

OCULUS SDI[®] 4

Stereoscopic Diagonal Inverter



INSTRUCTIONS FOR USE

Preface

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 the instructions for use before operating the device. In particular, pay attention to the safety instructions.

The instructions for use describe the following SDI® 4 models:

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

Due to ongoing development, the diagrams shown in the instructions for use 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. The OCULUS 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
- SDI® 4m (Leica Version)
with two protective dust covers and transporting lock
- SDI® 4m (Kaps Version)
with two protective dust covers and transportation lock
- SDI® 4e
with two protective dust covers and transportation lock
- SDI® 4e (Leica Version)
with two protective dust covers and transportation lock
- SDI® 4e (Kaps Version)
with two protective dust covers and transportation lock
- SDI® 4c
with two protective dust covers and transportation lock
- SDI® 4c (Leica Version)
with two protective dust covers and transportation lock
- SDI® 4cli (Leica CAN Version)
with two protective dust covers and transportation lock and
CAN connection cable
- SDI® 4eli (Leica CAN Slave Version)
with two protective dust covers and transportation lock and
CAN Slave connection cable

Accessories for each SDI® 4

- Sterilisable rubber cap
- Hexagon screw driver
- Instruction for Use
- Conditioning Instructions

Accessories for each SDI® 4eli

- Connection cable CAN Slave

Accessories for each SDI® 4cli

- Connection cable CAN

Product (Versions)

- Optional: Plug-in power supply NGE12I09
- Optional: extension cable for voltage power supply plug (approx. 5 m)

Required accessories:

- Combination foot switch SDI® 4c
- Foot switch for SDI® 4e
- Optional: extension cable to SDI® 4e foot switch (approx. 5 m)
- Leica M820/M822/M844 control cable for SDI® 4c/SDI® 4e
- Leica M820/M822/M844 supply cable for SDI® 4c/SDI® 4e

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 Safety Instructions



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

- ➔ Carefully read through the instructions for use.
- ➔ Make sure to keep the instructions for use in a safe place and available to operating personnel at all times.
- ➔ Observe the legal regulations with regard to accident prevention.

2.1 Symbols

2.1.1 On the Device / Name Plate



Fig. 2-1: Name plate SDI® 4c

Symbol	Description	Symbol	Description
	Manufacturer		Protection class
	Date of manufacture	IP 20	Level of protection
	Conformité européenne		Article number
	Follow the instruction for use		Serial number
	Disposal in household trash is prohibited		Attention
	Applied part, type B		Do not reuse
	Example: UDI number consisting of UDI-DI (device identification) UDI-PI (Product Identifier) machine-readable matrix code		Medical Device

2.1.2 On the Packaging

Symbol	Description	Symbol	Description
Transport		Storage	
	Permitted temperature range for transport		Permitted temperature range for storage
	Keep dry		Limit of humidity
	Transport upright		Limit of air pressure
	Fragile		

2.1.3 In this Manual



Warning

Identifies a potentially dangerous situation, which may cause serious injury.



Caution

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.

2.2 Safety Instructions for Use



Warning

Risk of personal injury or property damage due to improper operation

→ Observe the following safety instructions.



Warning

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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer (vigilance@oculus.de) and the competent authority of the region in which the user and/or patient is established.

2.2.1 Patient Environment Information

The patient environment is the space within which a contact is established between the patient and any part of the system, or between the patient and another person in contact with the system.

Within the patient environment, use devices conforming with IEC 60601-1. If the use of a device not conforming with the IEC 60601-1 standard is intended, always use an isolating transformer.

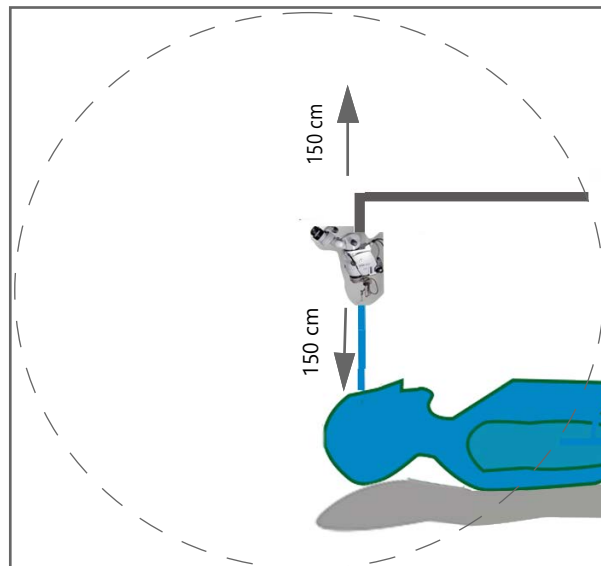


Fig. 2-2: Patient environment

2.2.2 Instructions for Operating a ME System

The SDI® 4c or SDI® 4cli, a connected BIOM® 5c/cl and a microscope constitute a Medical Electrical System (ME System) in accordance with IEC 60601-1. If you connect additional devices, those devices become part of the ME system.

- ➔ Make sure that all devices of the ME system meet the requirements of IEC 60601-1.

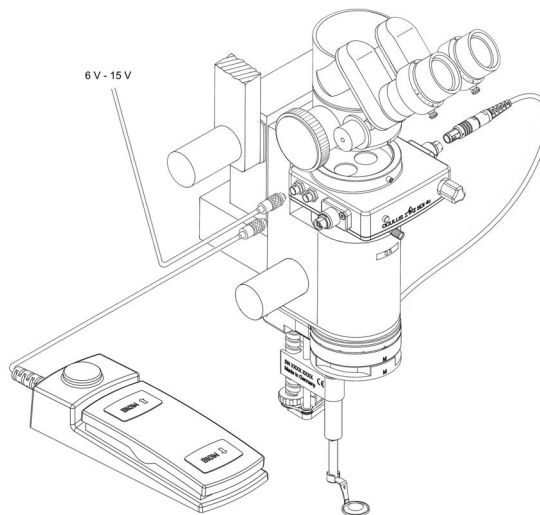


Fig. 2-3: ME-System consisting of SDI® 4, BIOM® 5, foot switch and microscope

2.2.3 EMC and Electrical Safety Information

- ➔ If you do not intend to provide power to the SDI® 4 via the microscope, you must then use the AC adapter mentioned in → chap. 12.5 (page 38).
- ➔ Do not stack the device with other devices.



Warning

Risk of electric shock caused by not providing two independent Means of Patient Protection

- ➔ The power supply shall provide separation from the mains by two independent Means of Patient Protection (2x MOPP) in accordance with IEC 60601-1, and shall be designed to ensure protection against electric shock (touch-safe).



Warning

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 IEC 60601-1: 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.



Warning

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.

3 Device Description

3.1 Device Components

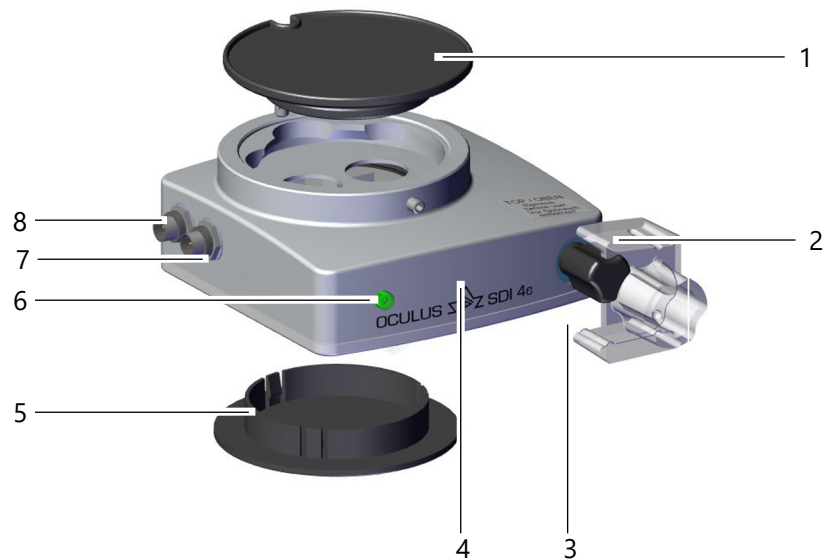


Fig. 3-1: Unit Components SDI® 4e

No.	Description	No.	Description
1	Top dust cover	5	Bottom dust cover
2	Transporting lock for star knob	6	Indicator lamp
3	Star knob	7	Connection for a foot switch (optional)
4	SDI® 4e	8	Power supply connection

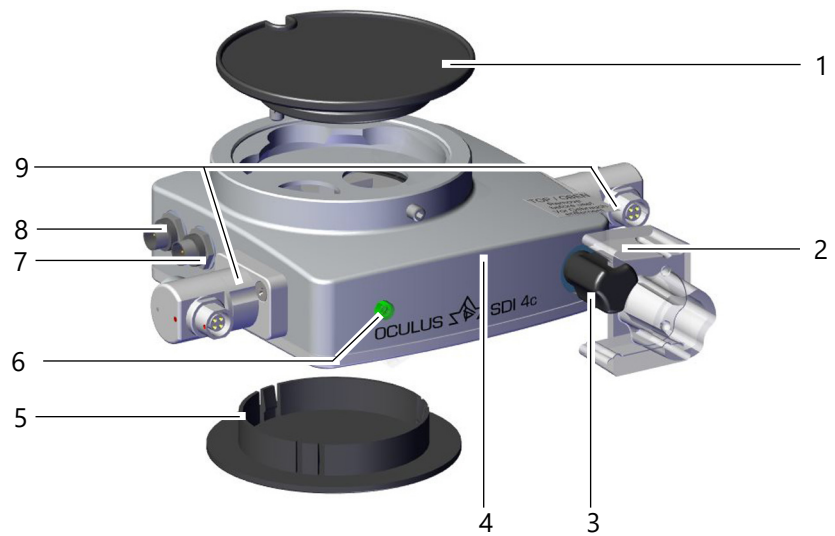


Fig. 3-2: Unit Components SDI® 4c

No.	Description	No.	Description
1	Top dust cover	6	Indicator lamp
2	Transporting lock for star knob	7	Connection for a foot switch
3	Star knob	8	Power supply connection
4	SDI® 4c	9	BIOM® 5c connection, pivotable
5	Bottom dust cover		

3.2 Principle of Operation

The SDI® 4 (Stereoscopic Diagonal Inverter) is used to reinvert images, e.g. that of a BIOM® 5 or BIOM® 6 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/SDI® 4cli

If you are using the SDI® 4c/SDI® 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/SDI® 4cli.

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

Respectively, you can control the SDI® 4c/SDI® 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.

3.3 Intended Purpose

3.3.1 Intended Use

These stereoscopic diagonal inverters SDI® 4m/4e/4c/4eli/4cli reverse the picture of indirect monitoring systems (BIOM® 5, BIOM® 6, 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 connection types, described in this Instructions for Use are used for the power supply.

The device may not be used in proximity to HF surgical units or inside of the HF shielded room of an ME system for magnetic resonance imaging.

3.3.2 Intended Medical Indication

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

3.3.3 Contraindication

none known

3.3.4 Possible Side Effects

none known

3.3.5 Intended Users

Make certain that the SDI® 4 is used exclusively in clinics and by clinical persons or eye specialists,

- who, due to their training or their knowledge and practical experience, can guarantee proper handling of the device.
- who have been instructed by OCULUS staff or an authorized dealer before the initial operation.

3.3.6 Patient Group

No limitations with regard to age, weight and health condition.

4 Set Up 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 or BIOM® 6.
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.

4.1 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.

4.2 Attaching the SDI® 4 to an Operation Microscope

- ➔ 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.

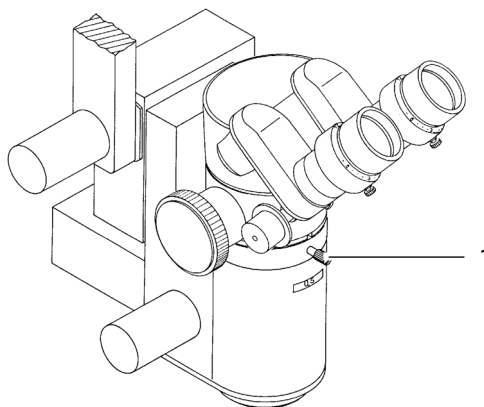


Fig. 4-1: Before the installation of the SDI® 4

No.	Description
1	Locking screw

- ➔ 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. 4-2 (page 21), 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 name plate.
If you use the AC adapter mentioned in → chap. 12.5 (page 38), then this will be guaranteed.
Make sure that the voltage supply in the mains socket is within the voltage range of the plug-in power supply unit.
 - The SDI® 4 can also be powered via the microscope.

**Warning**

Risk of electric shock caused by not providing two independent Means of Patient Protection

- The power supply shall provide separation from the mains by two independent Means of Patient Protection (2x MOPP) in accordance with IEC 60601-1, and shall be designed to ensure protection against electric shock (touch-safe).

- 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. 4-2 (page 21), items 3 and 4), lock them in place by turning the threaded connector (milled sleeve).

Connector SDI® 4c/SDI® 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.
- Plug the power supply plug (9 V) into the 3-pole jack.
 - Only use the AC adapter mentioned in → chap. 12.5 (page 38) or power the SDI® 4 via the microscope.
- 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.



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

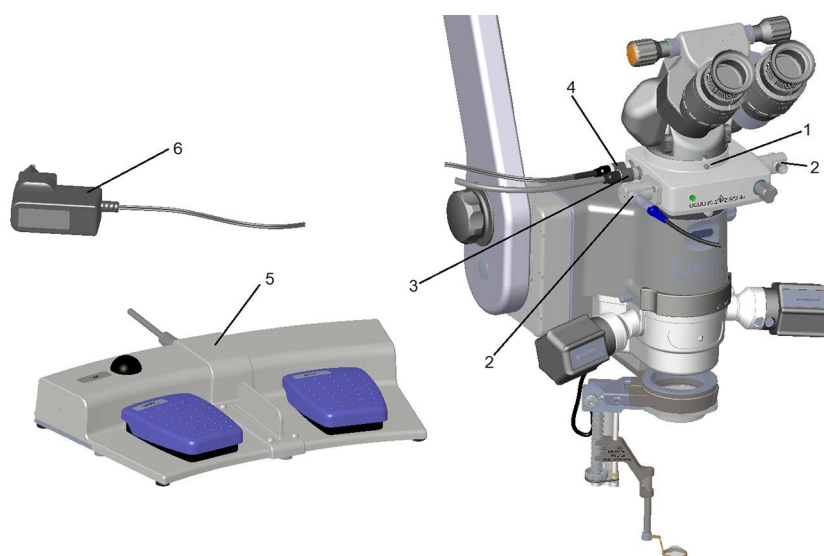


Fig. 4-2: Example: SDI® 4c at the microscope

No.	Description	No.	Description
1	Set screw of the SDI® 4	4	Connection jack for the power supply
2	Connection jack for the BIOM® 5cl	5	Combination foot switch for SDI® 4/BIOM® 5 or BIOM® 6
3	Plug for the combination foot switch	6	Power adapter including interchangeable plug adapter SDI® 4e/SDI® 4c

5 Operation



Caution

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.

- ➔ Only operate the equipment after you have read and understood the instructions for use.
- ➔ Do not touch the patient and the device at the same time.
- ➔ If a malfunction occurs that you cannot rectify by following the instructions in the troubleshooting table → chap. 6 (page 24), you must not use the device. Clearly mark the unit as non-operational and get in touch with the OCULUS service personnel.
- ➔ Familiarize yourself with all safety features and devices before you put the unit into initial operation.

5.1 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/SDI® 4cli and SDI® 4e/SDI® 4eli).
 - All electric functions are operational:
 - SDI® 4 on/off (SDI® 4e/SDI® 4eli and SDI® 4c/SDI® 4cli)
 - BIOM® focus up, BIOM® focus down (SDI® 4c)
 - the rubber covering for the adjustment button of the SDI® 4c is supplied and sterile.
- ➔ Set the binocular tube in a position that is as comfortable as possible.

5.2 Switching On

- ➔ Switch on the SDI® 4 by plugging in the power supply.

5.3 Information Regarding the Use

- ➔ Briefly press the foot switch, to adjust the optical system of the SDI® 4. The optic system then moves to its other position.
- ➔ Activate the SDI® 4 (indicator lamp at the SDI® 4c/cli and SDI® 4e/SDI® 4eli lights up, indicator remains empty on the SDI® 4m), when using
 - an optical inversion, e.g. BIOM® or
 - an indirect vitrectomy lens.
- ➔ Deactivate the SDI® 4 (The indicator light of the SDI® 4c/SDI® 4cli and SDI® 4e/SDI® 4eli is not illuminated in this case, and is yellow on the SDI® 4m and shows "0", when
 - using non-inverting optics, such as e.g. a Kilp contact lens,
 - the BIOM® is swung out

5.4 Switching Off

- ➔ Switch off the SDI® 4 by unplugging the power supply.

6 Troubleshooting



Caution

If a fault occurs which you are unable to correct by following the instructions below, label the device as “out of order” and contact the OCULUS service department. (Address → page 40).

→ Never operate a damaged SDI® 4.

Troubleshooting guide – 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 or BIOM® 6 are dirty	■ Clean the glass surface of the BIOM® 5 or BIOM® 6 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 too high	■ Carefully reduce the distance using the microscope fine adjustment mechanism ■ Reduce magnification of the microscope
Pronounced reflections on BIOM® 5 or BIOM® 6 -loupe or contact lens	■ The microscope light is on ■ Bright ceiling illumination	■ Turn the light off, illuminate only intraocular

7 Cleaning, Sterilisation and Maintenance

7.1 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 connection of the plug at the connecting cable, and pull the plug from the socket.

7.2 Cleaning



Warning

Risk of electric shock if the SDI[®] 4 is not completely disconnected from the power supply before cleaning.

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

Cleaning intervals

If required

Cleaning the Housing

- ➔ Only clean the outer surfaces of the device using a damp cloth (distilled water).
- ➔ Do not clean the SDI[®] 4 with aggressive, chlorinated, abrasive or sharp cleaning agents.



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

7.3 Sterilisation and Disinfection Procedures

Sterilization of the SDI® 4 is not possible.

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

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

see → Conditioning Instructions BIOM® 5 or BIOM® 6 and Accessories

Heed the product descriptions and instructions for use of products and equipment you use to care for and clean the unit and/or its accessories. Disinfection is not necessary.

7.4 Maintenance

To ensure satisfactory and reliable operation, we recommend that you:

- Have the SDI® 4 checked every two years by the OCULUS service department or an authorized dealer.



Warning

Risk of electric shock if the SDI® 4 is not completely disconnected from the mains

- Turn the SDI® 4 off by unplugging the power supply.
- Pull the power plug before maintenance. When disconnecting electrical conditions, pull on the respective plug and not on the cable itself.



Note

Faulty examinations due to damaged equipment

It an error occurs that you can not resolve

- Label the SDI® 4 as "out of order".
- Report the damage to the OCULUS service department or your authorized dealer.
- Use only undamaged SDI® 4 devices.

8 Transport and Storage



Caution

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.

- 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.

	Ambient conditions	Transport conditions	Storage conditions
Temperature	+10°C to +35°C	-40°C to +70°C	-10°C to +55°C
Humidity	30% to 90%	10% to 95%	10% to 95%
Air pressure	800hPa to 1060hPa	500hPa to 1060hPa	700hPa to 1060hPa

9 Disposal of Used Devices

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



In accordance with Guideline 2012/19/EG of the European Parliament and of the Council 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.

10 Guarantee and Service

10.1 Guarantee Provisions

- Prior to and while operating the device, it is important that you heed the instructions for use 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 guarantee 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.

10.2 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 instructions for use.
- 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 has been 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.

11 Technical Data

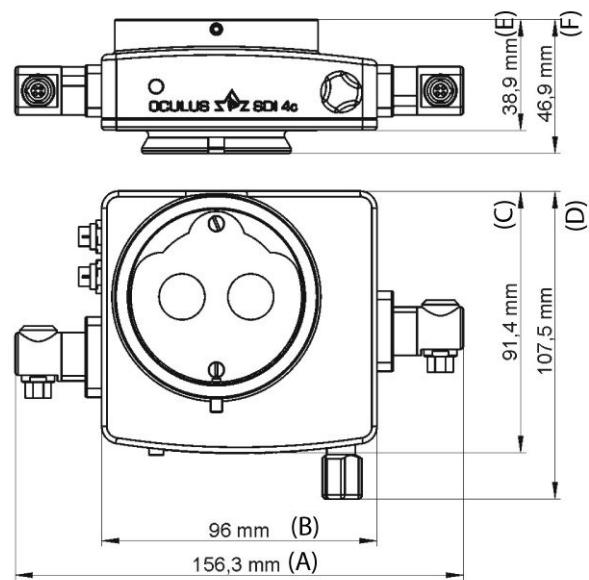


Fig. 11-1: Dimensions SDI® 4c/SDI® 4cli

Expected service life	6 years
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11.1 Dimensions

Width	96 mm
Depth	91.4 mm
Height	38.9 mm

11.2 Weight

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

11.3 Conformity

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



The unit is a Class I product.

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

11.4 SDI® 4e/SDI® 4eli/SDI® 4c/SDI® 4cli: 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
Power	The SDI® 4 is powered via the microscope or the power supply.
Mains protection	2x MOPP (IEC 60601-1), touch-safe

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

The device is not suitable for use in potentially explosive atmospheres, or with explosive mixtures of anaesthetics with oxygen or laughing-gas.

11.5 SDI® 4c/SDI® 4e: Power Adapter

Type	Mean Well NGE12109 (with specific connector)
Mains connection	100-240 V
Frequency	50/60 Hz
Power input, max.	57.5 VA
Rated power	12 W
Output voltage	9 V DC / 1.33 A

11.6 Power Supply

SDI® 4c/SDI® 4e

Power adapter

6-15 V AC / DC 0.5 A

SDI® 4cli/SDI® 4eli

Power adapter

24 V DC 0.5 A

11.7 Switching Options

SDI® 4c/SDI® 4cli

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

Star knob (manual)

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® 4cli.

SDI® 4m

Star knob (manual)

11.8 Compatible Microscopes

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

12 Appendices

12.1 Electromagnetic Compatibility (EMC)

Medical electrical equipment is subject to special precautionary requirements with respect to EMC, and must be installed and operated according to the EMC-Instructions contained in the accompanying paperwork.

OCULUS devices and systems are suitable for use in professional healthcare establishments, e.g. doctor's practices or clinics; however, they may not be used in proximity to HF surgical units or inside of the HF shielded room of an ME system for magnetic resonance imaging. Portable and mobile HF communications appliances can affect medical, electric equipment.

No special measures need to be observed in respect of OCULUS devices and systems.



Caution

The use of accessories, transducers and cables not specified by OCULUS (for example as replacement parts) may result in increased emissions or decreased immunity of the SDI[®] 4.

→ Use only the original accessories, transducers and cables specified by OCULUS.

The use of accessories, transducers and cables specified by OCULUS with devices other than the SDI[®] 4 may result in increased emissions or decreased immunity of the other device.

→ Do not use the accessories, transducers and cables specified by OCULUS with devices other than the SDI[®] 4.



Portable and mobile RF-communications devices can interfere with electrically operated medical devices.

The device is intended for use in an electromagnetic environment in which the radiated RF interference is uncontrolled. The user can help prevent electromagnetic interference by maintaining the following minimum distance, based on the maximum output of the communication equipment, between portable and mobile RF communication devices (transmitters) and the device.

→ Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) should not be any closer than 30 cm (12 inches) to any part of the device.

To be in compliance with the requirements of the IEC 60601-1-2 the following types of equipment, accessories, power adapters and cables must be used.

Order number	Description	
54320	SDI® 4	
54905	Plug-In Power Supply Unit NGE12I09	9 V DC / 1.33 A

12.2 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and manufacturer's declaration electromagnetic emissions of the SDI® 4

The OCULUS SDI® 4 is intended for operation in the electromagnetic environment specified below. The user of the SDI® 4 should ensure that it is being used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidances
RF emissions CISPR 11	Group 1	The SDI® 4 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.
HF-emissions CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

12.3 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Electromagnetic immunity			
Immunity test	Test level	Compliance level	Electromagnetic environment – guidances
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV ----- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_T ; 1 period and 70% U_T ; 25/30 periods Single-phase: at 0 degree 0% U_T ; 250/300 periods	0% U_T ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_T ; 1 period and 70% U_T ; 25/30 periods Single-phase: at 0 degree 0% U_T ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SDI® 4 requires continued operation during power mains interruptions, it is recommended that the SDI® 4 be powered from an uninterruptible power supply or battery.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity			
Immunity test	Test level	Compliance level	Electromagnetic environment – guidances
Conducted RF IEC 61000-4-6	3 V _{eff} 150 kHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz	V _{eff} = 3 V	Portable and mobile RF communications equipment should be used no closer to any part of SDI® 4, including cables, than the rec- ommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3, 5}{(V_1)} \right] \sqrt{P}$ $d = \left[\frac{3, 5}{(E_1)} \right] \sqrt{P} \quad \text{80MHz to 800 MHz}$ $d = \left[\frac{7}{(E_1)} \right] \sqrt{P} \quad \text{800 MHz to 2.5 GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recom- mended separation distance in metres (m). Field strength 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 equip- ment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz		
Note 1:	At 80 Hz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is af- fected 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 radios, AM and FM radio broadcast, and TV broadcast cannot be predicted the- oretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and elec- tromagnetic site survey should be considered. If the measured field strength in the location in which the SDI® 4 is used exceeds the applicable RF compliance level above, the SDI® 4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re- orienting or relocating the SDI® 4.			
b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

12.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the SDI[®] 4

The SDI[®] 4 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SDI[®] 4 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SDI[®] 4 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

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

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

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

12.5 Data Sheet for Plug-In Power Supply Unit NGE12I09 (54905)

MEAN WELL 12WAC-DC Reliable Wall-mounted Interchangeable Type Green Adaptor **NGE12 series**



(NGE12I) (NGE12E) (NGE12U)

■ Features

- MEAN WELL Patent Application Number: 202330347779.4
- Interchangeable AC plug (I-Type)
- Global certificates in multi-fields (ITE 62368-1, Medical 60601-1, Household 60335-1, Industrial 61558-1/2-16)
- 80-264Vac Universal AC input
- Ultra slim(28mm)
- No load power consumption: 0.075W
- Energy efficiency Level 1
- Class I power (No earth pin)
- Protections: Short circuit / Overload / Over voltage
- Pass LPS
- Extremely low leakage current <100uA
- 30℃~+70℃ wide range working temperature
- Various DC plug quick adaptor accessory available (Plug kit sold separately, please refer to : https://www.meanwell.com/uploader/pdf/dc_plug.pdf)
- 3 years warranty

■ Applications

- Consumer electronic devices
- Telecommunication devices
- Office facilities
- Industrial equipments
- Medical devices
- Household devices

■ GTIN CODE

MW Search: <https://www.meanwell.com/gtin/gtin.asp>

■ Description

NGE12 is a highly reliable, 12W wall-mounted style single-output green adaptor series, which is compact and convenient for carry. This product is equipped with 7 types of interchangeable AC plug (European, USA, U.K., Australian, China, Korea and India type) that makes it very suitable for travel use. NGE12 is a Class II power unit (no FG), accepting the input range from 80VAC to 264VAC that it can satisfy the demands for various types of electrical devices.

With the working efficiency up to 88.5% and the extremely low no-load power consumption below 0.075W, NGE12 is compliant with the latest USA energy regulation EISA 2007/DoE, Canada NRCan, Australia and New Zealand MEPS, Korea KMEPS, EU ErP and CoC version5. 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 ITE, medical, household and industrial appliance safety regulations; moreover, it adopts the 94V-0 flame retardant plastic case that it can effectively prevent users from electric hazard.

■ Model Encoding

NGE12 **I** **E** **U** **P** **1**

DC plug type (P1J: Plug for standard model, 2.1 ϕ $\times$ 5.5 ϕ $\times$ 11mm, C+ tuning lock type; USB-USB type A for 5V model only)

Output voltage (5V/9V/12V/15V/18V/24V)

AC Pin fixed: Universal version with interchangeable plugs

AC Plug: E: AC Pin fixed; EU version with non-interchangeable plug

Rated wattage

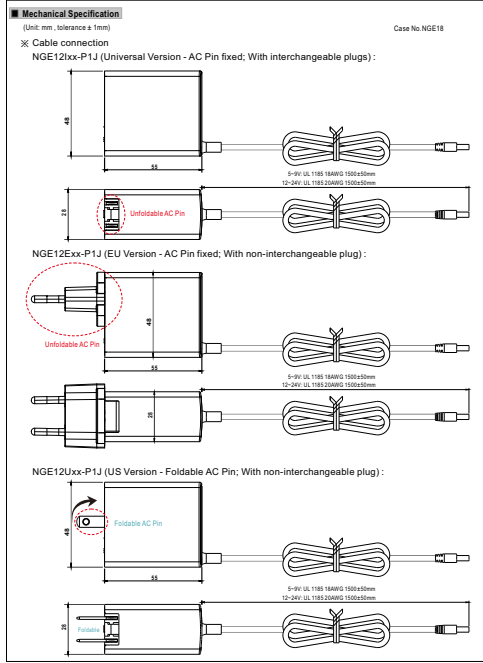
Series name

MEAN WELL 12WAC-DC Reliable Wall-mounted Interchangeable Type Green Adaptor **NGE12 series**

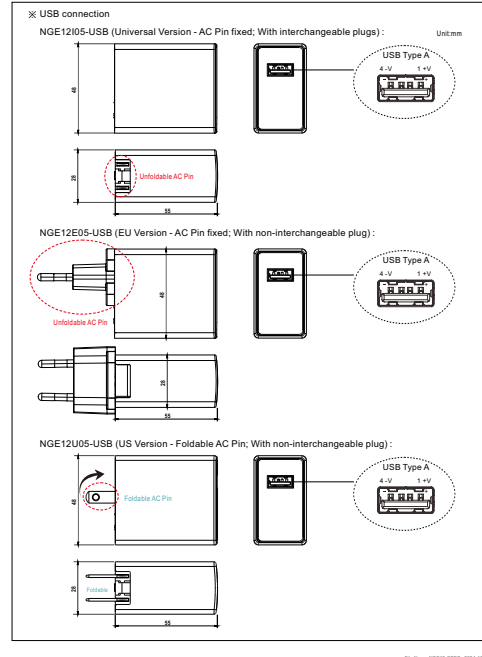
SPECIFICATION

ORDER NO.	NGE12I05-P1J	NGE12I05-P1J	NGE12I05-P1J	NGE12I05-P1J	NGE12I05-P1J	NGE12I05-P1J
DC VOLTAGE	5V	9V	12V	15V	18V	24V
RATED CURRENT	2.4A	1.33A	1.0A	0.8A	0.6A	0.5A
CURRENT RANGE	0~2.4A	0~1.33A	0~1.0A	0~0.8A	0~0.6A	0~0.5A
RATED POWER	12W	12W	12W	12W	10W	10W
EFFICIENCY (max)	88.5%	88.5%	88.5%	88.5%	88.5%	88.5%
VOLTAGE TOLERANCE	85%~115%	85%~115%	85%~115%	85%~115%	85%~115%	85%~115%
LINE REGULATION	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
LOAD REGULATION	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
SETUP, RISE, HOLD, SHUTDOWN TIME	1500ms, 30ms, 10ms / 220VAC	1500ms, 30ms, 10ms / 220VAC	1500ms, 30ms, 10ms / 220VAC	1500ms, 30ms, 10ms / 220VAC	1500ms, 30ms, 10ms / 220VAC	1500ms, 30ms, 10ms / 220VAC
VOLTAGE RANGE	85~264VAC	85~264VAC	85~264VAC	85~264VAC	85~264VAC	85~264VAC
FREQUENCY RANGE	47~120Hz	47~120Hz	47~120Hz	47~120Hz	47~120Hz	47~120Hz
EFFICIENCY (Typ.)	87.5%	88.5%	87.5%	87.5%	88.5%	88.5%
AC CURRENT	0.6A / 115VAC	0.3A / 230VAC	0.3A / 230VAC	0.3A / 230VAC	0.3A / 230VAC	0.3A / 230VAC
INrush CURRENT (max)	COLD START: 6A / 115VAC, 80A / 230VAC	COLD START: 6A / 115VAC, 80A / 230VAC	COLD START: 6A / 115VAC, 80A / 230VAC	COLD START: 6A / 115VAC, 80A / 230VAC	COLD START: 6A / 115VAC, 80A / 230VAC	COLD START: 6A / 115VAC, 80A / 230VAC
LEAKAGE CURRENT (max)	Touch current < 100uA (max) @250VAC	Touch current < 100uA (max) @250VAC	Touch current < 100uA (max) @250VAC	Touch current < 100uA (max) @250VAC	Touch current < 100uA (max) @250VAC	Touch current < 100uA (max) @250VAC
OVERLOAD	110%~150% rated output power	110%~150% rated output power	110%~150% rated output power	110%~150% rated output power	110%~150% rated output power	110%~150% rated output power
OVER VOLTAGE	Protection type: Hyster mode, recovery automatically after fault condition is removed	Protection type: Hyster mode, recovery automatically after fault condition is removed	Protection type: Hyster mode, recovery automatically after fault condition is removed	Protection type: Hyster mode, recovery automatically after fault condition is removed	Protection type: Hyster mode, recovery automatically after fault condition is removed	Protection type: Hyster mode, recovery automatically after fault condition is removed
WORKING TEMP.	-30~+70℃ (Refer to "Operating Temp")	-30~+70℃ (Refer to "Operating Temp")	-30~+70℃ (Refer to "Operating Temp")	-30~+70℃ (Refer to "Operating Temp")	-30~+70℃ (Refer to "Operating Temp")	-30~+70℃ (Refer to "Operating Temp")
WORKING HUMIDITY	20%~90% RH non-condensing	20%~90% RH non-condensing	20%~90% RH non-condensing	20%~90% RH non-condensing	20%~90% RH non-condensing	20%~90% RH non-condensing
STORAGE TEMP., HUMIDITY	-25~+85℃, 10~90% RH non-condensing	-25~+85℃, 10~90% RH non-condensing	-25~+85℃, 10~90% RH non-condensing	-25~+85℃, 10~90% RH non-condensing	-25~+85℃, 10~90% RH non-condensing	-25~+85℃, 10~90% RH non-condensing
TEMP. COEFFICIENT	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes
VIBRATION	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes	10~500Hz, 20 100ms, 100ms, period for 60min, each along X, Y, Z axes
SAFETY STANDARDS	UL: UL60950-1, IEC60950-1, IEC60950-2, IEC60950-3, IEC60950-4, IEC60950-5, IEC60950-6, IEC60950-7, IEC60950-8, IEC60950-9, IEC60950-10, IEC60950-11, IEC60950-12, IEC60950-13, IEC60950-14, IEC60950-15, IEC60950-16, IEC60950-17, IEC60950-18, IEC60950-19, IEC60950-20, IEC60950-21, IEC60950-22, IEC60950-23, IEC60950-24, IEC60950-25, IEC60950-26, IEC60950-27, IEC60950-28, IEC60950-29, IEC60950-30, IEC60950-31, IEC60950-32, IEC60950-33, IEC60950-34, IEC60950-35, IEC60950-36, IEC60950-37, IEC60950-38, IEC60950-39, IEC60950-40, IEC60950-41, IEC60950-42, IEC60950-43, IEC60950-44, IEC60950-45, IEC60950-46, IEC60950-47, IEC60950-48, IEC60950-49, IEC60950-50, IEC60950-51, IEC60950-52, IEC60950-53, IEC60950-54, IEC60950-55, IEC60950-56, IEC60950-57, IEC60950-58, IEC60950-59, IEC60950-60, IEC60950-61, IEC60950-62, IEC60950-63, IEC60950-64, IEC60950-65, IEC60950-66, IEC60950-67, IEC60950-68, IEC60950-69, IEC60950-70, IEC60950-71, IEC60950-72, IEC60950-73, IEC60950-74, IEC60950-75, 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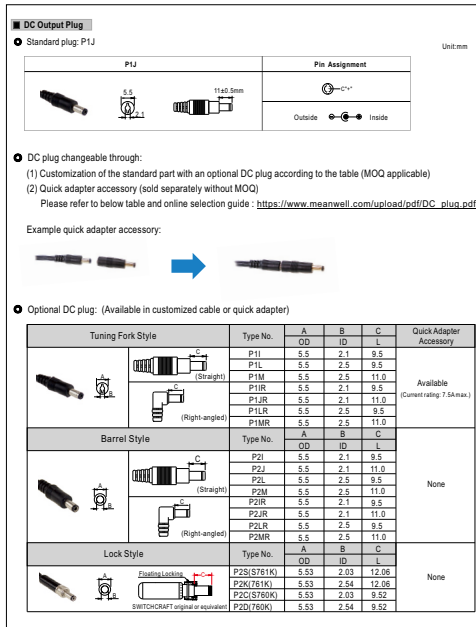
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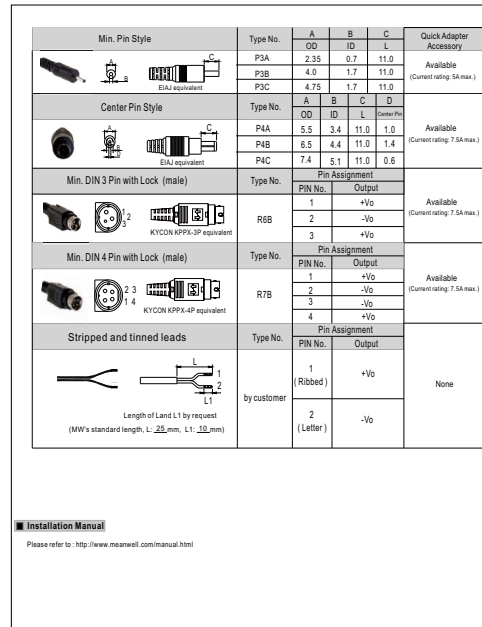
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