
INSTRUCTION MANUAL

Endo-Jet 2000 (EJ-2)



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Dear customer,

With the purchase of the Endo-Jet 2000 (EJ-2) you are joining all the former customers, who decided to use the most advanced power-rinsing device in endoscopy.

Congratulation, you now have the most effective rinsing device available today.

The present version of the Endo-Jet is the result of several years' use, feedback and improvement in cooperation with our customers.

With the Endo-Jet you take advantage of an easy to use medical device as well as easy possibilities of maintaining and exchanging accessories, which came in contact with liquids. The "EJ-2" is compatible with all flexible endoscopes.

The development of the EJ-2, with doctors and nurses from the University hospital of Göttingen in the early 1980s, set a milestone in new endoscopic examination and clear vision with focused rinsing.

An examination without the use of an allocated "EJ-2" is nearly not imaginable in endoscopic theatres or doctor's offices.

PAULDRACH medical GmbH guarantees the correct working order of the device, when delivered and gives a warranty of 12 months for the Endo-jet 2000.

Garbsen, October 2002

Important advice

Please read this instruction carefully first before the use of the Endo-jet 2000 to give you the most effective handling and usage of this device. You should follow these instructions permanently. If you have any questions to the use of the EJ-2, please contact your local distributor or PAUDLRACH medical GmbH.

There are no special precautions to be kept in your mind during the operation of the EJ-2.

The instruction manual as well as other attached documents should be stored in a way that they will be accessible for the user at anytime.

Questions concerning the instruction, the usage or the safety have to be addressed directly to your local distributor or PAULDRACH medical GmbH.

Please Note: The sales of EJ-2 has been terminated in September 2015 to EU-Countries.

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1. General description

Endo-Jet 2000 (EJ-2) is a power rinsing device which pumps fluid with sufficient force through the working channel or a special rinsing channel (jet-channel) of an endoscope. It is intended for the use in conjunction with a flexible endoscope, which will be introduced into the human body through natural openings. The examination time of the patient should not exceed 60 minutes.

The EJ-2 washes blood, coagulant, mucus, remaining stool or other dirt with its water-jet away and opens the vision for a continuous and safe examination for the doctor. Using a "Combined Rinsing and Working Adaptor" (ISA) a simultaneous rinsing and working with e.g. biopsy forceps or snares can be conditionally performed.

2. Technical dates, specifications and operating conditions

2.1. Device data

Measurement:	(w) 40 cm x (h) 29 cm x (d) 30 cm
Weight:	6 kg net, overall weight incl. package: 8 kg
Voltage:	230 V / 50-60 Hz
Power consumption:	130 VA
Mains fuse:	2 x 1,25 A medium
Maximum pressure:	2,30 bar
Free flow pressure:	Approx. 500mbar
Maximum flow rate:	Approx. 680 ml / minute at 50 Hz Approx. 820 ml / minute at 60 Hz
Regulation of quantity:	No

2.2. Classification

Protection against electricity, category of safety:	I, grounded chassis
Protection of humidity:	Covered against spillage of liquids
MDD 93/42/EWG classification, supplement IX:	IIa
Medical device according to MPBetreibV supplement 1/2:	No
UMDNS code:	12-300
UMDNS term:	Lavage unit

2.3. Recommended room conditions

Temperature:	10 - 40°C
Relative air humidity:	30 - 75%

2.4. Scope of supply



Figure 1: Scope of supply

- (1) - Endo-Jet 2000 power rinsing device, (main unit)
 - with EJ-2 roll pump tubing system (pre-assembled)
 - with EJ-2 sleeve for roll pump (pre-assembled)
 - with bottle holder (pre-assembled)
 - with pull relief knob (pre-assembled)
 - (2) - Line cord 1.5 m
 - (3) - EJ-2 pneumatic foot switch with 2 m extension tube and male Luer Lock connector
 - (4) - One-Way valves (5 pieces)
 - (5) - EJ-2 Extension rinsing tube, 2 m, FLL + MLL metal
 - (6) - EJ-2 air filter for water bottle plug (3 pieces)
 - (7) - EJ-2 water bottle plug
 - (8) - EJ-2 1 litre water bottle (flask)
- Packaging: carton with 2 cushions (no picture), instruction manual

3. Connecting and implementing the Endo-Jet 2000

3.1. Front panel

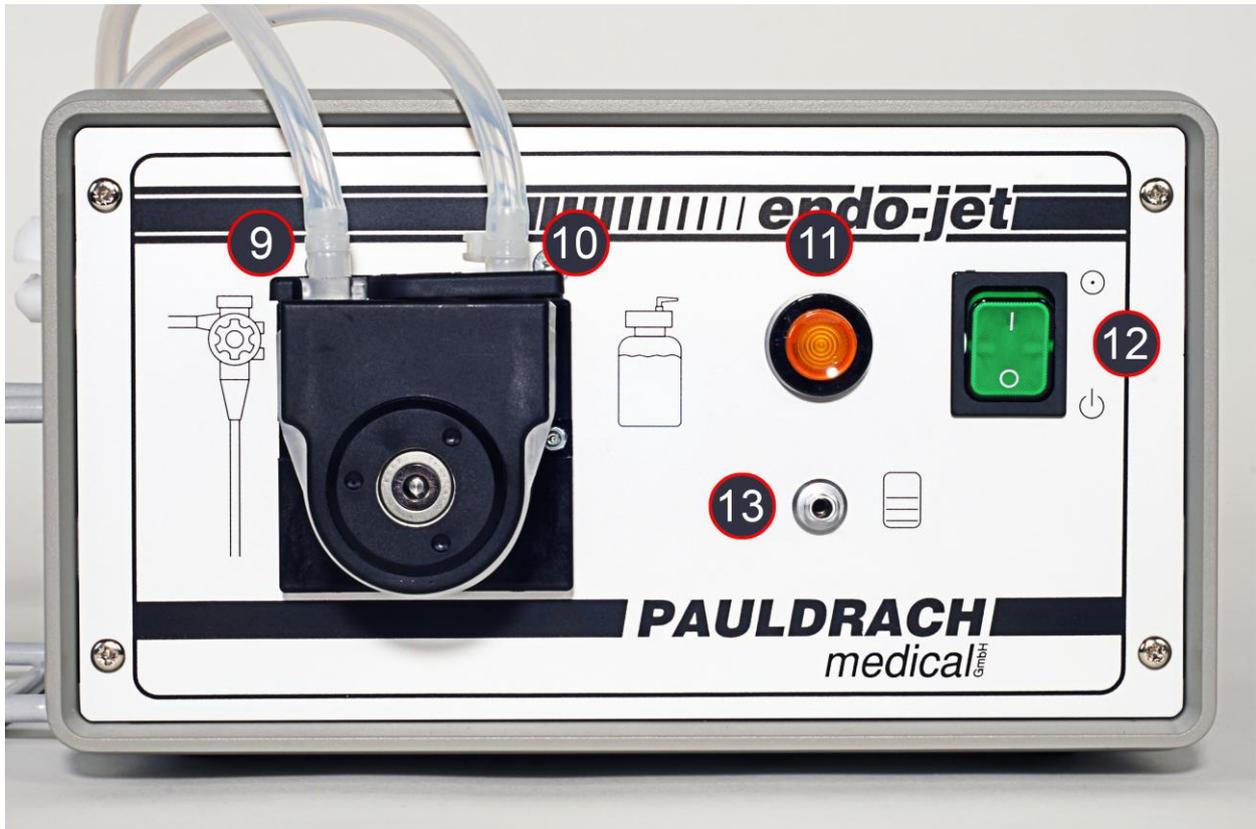


Figure 2: Front panel

- (9) - Pressure-side of roll pump tubing system, goes to endoscope
- (10) - Suction-side of roll pump tubing system, from the water bottle
- (11) - Push button to activate pumping by hand
- (12) - Main switch, symbols: I or \odot = Power ON, O or ⏻ = Power OFF
- (13) - Connector for pneumatic foot switch

3.2. Installation

Memorise the operation conditions, noticed in chapter "Specifications".
Place the EJ-2 on a flat level surface with enough space for air circulation.
Do not place the EJ-2 in explosive areas!

3.3. Line supply



Turn the green main switch (11) OFF.

Insert the right-angle plug into the line jack on the rear panel of the EJ-2 and insert the power plug into the 230 Volts socket.

The installation of the room underlies regulations of medical used rooms. The solid grounding of the EJ-2 is very important.

Figure 3: Plugging line cord

3.4. Setup the roll pump tubing system



Figure 4: Bottle in holder

Place the water bottle (7) in the holder on the left side of EJ-2. Afterwards place the water-bottle plug into the water-bottle opening and the air-filter in the middle drill hole of the water-bottle plug.



Figure 5: Connection suction line

Insert now the metal connector of the suction line of the tubing system in the side hole of the plug.



Figure 6: Pump connectors

The suction line of EJ-2 roll pump tubing system with metal-cylinder connection is located on the right side on top of the pump head and it's labelled with "SUCTION". The connection with male Luer Lock for the pressure line of the EJ-2 roll pump tubing system is located on the left side on top of the pump head and is labelled with "PRESSURE"

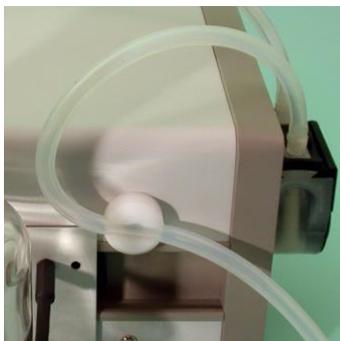


Figure 7: Tube in pull relief

Fix the pressure line of the EJ-2 roll pump tubing system at the white pull relief knob on the left side of the EJ-2 chassis.



Figure 8: Connection of extension rinsing tube

Connect the extension rinsing tube (5) with pressure line of the roll pump tubing system.



Figure 9: Connection to One-Way valve and ISA

Now connect the male Luer Lock of the pressure line with the One-Way valve (7). The further connection goes to the ISA ("Combined Rinsing and Working Adaptor") (visible on picture but not included to standard equipment) or directly to the endoscope. If your endoscope has a special jet channel available, a separate adaptor from the manufacturer possibly necessary, should be used.



Figure 10: Connection to pneumatic foot switch

Connect the male Luer Lock connector of the pneumatic foot switch (3) with the female Luer Lock connector (12) on the front panel of the Endo-Jet 2000 and place the foot switch to an available location on the floor.

3.5. Implementation



Figure 11: Power switch

To switch the EJ-2 on you have to press the green button on the front of EJ-2. The switcher gleams if EJ-2 is on. Now EJ-2 is ready for use.

To switch the Endo-Jet 2000 on, press the green main switch (11) at the front panel of the EJ-2. If power connections are perfectly done, the switcher glows green. Now the Endo-Jet 2000 is ready for use.

4. Operating the Endo-Jet 2000

Fill the water bottle (13) at the beginning of the endoscopic examination with the selected liquid (e.g. sterile filtered water, sterile water or physiological saline solution.)

To start with the power rinsing through the endoscope, press and hold down the foot switch (3) to activate the roll pump. The orange push button (10) will glow as operation control. The rinsing liquid will be transferred through the complete tubing system and the working channel of the endoscope to its distal end, to rinse the working area.



A second possibility to activate the roll pump is to press and hold down the orange push button (10), if manual operation is preferred. As operation control the push button will glow as long as it will be pressed.

Figure 12: Push button for pumping and optical control

Before the first use of the Endo-Jet 2000 press the foot switch or orange push button to fill the complete tubing system with liquid to allow a spontaneous and immediate rinsing.

After inserting the endoscope into the patient, connect either the "Combined Rinsing and Working Adaptor" (ISA) or the EJ-2 extension rinsing tube (10) to the endoscope working channel inlet.

Important advice: First check that the working channel or, if applicable, the rinsing (jet-) channel, is not blocked to ensure there is no possibility of internal pressure building up and exceeding the acceptable endoscope channel pressure level!

Please be aware that an inserted instrument into the working channel minimises the diameter, which will cause a reduction of the biopsy channel diameter and rinsing efficiency. It will be the same while the Endo-Jet is connected to a separate jet channel of an endoscope.

Simultaneous to the use of the Endo-jet you should suck the injected liquid from the patient with a suction pump.

Watch the fluid level in the water bottle (7) permanently and refill liquid in time.

After each use of the Endo-Jet 2000 empty the water bottle and switch off the green main switch (11).

Advice: Don't pump alcoholic or explosive liquids through EJ-2. Don't use the EJ-2 in explosive areas. If you use endoscopes with 2 working channels, the simultaneous application of water and HF-current is strictly forbidden!

5. Care and storage

5.1. Removal of roll pump tubing system



Figure 13: Unlock the sleeve

To take the pump tube out of the pump head, proceed in that way:

Turn the S-shaped locking clamp on the topside of the pump clockwise towards ON.

Remove the pump tubing together with the pump sleeve.

Then separate the pump tubing from the pump sleeve.

Caution! The pump sleeve is not autoclavable!

5.2. Cleaning and disinfection: According to the German Statutory technical order (MPBetreibV) or your domestic state law, cleaning and disinfection of medical products should be handled in a validated procedure. Please see your local state laws and recommendations (like Committee for Hospital Hygiene and Infection Prevention at the Robert-Koch-Institute or the Federal Institute for Drugs and Medical Devices (BfArM) in Germany).

Combined rinsing and working adapter (ISA): After each use, the used ISA should be taken apart as far as possible, cleaned in an ultrasonic cleaner, and disinfected with disinfection solution (Please follow the manufacturer's advice) rinsed and dried .

Tubings, Water Bottle and Water Bottle Plug: All reusable rinsing tubes, peristaltic tubes, water bottles and water bottle plugs having contact with rinsing medium (such as: physiologic salt solution, distilled water, sterile water or tap water) should be changed after each patient or at least once a day and cleaned manually with a validated process.

Storage: All components can be wrapped and sealed in a sterile bag and stored for the next use.

Clean the surface of the Endo-Jet box and the power cord with a wet cloth and non-corrosive disinfectant daily/weekly. Please avoid that moisture comes into contact with electric components. This could result in corrosion and cause electrical malfunctions.

Sterilization: All the silicone tubes and only these tubes can be autoclaved. Before autoclaving they must be separated from all other plastic adapters because they are not autoclavable.

Disposable Products: The one-way valve is a disposable product. If the one-way valve is used together with the "Combined Rinsing and Working Adapter" (ISA), it should be replaced after every patient to prevent contamination. Dispose this item according to legal requirements and your facility's infection control protocols.

This is valid to every application with a "disposable working channel biopsy valve with tube".

Recommendation: Replace the air filter once a week. The air filter is a consumable item and not autoclavable.

Disposable Tubing-set: Disposable tubing-set for Endo-Jet must be changed after each patient and disposed.

5.3. Assembling the roll pump tubing system

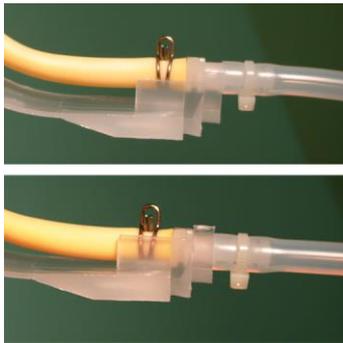


Figure 14: Position of spout in sleeve

Ensure that the reinforced pump tubing is correctly and securely placed into the pump sleeve without kinks or twists the smaller rectangle plastic block sits easily in the rectangle seatings of the pump sleeve. Watch the tubing clip's position should look inside wise.



Figure 15: Insertion sleeve

The pump sleeve is best put back with a light finger pressure from underneath, ensuring that the small wedges are also properly home.



Figure 16: Close locking

Now, close with a counter clockwise twist the S-shaped plastic clamp until it locks in place. The pump sleeve now is correctly re-assembled. Finally check that the PRESSURE and SUCTION tubing ends correspond with the text on pump head.

5.4. Storage

The Endo-Jet 2 as well as all accessories should be stored dry at room temperature. Beware the Endo-Jet and its compounds of impact, topple over and penetration of humidity.

External damages can be a sign for structural inner damages – in this case check the safety of the Endo-Jet 2000.

6. Service and maintenance

6.1. Replacing the fuse

If in any case the green light of the main switch (11) in "ON" position does not glow, please check if:

- the power supply of the used socket is duly,
- the line cord (2) is properly connected or damaged,
- the fuse is not blown.

Replacing of a blown fuse:

- unplug the line cord from power source and disconnect it from the rear panel connector.
- Remove the fuse boxes cap and
- exchange it for others of the same value only. (see specification at label)
- If fuse should blow again, call your distributor or contact *PAULDRACH medical's* service or hotline.

6.2. Ventilation vents

Dust at ventilation vents have to be eliminated with a vacuum cleaner. Don't blow dust into the Endo-Jet!

6.3. Periodical inspection

The user of the Endo-Jet must perform constant checkups of its function. In addition all accessories of the Endo-jet have to be checked as well, especially parts, which came in contact with liquid.

Please check all tubing's regularly of tightness and replace them if they're yellowed or their inner surface is covered with a dirt film.

To check the roll pump tubing system you have to remove it like described at Chapter 5.1. Check the elasticity of the tubing. In case of a refractory looking of the tubing, you should replace it immediately. We recommend an exchange of the reinforced pump tubing once to four times a year according the to the numerous uses.

6.4. MPBetreibV

The Endo-Jet excludes on the device groups, describes in the German Medical Product-Regulation for Operators of Medical Products (MPBetreibV), annex 1 or 2. No personal instruction of this device is required.

6.5. Safety control

To avoid accidents, which can arise because of aging, wear or function breakdown of medical-technical devices you have to organise security checks regularly. Please inform yourself about your federal laws.

The EndoJet-2000 has to be checked once a year.

The main checkups of the Endo-Jet 2000 are:

- Visual examination of good order and condition of accessories
- Ground wire check-up: IEC 60601-1 3rd. Edition
- Isolation check-up: VDE 0751-1
- Electric leakage current check-up: IEC 60601-1 3rd. Edition
- Examination of the Endo-Jet's functions
- Measurement of charging rate to idle speed and full power.

If defects are located during a check-up, which could endanger patients, employees or others, the device has to be taken out of order until an authorised technician or other authorised technical service will eliminate the defects.

7. Consumable material, spare parts and accessories

7.1. Consumable material



REF 182-101-23
EJ-2 Air filter for bottle plug



REF 182-204-12
One-Way valve (10 pieces)



REF 182-101-41
EJ-2 Pump tube with spout

7.2. Spare parts



REF 182-101-40
EJ-2 Roll pump tube system



REF 182-101-42
EJ-2 Pump sleeve



REF 182-101-43
EJ-2 Pump locking



REF 182-101-20
EJ-2 Water bottle 1 litre



REF 182-101-21
EJ-2 Water bottle plug



REF 182-101-30
EJ-2 Pneumatic foot switch



REF 182-101-24
EJ-2 Extended rinsing tube,
2meters, FLL/MLL metal



182-109-25 (10 pieces)
Disposable jet pipe



182-109-27 (10 pieces)
Disposable jet pipe with lance

7.3. Accessories



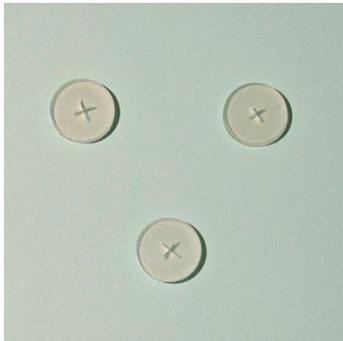
REF 182-201-10
ISA Combined Rinsing and Working Adapter for Olympus, Pentax (plus Adapter), Fujinon series 500, black plastics



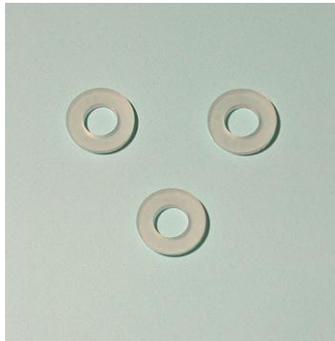
REF 182-302-10
ISA working Adapter essential for Pentax Endoscopes



REF 182-203-10
ISA Combined Rinsing and Working Adapter for Fujinon series 200, black plastics



REF 182-204-10
silicon sealing with cross recess for ISA of plastics, (25 pieces/package)



REF 182-204-11
silicon shim for ISA of plastics, (25 pieces/package)



REF 182-101-26
EJ-2 Tube connector for foreign bottles



182-102-21
Bottle Cap for 1x bottles with LLm connector



182-102-22
Bottle Cap for 1x bottles with CPC connector



182-109-20
CPC-LLm adapter for CPC Bottle Cap

8. Responsibility of the producer

PAULDRACH medical GmbH is responsible for the consequences of security, reliability and engine power of the device, if:

1. Changes, new mountings, extensions, adjustments, modification or repairs will be done by authorised *PAULDRACH medical GmbH* personal only.
2. The electrical installation of the room is to be up to standard of VDE / IEC rules or
3. The device is used as in accordance with this instruction manual.

PAULDRACH medical GmbH is not liable for repairs, modifications, adjustments or the like which are made by technical personal of the user (owner of this device) although they are using technical instructions from the manufacturer. The manufacturer isn't liable for any malfunctions caused by this technical personal, even if they declare this device repairable by the customers.

Guarantee: The Endo-jet 2000 is guaranteed for 12 month from date of purchase, however unauthorised opening of the pump housing or unauthorised repairs (other than user related activities mentioned above) will nullify the guarantee.

Garbsen, October 2003