 7-1: Before the installation of the SDI® 4

➔ Always take care when mounting or removing the SDI® 4 that none of the optics in the beam path become soiled.

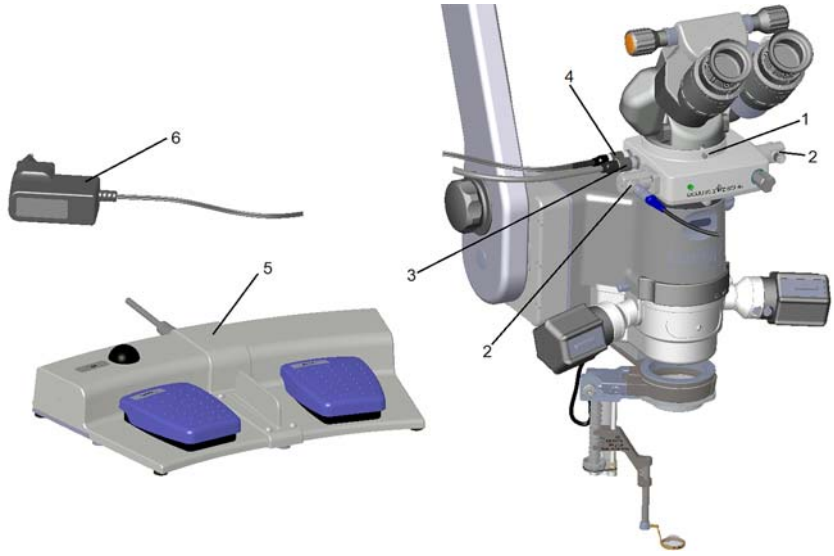
- ➔ Whilst protecting the binocular tube from falling down, please unscrew the locking screw on the main body of the microscope (1).
- ➔ The SDI® 4 is generally mounted below the beam splitter.
  To do so, remove the binocular tube, including the beam splitter from the body of the microscope.
  On some microscopes, the beam splitter is fully integrated into the microscope, in which case you then have to mount the SDI® 4 above the beam splitter.
- ➔ Place the flange of the SDI® 4 into the dovetail receptacle of the main body of the microscope. Check that the SDI® 4 is properly seated before carefully tightening the locking screw of the main body of the microscope. When properly mounted, the SDI® 4 should not wobble.
  Make sure of this before attaching the other microscope components.
- ➔ Proceed in the same manner when mounting the beam splitter, the binocular eyepiece and other components of the microscope;
  Carefully tighten the hexagon socket set screw of the SDI® 4 *(Fig. 7-2, page 13, item 2)* in the same way with the included hexagon screw driver and then make sure that each component is correctly seated.
- ➔ Before connecting the electrical versions of the SDI® 4 to the power supply, check to see whether the power supply voltage is within the voltage range given on the rating plate.
  This is guaranteed if the plug-in power supply unit provided by OCULUS is used.
  Make sure that the voltage supply in the mains socket is within the voltage range of the plug-in power supply unit.
- ➔ When connecting the hand or foot switch, please do not join the electrical plug-and-socket connections by excessive force.
- ➔ After inserting the plugs into the corresponding sockets *(Fig. 7-2, page 13, items 3 and 4),* lock them in place by turning the threaded connector (milled sleeve).

Connector SDI® 4c/4cli

- ➔ Make sure that the plugs are plugged into the appropriate jacks or sockets.
- ➔ Plug the plug for the foot switch into the 5-pole jack (3).
- ➔ Plug the power supply plug (9 V) into the 3-pole jack (4).
- ➔ After plugging in the plug, secure it by turning the screw connectors (knurled bushings).
- ➔ If you want to connect the SDI® 4 to a BIOM® 5c/cl: Plug the BIOM® 5c/cl plug into one of the rotating, 4-pole jacks (2).

Caution

The SDI® 4c/cli is connected to the BIOM® 5c solely via the 4-pole jacks (2).



1 Set screw of the SDI® 4
2 Connection jack for the BIOM® 5cl
3 Plug for the combination foot switch
4 Connection jack for the Power supply
5 Combination foot switch for SDI®/ BIOM®
6 Power adapter including interchangeable plug adapter for SDI® 4 e/c

Fig. 7-2: Example: SDI® 4c at the microscope

8 Operation

8.1 Prior to each Use

Before each use, check that

- the unit is in technically perfect condition
- all connections and fasteners that can be loosened are properly tightened and are in a safe condition
- all cables and plugs are free of damage
- the unit is connected to a proper voltage supply (SDI® 4c/4cli and SDI® 4e/4eli)
- All electric functions are operational:
  - SDI® 4 on/off (SDI® 4e/4eli and 4c/4cli)
  - BIOM®-focusing up, BIOM®-focusing down (SDI® 4c)
- the rubber covering for the adjustment button of the SDI® 4c is supplied and sterile.

➔ Adjust the binocular tube to as comfortable a position as possible.

8.2 Practical Tips for Use

➔ To adjust the optical system of the SDI® 4: Briefly press the foot switch. The optic system then moves to its other position.

➔ Always activate the SDI® 4 if you are using optical inversion, e.g. BIOM® or an indirect vitrectomy lens.
When the unit is activated, the indicator lamp at the SDI® 4c/cli and SDI® 4e/eli lights up. The indicator remains empty on the SDI® 4m.

➔ If you are using non-inverting optics, such as e.g. a Kilp contact lens, or if you have swung out the BIOM®, you must deactivate the inverting optics of the SDI® 4. The indicator light of the SDI® 4c/4cli and SDI® 4e/4eli is not illuminated in this case, and is yellow on the SDI® 4m and shows “0”.

9 Care and Maintenance

Cleaning of the SDI® 4 is described in this chapter.
Disinfection is not necessary.
Sterilization of the SDI® is not possible; only the rubber cap of the star knob on the SDI® 4 can be sterilized.

➔ Heed the product descriptions and instruction manuals of products and equipment you use to care for, clean, and disinfect the unit and/or its accessories.

9.1 Removing the Accessories

➔ Pull off the sterilisable protective cap of the SDI® 4 from the star knob.

➔ When disconnecting electrical connections: Do not pull on the cable, but pull the respective plug or loosen the screw connectors. To do so, take hold of the respective plug.

➔ To disconnect the hand or foot switch: Loosen the screw connector of the plug at the connecting cable and pull the plug out of the jack.

9.2 Cleaning

Attention

Risk of electric shock if the SDI® 4 is not completely disconnected from the power supply for these jobs.

➔ Before cleaning the SDI® 4, disconnect it from the power supply.

Required Materials

- Damp cloth (distilled water)

Cleaning intervals

Whenever necessary

Cleaning the Housing

➔ Clean only the exterior surfaces of the unit with a damp cloth.

➔ Do not clean the SDI® 4 with aggressive, chlorine-containing, abrasive or sharp cleaning agents.

If the protective glasses are dirty, contact OCULUS Service or an authorized dealer.

9.3 Conditioning of the rubber cap

If you are using the rubber cap for the star knob, it must be sterilized first.

The rubber cap for the star knob of the SDI® 4 can be autoclaved with steam (max. 134°C); also refer to the *Conditioning Manual BIOM® 5 and Accessories*.

10 Transport and Storage

Attention

Equipment damage due to improper transport and storage

- ➔ Transport the SDI® 4 with care.
- ➔ Store the SDI® 4 in compliance with the transport and storage conditions, the national regulations and the regulations of your hospital. Also see *sec. 14, page 21*.

- ➔ Avoid impacts when moving the SDI® 4 to another location, since this can have an adverse affect on the adjustments.
- ➔ With the use of the transporting lock for star knob you position the optical system of the SDI® 4 in the rest position. Only then the position is fixed.
- ➔ Check the unit and its accessories for damage after every transport.

11 Troubleshooting

Attention

If a fault occurs which you are unable to correct by following the instructions below, label the device as "out of order" and contact our service department. (Address: *sec. 12.2, page 19*).

➔ Never operate a damaged SDI® 4.

Fault list - SDI® 4

Fault	Possible cause	Remedy
No function when the hand switch / foot switch is pressed	■ The foot switch is not connected to the SDI® 4e/4eli/4c/4cli ■ No connection of the SDI® 4e/4eli/4c/4cli to the power supply ■ Power failure or power socket is not active ■ These are not active if the sockets of the stand are being used.	■ Establish connection to the SDI® 4e/4eli/4c/4cli ■ Establish the connection to the power supply ■ Inform the in-house electrician ■ Use the plug transformer ■ Switch the SDI® 4 mechanically ■ Activate the sockets in accordance with the instructions for the stand ■ Ask the microscope manufacturer for assistance
The image is cropped	■ The SDI® 4 or other components are incorrectly mounted at an angle ■ The optics of the SDI® 4 are not in operating position (locking position)	■ Correct the assembly ■ Turn it on or off again with the foot switch
Unclear image	■ The SDI® 4 or the optic of the BIOM® 5 are dirty	■ Clean the glass surface of the BIOM® 5 loupe ■ If the SDI® 4 optics are dirty, contact OCULUS Service or your authorized dealer.
The SDI® 4 or its fixtures wobble	■ The locking screws are loose	■ Tighten the locking screws
Fundus view is too narrow	■ Distance between ophthalmoscopic lens and eye too large (only when using BIOM® 5) ■ Magnification of the microscope system to high	■ Carefully reduce the distance using the microscope fine adjustment mechanism ■ Reduce magnification of the microscope
Pronounced reflections on BIOM®-loupe or contact lens	■ The microscope light is on ■ Bright ceiling illumination	■ Turn the light off, illuminate only intraocular

12 Guarantee and Service

Please note the following guarantee provisions:

- Prior to and while operating the device, it is important that you heed the instruction manual and safety instructions.
- The SDI® 4 carries a guarantee to which you are entitled in accordance with the legal provisions.
- If modifications are made to the SDI® 4 by unauthorized persons, all warranty claims shall be voided. Improper modifications and repairs may result in considerable hazards to users and patients.
- Any transport damage must be reported immediately to the shipping company. Have the transport damage noted on the bill of lading so that complaint handling and compensation of damages can proceed in an orderly manner.
- In general, our Business and Shipping Terms, shall be applicable on the date of purchase.
- All guarantee claims are voided if the housing of the SDI® 4 has been opened.

12.1 Assumption of Liability for Functions and Damage

OCULUS will only accept responsibility for the safety, reliability and serviceability of the SDI® 4 if the unit is used in compliance with the following terms:

- Only use the equipment in conformance with this instruction manual.
- There are no parts on the SDI® 4 that require maintenance or repair by the user. If assembly work, modifications, adjustments, repairs, changes or service are performed by unauthorized personnel, or if the SDI® 4 is improperly maintained or handled, then any liability by OCULUS is voided.
- If the housing of the SDI® 4 is opened, any liability by OCULUS is excluded.
- If the above-referenced work is performed by authorized persons, then a certification of the work shall be requested from this service technician which shall state any changes to factory defaults or to operating ranges. This certification must contain the date of performance and statement of the performing firm, with signature.
- If requested, OCULUS will provide to the service technician a list of spare parts and additional descriptive material for this purpose.
- Make certain that only original OCULUS parts are used.

12.2 Manufacturer's and Service Addresses

Supplemental information is available from our Service Department or from our authorized representatives.

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Str. 29
35582 Wetzlar
GERMANY
Tel.: +49 641 2005-0
Fax: +49 641 2005-299
E-mail: support@oculussurgical.de
www.oculus.de

USA:

OCULUS Surgical, Inc.
562 NW Mercantile Place, Ste. 104
Port St. Lucie,
FL 34986, USA
Phone: +1 772-236-2622 (outside of U.S.)
Phone: +1 855-SDIBIOM (Toll free in U.S.)
Fax: +1 772-336-1984
E-Mail: info@oculussurgical.com

13 Disposal of Used Devices

➔ Dispose of the SDI® 4 in compliance with the applicable legal requirements. Comply with the hygiene and disposal regulations of the hospital or clinic.

SDI® 4, electric

In accordance with Guideline 2012/19/EU of the European Parliament and also the law of the Federal Republic of Germany on the Commercialization, Recall and Environmentally Compatible Disposal of Electrical and Electronic Equipment, old electrical and electronic equipment must be sent out for recycling and may not be disposed in household trash.

14 Technical Data

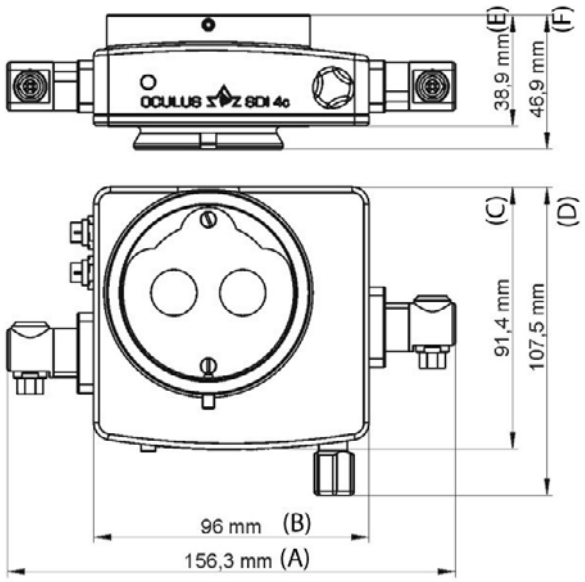


Fig. 14-1: Dimensions SDI® 4c/4cli

Serviceable life expectancy	6 Years

SDI® 4e/4eli and SDI® 4m - dimensions

Width	96 mm
Depth	91.4 mm
Height	38.9 mm

Classification according to IEC 60601 - 1

Type of protection against electric shock	Protection class 2
Degree of protection against electric shock	Type B
Housing protection class	IP20

Degree of protection if used in the presence of potentially explosive mixtures

The unit is not suitable for use in potentially explosive atmospheres or in the vicinity of potentially explosive mixtures of anaesthetics or laughing gas and oxygen.

Ambient, transport and storage conditions

	Ambient conditions	Transport conditions	Storage conditions
Temperature	+10°C to +35°C	-40°C to +95°C	-10°C to +55°C
Humidity	30% to 75%	10% to 95%	10% to 95%
Air pressure	800 hPa to 1060 hPa	500 hPa to 1060 hPa	700 hPa to 1060 hPa

These values also apply for all other SDI® 4 models.

Voltage supply SDI® 4c/4e

Power supply	80-264 V AC / 9 V DC / 0.5 A

Voltage supply SDI® 4cli/4eli

Power supply	24 V DC / 0.5 A

Weight

SDI® 4c/4cli	approx. 675 g
SDI® 4e/4eli	approx. 600 g
SDI® 4m	approx. 500 g

Switching options: SDI® 4c/4cli

Combination foot switch (electric, plugged into a 5-pole jack at the SDI 4c/4cli)
Star knob (manual)

Switching options: SDI® 4e

Combination foot switch (electric, plugged into a 5-pole jack at the SDI® 4e)
Star knob (manual)

SDI® 4eli only possible in combination with SDI®4 cli.

Switching options: SDI® 4m

Star knob (manual)

Sterilization and disinfection procedures

Combination foot switch	Wipe-down disinfection
Sterilisable cap for SDI® 4	Autoclaving, (max. 134°C (273° F))

see *Conditioning Instructions BIOM® 5 and Accessories*

The unit can be attached to the following microscopes:

- Zeiss
- Leica
- Haag Streit/MW
- Takagi
- Topcon
- Kaps
- Alcon
- Inami

CE in accordance with Regulation (EU) 2017/745 on Medical Devices

The unit is a Class I product.

CE

Conformity assessment procedure: (EU) 2017/745 MDR, Annex II and III.

14.1 Data sheet for plug-in power supply unit GEM12I 09-P1J (54905)

MEAN WELL 12W AC-DC High Reliability Interchangeable Medical Adaptor **GEM12I series**

(Standard)

(Optional)

IP21

Features

- Interchangeable AC plugs (plug kit sold sperately)
- Medical safety approved (2 x MOPP) accroding to AAMI/ANSI ES60601-1/ES60601-1-11,EN60601-1/EN60601-1-11 and IEC60601-1
- Suitable for BF application with appropriate system consideration
- Low leakage current <100μA
- No load power consumption< 0.075W(<0.1W for 18V/48V)
- Energy efficiency Level Ⅵ
- Comply with EISA 2007/DoE and EU ErP
- Class Ⅱ power (without earth pin)
- Protections: Short circuit / Overload / Over voltage
- Fully enclosed plastic case
- Optional lock type DC plug
- 3 years warranty

Applications

- Blood glucose meter
- Blood pressure meter
- Nebulizer
- Inhaler
- Portable medical device
- Sleep apnea devices

Description

GEM12I is a highly reliable, 12W wall-mounted style single-output green medical adaptor series, which is compact and convenient for carry. This product is equipped with an interchangeable AC plug (4 types, including European type, USA type, U.K. type and Australian type) that makes it very suitable for businessmen to use in the major countries around the globe. GEM12I is a class Ⅱ power unit (without FG), accepting the input range from 80VAC to 264VAC that it can satisfy the demands for various types of medical electrical devices. The circuitry design meets the international medical standards (2*MOPP), having an ultra low leakage current (<100μA), fitting the medical devices in direct electrical contact with the patients.

With the working efficiency up to 87% and the extremely low no-load power consumption below 0.075W, GEM12I is compliant with the latest USA energy regulation EISA 2007/DoE(Level Ⅵ) and EU ErP. The supreme feature allows the adaptor to save the energy when it is under either the operating mode or the standby mode. The entire series is approved for international safety regulations; moreover, it adopts the 94V-0 flame retardant plastic case that it can effectively prevent users from electric hazard.

Model Encoding

GEM12 I 05-P1J

- DC plug type
  - P1J: Plug for standard model, 2.1φ×5.5φ×11mm, C+ tuning fork type
  - USB: USB(type A) for 5V optional model only
  - Optional plug type available per request
- Output voltage
- Interchangeable AC plug
- Output wattage
- Series name

File Name:GEM12I-SPEC 2017-01-03

MEAN WELL 12W AC-DC High Reliability Interchangeable Medical Adaptor **GEM12I series**

Interchangeable AC plug Specifically for GEM12I~40I

TYPE					
	Australian type	U.K type	European type	US type	Mix four type
ORDER NO.	AC plug-AU2	AC plug-UK2	AC plug-EU2	AC plug-US2	AC plug-MIX2

SPECIFICATION

ORDER NO.		GEM12I05-□ (□=Standard USB/Optional)	GEM12I07-P1J	GEM12I09-P1J	GEM12I12-P1J	GEM12I15-P1J	GEM12I18-P1J	GEM12I24-P1J	GEM12I48-P1J
OUTPUT	SAFETY MODEL NO.	GEM12I05	GEM12I07	GEM12I09	GEM12I12	GEM12I15	GEM12I18	GEM12I24	GEM12I48
	DC VOLTAGE Note.2	5V	7.5V	9V	12V	15V	18V	24V	48V
	RATED CURRENT	2.4A	1.6A	1.33A	1A	0.8A	0.66A	0.5A	0.25A
	CURRENT RANGE	0 ~ 2.4A	0 ~ 1.6A	0 ~ 1.33A	0 ~ 1A	0 ~ 0.8A	0 ~ 0.66A	0 ~ 0.5A	0 ~ 0.25A
	RATED POWER (max.)	12W	12W	12W	12W	12W	12W	12W	12W
	RIPPLE & NOISE (max.) Note.3	60mVp-p	60mVp-p	60mVp-p	60mVp-p	80mVp-p	80mVp-p	80mVp-p	100mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±4.0%	±3.0%	±3.0%	±3.0%	±2.0%	±2.0%
	LINE REGULATION Note.5	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
	LOAD REGULATION Note.6	±5.0%	±5.0%	±4.0%	±3.0%	±3.0%	±3.0%	±2.0%	±2.0%
	SETUP, RISE, HOLD UP TIME	500ms, 30ms, 16ms/230VAC 500ms, 30ms, 16ms/115VAC at full load							
INPUT	VOLTAGE RANGE Note.7	80 ~ 264VAC 113 ~ 370VDC							
	FREQUENCY RANGE	47 ~ 63Hz							
	EFFICIENCY (Typ.)	80%	82%	82%	82.5%	84%	85%	85%	87%
	AC CURRENT	0.4A / 115VAC 0.2A / 230VAC							
	INRUSH CURRENT (max.)	30A / 115VAC 60A / 230VAC							
	LEAKAGE CURRENT(max.)	Touch current < 100uA/264VAC							
PROTECTION	OVERLOAD	110 ~ 200% rated output power Protection type : Hiccup mode, recovers automatically after fault condition is removed							
	OVER VOLTAGE	110 ~ 140% rated output voltage Protection type : Clamp by zener diode, output short							
ENVIRONMENT	WORKING TEMP.	-20 ~ +70℃ (Refer to "Derating Curve")							
	WORKING HUMIDITY	20% ~ 90% RH non-condensing							
	STORAGE TEMP., HUMIDITY	-20 ~ +85℃, 10 ~ 95% RH non-condensing							
	TEMP. COEFFICIENT	±0.03% / ℃ (0 ~ 40℃)							
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes							
SAFETY & EMC (Note. 8)	SAFETY STANDARDS	TUV EN60601-1/EN60601-1-11, AAMI/ANSI ES60601-1/ES60601-1-11(3.1 version), CAN/CSA-C22.3° edition approved							
	WITHSTAND VOLTAGE	I/P-O/P:5656VDC							
	ISOLATION RESISTANCE	I/P-O/P:100M Ohms / 500VDC / 25℃ / 70% RH							
	EMC EMISSION	Compliance to EN55011 class B, EN61000-3-2,3, FCC PART 15 / CISPR22 class B							
	EMC IMMUNITY	Compliance to EN61000-4, 2,3,4,5,6,8,11, light industry level, criteria A							
OTHERS	LIFE	3 years : 100% load 40℃, 12hours / day							
	MTBF	400Khrs min. MIL-HDBK-217F(25℃)							
	DIMENSION	73.9*39*48.5mm (L*W*H)							
	PACKING	Standard model: 118g; 72pcs / 9.5kg / CARTON for cable connection; Optional model 100g ; 110pcs / 12kg / CARTON for USB connection							
CONNECTOR	PLUG	See page 3							
	CABLE	See page 3							
NOTE	1.All parameters are specified at 230VAC input, rated load, 25℃ 70% RH ambient. 2.DC voltage: The output voltage set at point measure by plug terminal & 50% load. 3.Ripple & noise are measured at 20MHz by using a 12" twisted pair terminated with a 0.1uf & 47uf capacitor. 4.Tolerance: includes set up tolerance, line regulation, load regulation. 5.Line regulation is measured from low line to high line at rated load. 6.Load regulation is measured from 10% to 100% rated load. 7.Derating may be needed under low input voltage. Please check the derating curve for more details. 8.The power supply is considered as an independent unit, but the final equipment still need to re-confirm that the whole system complies with the EMC directives. For guidance on how to perform these EMC tests, please refer to "EMI testing of component power supplies." (as available on http://www.meanwell.com)								

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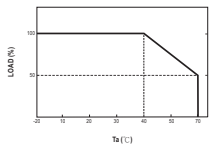
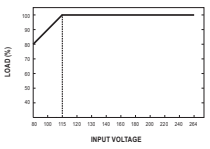
Derating Curve



Static Characteristics

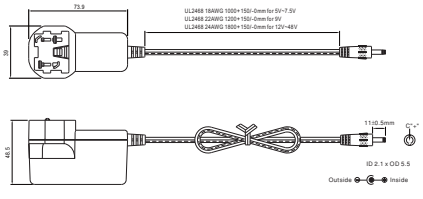


Mechanical Specification

Unit:mm

TYPE				
	Australian type	U.K type	European type	US type

※Cable connection (standard)



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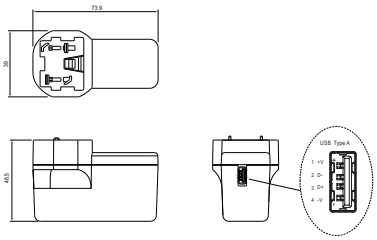
※USB connection (optional)



Plug Assignment

Standard plug: P1J

P1J	
P/N	OUTPUT
CENTER	+

Optional lock type plug: PZS
SWITCHCRAFT S761K plug equivalent

Installation Manual

Please refer to : http://www.meanwell.com/manual.html

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