Operating Instructions
AIR:MASTER

For blowing out and drying waterproof flexible endoscopes

CE

Updated 18.03.2024 Rev.3

Read the operating instructions to learn about the intended purpose, operation and manner of operation before using this medical equipment and its accessories for the first time.

We recommend that you keep these operating instructions close to the device so that you can always refer to them in case of doubt.

These Operating Instructions apply to the following products:

AIR:MASTER REF: 7000-K01

The AIR:MASTER is a Class I / Rule 13 active medical device as defined in Annex VIII of Council Regulation (EU) 2017/745. A Declaration of Conformity can be provided on request.

Standard and optional accessories
Use of the AIR:MASTER in accordance with the intended purpose requires special-purpose accessories that are listed under Point 3 and in Appendix II to these Operating Instructions.

All national laws and regulations applicable in the country of use as amended from time to time must be observed and applied.

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1 Instructions for use

1.1. Intended purpose

The AIR:MASTER has been developed exclusively for final drying (clean side) and air-flushing (contaminated side) of waterproof flexible endoscopes and their individual components (e.g. valves) made by OLYMPUS, FUJINON, STORZ, PENTAX and HUGER after reprocessing, provided they have a maximum of four additional channels (jet channel, air/water channel, biopsy channel, suction channel).

 The AIR:MASTER can be used on either the clean side or the contaminated side of the reprocessing room but not at the same time, i.e. not during the same reprocessing operation.

1.1.1 Patients

The AIR:MASTER does not come into contact with patients.

1.1.2 Staff

The requirements for expertise as defined in the German regulations governing the installation, operation, use and maintenance of medical devices (MPBetreibV) must be fulfilled. The users must have been instructed and trained in safe use of the device.

Initial instruction may only be carried out by the manufacturer (here: Creo Medical GmbH) or by a person or company authorised by the manufacturer.

1.1.3 Ambient conditions

When installing the device, ensure the ambient conditions listed below are complied with.

- Use in closed rooms
- Degree of contamination 2 (minor, normal contamination that may become conductive due to occasional dew formation or hand-transmitted sweat).
- The device must never be used in explosive atmospheres.
- 10° C to 35° C ambient temperature
- Air humidity max. 70%
- Operation up to an altitude of 2.000 metres (metres above sea level)
- This device must be installed and operated in accordance with the electromagnetic compatibility (EMC) instructions contained in this manual.
- Portable and mobile high-frequency (HF) communication equipment (e.g. mobile phones) may affect the way the device functions.
- The device may not be used stacked together with or beside other devices.

1.1.4 Mobility

- ME device placed on a table or equipment trolley in a reprocessing room which is used on an endoscope during reprocessing.

1.2 Contraindications

The AIR:MASTER must not be used inappropriately:

- It must not be used for purposes other than for blowing and/or drying endoscopes.
- It must not be used for drying endoscopes if no information regarding their suitability for use with the AIR:MASTER is available.
- It must not be used for drying endoscopes equipped with additional auxiliary channels, i.e. more than the four channels indicated (jet channel, air/water channel, biopsy channel, suction channel).
- It must not be operated without a sterile gas strainer.

1.2.1 Hazards and risks arising during use

- Infections can be transmitted when using the AIR:MASTER.
- The AIR:MASTER must not be used in rooms with flammable or explosive gases (within flash distance of potentially explosive anaesthetics or other potentially explosive substances).
- The AIR:MASTER must not be used simultaneously (i.e. during the same reprocessing operation) on the clean side and the contaminated side of the reprocessing room.

1.3 Key performance characteristics

- Channel monitoring system which detects blockages in the endoscope channels to be dried and prevents damage to the endoscope which would result from excess pressure in the channels.
- Channel monitoring can be switched on and off separately for both pumps.
- Sterile gas strainer with 0.2µ hydrophobic diaphragm and bidirectional gas flow.
- Freely selectable running time up to a maximum of 24 minutes.
- Connection of a blowgun.

2 Important safety and other notices when using this equipment

Read the operating instructions before using the AIR:MASTER for the first time and familiarise yourself with the functions and mode of operation of the device and accessories.

Never use any accessories other than those described in these Operating Instructions.

Failure to comply with these operating instructions may result in injury to patients, users, maintenance personnel and Third Parties, and may also result in damage to the device or endoscope, or the device and endoscope may stop working completely.

2.1 Liability & disclaimer

Creo Medical GmbH is not liable for any damage, direct or consequential, which occurs under the following conditions:

- If the device or accessories are operated, treated or maintained inappropriately
- If the instructions and specifications set out in these Operating Instructions are not observed
- If repairs, adjustments or modifications to the device or accessories have been carried out by unauthorised persons
- If the device has been opened by unauthorised persons
- If the prescribed inspection and maintenance intervals are not observed.
- If any accessories other than those described in these Operating Instructions are used.

2.2 Authorised service technicians

Only service technicians certified by Creo Medical GmbH are authorised to carry out repairs, adjustments or modifications to the device and accessories. Authorised service technicians are registered and certified exclusively by Creo Medical GmbH after appropriate instruction and training.

2.3 Instruction of staff

On-site training is provided by Creo Medical GmbH or a person authorised by us.

2.4 Functional test

Before every use, check the equipment to ensure all components are in place and that the AIR:MASTER is working properly.

Before using the device for the first time and after repairs have been carried out, always check that the equipment has been installed properly. Function checks are listed in Chapter 6.

2.5 General remarks on dangers and risks

 In the event there is serious risk of danger, disconnect the device from the power supply immediately (pull out the plug). 

Then call the service technician to remedy the fault, remove the hazard and recommission the device.

2.5.1 Unauthorised opening of the device

Live components become exposed when the device is open and can cause electric shocks if touched. Never open the device yourself. This device may only be opened by an authorised Creo Medical GmbH service technician.

2.5.2 Penetration of liquids

Liquid entering the device may prevent the device from working properly and/or present the risk of electric shock. Fluids should therefore never be permitted to enter the device. Always avoid placing fluids in the vicinity of the electrical components.
Do not operate if liquid has penetrated the device.

2.5.3 Operation in explosion-proof areas

The device is not explosion-proof. Operation in areas with explosive gases can lead to severe damage and cause serious injury.

2.5.4 Use of inappropriate accessories

The use of inappropriate accessories can cause the device to operate incorrectly, which may result in injury to patients, users, third parties and service technicians. Use only accessories specified for operation with the AIR:MASTER device (see Appendix II).

2.5.5 Faulty fuses

When replacing a faulty fuse, please ensure the new fuse corresponds with the specifications displayed on the device or set out in these Operating Instructions.
The use of the wrong fuses can cause the device to function incorrectly and may result in injury to users and others.

2.5.6 Faulty device

It is generally dangerous to operate a faulty device. If you know or suspect eve that the device is faulty, do not use it – make sure the device cannot be operated until checked by an authorised technician.

2.5.7 Installing the device

The device may not be used stacked together with or beside other devices. If operation beside or stacked with other units is unavoidable, ensure it can still be used in accordance with its intended purpose in this arrangement.

2.5.8 EMC Directive

This device is subject to specific provisions as regards electromagnetic compatibility and must be installed and operated in accordance with the electromagnetic compatibility (EMC) instructions contained in Chapter 12 of this manual.

Portable and mobile high-frequency (HF) communication equipment (e.g. mobile phones) may affect the way the device functions.

2.5.9 Instructions on operation

Before using the device for the first time and after servicing or repairs have been carried out always check that the equipment has been installed properly.

Before every use, check the equipment to ensure all components are in place and that the AIR:MASTER is working properly.

2.6 Maintenance and service life

Regular preventive maintenance is the basic prerequisite to ensure the functionality and operational safety of the AIR:MASTER over the entire expected service life. For this reason, the AIR:MASTER must be serviced every 12 months by the manufacturer,
Creo Medical GmbH or a company authorised by the manufacturer.

According to Council Regulation (EU) 2017/745, an expected service life must be defined. The expected working life of the AIR:MASTER is 7 years.

2.7 Responsibilities

The manufacturer is only responsible for the technical and safety-relevant characteristics of the device if all the installation, expansions, readjustments, modifications, repairs and servicing but also commissioning and instruction have been carried out by qualified persons authorised by the manufacturer and the electrical installation of the room meets the requirements of VDE provisions and the device has been used in accordance with the Operating Instructions.

3 Delivery

3.1 Parts supplied

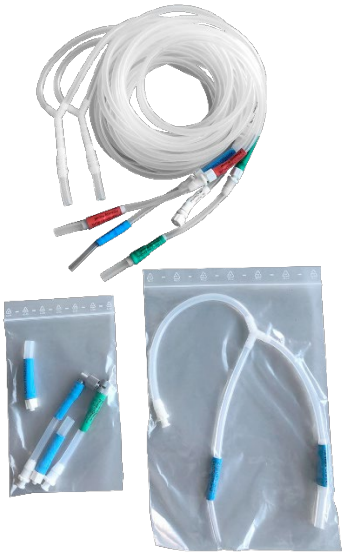
Check the device and accessories immediately upon delivery to ensure all components are included and look for any visible external damage.

The following components are supplied with the device as standard (customised orders may differ somewhat):

AIR:MASTER

Mains cable (REF 5020-010)

Two sterile gas strainers (REF 11 -2000)



Set of tubes (REF 7050-NS0)

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3.2 Returning the device

If you need to return the device, please use the original packaging. We will not accept responsibility for damage incurred during transport as a result of inappropriate packaging.

4 Device overview

① **Mains switch**: (OFF) 0 – (ON) 1

② **Two pressure monitoring devices**: for switching pressure monitoring ON and OFF

③ **Button**: Starts the drying process.

④ **Two compressed air outlets** for switching the pressure monitoring ON and OFF

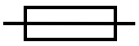
⑤ **Fuse compartment**: the device must only be operated with the fuses given on the rating plate

⑥ **Socket for shrouded 3-pin plug**: the device must only be operated with the voltage given on the rating plate

⑦ **Fan**: for forced-air cooling of the compressor pumps

4.1 Instructions attached to the device

Meaning of the pictographs and symbols used on the AIR:MASTER and its rating plate

Type	Article description
Ref	Spare part no.
~	Refers to operation with alternating current
IP 21	For use inside, drip-proof
P	Output
SN	Serial number
	Year of manufacture
	Precision fuse to IEC 60127
	Indicates to the user that it is essential to read the Operating Instructions and note the main, safety related details, such as warnings and precautions.
	CE marking

5 Electrical connection

Proper operation of the AIR:MASTER requires a dry operating environment with a relative air humidity of no more than 70% and an ambient temperature between 10 °C and 35 °C.

- Connect the AIR:MASTER to the power supply.
- Use the mains connection cable provided.
- The device must be connected to the mains via an earthed contact.
- Check the label on the back of the device to ensure that the mains voltage is appropriate. If the mains voltage is incorrect, the device may not function properly or could be damaged.

The AIR:MASTER will be ready for use as soon as it has been properly installed.

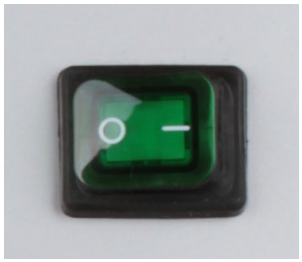
6 Operating the AIR:MASTER

The procedures outlined below should be carried out the first time the device is used and then at regular intervals during normal operation.

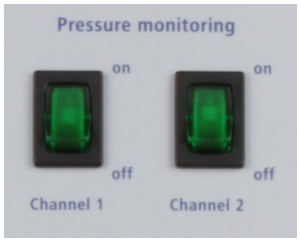
6.1 Functional check

Check that the mains electricity supply is correctly connected before performing the functional check.

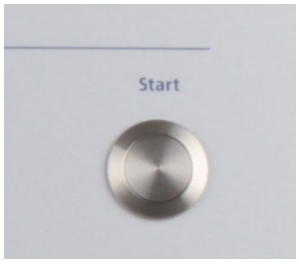
- Switch on the mains switch to start the device (switch position ‘I’).
- The mains switch will show green.



- Switch ON the pressure monitoring device for both channels (switch position ‘ON’).



- Start the AIR:MASTER by pressing the ‘START’ button.



- The AIR:MASTER pumps should be running audibly. You will notice a flow of air from both compressed air outlets on the front of the device (LL connections).
- To check that the pressure monitoring device is working, close off each of the compressed air outlets one at a time with an LL plug.
  (Suitable dedicated plugs are supplied as standard with the set of tubes (jet channel)).

- If the pressure monitoring device has been switched on and is functioning correctly, the AIR:MASTER will automatically switch off the pumps. The pressure monitoring system works independently for each separate channel.
- If the pressure monitoring device has not been switched on, the AIR:MASTER pumps will continue to run.

Switch the AIR:MASTER ‘OFF’ via the mains switch and remove the LL plug from the compressed air outlet.

Once the device has completed all the functions without error messages, the functional test has been passed.

6.2 Drying endoscopes

Note

When operating the AIR:MASTER, observe the generally applicable requirements for handling endoscopes as published by the Robert Koch Institute (RKI).

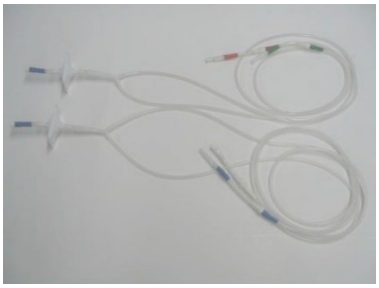
- 'Hygiene requirements when reprocessing medical equipment'.
- 'Hygiene requirements when reprocessing flexible endoscopes and additional instruments used in endoscopy'.
- 'Hygiene requirements as applied to the design and construction of endoscopy instruments'.

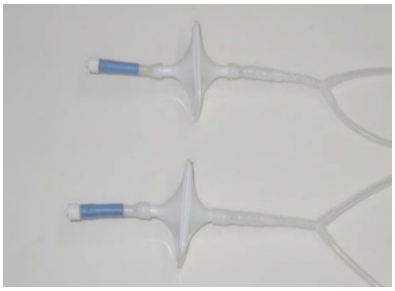
Endoscopes should always be dried thoroughly before they are stored to prevent germs developing (pseudomonads).

The effectiveness of isopropyl alcohol for cleaning endoscopes has not been fully researched. Using isopropyl alcohol is believed to cause damage to endoscopes.

6.2.1 Preparation

Connect the sterile gas strainer to one end of the connection tube set and connect the other end of the tube to the AIR:MASTER.





Note the date the strainer is installed in a clearly visible place and ensure it is not used beyond its four-week lifetime.

6.2.2 Connecting up the endoscope (clean side)

When using the AIR:MASTER on the clean side of the reprocessing room, please follow these instructions:

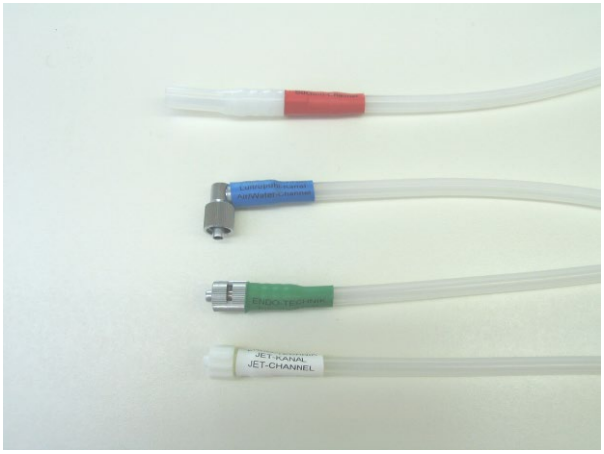
Remove the valves from the endoscope and close off the valve shafts with the correct adapters for that endoscope.

Connections to colour-coded tubes are as follows:

1. The suction channel (red) is connected directly to the endoscope body
2. The air/flush channel (blue) is connected directly to the endoscope body
3. The biopsy channel (green) is connected directly to the biopsy channel of the insertion tube
4. The jet channel (white) is connected directly to the jet channel of the endoscope.

Note

The adapters required for connecting up the tubes are available from the manufacturer of the endoscope.



If the endoscope you are drying does not have a jet channel, close off the jet channel tube so that the drying air is automatically distributed to the remaining tubes.

Note
The endoscope should be hung up before it is dried. Creo Medical GmbH provides suitable endoscope hangers for wall-mounting (further details available from our current catalogue).

6.3 After using the device
1. Disconnect the device from the mains by pulling out the mains plug.
2. Remove the detachable components
3. Disposable material must be disposed of according to national regulations.
4. All other components are prepared according to Chapter 8 of this manual.

7 Maintenance and care
7.1 Processing
At the end of the working day, clean and disinfect the housing and tubes of the AIR:MASTER as described in Chapter 8.

Do not use aggressive detergents or solutions containing alcohol to clean the AIR:MASTER housing.

7.1.1 AIR:MASTER on the clean side of the reprocessing room
Reprocess the sets of tubes (connection tubes) as explained in Chapters 8.2 to 8.2.10 of these Operating Instructions on a daily basis.

7.1.2 AIR:MASTER on the contaminated side of the reprocessing room
Thoroughly clean the tube set and adapter. The manufacturers recommend an additional disinfection and sterilisation stage (refer to Chapter 8.2).

7.2 Maintenance activities every four weeks
The sterile gas strainers must be changed every four weeks and replaced with new ones. The strainers are not suitable for reprocessing.

Notice
Use only strainers approved by Creo Medical GmbH as these are calibrated specifically to the AIR:MASTER pump capacity.

7.3 Maintenance activities once a year

7.3.1 Tube connections

Both the tubes inside the device and the connection tubes must be replaced once a year as part of the annual service.

7.3.2 Maintenance

Maintenance of the AIR:MASTER by Creo Medical GmbH or a technical equipment consultant authorised by us.

We recommend conducting a performance test after every maintenance and / or repair job.

8 Disinfecting and cleaning the device

Only validated processes may be used for the reprocessing of medical devices.

8.1 AIR:MASTER

8.1.1 Place of use

Unplug the device and remove the accessories used (e.g. set of tubes, blowgun)

8.1.2 Storage and transport

When transported outside the room in a closed container.

We recommend reprocessing medical devices as soon as possible, at the latest within 2 hours of use.

8.1.3 Preparation

Wear personal protective equipment (solid gloves, water-repellent protective coat, face mask or goggles and mask).

8.1.4 Manual cleaning and disinfection

8.1.4.1 Equipment required

Non-protein-fixing VAH-listed (VAH = Association for Applied Hygiene) instrument disinfectant based on quaternary compounds, acetals and aldehydes (e.g. Beta Guard RFU wipes, Dr Deppe GmbH)

8.1.4.2 Procedure

1) Take a disinfection wipe and wipe the surfaces of the device thoroughly.
2) Ensure that all surfaces, grooves and indentations in the device are wiped and thoroughly moistened during the cleaning process.
3) To clean the ventilation grille, wipe it thoroughly on the outside, then fold the disinfection wipe and clean all the gaps between the individual louvres (see photo).

4) Check the areas for cleanliness and, if contamination is still visible, repeat the above steps.
5) To disinfect the surfaces, take a further disinfection wipe and wipe the surfaces of the device thoroughly.
6) Ensure that all surfaces, grooves and indentations in the device are wiped and thoroughly moistened during the disinfection process.
7) To disinfect the ventilation grille, wipe it thoroughly on the outside, then fold the disinfection wipe and clean all the gaps between the individual louvres (see photo).
8) Allow the disinfectant to soak in for the time specified by the disinfectant manufacturer (e.g. Beta Guard RFU wipes require five minutes).
9) Allow the device to dry off.

8.1.5 Maintenance, inspection and testing

We recommend annual maintenance of such devices by Creo Medical GmbH or a person authorised by us.

8.1.6 Packaging

No special requirements.

8.1.7 Storage

Store the device in a dust-protected, cool, dark and dry place, the storage time must be in accordance with the specifications of the user.

8.2 Cleaning and disinfecting the tube sets

Note

Special attention is required when cleaning lumened instruments. Device cleaning and disinfection require a special load carrier with cavity flushing, e.g. load carrier for microinvasive instruments (MIC trolleys). The configuration of these load carriers varies depending on the manufacturer. The cleaning performance depends on the configuration and adaptability of the instrumentation on the load carrier and must be verified by validation of the processes.

Suitable disinfection solutions for reprocessing are aldehydic and peracetic acid solutions.

If correctly handled without contamination of the adapters and tubes, the tube set should be reprocessed every four weeks as part of the sterile gas strainer replacement process.

8.2.1 At the place of use
Depending on the set of tubes: Disconnect the sterile gas strainer from the tubes.

8.2.2 Storage and transport
It is recommended to transport the contaminated tube sets in a closed container.

8.2.3 Preparation
Wear personal protective equipment (solid gloves, water-repellent protective coat, face mask or goggles and mask).

8.2.4 Pretreatment
Equipment required: mains water / running water (20 ± 2 °C, at least drinking water quality), 20 ml syringe (e.g. B. Braun #4606205V), tub for mains water.

1) Place the tube system in a tub of water (at least drinking water quality) for at least five minutes. Fill the lumens of the tubes with water using a 20 ml syringe and ensure the tubes are free of air bubbles.
2) Remove the tubing system from the water and remove any residue from the lumen using an air-filled 20 ml syringe.

8.2.5 Manual cleaning
Note: Carry out manual pretreatment before subjecting the tube system to full manual cleaning (see Pretreatment).

Equipment required: multi-stage enzymatic cleaner (InstruZym, by Dr Deppe GmbH, #600001) mains water / running water (20 ± 2 °C, at least drinking water quality), cleaning brush (the following have been validated: Interlock #26024, brush head diameter: 2.5 mm, brush head length: 15 mm, overall length: 2.300 mm, Interlock #26090, brush head diameter: 2.5 mm, brush head length: 15 mm, overall length: 2.300 mm), 20 ml syringe (e.g. B. Braun #4606205V), tub for mains water.

3) Prepare the cleaning solution according to the manufacturer's instructions (e.g. InstruZym 3%, temperature between 35 °C and 45 °C).
4) Carry out all further cleaning steps with the items fully immersed in the liquid to prevent splashing of contaminated liquid.
5) Immerse the tube set completely in the cleaning solution.
6) Brush the hard-to-reach areas where it is not possible to assess the cleaning effect visually with a soft cleaning brush.
7) Then brush the lumens of the tubing system by pushing the brush completely through the lumen and then pull the brush through at the end of the tubes. Remove contaminations from the brush head. Repeat the step once more.
8) Fill the lumens of the tubes with cleaning solution using a 20 ml syringe and ensure the tubes are free of air bubbles.
9) Allow a total exposure time in the cleaning solution of at least five minutes (a period of five minutes has been validated).
10) Remove the tube system from the cleaning solution and remove any residues of cleaning solution from the lumens using an air-filled 20 ml syringe.
11) Place the tube system in a tub of water (at least drinking water quality) for at least one minute (a period of one minute has been validated). Rinse the lumens with a 20 ml syringe at least once to remove the residue of the cleaning solution completely.

Check the tube set for cleanliness and, if contamination is still visible, repeat the above manual cleaning steps.

8.2.6 Manual disinfection
Equipment required: non-protein-fixing VAH-listed (VAH = Association for Applied Hygiene) instrument disinfectant based on quaternary compounds, acetals and aldehydes (e.g. InstruPlus viruguard, Dr Deppe GmbH #600052) preferably demineralised water (deionised

water, according to KRINKO / BfArM recommendation free of facultatively pathogenic microorganisms), 20 ml syringes (e.g. B. Braun #4606205V), tub for disinfectant, tub for deionised water, lint-free cloth, medical-grade compressed air (in accordance with the European Pharmacopoeia).

1) Prepare the disinfectant solution according to the manufacturer's instructions (InstruPlus viruguard 5%).
2) Immerse the tube set completely in the disinfection solution.
3) Fill the lumens of the tubes with disinfection solution using a 20 ml syringe and ensure the tubes are free of air bubbles.
4) The soak phase in the disinfectant solution according to the manufacturer of the disinfectant (InstruPlus viruguard 5%): 15 minutes)
5) Remove the tube system from the disinfection solution and remove any residues of disinfection solution from the lumens using an air-filled syringe.
6) Place the tube set in a tub of deionised water for at least one minute. Rinse the lumens with a 20 ml syringe at least once to remove any residues of the disinfection solution completely.
7) Wipe with a lint-free disposable cloth and dry the lumens with medical-grade compressed air.

8.2.7 Automated cleaning and disinfection (AER)

Note: Carry out manual pretreatment before subjecting the tube system to full automated cleaning (see Pretreatment).

Equipment required: automated endoscope reprocessor (AER) according to DIN EN ISO 15883-1+2 with a thermal programme (temperature 90 °C to 95 °C), mild alkaline cleaner (LabomatMA , Dr Deppe GmbH #600032), neutralising (LabomatKS, Dr Deppe GmbH #600021), medical-grade compressed air (according to European Pharmacopoeia).

1) Place the tube set in a suitable mesh basket or place it on the load carrier in such a way that all the inner and outer surfaces of the tubes can be cleaned and disinfected.
2) The tube set must be connected to the load carrier (e.g. MIC trolley) or to a manifold (manifolds have been validated) for rinsing by means of adapters in order to flush the inner lumens. Check that the adapters are firmly attached before starting the device and at the end of the process.
3) Close the AER and start the programme, refer to the table below for the programme sequence:

Prog. step	Water	Dosage	Time	Temperature
Prerinse	Cold water		5 min.	
Dosage for cleaner		According to manufacturer		According to manufacturer
Cleaning	Demin. water		10 min.	55 °C
Dosage for Rinse aid		According to manufacturer		According to manufacturer
Rinsing	Demin. water		2 min.	
Disinfecting	Demin. water		3 min.	A0 value >3000[1] (e.g. 90 °C, 5 min.)
Drying			15 min.	Up to 121 °C
[1] Within the range of their authorisation, local authorities may adopt other rules (parameters for effective disinfection).				

4) At the end of the programme, remove the tube set.
5) Check that the set is dry and, if necessary, dry using medical-grade compressed air

6) After removal from the AER, the items must be examined by means of a visual inspection to ensure they are clean. If contamination is still visible, clean the tube set manually. After this manual cleaning operation, the tubes must then be reprocessed again in an automated process.

8.2.8 Maintenance, inspection and testing

1) The tube set must be visually checked for cleanliness, intactness and operability, if necessary by means of an illuminated magnifier (3 - 6 dioptres).
2) Then check the tube set for function, damage and wear.

Note: Never use products with kinks, cracks, holes or similar impairments.

8.2.9 Sterilising

8.2.9.1 Packaging

Equipment required: film-and-paper packaging (the following have been validated: steriCLIN, art. no. 3FKFS230112 and 3FKFS230114), sealing device (HAWO, type 880 DC-V has been validated).

1) A suitable method (sterile barrier system) must be used to pack the tube set. Packaging according to DIN EN ISO 11607 (single) or DIN 58953-9 (sets).

Individually: a sterile barrier system (foil-and-paper packaging has been validated) according to DIN EN ISO 11607 must be used, which has been approved by the manufacturer for steam sterilisation. Tube sets can be packaged singly or in pairs. The packaging must be large enough to ensure that the sealing seam is not under tension (validation involved double packaging, in foil-and-paper packaging).

Note: after heat-sealing, check visually that the sealing seam does not have any defects. In the event of any defects, the packaging must be opened and the tubing set repacked and resealed.

8.2.9.2 Sterilisation

Equipment required: steriliser according to DIN EN 285 or small steam steriliser according to DIN 13060, type B method.

Method: steam sterilization with fractionated prevacuum, 134 °C, exposure time at least 3 minutes, or 132 °C exposure time at least 3 minutes (longer exposure times are possible) (134 °C, 3 min. has been validated).

1) Place the packaged tube set in the sterilisation chamber.
2) Run the programme.
3) At the end of the programme, remove the tube set and allow to cool.
4) Then check the packaging for any damage. Packaging that is impaired in any way must be treated as non-sterile. Those instruments must be repackaged and sterilised.

8.2.10 Storage

Storage (at least protected against dust and moisture) and storage duration must be according to the user's specifications.

8.3 Additional information

Only validated processes may be used for the reprocessing of medical devices.

9 Troubleshooting

Device is not working: Green light on the power switch is not lit.

- Ensure the plug is inserted firmly into the power socket.
- Check the mains power supply and socket.
- Check the fuse on the device.

If the problem persists: contact an authorised service technician.

10 Final disposal

At the end of its useful service life, the AIR:MASTER and its detachable components have to be disposed of in accordance with applicable local regulations.

11 Technical specifications

Mains supply, rated	230 V
Mains frequency	50 Hz
Fuses	T 800 mA, IEC 127 (2 off)
Maximum power input	190 W
Maximum current consumption	0.83 A
Protection class	I
Dimensions (height x breadth x depth)	157 x 278 x 298 mm
Weight (without accessories)	7.2 kg
Max. air pressure	0.5 bar
Max. back pressure	0.8 bar
Operating condition: ambient temperature	10 °C to 35 °C
Operating condition: relative air humidity: max	70%
Classification according to Council Regulation (EU) 2017-745	Risk class I, Rule 13
Electrical safety	complies with EN 61010-1:2010
Electromagnetic compatibility	complies with EN 61326-1:2013
Ingress protection	IEC 60529 IP21
Protection category	1, type BF

CE The CE marking certifies that the product complies with EU Council Regulation 2017/745 for medical devices.

12 EMC conditions

In accordance with EN 61326-:12013

- Radiated interference Group 1 Class B (Section 7.2)
- Electromagnetic noise immunity: To Table 2

Testing requirements for radio-frequency interference of equipment intended for use in an industrial electromagnetic environment

Connection	Interference factor	EMC Basic standard	Test value	Evaluation criterion
Housing	Discharge of static electricity (ESD)	IEC 61000-4-2	4 kV contact discharge	B
			8 kV air discharge	B
	Electromagnetic fields	IEC 61000-4-3	10 V/m (80 MHz to 1 GHz)	A
			3 V/m (1.4 GHz to 2 GHz)	A
			1 V/m (2.0 GHz to 2.7 GHz)	A
	Mains-frequency magnetic fields	IEC 61000-4-8	30 A/m (50 Hz, 60 Hz) [e]	A
AC power supply connection (including protective earth conductor connection)	Voltage dip	IEC 61000-4-11	0% for 1 cycle	B
			40% for 10/12 cycles[g]	C
			70% for 25/30 cycles[g]	C
	Brief interruption	IEC 61000-4-11	0% for 250/300 cycles[g]	C
	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A
DC supply connection [f] (including protective earth conductor connection)	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A
Input/output connection (including functional earth connection)	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A
Input/output connector with direct connection to the power supply network	Fast transients	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge voltage	IEC 61000-4-5	1 kV[a] / 2 kV[b]	B
	Conducted HF signals	IEC 61000-4-6	3 kV[f] (150 kHz to 80 MHz) N1)	A

[a] Symmetrical: conductor to conductor.

[b] Conductor to PE (earth).

[c] Only for long cables (see 3.10).

[d] Only for cables longer than > 3 m.

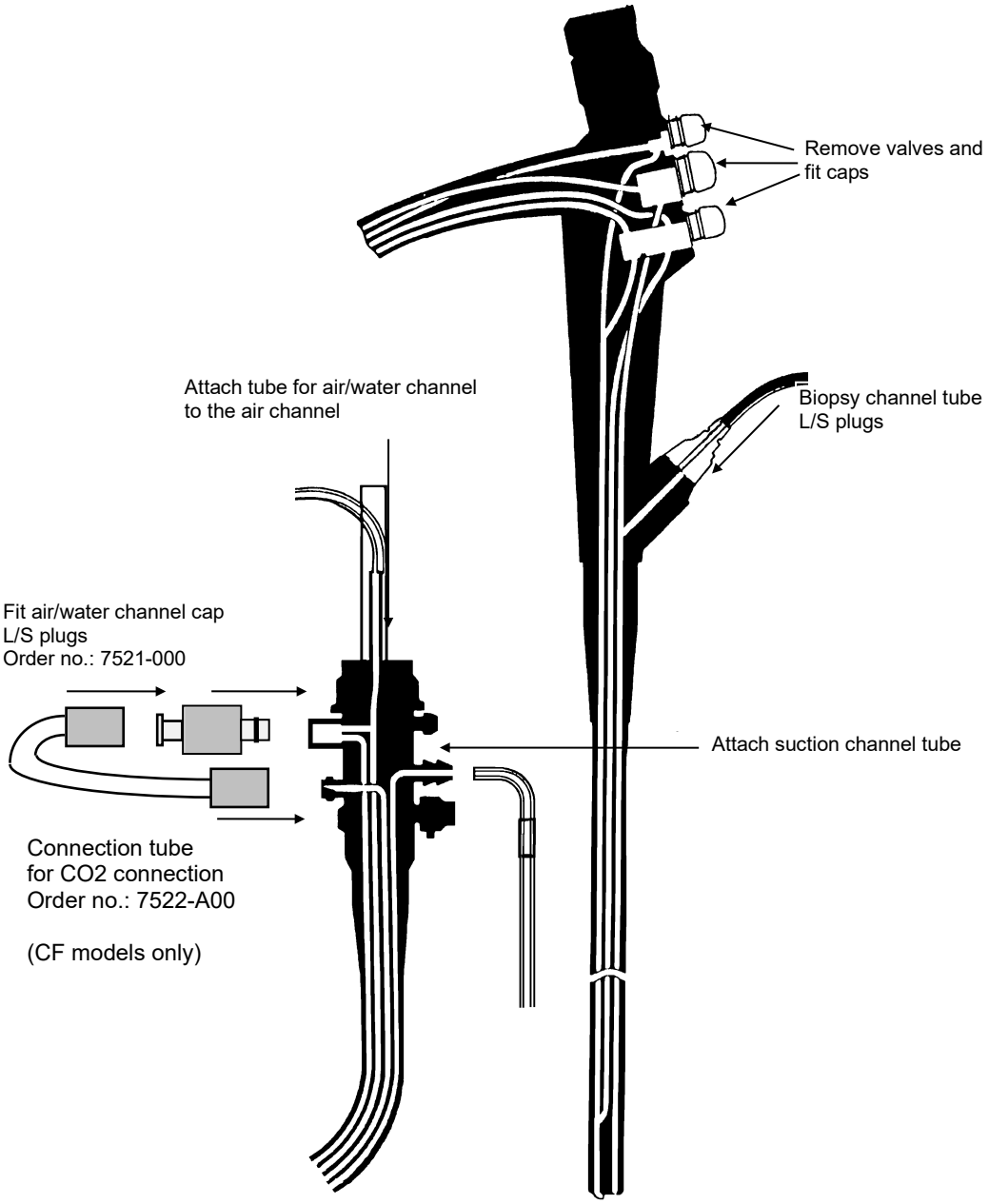
[e] Only for magnetically sensitive devices. Interference on cathode ray tube screens may occur at field strengths above 1 A/m.

[f] DC voltage connections between parts of equipment or systems not connected to a DC voltage network are treated as input/output connections.

[g] For example, '25/30 cycles' means '25 cycles for 50 Hz mains frequency tests' or '30 cycles for 60 Hz mains frequency tests'.

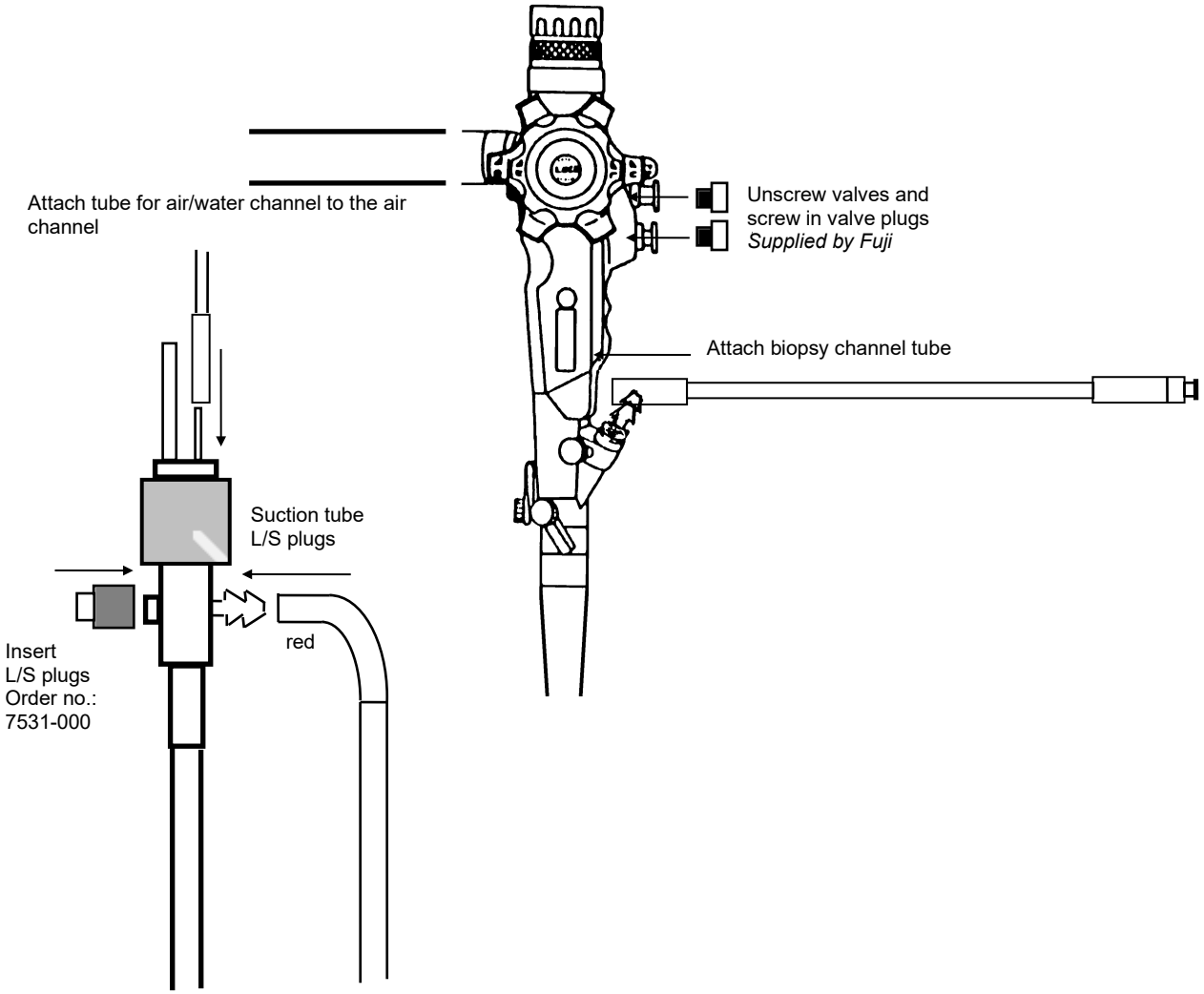
Appendix I Connecting up an endoscope

Connecting Olympus Series 10, 20 and 30 endoscopes

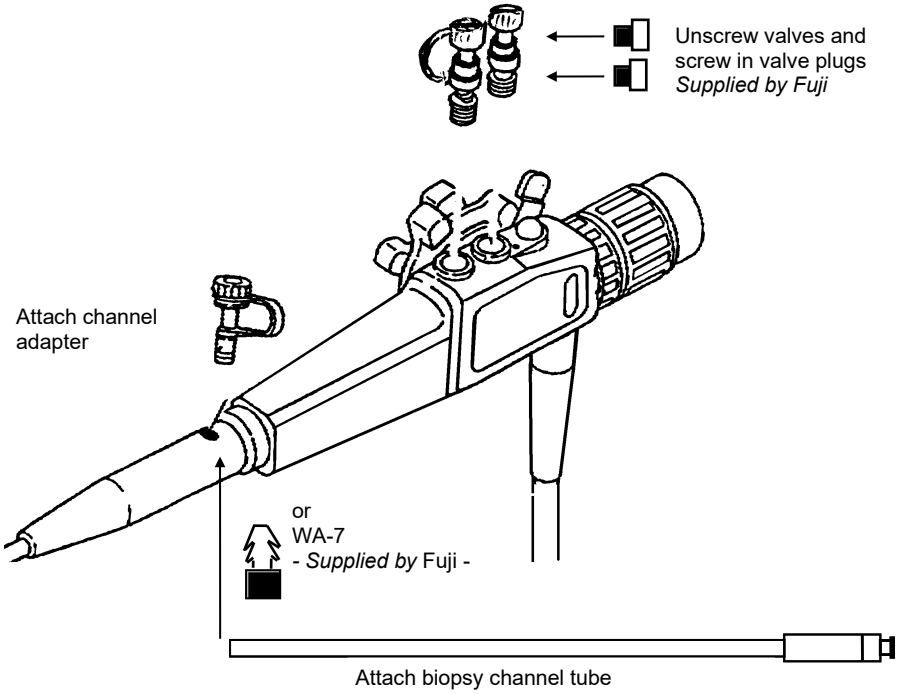


For Olympus Series 40 endoscopes, use the air/water channel cap supplied with the endoscope. (Supplied by Olympus)

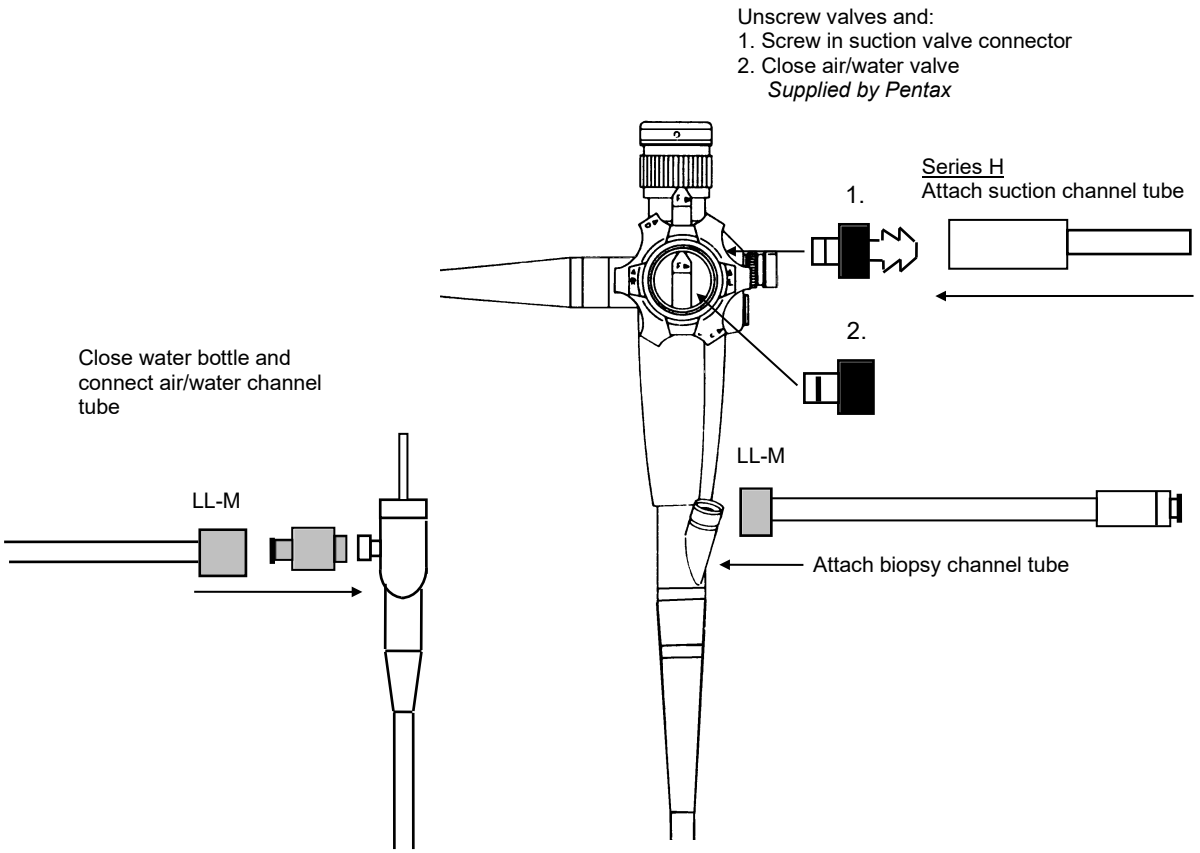
Connecting Fuji Endoscopes System 2000



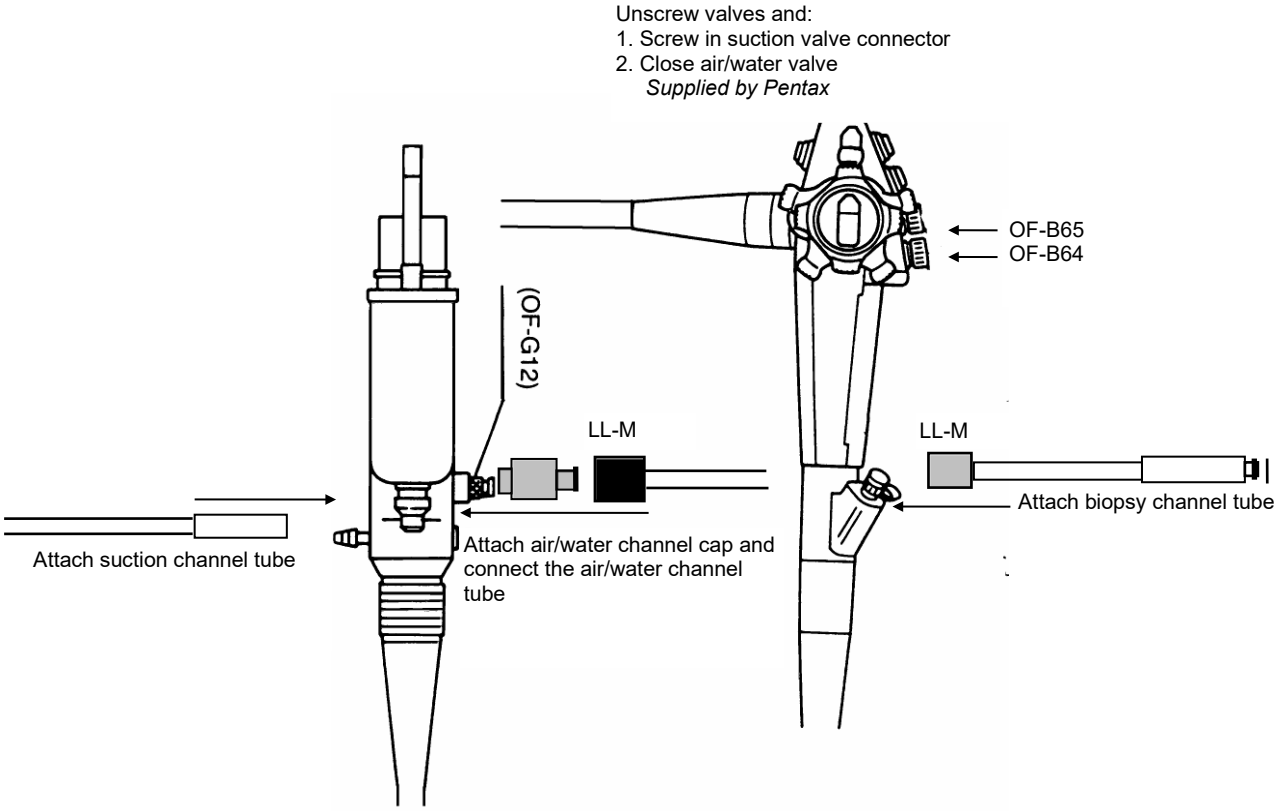
Connecting Fuji Video Endoscope Series 300



Connecting Pentax endoscopes



Connecting Pentax video endoscopes



Appendix II Accessories

REF	Description
7050-NS0	Connection set suitable for Olympus / Fujinon endoscopes
11-2000	Sterile gas strainer
7000-BP1-001	Blow-out pistol

Appendix III Replacement parts

REF	Description
5020-010	Mains cable 2.5 m, angled earthed plug at one end, CEE plug at the other
5220-600	Rocker switch, 2-pin, green
7003-620	1-pin ON/OFF switch
14-9202	Stainless steel pushbutton
7001-600-R	LL-W small, for front panel assembly RF
7001-621	Blue plate ring for LL-W assembly
7003-510	Fuse insert for 2-pin mains plug 7003-500
7003-500	2-pin mains plug without fuse insert (without fuses)
7003-920	Fine fuse 5/20 T 0.8 A (10 fuses)

Reporting

Any and all incidents and near incidents occurring in connection with this product under the German Medical Devices Safety Plan Ordinance (MPSV) are to be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

For the Federal Republic of Germany, this is:

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