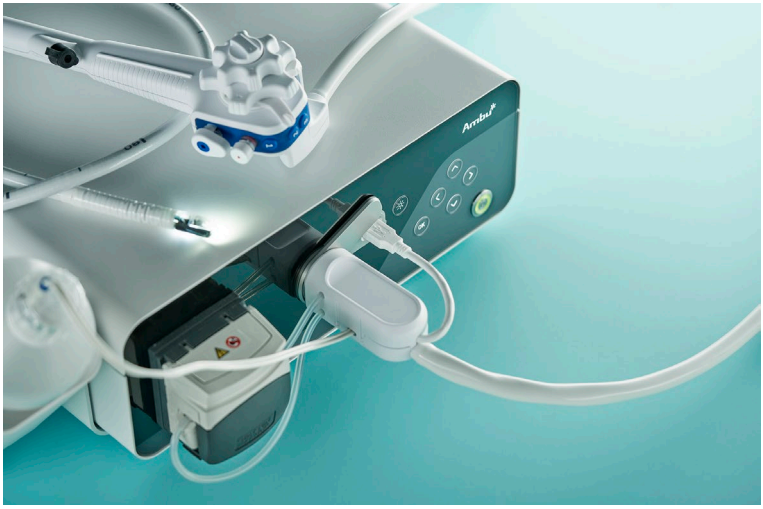
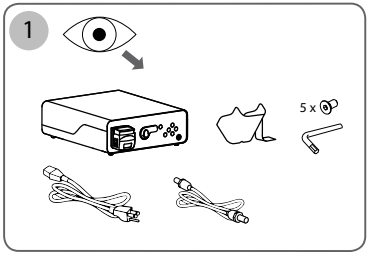
Instruction For Use
Ambu® aBox™ Duodeno

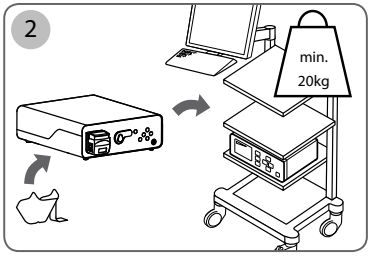


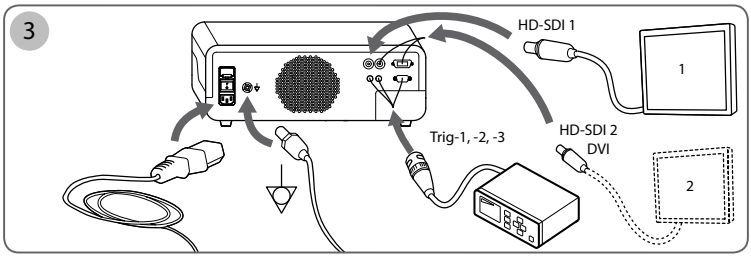
For use by trained clinicians/physicians only.

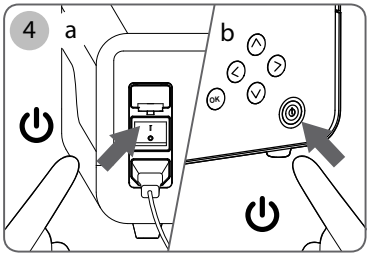
For in-hospital use.

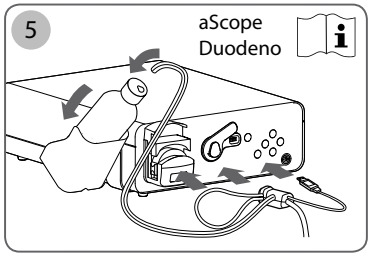
For use with Ambu® aScope™ Duodeno.

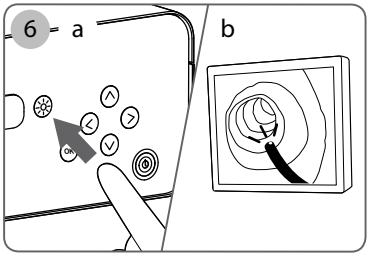


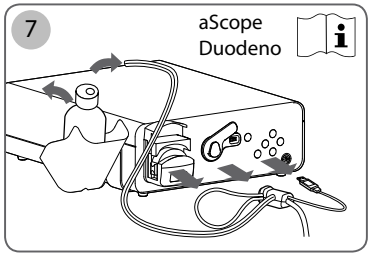


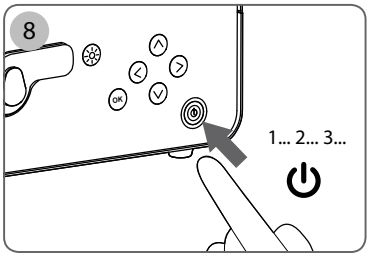


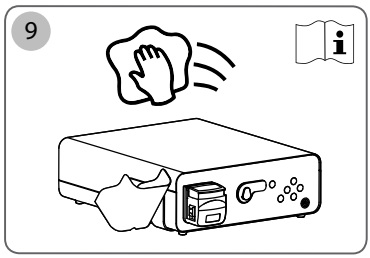












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1. Important Information – Please Read Before Use!

Read this Instructions For Use (IFU) before operating and keep for future reference. Failure to read and thoroughly understand the information presented in this IFU, as well as those developed for ancillary endoscopic equipment and accessories, may result in serious injury to the patient and/or user. Furthermore, failure to follow the instructions in this IFU may result in damage to, and/or malfunction of, the equipment.

This IFU describes the recommended procedures for inspecting and preparing the equipment prior to its use. It does not describe how an actual procedure is to be performed, nor does it attempt to teach the beginner the proper technique or any medical aspects regarding the use of the equipment. It is the responsibility of each medical facility to ensure that only appropriately trained personnel, who are competent and knowledgeable about the endoscopic equipment, antimicrobial agents/processes and hospital infection control protocol are involved in the use, handling and the care of these medical devices. The IFU may be updated without further notice. Copies of the current version are available upon request.

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 or IEC 62368 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical grade electrical systems (see clause 16 of the latest valid version of IEC 60601-1). Anybody connecting additional equipment to medical grade electrical equipment which configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. If in doubt, consult your local representative or the technical service department. US federal law restricts this device for sale only by, or on the order of, a physician.

1.1. Intended Use / Indication For Use

The aBox™ Duodeno is designed to be used with the aScope™ Duodeno, endoscopic accessories (e.g. biopsy forceps) and other ancillary equipment (e.g. medical grade video monitor) for endoscopy and endoscopic surgery within the duodenum.

Note: Do not use this device for any purpose other than its intended use. Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this IFU.

1.2. Target User Groups And User Qualifications

The operators of the system are physicians trained in diagnostic and therapeutic GI Endoscopy. If there are official standards for user qualifications to perform endoscopy and endoscopic treatment that are defined by the hospital´s medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (e.g. department of internal medicine, etc.).

The physician should be capable of safely performing the planned endoscopy and endoscopic treatment following guidelines set by the academic societies on endoscopy, etc., and considering the difficulty of endoscopy and endoscopic treatment. This manual does not explain or discuss endoscopic procedures.

1.3. Contraindications

Contraindications depend on the device used and the endoscopic procedure. For detailed information regarding contraindications please refer to the IFU of the aBox™ Duodeno.

1.4. Installation And Maintenance

The medical devices described in this IFU must be tested/inspected in accordance with national regulations during installation and regular inspection. The medical device does not require regular maintenance.

1.5. Warnings And Cautions

Failure to observe these warnings and cautions may result in patient injury or damage to the equipment. The manufacturer is not responsible for any damage to the system or patient injury resulting from incorrect use.

Warnings
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

Preparation for Use

- Do not connect non-medical grade devices to the aBox™ Duodeno. Connection of devices that are not medical grade (IEC 60601 conform) could have negative impact on the safety of the system. Connect only medical grade equipment to the aBox™ Duodeno.
- Never use the aBox™ Duodeno if an abnormality is suspected. Damage or irregularity in the device may compromise patient and/or user safety and may result in more severe equipment damage.
- Keep fluids away from all electrical equipment. If fluids are spilled on or into the unit, stop operation of the aBox™ Duodeno immediately and contact Ambu. Do not prepare, inspect or use the aBox™ Duodeno with wet hands.
- In case of instrument failure or malfunction, always keep another aBox™ Duodeno in the room ready for use.
- Never insert or spray anything into the ventilation grills of the aBox™ Duodeno. It can cause an electric shock and/or fire.
- Always set the minimum required brightness. The brightness of the image on a medical grade video monitor may differ from the actual brightness at the distal end of an endoscope. Although the illumination light emitted from the endoscope's distal end is required for endoscopic observation and treatment, it may also cause alteration of living tissues such as protein denaturation of liver tissue and perforation of the intestines by inappropriate use.
- Do not leave the endoscope illuminated before and after examination otherwise the LEDs could be redirected to the opened eyes of the sedated patient and can cause retina burns. This product may interfere with other medical grade electronic equipment used in combination with it.
- Before use, refer to the Appendix 1 to confirm the compatibility of this instrument with all equipment to be used.
- Do not use this product in any place where it may be subject to strong electromagnetic radiation (for example, in the vicinity of a microwave therapeutic device, MRI, wireless set, short-wave therapeutic device, cellular/portable phone, etc.). This may impair the performance of the product.
- If the endoscopic image dims during use, blood, mucus or debris may adhere to the light guide on the distal end of the endoscope. Try to clear the LEDs by rinsing. If image is still dimmed, carefully withdraw the endoscope from the patient and remove the blood or mucus in order to obtain optimum illumination and to ensure the safety of the examination. If you continue to use the endoscope in such a condition, the distal end temperature may rise and cause mucosal burns. It may also cause patient and/or operator injury.
- To display observation images, connect the output terminal of the aBox™ Duodeno directly to the monitor. Do not make the connection via any ancillary equipment. Images may disappear during observation depending on the condition of ancillary equipment.

Inspection of the aBox™ Duodeno

- Do not connect the power plug to the 2-pole power circuit with a 3-pole to 2-pole adapter. To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not use the aBox™ Duodeno if not inspected as instructed. Inspect other equipment to be used with the aBox™ Duodeno as instructed in their respective instruction manuals. Should any irregularity be observed, do not use the aBox ™ Duodeno and see section 12, troubleshooting. If the irregularity is still observed after consulting section 12, contact Ambu. Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.
- Do not use this device when the live image cannot be observed. Otherwise, patient injury may occur.

Connection to the AC Mains Power Supply

- Always keep the power plug dry. A wet power plug may cause electric shocks.
- Confirm that the hospital-grade wall mains outlet to which this device is connected has adequate electrical capacity that is larger than the total power consumption of all connected equipment. If the capacity is insufficient, fire can result or circuit breaker may trip and turn OFF this device and all other equipment connected to the same power circuit.
- Be sure to connect the power plug securely to prevent erroneous unplugging during use. Otherwise, the equipment will not function.
- If combinations of equipment other than those shown below are used, the full responsibility should be assumed by the medical treatment facility. Such combinations do not only allow the equipment to manifest their full functionality but may also imperil the safety of the patient and medical personnel. In addition, the endurance of the video system center and ancillary equipment is not guaranteed. Troubles caused in this case are not covered by free-of-charge repair. Be sure to use the equipment in one of the recommended combinations.

Operation of the aBox™ Duodeno

- To guard against dangerous chemicals and potentially infectious material during the procedure and danger of unintentional diathermy burns, wear personal protective equipment such as eyewear, face mask, moisture-resistant clothing, and chemical and electrical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Please note that a new pair of gloves is required prior to each procedure.
- Never use the aBox™ Duodeno if an abnormality is suspected. Damage or irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.
- If any other abnormality occurs or is suspected, immediately stop using the equipment, turn OFF all equipment, and gently withdraw the endoscope from the patient as described in the endoscope's instruction manual. Then refer to the instructions in section 12, troubleshooting. If the problems cannot be resolved by the remedial action described in section 12, do not use the equipment and contact Ambu.
- Clean the device and change gloves prior to touch the device and between cases. No changes of gloves could lead to a cross-contamination.

Ancillary Equipment

- When using spray-type medical agents such as lubricant, anesthetic, or alcohol, use them away from the aBox™ Duodeno so that the medical agents do not come into contact with the aBox™ Duodeno. Medical agents might leak into the video system through the ventilation grills and may cause equipment damage.
- Do not use non-compatible electrosurgical equipment with this device. Interference on the monitor can occur or the loss of the endoscopic image.
- Do not use a humidifier near the video system center as dew condensation possibly might occur and it may cause equipment failure.
- When recording the images, be sure to record the images together with the patient data. Otherwise distinction between different observations may become difficult.

Fuse Replacement

- Never use a fuse other than the fuse model designated by Ambu. Otherwise, malfunction or failure of the aBox Duodeno may cause a fire or electric shock hazard.
- Be sure to turn the aBox™ Duodeno OFF and unplug the power cord before removing the fuse from the aBox™ Duodeno. Otherwise, fire or electric shock may result.
- If the power fails to come on after replacing the fuses, unplug the power cord immediately from the AC mains power inlet and then contact Ambu. Otherwise, electric shock may result.
- Do not position the device above the patient. If the front is destroyed due to strong external impacts, splintering may occur. Falling splinters could cause injury to the patient.
- Insert the fuse box into this device until it clicks into position. If the fuse box is inserted incompletely, the power may fail to come ON or a power failure may occur during operation.

Care and Storage

- After wiping with a piece of moistened gauze, dry the aBox™ Duodeno thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.
- Do not use the device without thoroughly understanding the IFU. If the system is not properly prepared before each use, equipment damage, patient and operator injury and/or fire can occur.

Potential of Fire

- The system is not protected against fire and explosion. When using the device in areas with flammable or explosive gases or in areas with oxygen-enriched air, fire or explosions may occur in the unit. Do not operate the device in areas with flammable or explosive gases or gas mixtures. Do not operate the device in an oxygen-enriched environment.

Installation, Repair and Maintenance

- The device contains no parts that can be repaired by the user. Any disassembling, change or attempt to repair can lead to injury of patient or user and damage of the system. Installation, repairs and maintenance must be performed by Ambu staff or Ambu approved staff. Please read section 12. for more information regarding troubleshooting.

Cautions

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.

General

- Do not use a pointed or hard object to press the buttons on the front panel. This may damage the buttons.
- Do not apply excessive force to the aBox™ Duodeno and/or other instruments connected. Otherwise, damage and/or malfunction can occur.
- Clean and vacuum dust the ventilation grills of the aBox™ Duodeno using a vacuum cleaner, when necessary. Keep the ventilation grill clear. Otherwise, the aBox™ Duodeno may break down and get damaged from overheating.
- Be sure that this device is not used adjacent to or stacked with other equipment (other than the components of this system) to avoid electromagnetic interference.
- Electromagnetic interference may occur to this device when it is placed near equipment marked with the following symbol (((ı))) or other portable and mobile RF communications equipment such as cellular phones. If radio interference occurs, mitigation measures may be necessary, such as reorienting or relocating this device or shielding the location.
- Do not place any object on the top of the aBox™ Duodeno. Otherwise, equipment deformation and damage can result.
- Place the aBox™ Duodeno on a stable, level surface. Otherwise, the aBox™ Duodeno may topple down or drop, and user or patient injury may occur, or equipment damage can result.
- If a trolley other than the mobile workstation is used, confirm that the trolley can withstand the weight of the equipment installed on it.
- US federal law restricts this device for sale only by, or on the order of, a physician.

Care and Storage

- Do not clean the power cable socket, the connections and the AC mains power inlet. Cleaning them can deform or corrode the contacts, which could damage the aBox™ Duodeno.
- Do not store the device in a location exposed to direct sunlight, X-rays, radio activity or strong electromagnetic radiation (e.g. near microwave medical treatment equipment, short-wave medical treatment equipment, MRI equipment, radio or mobile phones). Damage to the aBox™ Duodeno can occur.

- When disposing of this device or any of its components (such as fuses), follow all applicable national and local laws and guidelines.
- Turn OFF all ancillary equipment before connecting them to the aBox™ Duodeno and use appropriate cables only. Otherwise, equipment damage or malfunction can result.
- Close the connector cover before you clean the aBox™ Duodeno. Do not open the cover while cleaning the aBox™ Duodeno, otherwise fluid can penetrate the connector and damage the device.
- Do not autoclave or sterilize the aBox™ Duodeno. This could lead to a damage of the device.
- The cables should not be sharply bent, pulled, twisted or crushed. Cable damage can result.
- Never apply excessive force to connectors. This could damage the connectors.
- Use this instrument only under the conditions described in "Transportation, storage, and operation environment" and "Specifications" in the Appendix. Otherwise, improper performance, compromised safety and/or equipment damage may result.

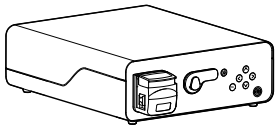
Accessories

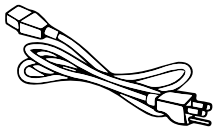
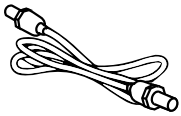
- Do not attach anything other than the bottle holder to the aBox™ Duodeno. Otherwise equipment damage or deformation my result.
- Only place a bottle of sterile water into the bottle holder, otherwise the bottle holder can be damaged.
- When the device is used with energized endoscopic devices, leakage current may be additive. Use only endoscopic devices of type BF or CF. Check the compatibility of the accessory/endoscopic device before use to any criteria for safe use.

2. System Description

2.1. System Parts

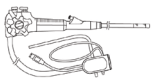
The aBox™ Duodeno is reusable. No modification of this equipment is allowed. The aBox™ Duodeno is shipped with one power cable that supplies the power necessary to run the aBox™ Duodeno, a bottle holder for the sterile water bottle and a potential equalization cable (POAG).

Ambu® aBox™ Duodeno Reusable Device

Bottle Holder


Power Cable

POAG Cable


The aBox™ Duodeno is not available in all countries. Please contact your local sales office.

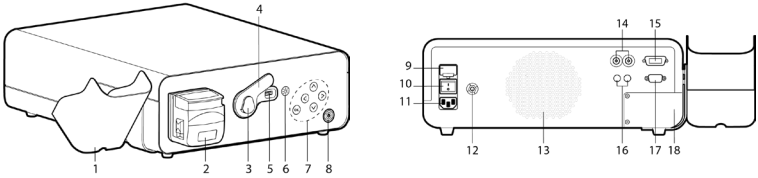
2.2. Compatible Device (Application Part)

Ambu® aScope™ Duodeno Sterile and single-use device	Part number	Distal End Outer Diameter ø	Working Channel Inner Diameter ø
	482001000.	41.2 Fr (13.7 mm).	12.6 Fr (4.2 mm).

The aScope™ Duodeno is not available in all countries. For detailed information please contact your local sales office.

2.3. aBox™ Duodeno Description And Function

The aBox™ Duodeno is the console that is necessary for processing the endoscope camera´s video image, the remote switches and output video and recorder data. The aBox™ Duodeno is designed to be used with the aScope™ Duodeno.



No.	Part	Function
1	Bottle Holder (sterile water)	Retainer for sterile water.
2	Rinsing Pump (peristaltic pump)	Lens washing.
3	Connector snap	Bracket for endoscope connector.
4	Endoscope connector cover	Protection cover.
5	Endoscope connector socket	Electrical connection between aScope™ Duodeno and aBox™ Duodeno.
6	Light source button	Press the button for power ON and OFF the LEDs.
7	Control panel	Buttons for navigation through the settings and information menu of the aBox™ Duodeno.

No.	Part	Function
8	Power button with power indicator	Press button for power ON before procedure and power OFF after procedure. The button will light up green when turned ON.
9	Main fuse	Device protection.
10	Main switch	Switch button for power ON and power OFF.
11	AC power inlet	AC power cord socket.
12	POAG socket	Socket for potential equalization.
13	System ventilation	Ventilation.
14	HD-SDI connections	Video output.
15	DVI connection	Video output.
16	Stereo jack 3.5 mm	Trigger output for video and image capture.
17	D-SUB 9P	Trigger output for video and image capture.
18	Service panel	Access for service technicians.

3. Explanation Of Symbols Used

3.1. Symbols

Symbols	Indication	Symbols	Indication
	Consult *Instruction for Use.*		NRTL Symbol.
	Protect the packaged product from moisture.	MD	Medical Device.
	Waste Bin symbol, indicating that waste must be collected according to local regulation and collection schemes for disposal of electronic and electrical waste (WEEE).		Protection against electric shock - Type BF, safetly class IEC60601-1.
		Rx Only	Prescription Device.
IP 21	Ingress protection.		Don´t touch moving parts.
SN	Serial Number (consisting of number and year of manufacturing).	REF	Reference Number.
	Ground connection.		Potential equalization.

4. Ancillary Equipment And Accessories

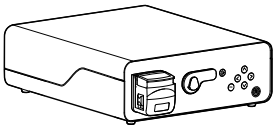
- The following ancillary equipment must be connected for the system to become functional and for recording patient data. Inspect the following equipment as described in their respective instruction manuals.
- Bottle holder (part of the system).
- Sterile water for rinsing equal to or greater than 1000ml in volume.

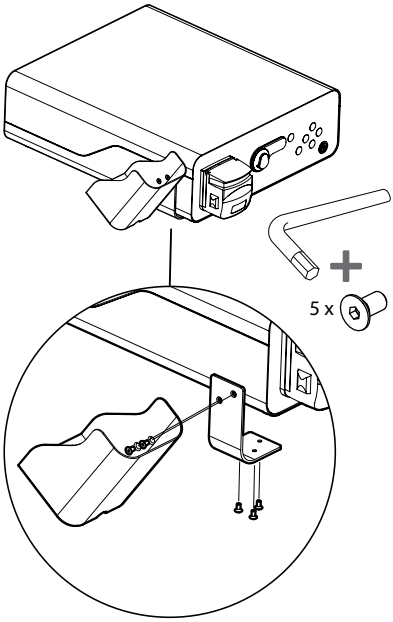
It is recommended that the bottle of sterile water be placed in the designed bottle holder on the left side of the aBox™ Duodeno. For detailed information regarding attaching the bottle holder to the aBox™ Duodeno please refer to the section 4.1 below.

- Medical Grade monitor with resolution at least 1920x1080 and a monitor size of at least 27" with DVI or HD-SDI input(s). Recommended color space is sRGB.
- Image Capture Report and/or writing workstation.
- Vacuum source at least -7psi (-50kPa) with suction system.
- Insufflation source approved for use in G.I. endoscopic procedures.

4.1. Attaching The Bottle Holder To The aBox™ Duodeno

The aBox™ Duodeno ships with one bottle holder that must be attached to the left side of the device. Follow the illustrations below to properly attach the bottle holder.

Ambu® aBox™ Duodeno	Bottle Holder
	



5. Preparation And Inspection For Use

Numbers in gray circles below refer to illustrations on page 2. Inspect all ancillary equipment to be used with this instrument as instructed in their respective instruction for use manuals. Should any irregularity be observed after inspection, follow the instructions as described in section 12, Troubleshooting. If this instrument malfunctions, do not use it. Contact your Ambu sales representative for further assistance.

- Inspect the contents of the aBox™ Duodeno. Match all items in the package with the components shown in the device description in section 2. 1
- If the device is damaged, a component is missing or you have any questions, do not use the instrument, immediately contact Ambu.
- It is recommended that the aBox™ Duodeno to be placed on level surfaces with the capability of movement (i.e. mobile cart, medical equipment booms) such that the system can be moved to the most advantageous position for any given patient and/or as required to satisfactorily perform the intended patient procedure. All such carts or booms should be designed for this purpose and rated for the weight requirements necessary (refer to the technical data section 10, as well as possessing a locking mechanism to prevent inadvertent rolling or movement during a procedure. 2
- Attach the Bottle Holder to the aBox™ Duodeno as described in section 4.1. 2
- One (1) hospital grade power supply cable is provided with the aBox™ Duodeno and is necessary to supply power from the electrical mains to the aBox™ Duodeno (refer to the technical data section 10 for electrical ratings and other applicable information). The power supply cord is not integral part of the aBox™ Duodeno. Connect the power supply cable to the AC Main Connection and to a grounded power source socket. 3
- This medical device may be connected to a network of medical grade devices. Use the potential equalization conductor as determined necessary by your facilities Biomedical/ Clinical/Technical Engineering staff. The potential equalization conductor (is easily identifiable as the green cable with a yellow line running along its length) serves as a conductor for possible differences in ground potentials between network components which can result in a leakage current that can flow through to the patient and is potentially dangerous. The potential equalization conductor works to remove this hazard. 3
- Connect the aBox™ Duodeno to at least one medical grade monitor. It is recommended to use HD-SDI 1 for the main monitor and choose a medical grade monitor with a full HD resolution. Please refer to Appendix 1 for specific connections details. 3
- An additional medical grade monitor or a medical grade recorder can be connected to HD-SDI 2 or DVI. 3
- Use the "TRIG 1, TRIG 2 and / or TRIG 3" output for the remote triggering signal cable to the medical grade recorder whenever a recorder is connected. For detailed information regarding connections please refer to Appendix 1. 3

5.1. Powering Up And Starting The aBox™ Duodeno

Once all the above connections have been made the aBox™ Duodeno can be powered up.

- Switch the aBox™ Duodeno by using the main switch on the back of the unit and then by pressing the power button on the front (right) side of the unit. The power button will light up green when the aBox™ Duodeno is powered up. 4a
- The aBox™ Duodeno indicates when it is ready by displaying the information message on the main monitor screen: "please connect endoscope". Once the endoscope was connected the system will confirm by displaying the message "endoscope connected" on the main monitor screen.

5.2. Preparing And Connecting The Ambu® aScope™ Duodeno

Please refer to the IFU of the aScope™ Duodeno. 5

5.3. The Main Monitor Screen

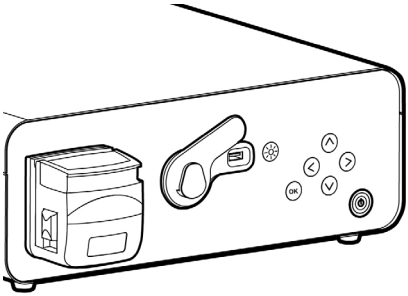
Following all of the steps, instructions and connections in section 4. and 5., the system will perform an internal system check and display the status on the main monitor screen.

You will now have to confirm that a new bottle of sterile water was prepared prior the procedure and connect the CO_2 and the vacuum source as indicated. Once the connections

have beed made, you can perform the functional check of the endoscope. To confirm please press the (OK) button on the control panel of the aBox™ Duodeno. After confirmation the aBox™ Duodeno will display the live image on the main monitor screen. Press the light source button for light. 6

5.4. Control Panel Navigation

The settings and information menu can be displayed by pressing any button on the control panel of the aBox™ Duodeno.



Explanation of control panel buttons		
Button	**Name**	**Function**
	Light source button	Turns the aScope™ Duodeno LEDs ON and OFF.
	Left button	Navigate to the left. The left button is used to hide informations and settings menu.
	Right button	Navigate to the right.
	Up button	Navigate upwards.
	Down button	Navigate downwards.
OK	OK button	Confirms messages and/or settings.

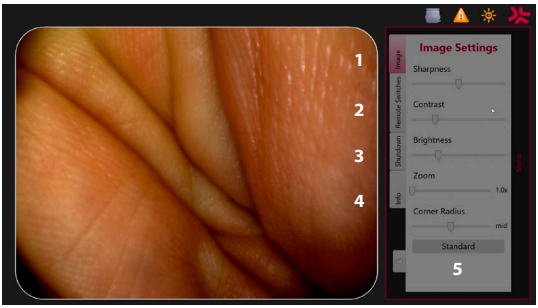


Image settings 1. Open the menu by pressing any button on the control panel, set-up and then go back with the **left button** . Press once to exit the setting and twice to close the menu.

Remote switches (2). Open the menu by pressing any button on the control panel and select remote switches. The available function for each remote switch will be displayed when entering the settings in a pull-down submenu. Set the desired function for each remote switch and save.

- To exit the information and settings menu use the left button (<). Press once to exit the setting and twice to close the menu.
- The remote switches standard configuration is: 1 for image capture, 2 and 3 has no preset function.

Shutdown (3). After the final procedure of the day select the Shutdown button on the settings and information menu. After selecting the shutdown button for ending the daily session, press the (OK) button on the control panel to confirm. The system will now begin the process of powering down. Shutdown is completed when the power button on the aBox™ Duodeno is no longer lit.

Info button (4). When setting up the aBox™ Duodeno you will be required to confirm that a new bottle of sterile water was prepared prior procedure. The info option will save every message which might pop-up during the procedure e.g. "Lid of the peristaltic pump is open". Press the (OK) button to confirm and the **left button** (<) to close the menu.

Standard button (5). Press the standard button from the settings menu to return to standard settings.

The system will display messages on the main screen monitor if an irregularity occurs. For detailed information please see section 10. Technical data (standard messages).

Explanation of the Symbols		
Symbol	**Name**	**Description**
	Persitaltic pump	Icon will be displayed when the lid of the peristaltic pump is open.
	Warning	Icon appears if a message is displayed and not confirmed.
	LEDs ON	The number in this symbol will indicate the level of increased or decreased brightness.
	LEDs OFF	The number in this symbol will indicate the level of increased or decreased brightness.
	Image capture	This icon will be displayed when a image has been captured.
	Video recording	This icon will be displayed when video recording begins.
	Zoom	This icon will be displayed when the zoom function is ON.
	Rinsing	This icon will be displayed when the rinsing function is activated.

6. Ending A Procedure And Shutting Down The System

6.1. Concluding A Patient Procedure

To conclude a patient procedure, remove the endoscope connector plug from the connector socket of the aBox™ Duodeno. For detailed information and disposal of the endoscope, please refer to the IFU of the aScope™ Duodeno. [7]

6.2. System Shutdown

After the final procedure of the day push the power button for 3 seconds. The system will now begin the process of powering down. Shutdown is completed when the power button on the aBox™ Duodeno is no longer lit.

Notice that incorrect shut-down of the aBox™ Duodeno may impair its functionality permanently and may require service. [8]

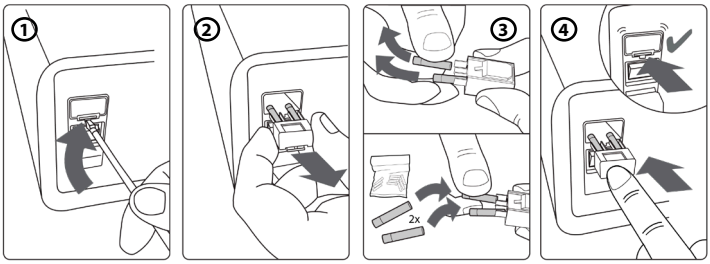
7. Fuse Replacement

Always use the fuses recommended by Ambu. To order new fuses please contact your sales representative. Make sure that only appropiately trained personnel are in charge of the fuse replacement.

Turn the aBox™ Duodeno OFF and disconnect the power cable from the walls mains outlet.

- Release the fuse by squeezing the lower tab of the fuse box using a screwdriver.
- Pull the fuse box straight out.
- Replace both fuses.
- Insert the fuse box into the aBox™ Duodeno until it clicks into position.

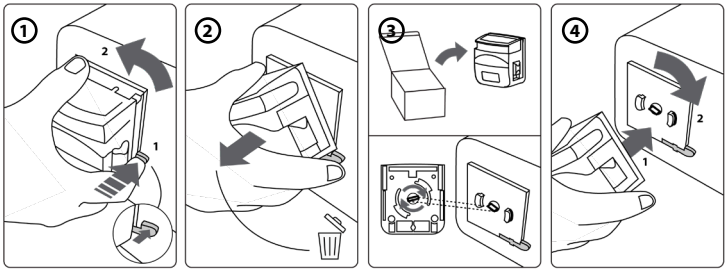
Connect the power cable to a grounded power source socket and turn the aBox™ Duodeno ON and confirm the power output.



8. Peristaltic Pump Replacement

Ensure the aBox™ Duodeno is powered off and that the peristaltic pump housing is completely closed.

- Release the entire peristaltic pump assembly by pressing the release tab on the lower-right side of the pump housing.
- Rotate the peristaltic pump to your the left and pull it towards you in one continuous motion.
- Align the key of the replacement peristaltic pump assembly with the corresponding notch on the aBox™ Duodeno then push and rotate the pump assembly to the right until it locks into position.
- When properly secured the roller pump should not rotate in any direction.



9. Cleaning Of The aBox™ Duodeno External Surfaces

The aBox™ Duodeno should be cleaned before and after each procedure. Clean the aBox™ Duodeno according to good medical practice using the procedures below: 9

Procedure -SUPER- SANI-CLOTH® from PDI or equivalent

Use a wipe to remove heavy soil. All blood and other body fluids must be thoroughly cleaned from all surfaces and objects before using germicidal wipe.

The treated surfaces must remain visibly wet for a full two (2) minutes. Use additional wipes if needed to assure continuous 2 minutes wet contact time. Let the aBox™ Duodeno air dry.

10. Technical Data

All the following reported measurements (e.g. weight, dimensions) are average values. Therefore, small variations may occur, which however have no effect on the performance and safety of the system.

10.1. aBox™ Duodeno Specifications

Power Supply	Voltage	AC 120 V / 230 V
	Frequency	50 / 60 Hz
	Consumption electric power	91 VA
	Fuse rating	2x 5 A H 250 V T
	Fuse size	5 mm x 20 mm
Size of the aBox™ Duodeno	Dimensions	494 (D) x 487 (W) x 145 (H) mm
	Weight	13 kg
Classification (medical electrical equipment)	Type of protection against electric shock	Protection Class I
	IP Classification	IP21

10.2. Storage And Operation Environment Specifications

Transportation temperature	-5 °C – 40 °C (23 °F – 104 °F)
Storage temperature	10 °C – 25 °C
Operation temperature	10 °C – 40 °C
Relative humidity transportation and operation	30 – 85 % relative
Relative humidity storage	10 – 43 % relative
Atmospheric pressure	80 – 109 kPa (100 kPa=1 Bar) 11.6 – 15.8 psi 600 – 818 mmHg

10.3. Accessories

General Information.	Connected equipment, especially electrical equipment, must conform to relevant medical standards (medical grade) as described in section 4.

10.4. List Of Accessories-Examination

Accessory	Information	Part of the System
Rinsing water.	Sterile water available in clinical environment, with at least 1000ml (bottles with a punch-through hole in the cap for an IV spike are recommended).	No
Bottle Holder.	Holder for bottles of sterile water.	Yes
Waste Canister.	Medical grade vacuum suction canister. Any marketed canister can be used.	No

11. Environmental Protection

With regards to European Union Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) all medical waste electrical and electronic equipment (WEEE) should be disposed of and collected separately. This product is Electrical and Electronic Equipment and should be disposed of in accordance with national and local legislation and requirements.

12. Troubleshooting

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of **aBox™ Duodeno**. Troubles or failures other than those listed in the following table need repair. As repair performed by persons who are not qualified by Ambu could cause patient or user injury and/or equipment damage, be sure to contact Ambu for repair.

Irregularity Description	Possible Cause	Solution
The power fails to come on.	The power switch and/or the power button of the aBox™ Duodeno is set to OFF.	Set the power switch to ON.
	The power cord is not connected.	Connect the power cord with an electrical source as described in section 5.
No video image.	The aBox™ Duodeno or ancillary equipment is not switched ON.	Switch aBox™ Duodeno and ancillary equipment on.
	Medical grade monitor not/ not properly connected or defect.	Connect the medical grade monitor properly.
	aScope™ Duodeno not/not properly connected or defect.	Connect the aScope™ Duodeno correctly or connect a new aScope™ Duodeno.
	LEDs not switched ON.	Switch the LEDs ON.
aBox™ Duodeno does not boot up.	aBox™ Duodeno not powered ON.	Power the aBox™ Duodeno ON.
	Medical grade monitor not/ not properly connected or defect.	Shutdown aBox™ Duodeno and connect the medical grade monitor properly. Try to power ON the aBox™ Duodeno after 10 sec again.
Power fails to come on.	Power cable not connected.	Connect the power cable.
	Fuse blown.	Replace fuse. Please refer to section 7.

Irregularity Description	Possible Cause	Solution
aBox™ Duodeno will not shut down.	aScope™ Duodeno still connected.	Please unplug the aScope™ Duodeno from the aBox™ Duodeno and press the power button for 3 secs. to shut down the system.
	Power button was pressed too short.	Press the power button for at least 3 sec.
	aBox™ Duodeno defect.	Switch the aBox™ Duodeno off by using the mains switch on the back panel of the aBox™ Duodeno and contact support.
Rinsing not possible.	Peristaltic pump defective.	Replace the peristaltic pump. Please see Section 8. (peristaltic pump replacement).
Control panel does not work.	aBox™ Duodeno not powered ON.	Power the aBox™ Duodeno ON.
	Sterile water bottle not confirmed.	Confirm the message on the settings and information menu that a new bottle of sterile water was connected.
	aScope™ Duodeno is not connected.	Connect the aScope™ Duodeno.
The endoscopic image is too dark.	LEDs are not switched ON	Switch the LEDs on as described in section 5.
	The image settings of the aBox™ Duodeno are incorrect (brightness and contrast).	Set the image settings correct as described in section 5.4.
	The medical grade monitor settings are improper (brightness and contrast).	Set a proper brightness as described in the medical grade monitor's instruction manual.
	LEDs are running in reduced power mode.	Check the sterile water bottle and connect a new bottle of sterile water if necessary or check if the process water tubing is sufficiently inserted in the sterile water bottle.
		Check the suction system for proper functionality. See section 12. Troubleshooting in the aScope™ Duodeno IFU.
The endoscopic image is too bright.	The image settings of the aBox™ Duodeno are incorrect (brightness and contrast).	Set the image settings correct as described in section 5.4.
	The monitor settings are improper (brightness and contrast).	Set a proper brightness or contrast as described in the monitor's instruction manual.

Irregularity Description	Possible Cause	Solution
The color tone of the endoscopic image is unusual.	The medical grade monitor settings are improper.	Adjust the color setting at the monitor according its IFU, starting from standard color setting (D65).
	The monitor cable is connected incorrectly.	Connect the monitor cable properly as described in Section 5.
	The medical grade monitor cable is defect.	Connect a new power cable to the medical grade monitor.
The endoscopic image remains frozen.	The freeze button is still set.	Press the freeze button to restore the real-time image.
The image cannot be stored.	No video recorder connected.	Connect a video recorder.

Standard Messages During Set-up And Procedure

Message	Possible Cause	Solution
Please connect a new bottle of sterile water.	Standard request before each examination.	Confirm, that a new bottle of sterile water was connected.
Lid of the peristaltic pump is open.	Lid of the peristaltic pump is open.	Close the lid of the peristaltic pump.
Please check process water and the connection of the suction pump.	Increased temperature of the distal end.	Check process water and the connection of the suction pump.
Image initializing. Please wait.	Standard message after an image drop-out was detected.	Please wait until the aBox™ Duodeno initialize displays an image on the monitor. If nothing happens contact service.

Error Messages

Message	Possible Cause	Solution
Video signal issue identified (E1).	aScope™ Duodeno defect.	Please connect a new aScope™ Duodeno.
	Electrosurgical instrument set on increased intensity.	Reduce the intensity of the electrosurgical instrument low.
aBox™ Duodeno defective (E2).	Framer grabber not connected/ defective/detected.	End the procedure and contact service.
aBox™ Duodeno defective (E3).	No communication between the controller board and the aBox™ Duodeno.	End the procedure and contact service.
aBox™ Duodeno defective (E4).	Wrong settings in the controller board.	End the procedure and contact service.
Remote switches and rinsing function access limited.	Limited functionality of the endoscope due to a defect endoscope.	If necessary, take a new aScope™ Duodeno for concluding the procedure.
aBox™ Duodeno defective (E5). Contact service.	Hardware and software error.	End the procedure and contact service.

12.1. Returning The aBox™ Duodeno To Ambu

Should it be necessary to return an aBox™ Duodeno to Ambu for investigation, please contact your Ambu representative beforehand for instructions and/or guidance. To prevent infection, it is strictly forbidden to ship contaminated medical devices. Hence, the aBox™ Duodeno must be decontaminated on site before shipment to Ambu. Ambu reserves the right to return contaminated medical devices to the sender. In an event of a serious incident, please inform Ambu and the competent authority.

12.2. Compliance And Licensing

The system conforms to the standard of IEC 60601–1 / ANSI/AAMI ES60601-1, IEC 60601–1–2 and IEC 60601–2–18.

12.3. Electromagnetic Compatibility

General Information

Medical electrical equipment is subject to special precautions with respect to EMC and must be installed according to the instructions in the accompanying documentation.

The manufacturer can only guarantee compliance of the equipment if the accessory parts listed in the accompanying documentation are used.

The device is intended for use exclusively by trained medical personnel. This device can cause radio interference or interference with the operation of other equipment in its close vicinity. It may be necessary to take suitable corrective measures, such as readjustment, a different system layout, or shielding.

Special Instructions.	Regulations applying to medical devices require us to provide you with the following information. (See the following pages of all tables. Table 1 Recommended safety distances. Table 2 Electromagnetic compatibility 1. Table 3 Electromagnetic compatibility 2. Table 4 Electromagnetic transmission.

Table 1 Recommended Safety Distance

Recommended safety distance between portable and mobile HF telecommunications systems and the aScope™ Duodeno.

The system is intended for operation in an electromagnetic environment in which HF interference is controlled. The user of the system can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF telecommunications systems and the System, depending on the output power of the communication unit, as specified below.

Nominal power, P, of transmitter, measured in watts [W]	Recommended safety distance, d, expressed in meters, based on the nominal transmitter power and transmission frequency.		
	150KHz – 80MHz d=3.5/3 √P	80MHz – 800MHz d=3.5/3 √P	800MHz – 2.5GHz d=3.5/3 √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitter where the maximum nominal power is not specified, the recommended safety distance can be determined by use of the formulas above.

Table 2 Electromagnetic Compatibility 1			
Guidelines and manufacturer's declaration – resistance to electromagnetic interference			
The aScope™ Duodeno is intended for operation in the electromagnetic environment specified below. The user of the aScope™ Duodeno should ensure that it is used in such an environment.			
Electromagnetic compatibility testing	IEC 60601 test level	Compliance level	Electromagnetic Environment Guidelines
Electrostatic discharge (ESD) according to IEC 61000 – 4 – 2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be wood or concrete or covered with ceramic tiles. If the floor is a synthetic material, the relative humidity must be at least 30 %.
Fast transient electric interference (burst) according to IEC 61000 - 4 – 4	± 2 kV for power lines	± 2 kV for power lines	The quality of the power supply voltage must correspond to a typical hospital or business power supply.
Voltage drops, temporary power outages, and variations in the power supply voltage according to IEC 61000 – 4 – 11	0 % reduction during 0,5 cycle 0 % reduction during 1 cycle 70 % reduction during 25 cycles 0 % during 250 cycles	0 % reduction for 2 ms (drop) 0 % reduction for 4 ms (drop) 70 % reduction for 500 ms (drop) > 95 % reduction for 10 ms (drop)	The quality of the power supply voltage must correspond to a typical hospital or business power supply. If the user requires continued functionality even after failure of the power supply, we recommend operating the aScope Duodeno from an uninterruptible power supply.
Magnetic field at the power supply frequency (50/60Hz) according to IEC	30A/m (50Hz)	30A/m (50Hz)	

Table 3 Electromagnetic Compatibility 2			
Guidelines and manufacturer's declaration – resistance to electromagnetic interference.			
The aScope™ Duodeno is intended for operation in the electromagnetic environment specified below. The user of the aScope™ Duodeno should ensure that it is used in such an environment.			
Electromagnetic compatibility testing	IEC 60601 test level	Compliance level	Electromagnetic Environment Guidelines
Line-conducted HF coupling according to IEC 61000 – 4 – 6 Electromagnetic fields according to IEC 61000 – 4 – 3	3 V; AM/1 kHz/80 % 150 KHz – 80 MHz 3V/m; 80 MHz – 2.7 GHz	3 V 3 V/m	Portable and mobile radio equipment should not be used closer to the unit, including cords, than the recommended safety distance calculated according to the formula appropriate to the transmission frequency: d=3.5/3 √P up to 80MHz d=3.5/3 √P 80MHz – 800MHz d=3.5/3 √P 800MHz – 2.5GHz where P is the nominal power of the transmitter in watts and d is the safety distance in meters.
The field strength of stationary transmitters should be lower in all frequencies than the compliance level, according to an examination on site. Malfunctions are possible in the vicinity of equipment with the following symbols.			
			

Table 4 Electromagnetic Transmition		
Guidelines and manufacturer's declaration – resistance to electromagnetic interference.		
The aScope™ Duodeno is intended for use in the electromagnetic environment specified below. The user of the aScope™ Duodeno should ensure that it is used in such an environment.		
Transmission measurement	Compliance	Electromagnetic Environment Guidelines
HF transmission according to CISPR 11	Group 1	The aScope™ Duodeno uses HF power internally only. Its HF transmission is therefore very low and it is improbable that it will cause interference with electrical equipment in its vicinity.
HF transmission according to CISPR 11	Class A	The aScope™ Duodeno is suitable for use in facilities other than residential areas that are connected directly to the public power grid that also supplies buildings used for residential purpose, provided that the following warning is observed: **Warning:** This device is intended only for use by trained medical personnel. This is a Class A device according to CISPR 11. In a residential area, this unit can cause radio interference, so it is necessary in this case to take suitable corrective measures, such as readjusting it, rearranging it, or shielding the unit or filtering its power connection.
Upper harmonics according to IEC 61000 – 2 – 3	Class A	
Voltage fluctuations / flicker according to IEC 61000 – 3 – 3	Satisfied	

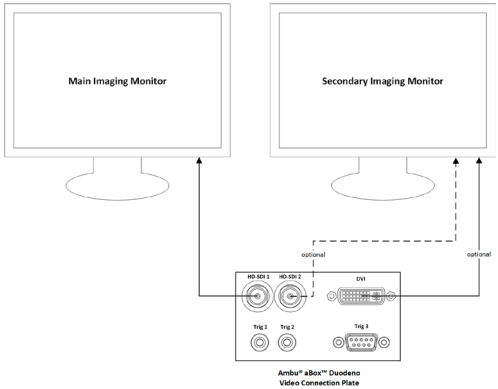
13. Contact

Manufacturer
Ambu A/S
Baltorpbakken 13
2750 Ballerup, Denmark

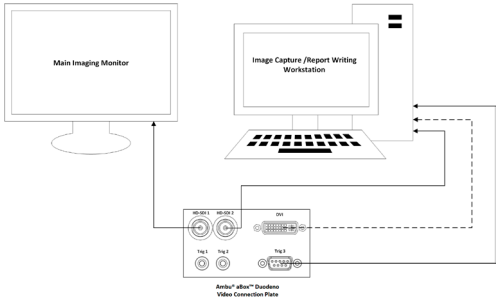
Appendix1. Connection Configurations Descriptions

The aBox™ Duodeno is equipped with multiple video outputs for viewing by clinicians and several options for documentation via additional video outputs and a remote signal (i.e. “trigger”) to activate common recording devices. The steps in this appendix will guide the installer through the various available connections and the required cabling for each configuration.

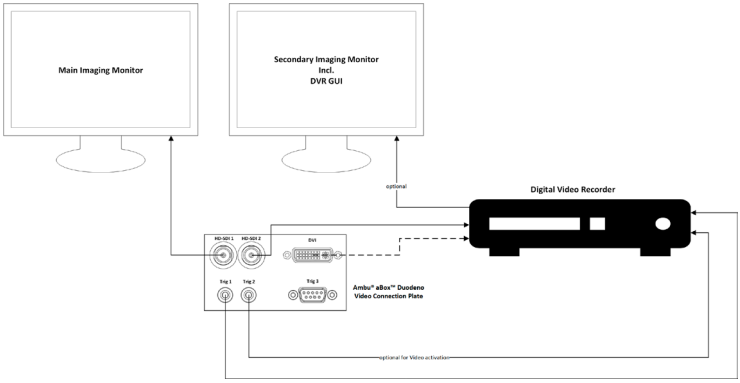
Connecting the Mandatory Main Primary Imaging Monitor using the HD-SDI 1 Video Signal Connecting the Optional Secondary Imaging Monitor using the HD-SDI 2 or DVI Video Signal



Connection of an Image Capture / Report Writing Workstation using the HD-SDI 2 or DVI Video Signal and TRIG 3



Connection of a Digital Video Recorder using the HD-SDI 2 or the DVI Video Signal and TRIG 1 and/or TRIG 2



Appendix2. WPF-Mediakit

WPF-Mediakit is an open source library.

It provides a control for Visual Studio .NET to display video from a Windwos imaging device.

https://github.com/Sascha-L/WPF-MediaKit/wiki

Version: 2.2.0

Release Date: 2017-01-19

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