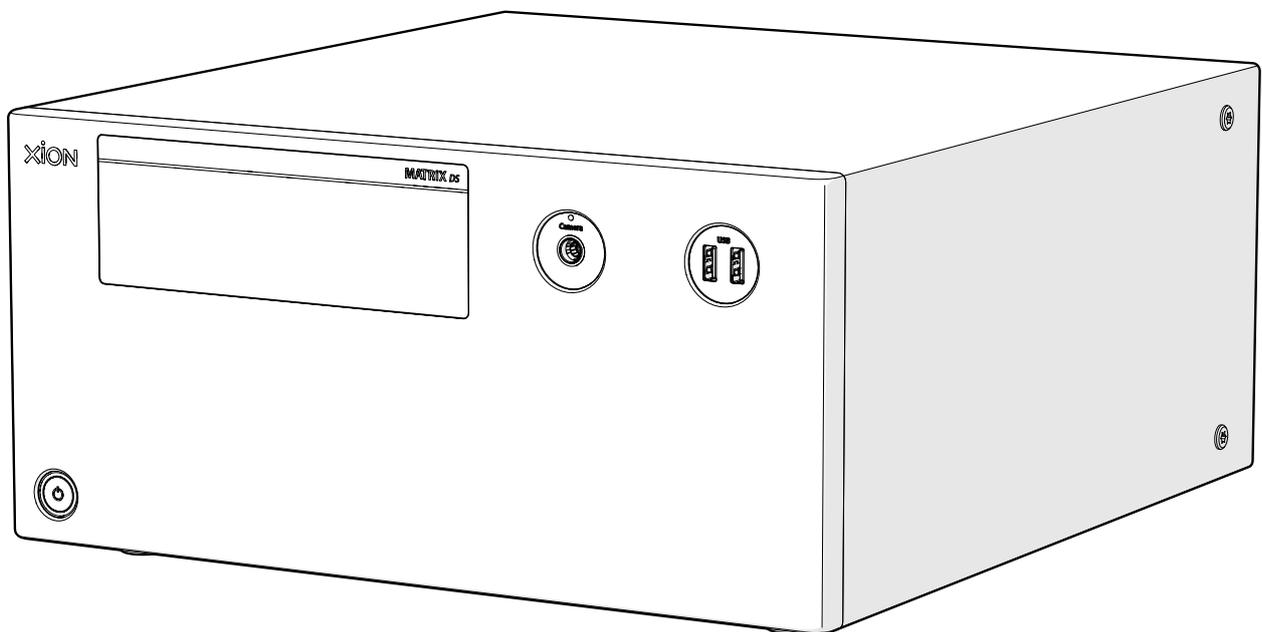


MATRIX DS

Data acquisition station

Type DS6



Instruction for Use



General

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1 Directions for Using the Manual

1.1 Read the Instructions for Use

The User Manual provides information about the safe, proper and efficient use of the medical device.



To avoid injury to users, patients and third parties and to prevent material damage:

- Before using the equipment, read the Instructions for Use
- Read the Instructions for Use for the application parts and other XION devices
- Follow the safety and warning notices
- Store the Instructions for Use near the device so that they are always within reach
- If you forward the device to a third party, make sure to also pass on the Instructions for Use.

1.2 Function of the safety and warning notices

Follow the safety and warning notices to prevent personal injury and material damage. The following hazard levels are used:



WARNING!

Dangerous situation that could result in serious injury or death unless avoided.



CAUTION!

Dangerous situation that could result in minor to moderate injury unless avoided.



NOTE!

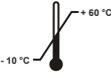
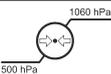
Dangerous situation that could result in material damage unless avoided.

Table of Contents

1	Directions for Using the Manual.....	3
1.1	Read the Instructions for Use.....	3
1.2	Function of the safety and warning notices.....	3
2	Symbols and pictograms.....	6
3	Intended Purpose.....	7
3.1	Intended use.....	7
3.2	Intended user.....	7
3.3	Indication.....	7
3.4	Contraindication.....	7
4	Safety of patients, users and third parties.....	8
4.1	Usage environment.....	8
4.2	Combination with other medical devices.....	8
4.3	Hazards due to electric current.....	8
4.4	Hazard of overheating.....	9
4.5	Risks due to unsuitable ambient conditions.....	10
4.6	Electromagnetic Compatibility (EMC).....	10
5	Product Description.....	11
5.1	Performance Features.....	11
5.2	Front panel of the device.....	11
5.3	Rear panel of the device.....	12
5.3.1	Option Frame Grabber Basis.....	12
5.3.2	Option Frame Grabber PREMIUM Light.....	13
5.4	Scope of Delivery.....	14
5.5	Technical Data.....	15
5.6	Interfaces of the grabber card.....	16
5.7	Accessories.....	16
5.8	Sample Configuration.....	17
5.9	Installed software.....	18
6	Setting up and commissioning.....	19
6.1	Instructions for setting up.....	19
6.2	Cable connections.....	19
6.2.1	MATRIX DS with Frame Grabber Basis.....	20
6.2.2	MATRIX DS with Frame Grabber PREMIUM Light.....	22
6.2.3	Monitor switching – always a live image.....	24
6.2.4	Potential equalization.....	24
6.2.5	USB Blink (USB LED).....	25
6.3	Commissioning.....	27

6.3.1	Switching on the MATRIX DS	27
6.3.2	DiVAS licensing	28
6.3.3	Data security – Activating BitLocker encryption	28
6.3.4	IT Network	29
6.4	Shutting down	30
6.4.1	Switching off the MATRIX DS	30
7	Application.....	31
7.1	Veezar Application Part	31
8	Cleaning and Disinfecting.....	32
9	Maintenance and Service	33
9.1	Re-examinations / safety checks	33
9.2	Manufacturer's Service	33
9.2.1	Address for repairs and return shipments:.....	33
9.2.2	Article numbers and serial numbers	34
9.3	Repair process	34
9.4	Responsibility	35
9.5	Warranty	35
9.6	Disclaimer	35
9.7	Disposal	35
9.8	Service Adress.....	35
10	Trouble shooting	36
11	Declarations concerning EMC	37
12	Manufacturer and Distributor.....	38
	Glossary.....	41

2 Symbols and pictograms

Symbol	Meaning
	Refer to instruction manual/booklet
	Tip! Useful additional information about using the device.
	Manufacturer
	Year of manufacture
IP 21	Type of protection
REF	Article number
SN	Serial number
	Disconnect power plug
	ESD-protection measures required
	Potential equalization
	Temperature limit
	Relative humidity
	Atmospheric pressure
	Keep away from sunlight
	Keep dry
	Fragile, handle with care
	Disposal of electrical equipment
CE	CE marking

3 Intended Purpose

3.1 Intended use



The MATRIX DS provides the facilities necessary for executing the XION DiVAS software, and is used to capture and manage image and audiovisual data in combination with other accessories.

3.2 Intended user

The intended user is a trained/experienced physician, who has read these Instructions for Use.

This equipment is not intended for operation by medical assistants.

3.3 Indication

The MATRIX DS is used in the field of clinical endoscopy.

3.4 Contraindication

Contraindications that relate directly to the medical device, are currently unknown. Deploying XION Data Stations is contraindicated if, in the opinion of a qualified physician, such an application would endanger the patient.

4 Safety of patients, users and third parties



WARNING!

If you ignore the following safety instructions, patients, users and third parties may be harmed. Therefore:

- Read the notes carefully
- Follow the instructions
- Any serious incident occurring in conjunction with the medical device must be reported to the manufacturer and the competent authority.

Please note:

- This device may not be modified without the permission of the manufacturer.

4.1 Usage environment

A defined operating environment is required to ensure that the device can function safely and that patients, users and third parties are not harmed.

- The device shall be operated only in the environment of professional healthcare facilities.
- The device is **NOT** suitable for operating in MRT rooms due to the ferromagnetic interactions encountered there.
- The medical device is **NOT** suitable for operating in potentially explosive areas and/or in oxygen enriched environments. For example, when using combustible and volatile skin cleaning and skin disinfecting substances, make sure that the device is not used in a hazard zone as defined by the manufacturer.
- The device is not designed for operation in the vicinity of massive X-ray radiation sources (e.g. C-arm).

4.2 Combination with other medical devices

The use unauthorised devices or components or make unauthorised modifications to the product, users, patients or third parties may be harmed.

- Only mains-powered devices that meet the requirements of IEC 60601-1 shall be connected.
- If a medical electrical (ME) system is created, trained electrical specialists must be called in to check the leakage currents.
- During its application on the patient, neither service work nor modifications to the ME system (e.g. replacing connector cables) shall be carried out.
- Applications in conjunction with laser light sources and high-frequency devices is not permitted.

4.3 Hazards due to electric current

An electric shock poses a high risk of injury to patients, users or third parties. It is thus essential to follow the instructions below:

- Prior to commissioning the device, check whether its operating voltage is the same as the local mains voltage. See the type plate or the Technical Data section for the approved operating voltage.
- Connect the device to a properly earthed electric safety socket.
- Do not turn on the device until all necessary connection lines have been fully connected.
- Always avoid directly touching any exposed plug contacts.
- Exposed contacts on the device must not come into contact with the patient at the same time.
- Maintenance and repair work on the ME device shall be carried out only by XION employees.

- Do not subject the device to rain or moisture. Do not allow anything to drop on the device. Moisture or objects dropping on to the device can cause permanent damage to it or can induce the risk of electric shock. In such an event immediately switch off the device, disconnect it from the mains and commission qualified service personnel to perform the required service or repair work.
- ALWAYS use a network isolator for a network connection (see accessories [► 16]).

4.4 Hazard of overheating

The air cooling system of the device prevents it from overheating. Excessively high temperatures can lead to loss of function and hot external surfaces. Patients, users and third parties may be injured.

- Make sure to provide adequate air circulation so that the device does not overheat.

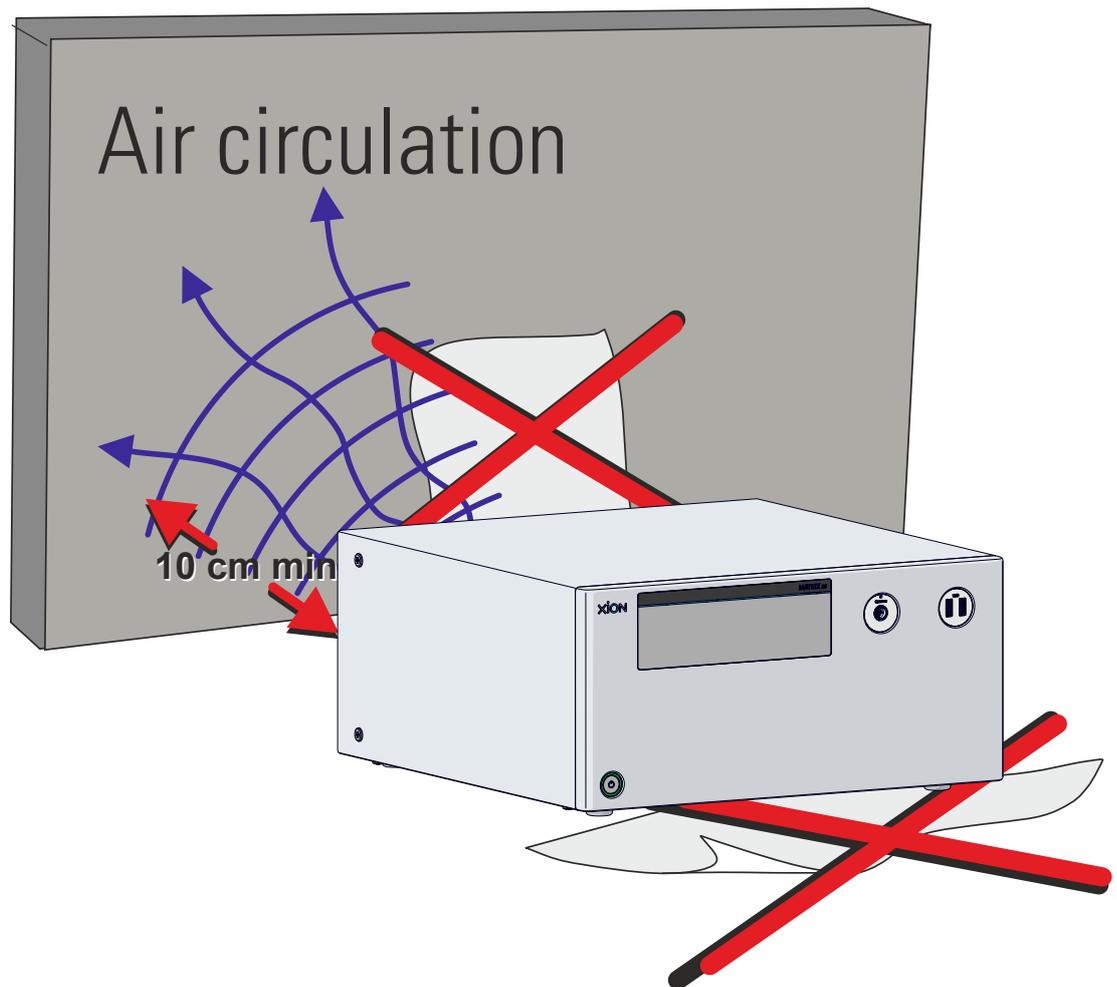


Illustration 1: Instructions for setting up the MATRIX DS

- Keep a distance of at least 10 cm from the back of the device.
- There shall be no flammable objects in the immediate vicinity of the appliance (10 cm radius).
- Make sure that the ventilation slots at the bottom of the device and in the rear panel of the device are not covered.
- Dust and dirt can block the ventilation slots. For this reason, make sure to keep the ventilation slots clean.
- Observe the "Ambient conditions for operation" Technical Data [► 15].

4.5 Risks due to unsuitable ambient conditions

If the product is stored, transported or used under deviating environmental conditions, patients, users or third parties may be harmed during use.

- Therefore always observe the ambient conditions specified in the technical data.

4.6 Electromagnetic Compatibility (EMC)

Deployment directly next to other devices or with other devices in stacked form should be avoided, as this could result in faulty operation. However, if for some reason it is absolutely necessary to use the device in the above described manner, it is essential to keep observing the device and the other devices to ensure that they are working properly.

The use of accessories, transducers and cables other than those specified or supplied by XION may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system and result in improper operation.

Mobile RF communications equipment (radios including their accessories such as antenna cables and external antennae) should be used at a distance of no less than 30 cm (12 inches) from the devices identified by XION and the conductor lines of the MATRIX DS. Failure to observe this requirement can significantly reduce the performance of the device.

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.

- Always avoid directly touching any exposed plug contacts.

5 Product Description

The MATRIX DS Data Acquisition Station is a configured PC that has been optimised for running the XION DiVAS software and is therefore suitable for use in a medical environment. It therefore supports the capture and management of image and audiovisual data in conjunction with other accessories.

The MATRIX DS Data Acquisition Station can be compiled and configured to meet your particular specifications, and can also be extended with further optional hardware or software.



This User Manual generally describes the device type referred to as MATRIX DS6 – the specific device type is not mentioned.

5.1 Performance Features

- A Veezar interface on the front panel, for connecting the Veezar Video Otoscope VO10
- 2 front-panel USB 3.2 interfaces
- Incorporates the Base / Patient Management module of DiVAS
- Overall height 4 height units, with the option to mount directly within the XION Equipment Trolley
- Standby/PowerOn functionality for central power-on control via XION Equipment Trolleys
- Appropriate cut-outs in the housing facilitate securing the devices by means of a Kensington lock, if required.

5.2 Front panel of the device

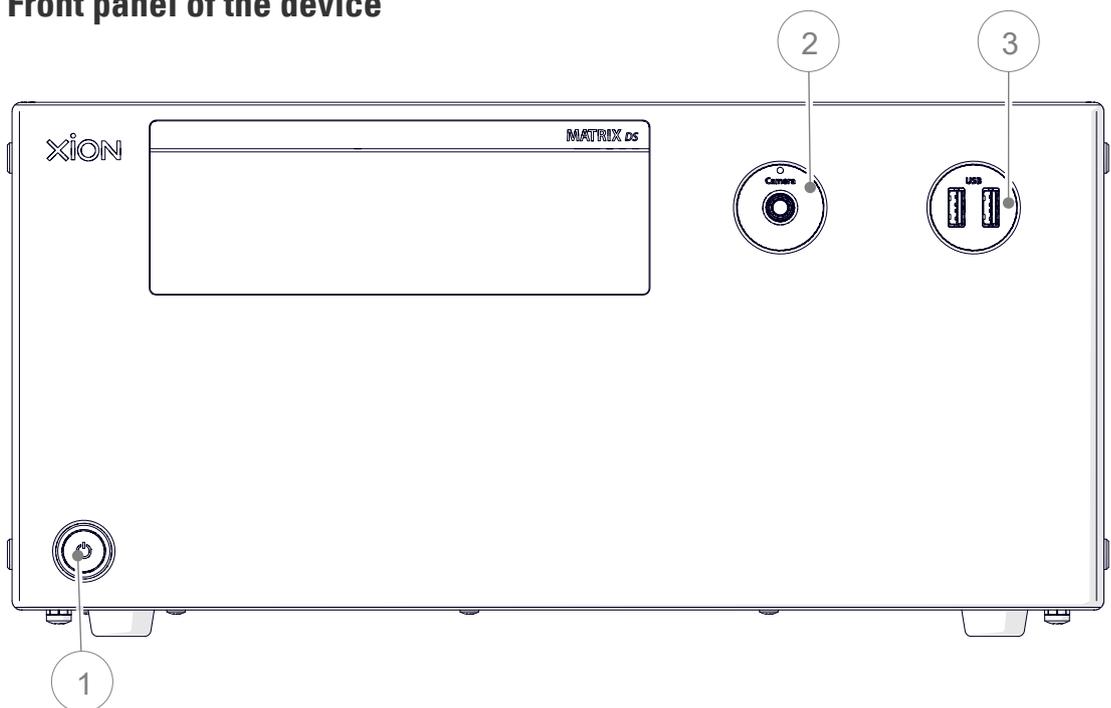


Illustration 2: Front of the MATRIX DS, Data Acquisition Station

- (1) Power button with LED control indicator
Switching between:
LED green = Mains on
LED orange = STANDBY
- (2) **Camera** – Connector port for the Veezar Video Otoscope VO10
- (3) **USB 3.2 sockets**

5.3 Rear panel of the device

5.3.1 Option Frame Grabber Basis

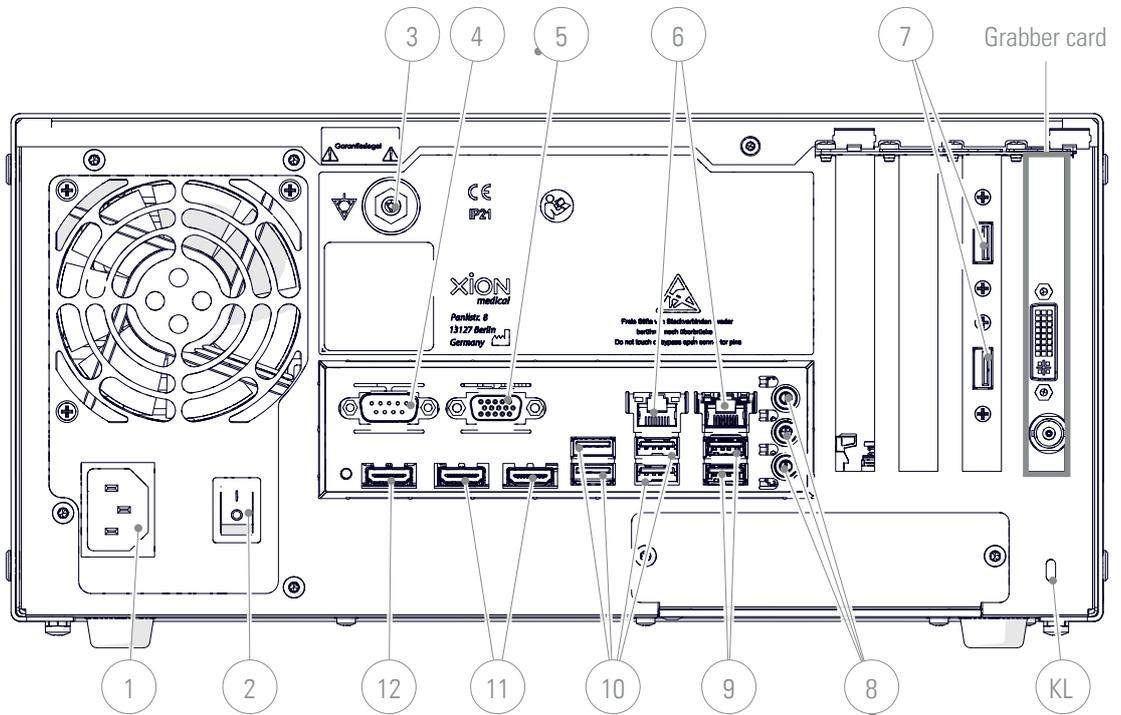


Illustration 3: Connector ports and functional elements on the rear panel of the MATRIX DS Basis

- (1) Mains power connection 100 – 240 V~ 50Hz – 60Hz
- (2) On/Off switch
- (3) Connector for potential equalization
- (4) Serial port (RS232), monitor switching
- (5) Video output VGA
- (6) LAN (RJ45) ports
- (7) USB 2.0 sockets
- (8) Audio sockets: Line-in, Mic-in, Line-out
- (9) 2x USB 3.2 Gen 2
- (10) 4x USB 3.2 Gen 1
- (11) Video output 2x HDMI 1.4
- (12) Video output HDMI 2.0
- (13) Video input DVI-I
- (14) Video input BNC (3G-SDI)
- KL Kensington Lock** - Anti-theft device

Interfaces of the grabber card (YUAN)

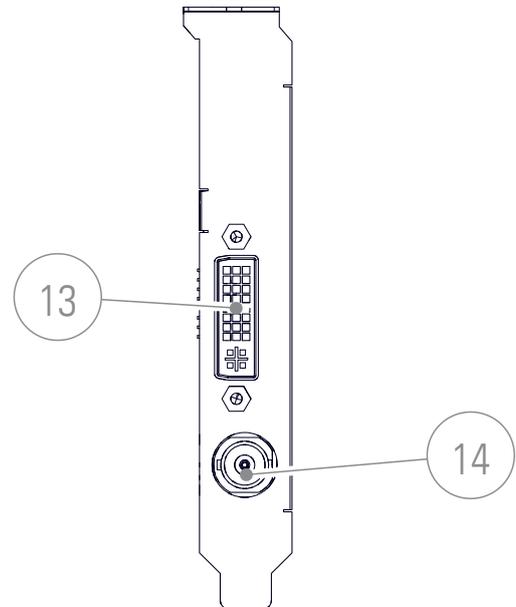


Illustration 4: Interfaces of the grabber card (YUAN)

5.3.2 Option Frame Grabber PREMIUM Light

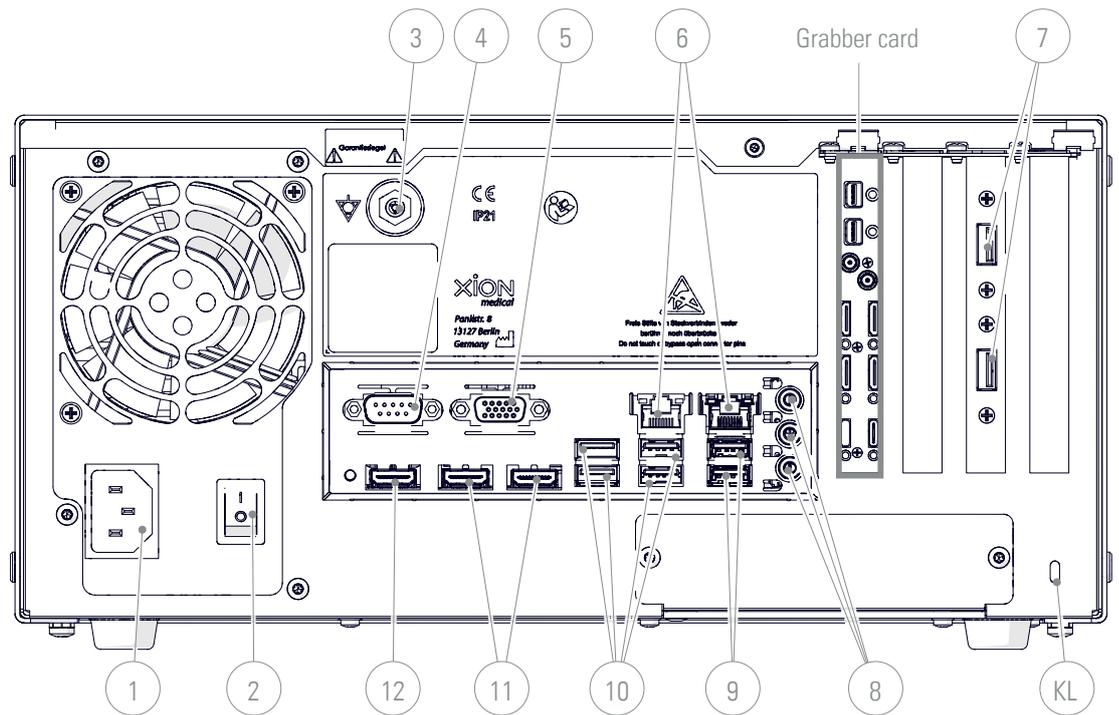


Illustration 5: Connector ports and functional elements on the rear panel of the MATRIX DS (PREMIUM Light)

- (1) Mains power connection 100 – 240 V~ 50Hz – 60Hz
- (2) On/Off switch
- (3) Connector for potential equalization
- (4) Serial port (RS232), monitor switching
- (5) Video output VGA
- (6) LAN (RJ45) ports
- (7) USB 2.0 sockets
- (8) Audio sockets: Line-in, Mic-in, Line-out
- (9) 2x USB 3.2 Gen 2
- (10) 4x USB 3.2 Gen 1
- (11) Video output 2x HDMI 1.4
- (12) Video output HDMI 2.0
- (13) Video input 2x mDisplayPort (1.2)
- (14) Video input BNC (12G-SDI)
- (15) Video input 2x mHDMI (2.0)
- (16) Video input 2x mHDMI (1.4)
- (17) Video input 2x USB-C
- KL** **Kensington Lock** - Anti-theft device

Interfaces of the grabber card (Clarity)

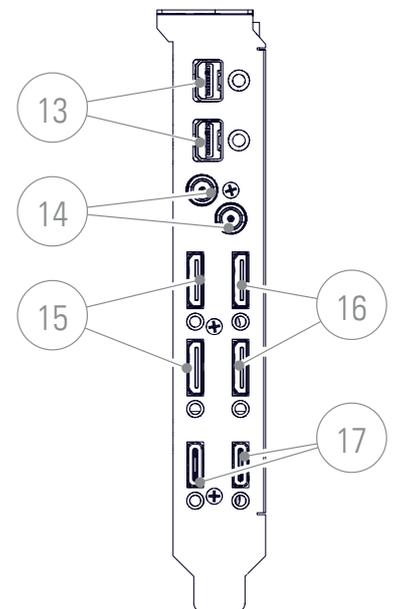


Illustration 6: Interfaces of the Grabber card (Clarity)

5.4 Scope of Delivery



After unpacking, first please check the goods for shipment damage. In the event of any damage, use key words to describe the apparent extent of damage and report it to your dealer or manufacturer.

Please refer to your delivery note for the detailed scope of delivery.

Article	Article number
MATRIX DS data acquisition station	350 010 884
Option Frame Grabber Basis	350 010 032
Option Frame Grabber PREMIUM Light	350 010 031
Windows 10 installation	350 009 520
Microsoft Office 2021 Multilanguage installation	350 009 513
DiVAS Basic / Patient Management module	350 020 000
Audio connector cable, 3.5 mm jack, length 1.2 m	320 009 045
Cable HDMI plug to DVI-D plug, 2 m	320 009 070
USB-2.0 cable 1 m, A->B (plug/plug)	350 009 056
USB recording display (USB flashes)	350 010 047
Mains cable, length 2.0 m, EURO standard	320 009 007
Electrical Safety Protocol	

Table 1: Scope of delivery XION Data Stations

5.5 Technical Data

MATRIX DS Data Acquisition Station	350 010 884
Computer hardware	
CPU	Intel Core i5 10th Gen.
Chipset	Intel® Q470 Express Chipset
RAM	2x 8 GB DDR4
HDD	M.2 hard drive 512GB (operating system)/ 3.5" HDD, min. 4TB (for data)
Graphic card	Integrated graphics processor, Intel® Graphics Media Accelerator
Interfaces	
• Audio	
Line In/Out	2x 3.5 mm jack socket
Mic In	1x 3.5 mm jack socket
• Video	
HDMI	1x HDMI V2.0 / 2x HDMI V1.4
Serial	1x RS232 (9pin D-SUB)
VGA	1x
• External	
USB	Front panel: 2x USB 3.2 Gen1 Rear panel: 4x USB 3.2 Gen1 / 2x USB 3.2 Gen2 / 2x USB 2.0
LAN	2x RJ45 (10/100/1.000 MBit)
• Miscellaneous	
Application parts	1x Veezar application part (Veezar Video Otoscope VO10)
Electrical Data	
Voltage	100 - 240 V ~
Frequency	50 Hz - 60 Hz
Power consumption	max. 320 VA
Mechanical Data	
Dimensions (W x H x D)	350 x 172 x 364 mm
Weight	9,100 g
Ambient conditions operation	
Temperature	+10°C to +35°C
Relative humidity	30% to 90%, non-condensing
Altitude	≤ 3,000 m
Ambient conditions storage and transport	
Temperature	-10°C to +60°C
Relative humidity	30% to 90%, non-condensing
Pressure	50 - 106 kPa
Classification	
Protection class	I
Type of protection	IP21
Conformity	CE
Norm conformity	IEC 60601-1; IEC 60601-1-2

Table 2: Technical data MATRIX DS Data Stations

5.6 Interfaces of the grabber card

Overview of grabber card interfaces

Interface/ grabber card	SDI	DVI	HDMI	DisplayPort	USB-C
PREMIUM Light	2x HD-BNC (12G)	-	2x mHDMI (1.4) 2x mHDMI (2.0)	2x mDP 1.2	2x
Basis	1x BNC (3G)	DVI-D	-	-	-

5.7 Accessories

Article	Article number
Veezar Video Oscope VO10	133 100 020
Medical flat panel monitor, external power supply, SONY LMD-X310MD	330 031 001
USB recording display (USB flashes)	350 010 047
Medically suitable keyboard with touchpad, German, USB, disinfectable	350 009 066
DELL Soundbar AC511M	350 009 108
Adapter D-SUB 9-pin plug/plug (gender changer)	320 009 055
DVI-D cable, length 2,0 m	320 009 043
Cable null modem 9-pin socket/socket, 2 m	320 009 054
Cable Mini HDMI plug to DVI-D plug, 2m	320 009 069
Audio connector cable, 3.5 mm jack, length 1.2 m	320 009 045
12G-SDI cable, 2 m, mini HD BNC plug/BNC plug	320 009 073
Mains cable, length 2.0 m, EURO standard	320 009 007
Potential equalization cable, length 2 m	340 009 003
Network cable 2 m (patch cable), Cat. 6 or better	350 009 032
USB-2.0 cable 1 m, A->B (plug/plug)	350 009 056
Network isolator for 1Gbit Ethernet networks	350 009 080

Table 3: Accessories XION Data Stations



For further accessories and their cabling, please see the "Cabling manual".

5.8 Sample Configuration

The XION MATRIX DS Data Acquisition Station is a component within a diverse system offered by XION GmbH. Due to the different system variations possible, the installation and the cable connections always depend on the respective situations and components of your system.

The following sample configuration represents a XION system environment with different XION accessories.

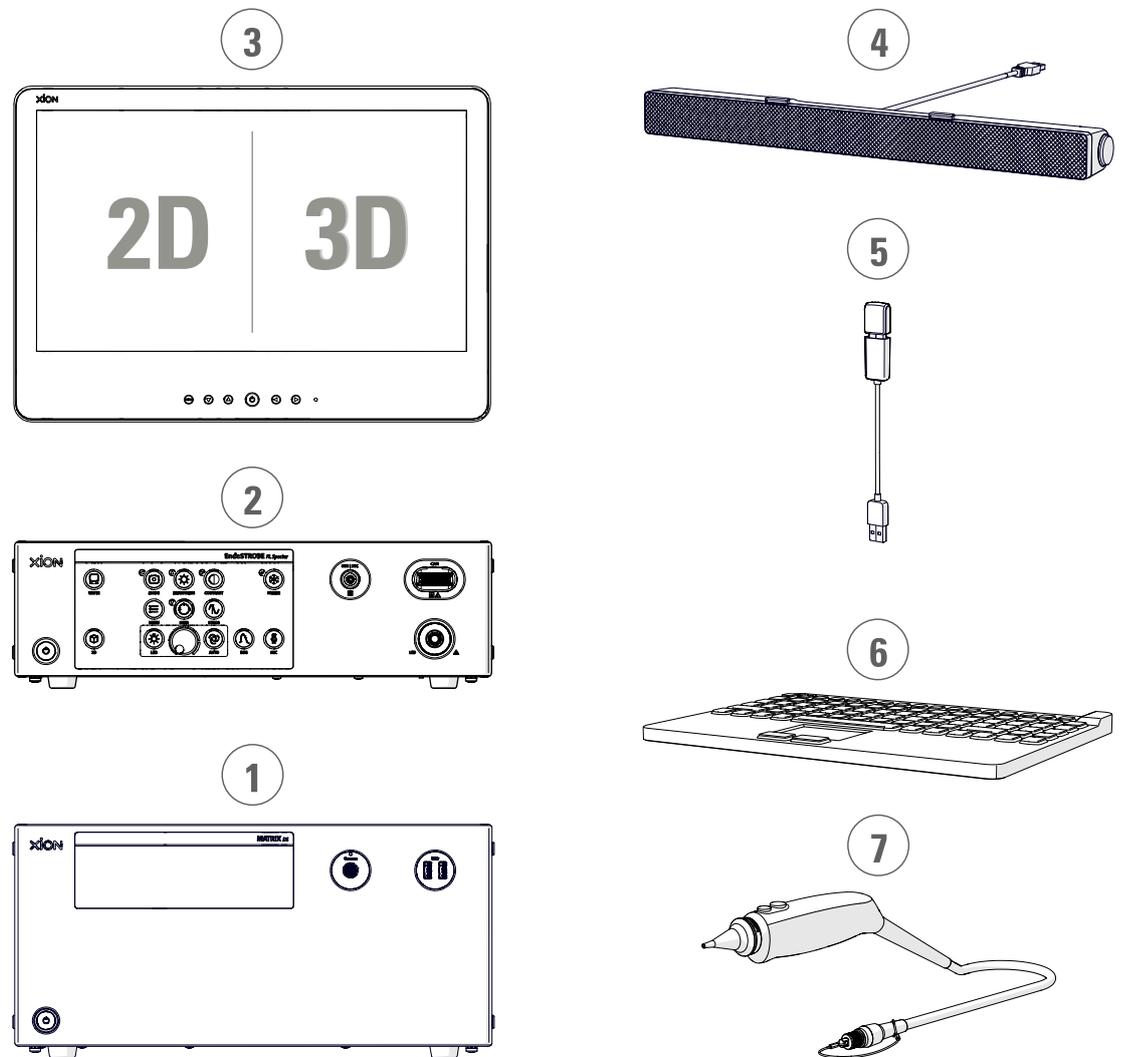


Illustration 7: MATRIX DS sample configuration

- (1)** MATRIX DS Data Acquisition Station
- (2)** XION Camera Processors
- (3)** Monitors in various output formats and resolutions

- (4)** Soundbar
- (5)** Recording display USB Flash
- (6)** Medical keyboard
- (7)** Veezar Video Otoscope VO10

5.9 Installed software

The following software is installed on your MATRIX DS, Data Acquisition Station:

- MS Windows operating system. You can find the license key for your MS Windows operating system on the rear side of the device.
- MS Office
- DiVAS Basic / Patient Management module



Do you want to install additional software (e.g. anti-virus software, Microsoft Office package, etc.)? To avoid possible incompatibilities, please contact your XION service team BEFORE installing such additional software.

6 Setting up and commissioning

6.1 Instructions for setting up

- Place the device on a clean slip-resistant surface in a clean, dry place, or set it up in a XION trolley/roller stand.
- Keep a distance of at least 10 cm from the back of the device.
- There shall be no flammable objects in the immediate vicinity of the appliance (10 cm radius).
- Make sure that the ventilation slots at the bottom of the device and in the rear panel of the device are not covered.
- To avoid the risk of injury and/or damage to the device, please run all connecting cables in such a manner that nobody can step on them, trip over them or place heavy objects on them.
- Position the device so that it can be easily disconnected from the mains supply at any time.
- Do not move the device while it is in operation.

6.2 Cable connections

To ensure that the resulting ME system complies with operator and patient protection requirements, it is recommended to connect only XION-listed accessories.



An ME system is created by combining individual devices, at least one of which must be an ME device; the connection is made by means of a functional connection (e.g. monitor cable, LAN cable) or by using a multiple socket.

When an ME system is created, specialised electrical personnel must be consulted and attention must be paid to compliance with the leakage current limits (even in the event of a fault). The leakage currents generated by the MATRIX DS ME device are listed in the enclosed [Electrical Safety Protocol](#).



Do not touch or bridge any free pins of connectors!

When installing the connectors on the rear side, especially the RS232 interface, [ESD](#) measures shall be taken to prevent damage to the ME device.



For further accessories and their cabling, please see the "Cabling manual".

6.2.1 MATRIX DS with Frame Grabber Basis

6.2.1.1 Example configuration: Spectar* camera processors with a monitor

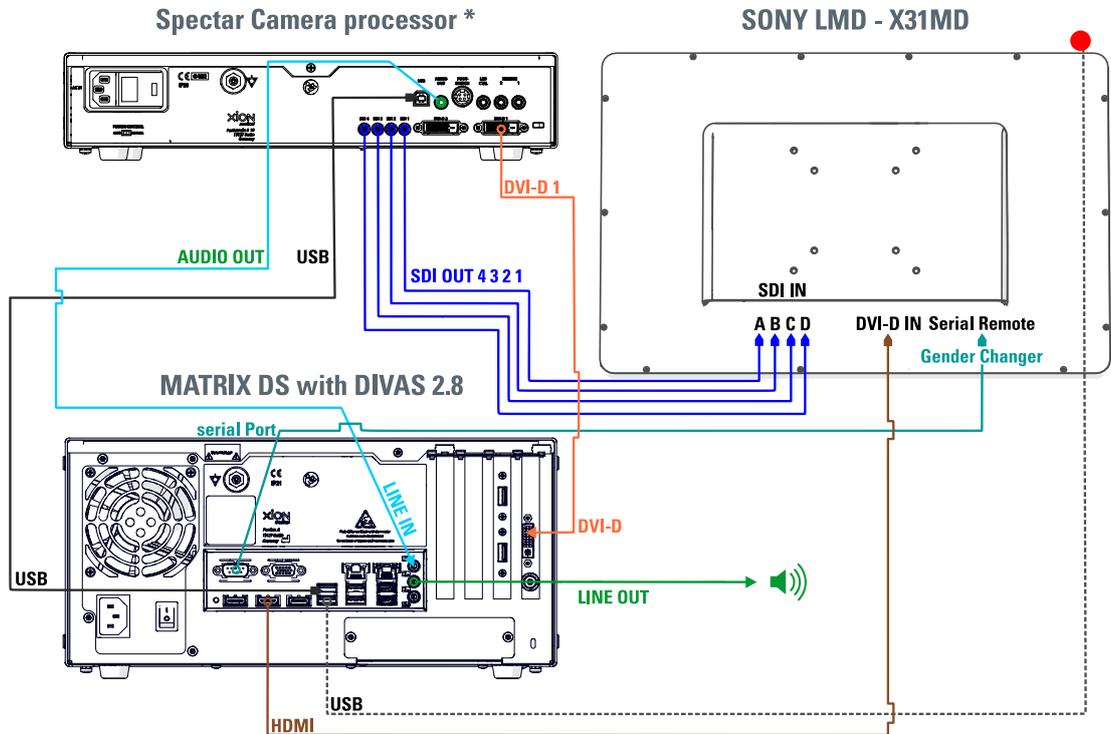


Illustration 8: MATRIX DS in combination with a MATRIX Spectar (Basis) and a monitor (SONY)



SDI cabling between Spectar camera processors and monitor must be properly assigned.

SONY

SDI 1,2,3,4 <-> SDI A,B,C,D



You need the **Cross connection cable** with **Gender Changer**. The Gender Changer **MUST** be plugged into the Serial Remote Port at **Screen**.



For further accessories and their cabling, please see the "Cabling manual".

Legend:

————— Required cabling

----- Optional cabling



Symbolises the USB LED. This is required in the 1-monitor setup to display the recording to the user. It is optional in the 2-monitor setup. It is attached to the back of the monitor. See USB LED (USB Blink).

* Sample configuration with MATRIX P Spectar. The back of your device may have a different design.

6.2.1.2 Example configuration: Spectar* camera processors with several monitors

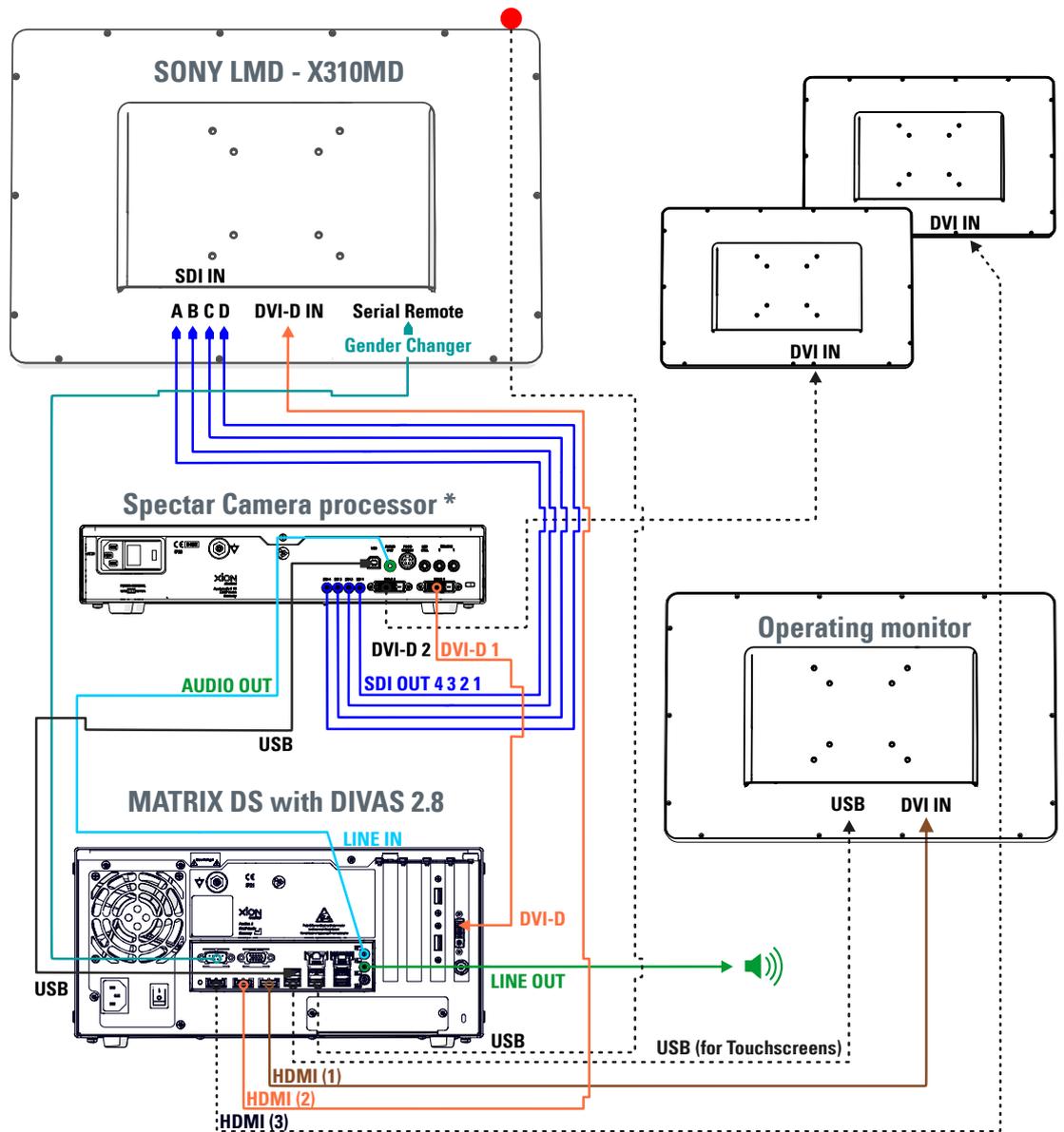


Illustration 9: MATRIX DS in combination with a MATRIX Spectar (Basis) and many monitors (SONY)



SDI cabling between Spectar camera processors and monitor must be properly assigned.

SONY

SDI 1,2,3,4 <-> SDI A,B,C,D



You need the **Cross connection cable** with **Gender Changer**. The Gender Changer **MUST** be plugged into the Serial Remote Port at **Screen**.



For further accessories and their cabling, please see the "Cabling manual".

Legend:

————— Required cabling

- - - - - Optional cabling



Symbolises the USB LED. This is required in the 1-monitor setup to display the recording to the user. It is optional in the 2-monitor setup. It is attached to the back of the monitor. See USB LED (USB Blink).

* Sample configuration with MATRIX P Spectar. The back of your device may have a different design.

6.2.2 MATRIX DS with Frame Grabber PREMIUM Light

6.2.2.1 Example configuration: Spectar* camera processors with a monitor

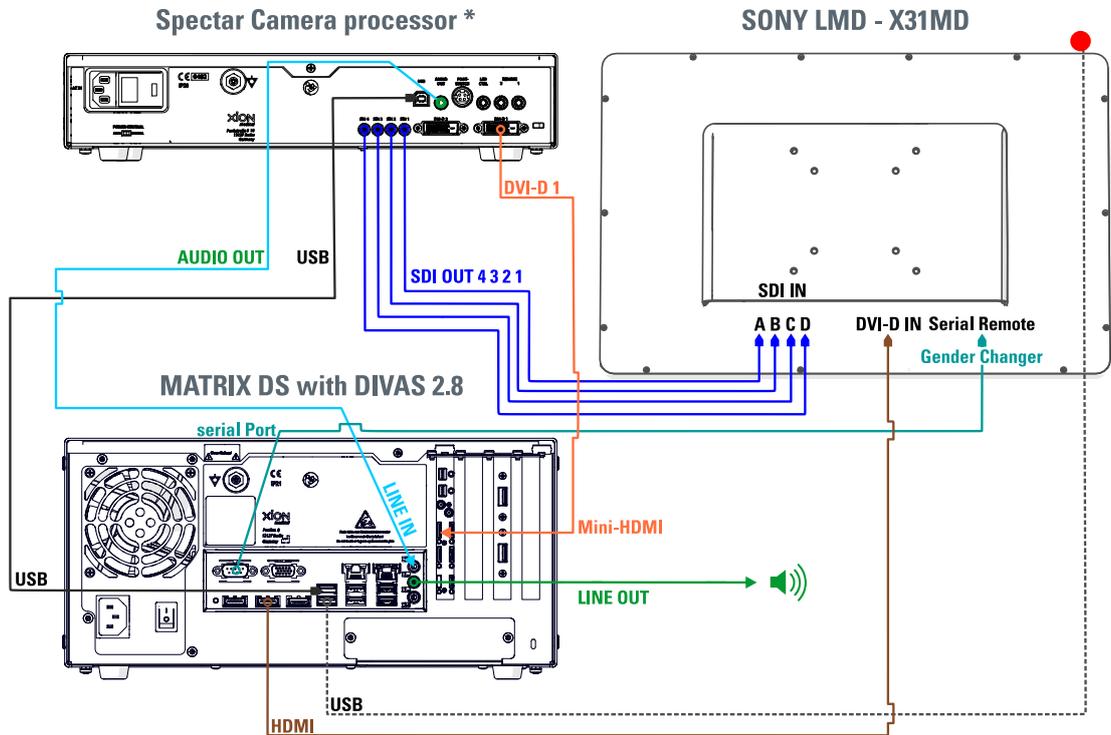


Illustration 10: MATRIX DS in combination with a MATRIX Spectar (Premium Light) and a monitor (SONY)



SDI cabling between Spectar camera processors and monitor must be properly assigned.

SONY

SDI 1,2,3,4 <-> SDI A,B,C,D



You need the **Cross connection cable** with **Gender Changer**. The Gender Changer **MUST** be plugged into the Serial Remote Port at **Screen**.



For further accessories and their cabling, please see the "Cabling manual".

Legend:

———— Required cabling

----- Optional cabling



Symbolises the USB LED. This is required in the 1-monitor setup to display the recording to the user. It is optional in the 2-monitor setup. It is attached to the back of the monitor. See USB LED (USB Blink).

* Sample configuration with MATRIX P Spectar. The back of your device may have a different design.

6.2.2.2 Example configuration: Spectar* camera processors with several monitors

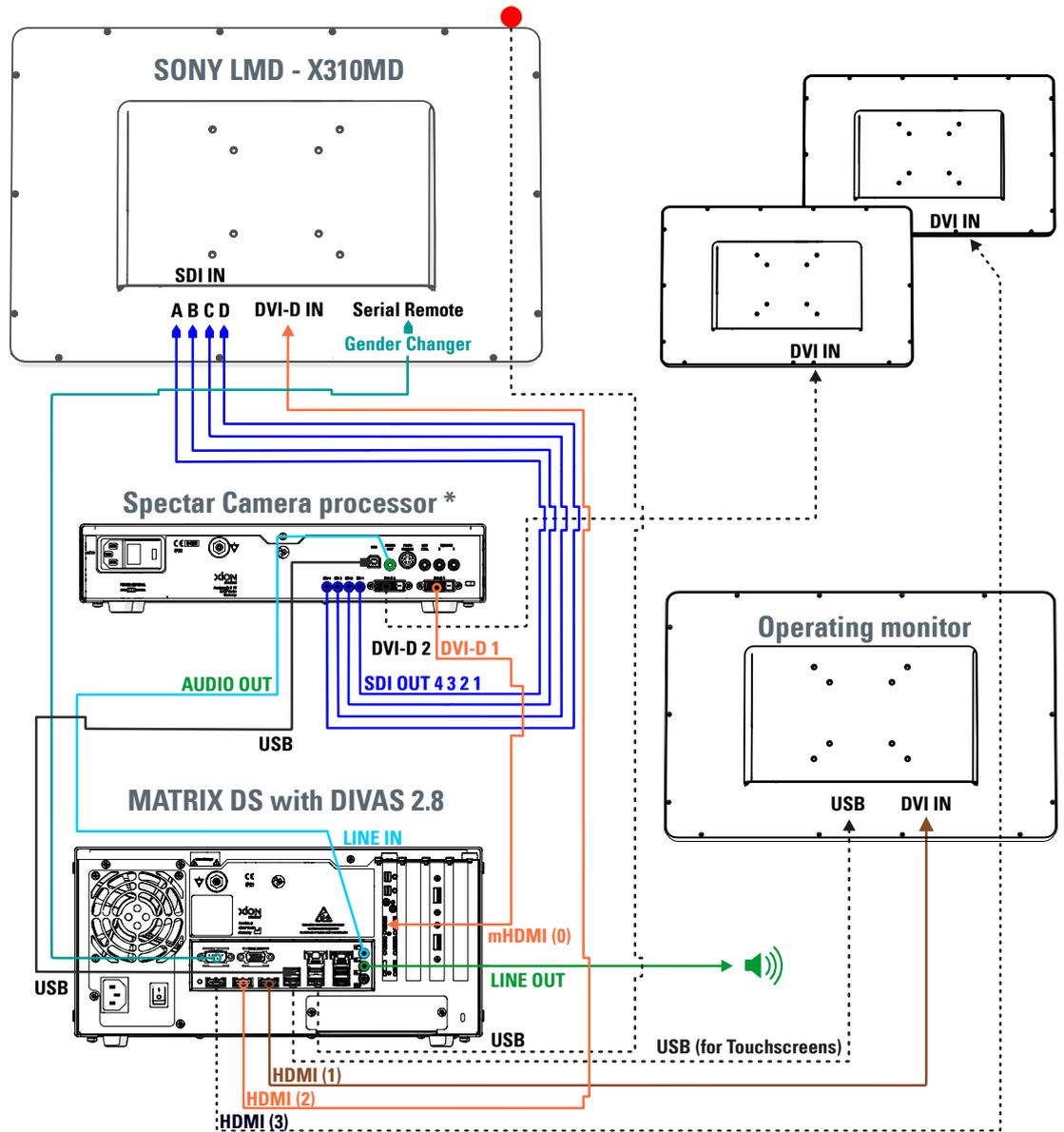


Illustration 11: MATRIX DS in combination with a MATRIX Spectar (Premium Light) and many monitors (SONY)



SDI cabling between Spectar camera processors and monitor must be properly assigned.

SONY

SDI 1,2,3,4 <-> SDI A,B,C,D



You need the **Cross connection cable** with **Gender Changer**. The Gender Changer **MUST** be plugged into the Serial Remote Port at **Screen**.



For further accessories and their cabling, please see the "Cabling manual".

Legend:

————— Required cabling

----- Optional cabling



Symbolises the USB LED. This is required in the 1-monitor setup to display the recording to the user. It is optional in the 2-monitor setup. It is attached to the back of the monitor. See USB LED (USB Blink).

* Sample configuration with MATRIX P Spectar. The back of your device may have a different design.

6.2.3 Monitor switching – always a live image



By combining the MATRIX DS with a XION camera processor of the Spectar series and a corresponding monitor, thanks to the [monitor switching](#) function, you always have a live image available. XION GmbH recommends using the monitors sold by XION; these are listed in the "Cabling manual". When these monitors are used, DiVAS supports automatic monitor switching for these monitors. This ensures that - even in the event that a data station fails - you still have a live image.

RS-232 activated?

Verify whether RS-232 is activated in your monitor menu (buttons on the monitor). For instructions on how to activate the RS-232 interface on your XION monitor, please see the "Cabling manual" or the Instructions for Use of your monitor.

6.2.4 Potential equalization

Your device is equipped with a connector for potential equalization, which can be used when an ME system is created.

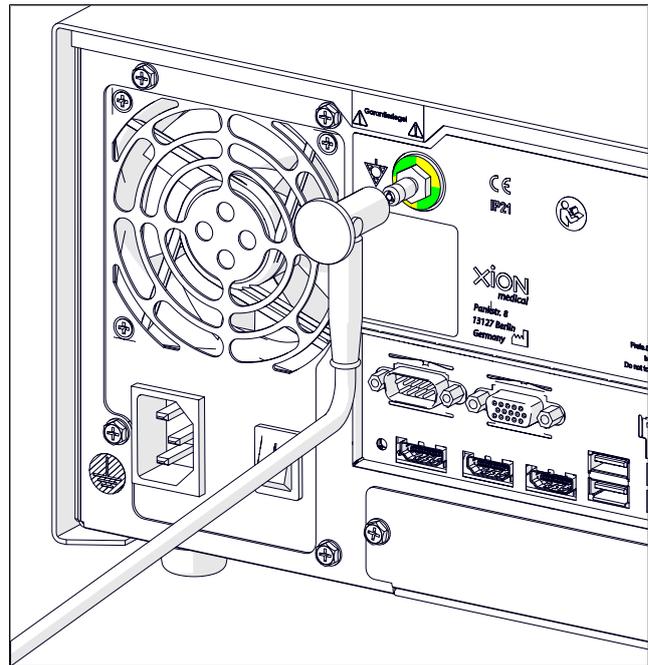


Illustration 12: Potential equalizing connector



Connecting the device to a potential equalizer provides additional protection. If potential equalization is present, connecting the device is recommended.

6.2.5 USB Blink (USB LED)

Do I need the USB LED?

Starting with DiVAS version 2.8.3 and adapted cabling, DiVAS switches the live image of the camera to the monitor at the beginning of the session. Since this is a full screen, you CANNOT see the operating status (recording, stop) of a 1-monitor system. The optical signal of the USB LED allows you to distinguish between recording and stop.

USB Flash on the front panel

To use the USB Flash on the front panel, you need to:

1. Disconnect the USB Flash from the USB cable and

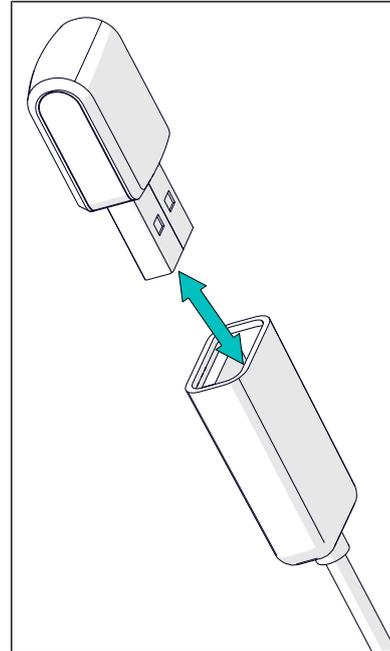


Illustration 13: Disconnecting the USB Flash from the USB cable

2. Plug the USB Flash into the front panel of the MATRIX DS.
3. The hardware is recognised and is immediately ready for operation.

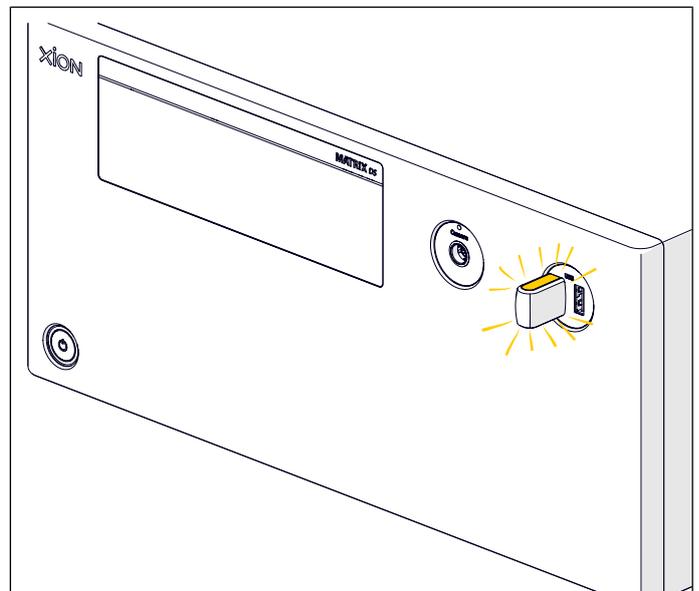


Illustration 14: USB Flash in USB socket on the front panel of the Matrix DS

Mounting on the monitor

Insert the USB plug (3) of the USB LED into a USB socket (rear) of your MATRIX DS. Using the double-sided adhesive tape (2) provided, fasten it to the back of your monitor. The LED (1) must protrude over the edge of the monitor. We recommend that you fasten the USB LED centrally on the rear side of the monitor.

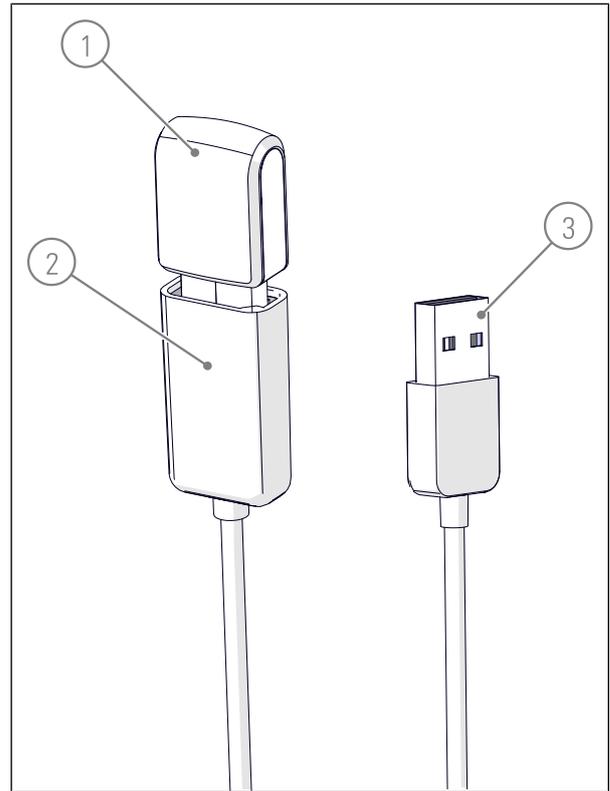


Illustration 15: USB Flash with USB plug



Degrease the area on the back of the monitor where you want to attach the USB LED with medical alcohol.

Operation indicator USB LED

Operation	Signal	Colour
Recording (Video)	Constant glowing	Orange
Pause (Video)	Flashing (configurable)	Orange
Camera head initialization running	Blinking	Yellow -> Green -> extinguishes
Initialization of camera head completed	Constant glow, fades out	Green
Recording (Foto)	Short flash	White



In DiVAS, you can choose between different display options. See DiVAS 2.8 User Guide Chapter Options -> Video.

6.3 Commissioning



Note!

Before starting the system for the first time after it was transported at a temperature below 0°C, the device must be kept in an unpacked and switched-off condition at the specified operating temperature (between +10°C and +40°C) for at least 24 hours, to acclimatize it and to prevent condensation forming!



To commission the application parts and accessories, follow the instructions provided in the respective Instructions for Use.

6.3.1 Switching on the MATRIX DS

Actuating the mains switch on the front panel switches the device on.

The behaviour of the MATRIX DS, Data Acquisition Station when it is switched on depends on whether the device is configured for use in the XION PREMIUM Light model equipment trolley or as a standalone (i.e. for operation in the XION Basic model equipment trolley, or outside of an equipment trolley).

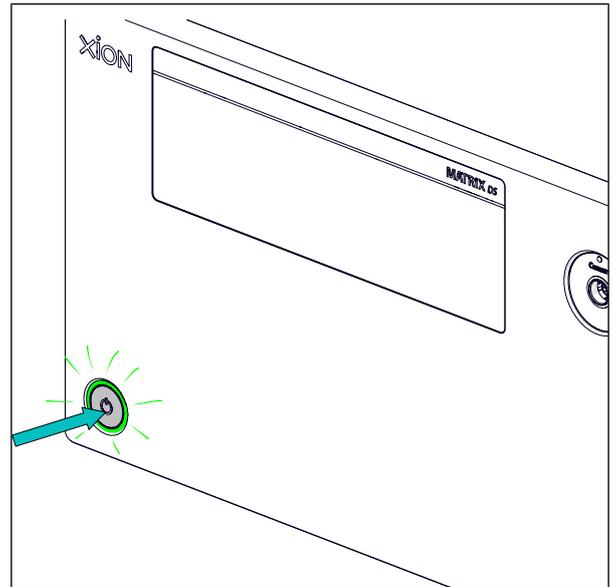


Illustration 16: Switching on the MATRIX DS



The type of switch-on behaviour is defined by the BIOS of the data station, and is correspondingly factory-programmed by the manufacturer.

6.3.1.1 MATRIX DS as a "stand alone" or in the XION BASIC equipment trolley model



OFF

The MATRIX DS, Data Acquisition Station is not connected to the power supply. Use the mains cable supplied with the device to establish the connection.



STANDBY

The power button lights up orange and signals that voltage is present. At this stage the Data Acquisition Station is still in its OFF state.



ON

Use the power button to turn on the Data Acquisition Station. The power button lights green indicating the switched-on state.



If you press the power button immediately after switching off, the device starts with a delay of up to 10 seconds. Therefore, wait at least 10 seconds between switching the device off and then back on again.

In certain situations, Windows requires you to enter a user name and password before it boots up.

In this case, please contact XION Service.

6.3.1.2 MATRIX DS in a XION equipment trolley PREMIUM Light

If your MATRIX DS, Data Acquisition Station is integrated in a XION PREMIUM Light equipment trolley for operation, the automatic "central control" integrated in the equipment trolley follows a predefined sequence to switch on all the installed devices.

For details about the switch-on procedure and the associated processes, please see the User Manual for your equipment trolley.

6.3.2 DiVAS licensing



Please refer to the DiVAS Basic Manual for information on how to licence your DiVAS version.

6.3.3 Data security – Activating BitLocker encryption



NOTE!

Data is lost if password is lost

When encrypting the files, **Windows** will ask you to assign a password. If you lose your password, neither you nor XION GmbH will be able to access your data. XION accepts no liability for lost data.

Activating [BitLocker](#)

Follow the instructions in the chapter titled "Activating standard BitLocker encryption" in the Microsoft guide: <https://support.microsoft.com/de-de/windows/aktivieren-der-geräteverschlüsselung-0c453637-bc88-5f74-5105-741561aae838>

Trouble shooting

If BitLocker cannot be activated, check whether the BIOS settings are correct as follows:

When the MATRIX DS is starting, press and hold the DEL key – this will give you access to the BIOS. You will need to enter the BIOS password, which you will receive from the XION Service [▶ 35].

Now switch to the "Security" tab and select "Secure Boot".

System Mode: User

Secure Boot: [Enabled]

Secure Boot Mode: [Standard]

Your settings must match those shown in the following screenshot.

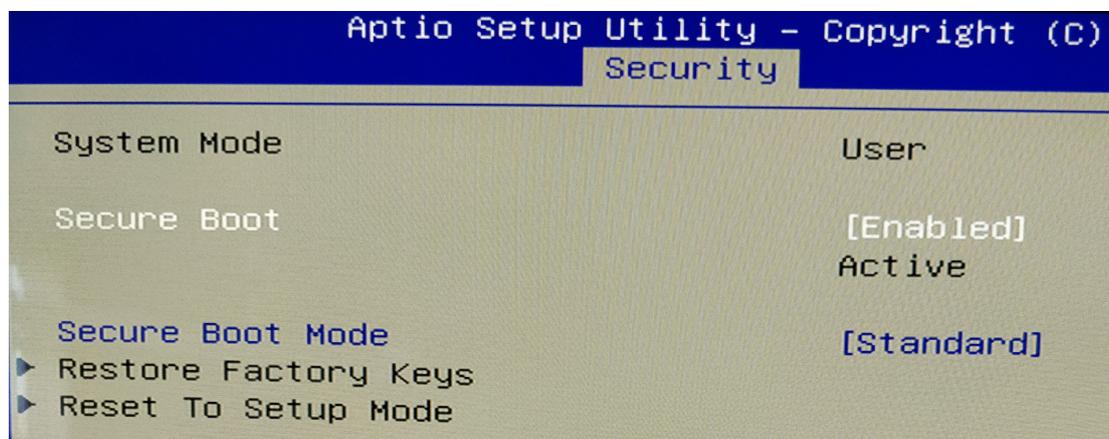


Illustration 17: "Secure Boot Control" Enabled, active

6.3.4 IT Network

You can connect your MATRIX DS Data Station to a hospital network (HIS/PACS or DiVAS server) to retrieve patient master data and export session data (photos, videos, doctor's letters). MATRIX DS data acquisition station

- Retrieve patient master data and
- Export session data (photos, videos, doctor's letters)

Technical specifications

- Network with at least 10 MBit/s download/upload speed
- Windows network connection with firewall
- Encryptions TLS/SSL



The network connection is optional for the MATRIX DS Data Station. MATRIX DS data acquisition station If the network connection fails, this only means that access to the network is lost. Your patient master data remains intact and unchanged. As soon as the network connection is re-established, it is again possible to exchange data.



The information flow between the MATRIX DS Data Station and the IT network, as well as the Windows configurations required to use DiVAS, can be found in the DiVAS 2.8 User Manual. MATRIX DS data acquisition station



Integrating the MATRIX DS into an IT network that includes other devices can lead to risks that were hitherto unknown. The responsible organisation should identify, analyse, assess and manage these risks. The following alterations to the IT network can lead to new risks and therefore require additional analyses:

- Alterations to the IT network configuration;
- Connecting additional elements to the IT network or removing elements from the IT network;
- Updates and upgrades to devices that are connected to the IT network;



CAUTION!

In network connections, ALWAYS use a network isolator (see Accessories [▶ 16]).

6.4 Shutting down



The device is equipped with a standby function. An all-pole power-disconnect is only accomplished by separating the mains leads from the device or the mains power supply.

In order to safely stop operation of the MU device, proceed as follows:

1. Switch off the Data Acquisition Station by briefly pressing the Power button. Windows is shut down and the device is switched to STANDBY mode.

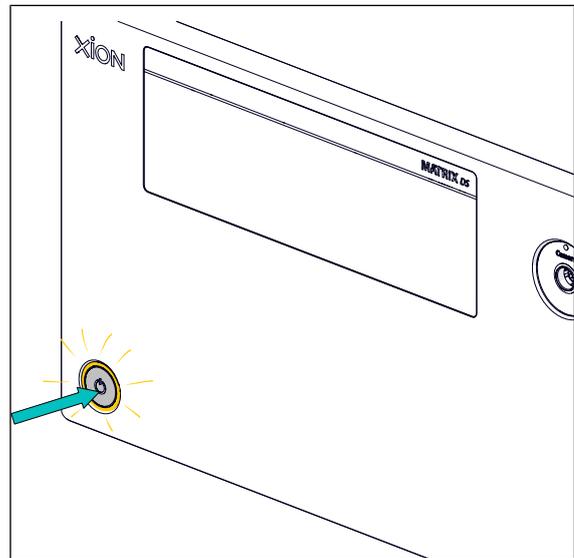


Illustration 18: Switching Off the MATRIX DS

2. Disconnect the plug from the wall outlet or the power cable from the power connector on the back of the device (all-pole power disconnection).

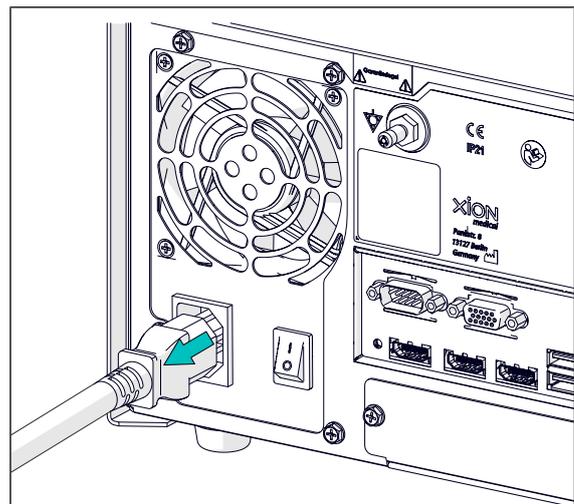


Illustration 19: Disconnect the IEC plug from the MATRIX DS

6.4.1 Switching off the MATRIX DS

The MATRIX DS Data Station can be switched off at any time. Any DiVAS software that may still be open will automatically save the application data and is then closed.



Switching off

To switch off the Data Station, briefly press the power button or shut down Windows. In both cases, the MATRIX DS is then in standby mode.

Please note carefully: As soon as this computer is integrated into a domain environment, its behaviour may differ depending on the active group policies.



To switch off the MATRIX DS, press the Power button just briefly!

If you press the Power button longer than 4 seconds, the device immediately switches off completely! In this case, any software that may still be open at this time is then not properly closed down, which causes the system to malfunction.

7 Application



The XION DiVAS software is installed on your MATRIX DS Data Station. With the help of DiVAS, you can control the application parts, configure the interfaces and record images and sound.

For information on the functions and using the software, please refer to the User Manual for DiVAS, the Veezar Otoscope and the other devices connected to the MATRIX DS.



WARNING!

Wrong orientation during patient contact

To prevent injury to the patient, each time before using the device, check whether you are being shown a live image or a saved image.

7.1 Veezar Application Part

The Veezar Video Otoscope VO10 is connected to the MATRIX DS data acquisition station by means of the Veezar Connector.

The Veezar Connector of the Veezar Video Otoscope VO10 is coded with a **blue** ring.

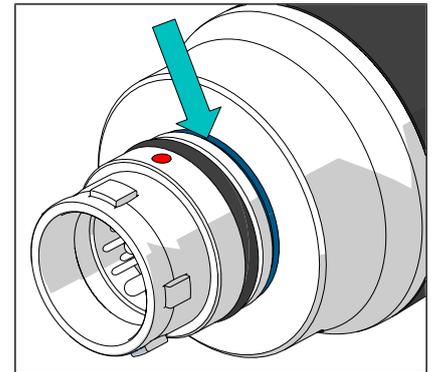
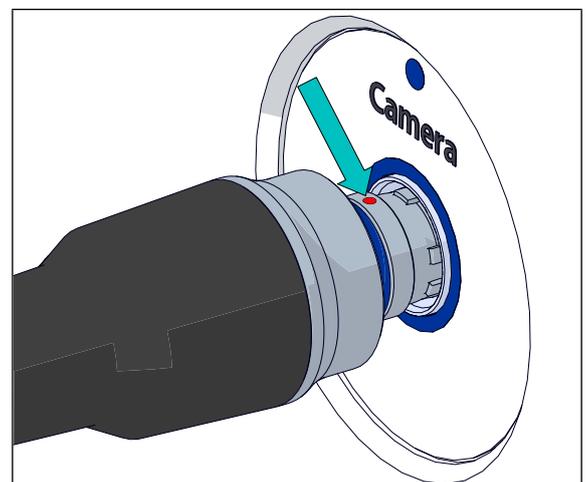
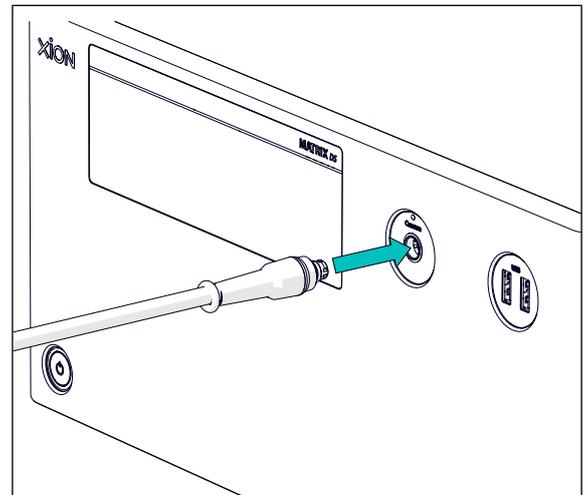


Illustration 20: Plug coding on the Veezar Video Otoscope VO10

Plug the Veezar Connector into the appropriate connector socket on the front panel of the MATRIX DS data acquisition station (observe colour coding).

When connecting the plug connector, make sure that the dot markings on the connector plug and the connector socket are aligned to each other as shown below.



All Veezar application parts are colour-coded on the Veezar connectors (**red**, **green** or **blue**). Because the devices (e.g. MATRIX DS, EndoCOMPACT Veezar) also have colour-coded sockets, this makes it easier to allocate them.

8 Cleaning and Disinfecting

The device can be wiped. [Incidin™ OxyWipe S](#) from Ecolab (hydrogen peroxide) or [mikrozid® universal wipes premium](#) from Schülke (alcoholic) can be used for cleaning and disinfection.

For wipe disinfection, remove the wipes individually and make sure that the surfaces to be treated are wetted completely. The manufacturer's instructions for use shall be followed closely.



CAUTION!
Inadvertent operation

To avoid accidentally triggering functions (light) on the front panel when cleaning the appliances (wiping), before cleaning and disinfecting, set the appliance to Standby mode.



CAUTION!
Liquid inside the device

Liquid inside the device can lead to loss of basic safety ([IEC 60601-1](#)) – users, patients and third parties are at risk. Make sure that no liquid penetrates the device!

9 Maintenance and Service

9.1 Re-examinations / safety checks

**WARNING!****Risk of injury due to wear and tear/product ageing**

Patients, users and third parties may be injured because safety may no longer be guaranteed due to wear and tear and/or product ageing.

You are required to perform and record repetitive tests / safety checks on your device or application part in accordance with **IEC 62353**. The tests shall be carried out **annually** by a **trained electrician**.

The measurements shall be carried out in accordance with IEC 62353. Take the limit values from the current standard.

In addition, observe the inspection intervals and accident prevention regulations of the country in which the device or application part is operated.

9.2 Manufacturer's Service

XION medical devices shall be repaired only by authorized personnel (commissioned by Messrs. XION GmbH). Use only original spare parts.

If repairs are required, inform your competent dealer or contact XION GmbH directly.

9.2.1 Address for repairs and return shipments:

XION GmbH

Pankstrasse 8
13127 Berlin
Germany

Fon: +49 (0)30 / 47 49 87 - 22
Fax: +49 (0)30 / 47 49 87 - 11
E-Mail: repair@xion-medical.com
www.xion-medical.com/de/service/reparatur

9.2.2 Article numbers and serial numbers

When a return shipment is required, it is essential to specify the Article number [REF] and the Serial number [SN]!

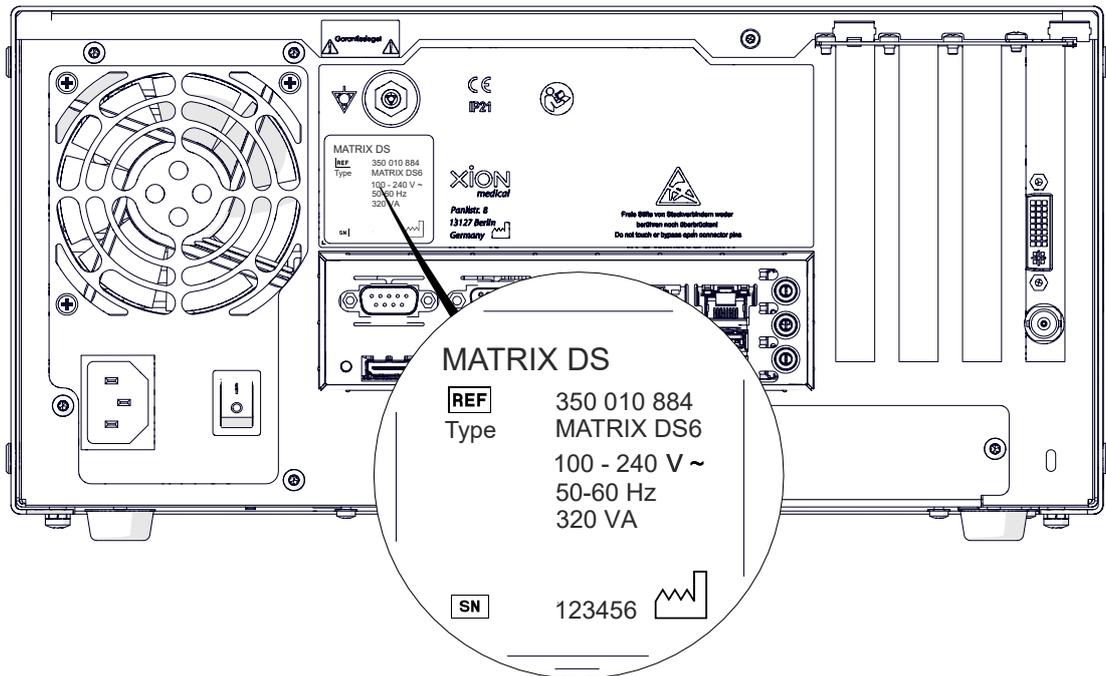


Illustration 21: Position of the Article number and Serial number

9.3 Repair process

1. Service Document

Report the defective device to XION together with this completed Service Document.

2. RMA Number

XION will send an [RMA Number](#) to you; note this number on the adhesive label provided.

3. Packaging & shipping

Safely pack the cleaned device in the original packaging. Now attach the completed adhesive shipping note and the RMA number label to the package.

4. Sterilization (instruments and endoscopes only)

To protect our employees, instruments and endoscopes are only accepted in a decontaminated condition. The reprocessing procedure must be verified by means of a Decontamination Certificate. You can receive this certificate directly with the Return Service Card or at www.xion-medical.com. A completed Declaration of Decontamination is a prerequisite for our acceptance and further processing of the returned goods. If the returned goods are not accompanied by a corresponding declaration, we will perform decontamination at your expense, or we reserve the right to refuse acceptance.



The manufacturer may reject repairing a contaminated product.

5. Cost estimate

The device will be professionally inspected and you will receive from XION a cost estimate for your approval of the repair.

6. Approval

If approved, please send the signed cost estimate back to XION by e-mail or fax.

7. Repair

Following your approval, repair work will begin immediately.

8. Shipment

Your repaired device will be sent back to you.

9.4 Responsibility

The manufacturer guarantees that the device and accessories have been carefully checked before leaving the factory. The manufacturer will only be responsible for the technical safety features within the framework of legal provisions when all work on the product is performed by service personnel authorized by the manufacturer, and the device and accessories are only used according to the intended use of the device. Authorized service personnel may only be trained and certified by the manufacturer.

9.5 Warranty

For a period of one year from the date of delivery to the final customer, we shall without cost replace verifiably faulty material or improper workmanship. This does not include shipping costs or shipment risks.

9.6 Disclaimer

As soon as you yourself or any other non-authorized person/s open the device and/or perform repairs or modifications, XION GmbH is released from any and all liability for the operational safety of the device. At the same time, all and any warranty claims become void.

9.7 Disposal



Defective or decommissioned products shall be disposed of as electronic waste in accordance with the EU Directive Waste of Electrical and Electronic Equipment – WEEE Directive 2012/19/EU.

Ask your local specialist dealer for the responsible collection point or return your device to XION GmbH.

9.8 Service Address

XION GmbH
Pankstrasse 8
13127 Berlin
Germany

Fon: +49 (0)30 / 47 49 87 – 32
Fax: +49 (0)30 / 47 49 87 – 11
Email: service@xion-medical.com
www.xion-medical.com/en/service

10 Trouble shooting

Faults	Possible cause	Remedy
LED control display for POWER does not light up after switching on	No mains supply	Check mains supply on site, plug power cables properly.
Application part is not being recognised	Plug contacts are contaminated	Check the contacts for dirt
	Unknown	Please unplug the application part and then plug it in again.
Image transmissions are interrupted	Plug contacts are contaminated	Check the contacts for dirt
	Damaged cable (interruptions occur when moving/bending the cable)	Please send the device in for repair work [▶ 34] .
No image	Data Acquisition Station not switched on, monitor not connected / not switched on	Check that the device is connected to the mains outlet and that all switches are in the ON setting (green light on mains switch of the control unit). Check the cable connections.
	The on/off switch on the power supply unit (rear side) is set to "0" (off).	Set the on/off switch on the power supply unit (rear side) to "1" (On).
	Wrong connector selected for the monitor	Check the input source selected for the monitor. Check that the connector cables to the monitor are properly connected.
	Device malfunction	Switch off the device, wait 10 seconds, and then switch it back on.
	<u>Monitor switching</u> is missing or has not been set up.	Check the settings for monitor switching. Or, if possible, set up a monitor switching feature.
No response to inputs, abnormal behaviour, functional faults	Device malfunction	Switch off the Data Acquisition Station and disconnect the mains plug. Then press the Power button for at least 10 seconds. Next, put the data station back into operation.
Before booting up, WINDOWS prompts the user for the user name and password	Unknown	Please contact the XION Service department.

11 Declarations concerning EMC

Guidelines and Manufacturer Declaration

Electric medical devices are subject to particular precautionary measures with regard to electromagnetic compatibility (EMC) and must be installed and commissioned according to EMC guidelines.

The device is intended for use in the following specified electromagnetic environments. The customer or user should ensure that it is only used in these environments.

Electromagnetic environment

The device uses HF energy exclusively for its internal function. For this reason, its HF emissions are very low and it is improbable that neighbouring electronic devices are affected.

Lines tested according to IEC 60601-1-2

Article	Article number
DELL Soundbar AC511M	350 009 108
USB recording display (USB flashes)	350 010 047
Medically suitable keyboard with touchpad, German, USB, disinfectable	350 009 066
Mains cable, length 2.0 m, EURO standard	320 009 007
Audio connector cable, 3.5 mm jack, length 1.2 m	320 009 045
12G-SDI cable, 2 m, mini HD BNC plug/BNC plug	320 009 073
Cable null modem 9-pin socket/socket, 2 m	320 009 054
USB-2.0 cable 1 m, A->B (plug/plug)	350 009 056
Cable HDMI plug to DVI-D plug, 2 m	320 009 070
Network cable 2 m (patch cable), Cat. 6 or better	350 009 032
Potential equalization cable, length 2 m	340 009 003
Connector cable with 3.5 mm stereo jack plug	310 009 026

Table 4: Tested cables

12 Manufacturer and Distributor

XION GmbH

Pankstrasse 8
13127 Berlin
Germany

Fon:	+49 (0)30 / 47 49 87 - 0
Fax:	+49 (0)30 / 47 49 87 - 11
Email:	info@xion-medical.com
	www.xion-medical.com/en

List of Figures

Illustration 1	Instructions for setting up the MATRIX DS	9
Illustration 2	Front of the MATRIX DS, Data Acquisition Station	11
Illustration 3	Connector ports and functional elements on the rear panel of the MATRIX DS Basis	12
Illustration 4	Interfaces of the grabber card (YUAN)	12
Illustration 5	Connector ports and functional elements on the rear panel of the MATRIX DS (PREMIUM Light)	13
Illustration 6	Interfaces of the Grabber card (Clarity)	13
Illustration 7	MATRIX DS sample configuration	17
Illustration 8	MATRIX DS in combination with a MATRIX Spectar (Basis) and a monitor (SONY)	20
Illustration 9	MATRIX DS in combination with a MATRIX Spectar (Basis) and many monitors (SONY)	21
Illustration 10	MATRIX DS in combination with a MATRIX Spectar (Premium Light) and a monitor (SONY)	22
Illustration 11	MATRIX DS in combination with a MATRIX Spectar (Premium Light) and many monitors (SONY)	23
Illustration 12	Potential equalizing connector	24
Illustration 13	Disconnecting the USB Flash from the USB cable	25
Illustration 14	USB Flash in USB socket on the front panel of the Matrix DS	25
Illustration 15	USB Flash with USB plug	26
Illustration 16	Switching on the MATRIX DS	27
Illustration 17	"Secure Boot Control" Enabled, active	28
Illustration 18	Switching Off the MATRIX DS	30
Illustration 19	Disconnect the IEC plug from the MATRIX DS	30
Illustration 20	Plug coding on the Veezar Video Oscope VO10	31
Illustration 21	Position of the Article number and Serial number	34

List of Tables

Table 1	Scope of delivery XION Data Stations.....	14
Table 2	Technical data MATRIX DS Data Stations.....	15
Table 3	Accessories XION Data Stations.....	16
Table 4	Tested cables.....	37

Glossary

Application part

XION application parts are all current-carrying devices that have patient contact (e.g. video nasopharyngoscopes, video-otoscopes) or establish patient contact (e.g. camera heads)

BitLocker

BitLocker encryption is Windows data encryption on devices operating with Windows 10 or higher.

DiVAS

"Digital Video Archive software" Software, with which XION hardware devices can be controlled

Electrical Safety Protocol

Indication of the measured discharge currents of the device.

EMC

Electromagnetic compatibility (EMC) refers to the ability of a technical device not to interfere with other devices by unwanted electrical or electromagnetic effects or to be interfered with by other devices.

Environment in professional healthcare facilities

Physiology practices, dental practices, clinics, first aid facilities, independent surgical centres, independent birthing centres, polyclinics, hospitals (emergency rooms, sickbays, intensive care, operating theatres except near RF SURGERY DEVICES, outside the RF-shielded room of an ME system for magnetic resonance imaging). Source 60601-1-2

ESD

Electrostatic discharge (ESD) are voltage discharges caused by large potential differences. These discharges (possibly visible as sparks) cause a short, high electrical current and can lead to the ignition of flammable substances.

Frame grabber

The frame grabber is a device or component that captures video images from a camera (application part) or a video signal and converts them into digital data.

IEC 60601-1

International standard for the basic safety and essential performance characteristics of medical electrical equipment and medical electrical systems.

IEC 60601-1-2

Medical electrical equipment - Part 1-2: General requirements for safety including essential performance characteristics - Supplementary standard: Electromagnetic compatibility - Requirements and tests. Test standard of the electrical XION devices.

IEC 62353

Medical electrical devices - Recurrent testing and post-repair testing of medical electrical devices (IEC 62353); German version EN 62353

Incidin™ OxyWipe S (Ecolab)

Sporicides (c. Diff.) Ready-to-use cleaning and disinfecting wipe -> Wipe disinfection

mikrozid® universal wipes premium (Schülke)

Low-alcohol wipes for disinfecting medical devices and surfaces of all kinds -> Wipe disinfection

Monitor switching (automatic)

The main monitor of the Data Station is connected redundantly in accordance with the cabling plan supplied. In the unlikely event that the Data Station fails, this ensures that the image from the camera continues to be displayed.

RMA number

Return number. The RMA number (Return Merchandise Authorization or also Return Material Authorization) is an identification number assigned by the supplier for the return of goods.

Serious incident

"Serious incident" means an incident that has had, could have had or may have had, directly or indirectly, any of the following consequences: (a) the death of a patient, user or other person; (b) the temporary or permanent serious deterioration of the health status of a patient, user or other person; (c) a serious risk to public health. Art.2 No. 65 Regulation (EU) 2017/745 (MDR)

Spectar Camera Processor

Spectar series devices are camera processors for connecting different XION application parts (camera heads and video endoscopes and video-endoscopes).

Veezar Video Oscope V010

Veezar series otoscope, for connecting to the MATRIX DS Data Acquisition Station and the EndoCOMPACT Veezar Console.