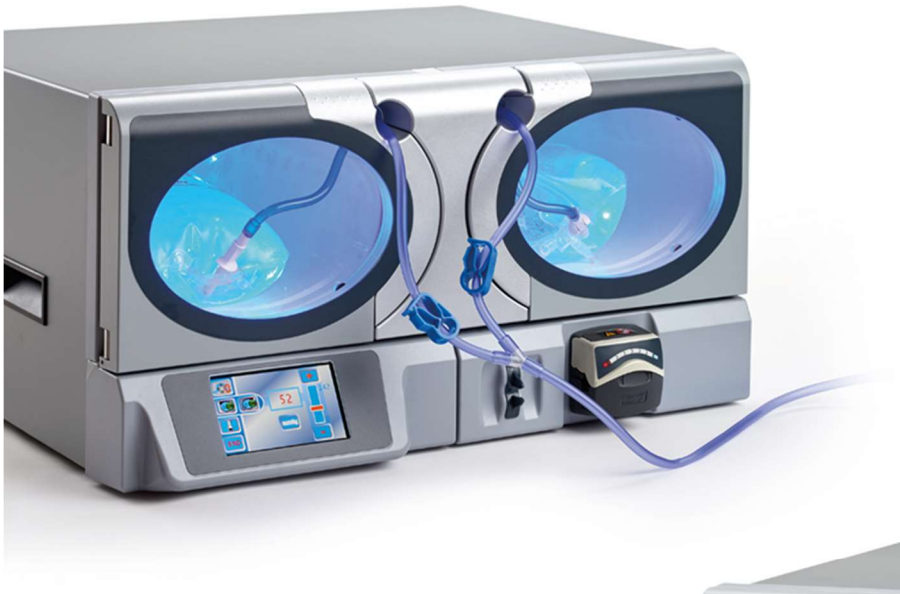
ROCAMED

ENDOFLOW®II

Irrigation, Warming and Suction System



User Manual

(English)

CE 0459

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ENDOFLOW® II Instruction for Use.
REF: MEN01, MEN02P

This revision supersedes and replaces all previous revisions.

Every effort has been made to ensure that the information in this manual is accurate and details provided are correct at the time of printing. The company, however, reserves the right to improve the equipment shown.

ENDOFLOW® is a trademark from ROCAMED SAM.

Contents

1. About this Manual

This Instruction for Use describes the set-up and use of the ENDOFLOW® II Irrigation System.
The manual is intended for qualified healthcare professionals who have knowledge to operate existing devices.

Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions could result in death or serious injury to the patient or user.

2. Description

The ENDOFLOW® II Irrigation System is an irrigation device which can precisely control the intracavity pressure (isostatic pump).
It has the characteristic of heat to body temperature the liquid used.
This non-invasive method employs single-use, disposable, irrigating and suction sets.

The ENDOFLOW® II has to be used exclusively with the ROCAMED Disposable Sets.

ENDOFLOW® II range includes the following devices:

- **MEN01** ENDOFLOW® II single chamber (220-230V, 50/60Hz)
- **MEN02P** ENDOFLOW® II double chamber with aspiration pump (220-230V, 50/60Hz)

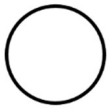
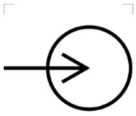
ENDOFLOW® II is provided with the following accessories:

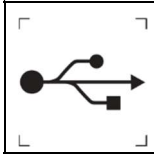
- MENCAIR AIR MEDICAL HOSE adapted to customers fittings;
- MENELEC POWER SUPPLY CORD adapted to customers plug, socket and voltage.

ENDOFLOW® II can also be controlled for specific function by a footswitch.

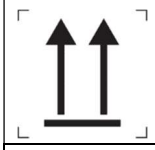
- MENP2RY DOUBLE FOOT-SWITCH "SUCTION SPEED AND BOOST PRESSURE".

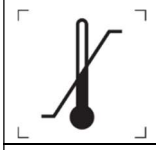
3. Symbols Used on Labeling

SYMBOL	DESCRIPTION
CE	CE marking. Conforms to the European Union regulation.
MD	Medical Device
REF	Catalog number
	Refer to instruction manual/booklet
	OFF Main electrical power off.
	Alternating Current.
	Equipotential Terminal
	Input
IP20	Protection against ingress of fingers or similar objects
	Foot Switch
	Radio-Frequency (RF) energy (non-ionizing radiation)

SYMBOL	DESCRIPTION
	Manufacturer
	Distributor
SN	Serial number
	Caution
	ON Main electrical power on.
	Circuit breaker, fuse.
	Equipment Classification Only tank for user and accessories for patient are considered as Type BF Applied Part.
	DO NOT Allow Fingers to Contact Moving Parts
	General warning sign
	Manual cleaning
	Universal Serial Bus (USB), port/plug

Symbol used only on packaging:

SYMBOL	DESCRIPTION
	This way up
	Fragile; handle with care

SYMBOL	DESCRIPTION
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

4. Indication for Use

4.1. Intended purpose

The ENDOFLOW® II is intended to both irrigate and aspirate body cavities and wounds typically during an endoscopic surgical procedure (Urology, Gynecology and General Surgery), usually to facilitate observation. It is intended to remove tissues/fluids/debris through suction, and to irrigate the surgical site with a sterile fluid (e.g., saline).

4.2. Intended user

The ENDOFLOW® II is intended to be used in medical facilities under direction of a qualified physician who have knowledge to operate existing devices.

4.3. Intended use conditions

The ENDOFLOW® II is intended to be used in medical facilities, such as are a surgical suite in a hospital environment.
The ENDOFLOW® II is designed to be used in operating room according to standards in force in the country of use. Appropriate values of temperature and humidity are required for the proper functioning of the device.

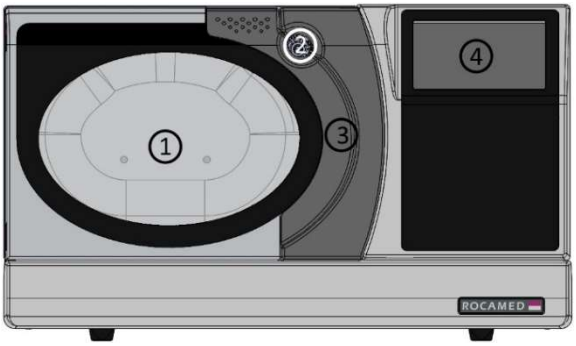
4.4. Intended patient population

The ENDOFLOW® is intended to be used on adult patients only.

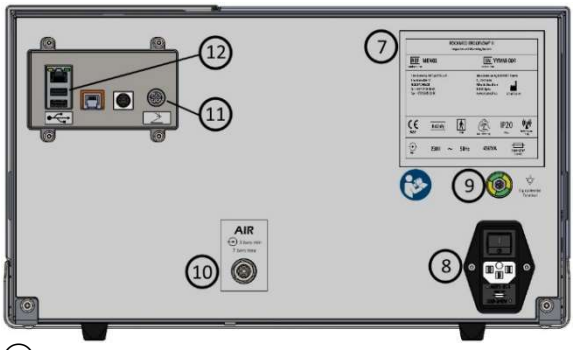
5. Operating Instruction

5.1. Device Description

5.1.1. MEN01 & MEN01US

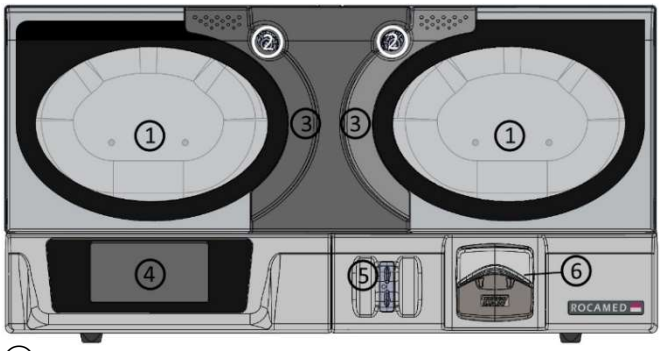


① = Pressurization and Warming chamber
② = Housing for the seal plug
③ = Automated opening door
④ = Touch screen control panel

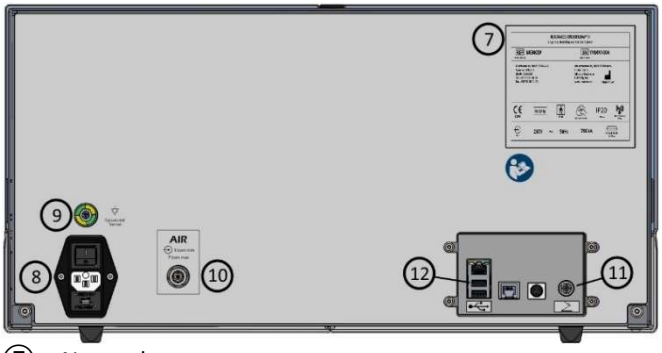


⑦ = Nameplate
⑧ = Electrical connection
⑨ = Equipotential connection
⑩ = Pneumatic connection
⑪ = ROCAMED footswitch connection
⑫ = USB connection for Software Update

5.1.2. MEN02P & MEN02PUS

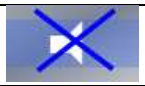
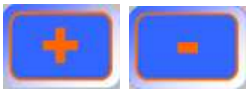


① = Pressurization and Warming chamber
② = Housing for the seal plug
③ = Automated opening door
④ = Touch screen control panel
⑤ = Suction pipe detection switch
⑥ = Peristaltic suction pump



⑦ = Nameplate
⑧ = Electrical connection
⑨ = Equipotential connection
⑩ = Pneumatic connection
⑪ = ROCAMED footswitch connection
⑫ = USB connection for Software Update

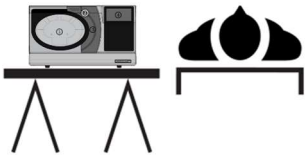
5.2. Signification of Touch Screen Icons

SYMBOLS	FUNCTIONS	COMMENTS
	Settings Menu	Provides access to the options menu of the machine
 	Sound	In the Settings menu: Enable or disable the beep of the machine.
 	Brightness	In the Settings menu: Adjusts the screen brightness (High or Low).
	Date/Hour	In the Settings menu: Sets the date and time of the machine.
	Heater	RED HALO = ON BLINK = Warming in progress
	Door	Door closed Chamber under pressure
		Door closed Depressurization of the chamber in progress
		Door open
	RFID	Used to validate the correct RFID detection of the disposable set connected to the device.
	Pressure	Allows you to increase or decrease the pressure (see Specifications)
	Units	Allows you to change the units of pressure.
	Suction speeds	Only with MEN02P & MEN02PUS (see Specifications)
	End of the intervention	Used to finish the procedure. The chambers are depressurized. A second END press button will be display to validate the end of the procedure.
	Next screen	When this icon is present, several screens are visible. Pressing this button will display one by one the different screens.
	Back	When this icon is present, return to the previous screen is possible

5.3. Set-Up for Use

5.3.1. Positioning of the device

The device must be placed at the same height as the patient to ensure that the pressure displayed on the ENDOFLOW® II screen correspond to the pressure in the surgical cavity.



ENDOFLOW® II requires caution with respect to Electromagnetic Compatibility (EMC) and must be operated according to EMC information in this document.

Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the power supply or battery charger, including cables. Otherwise, degradation of the performance of this equipment could result.

ENDOFLOW® II should not be used adjacent to or stacked with other equipment.
It could result in improper operation. If such use is necessary, ENDOFLOW®II and other equipment should be observed to verify that they are operating normally.

The device is not designed to operate in areas with risk of explosion. This means among other things that, in case of use of anesthetics by inhalation flammable and explosive, or mixtures in which they are contained, the device must not be put into service within the area risks described. This also applies for flammable and explosive chemicals, such as disinfectants and skin disinfectants fast surface

5.3.2. Electrical Connection

Connect the equipment using the power cord to the wall socket

Before use, make sure that the electrical installations of the operating room meet the standards (IEC) and make sure to use only CE marked electrical connections and / or meets the standards for these connections (standard or ISO standard in force in the country of use).

Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.

Exposed conductor on MAINS power cord can cause an electrocution hazard. Remove device from service if MAINS power cord has exposed wires.

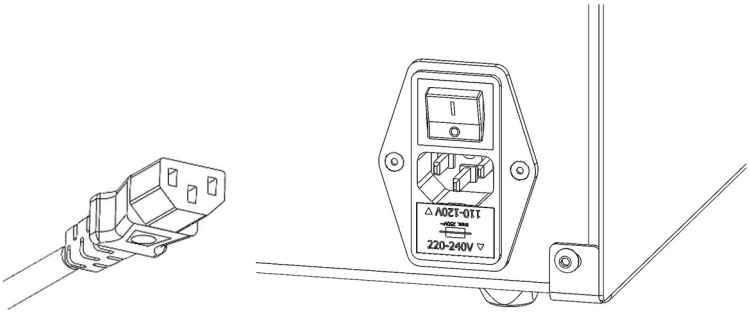
The unit is equipped with a connector for equipotential whose connection must be made in accordance with national regulations.

Use of accessories, transducers and cables other than those provided by the manufacturer could result in increased electromagnetic EMISSIONS or decreased electromagnetic IMMUNITY of the ENDOFLOW® II and result in improper operation.

The ENDOFLOW® II is for use only with ROCAMED supplied or approved parts or accessories. The device may not function as intended with the use of unapproved parts or accessories.

Do not interrupt the protective earth and do not use in combination with an adapter or an extension.

Do not position the ENDOFLOW® II so that it difficult to operate the disconnection of the device.

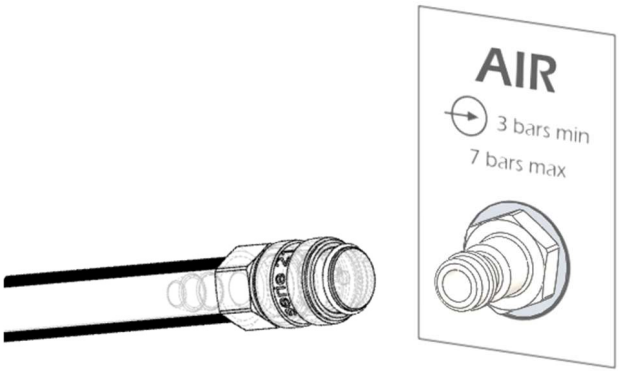


5.3.3. Pneumatic Connection

Connect the air supply hose to the air medical wall socket.

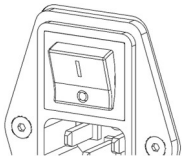
Connect the air supply hose to the device.

On device side, do not try to screw the connector. This is a push-pull connector. Push the connector until the “clic”.



5.3.4. Turn ON

Turn on the switch on the rear panel.
A beep is heard. An orange light lights the chambers.
If no problem occurs during startup, the chambers are lit in blue and the touch screen is turn on.
The firmware version is displayed.

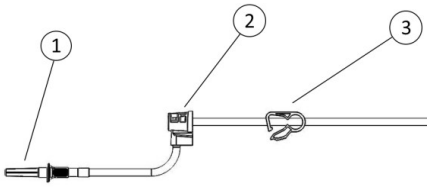


5.3.5. Warming

Touch the heater symbol on the touch screen.
During the warm-up state, the heat button is blinking.

5.4. Using the ENDFLOW®II

5.4.1. Irrigation



Connection part of ROCAMED Irrigation Tubing
① = Spikes (pouches side)
② = Seal plugs
③ = Clamps

The ENDOFLOW® II is for use only with ROCAMED Disposable Sets. The device may not function as intended with the use of unapproved Disposable Sets.

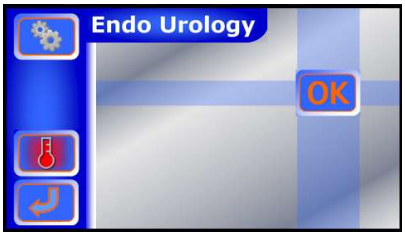
All ROCAMED set are disposable products and **SHOULD NEVER BE REUSED OR RE-STERILIZED AFTER AN INTERVENTION** to reduce the risk of cross contamination.

The system is only intended for use with flexible fluid containers.

The assistant located in the sterile area should hold the end of the set used for irrigation (patient side) and give the opposite end (pouch side) to the assistant in charge of connecting it to the ENDOFLOW®II.

Close the clamp (3) of the irrigation set.

Remove the protective cap and place the spike (1) into the bag.

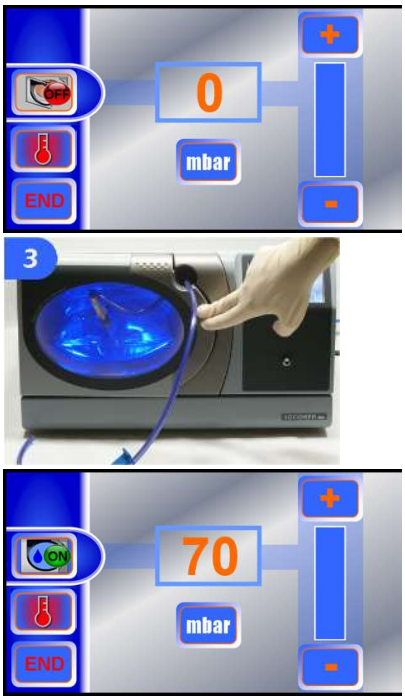


Place the seal plug (2) in its holder.

RFID detects the set and the associated application. Confirm by pressing OK if the application is correct.

If the irrigation set detected is not the expected one, disconnect the set and select the return button.

The following screen appears.



Select the desired pressure units.

Close the door gently to the first click. Then the door locks automatically.

The bag is pressurized.

Open the clamp on the irrigation set.

5.4.2. Changing the fluid Bag

Close the clamp of the irrigation set.

Open the door by pressing the door symbol 

When the button is pressed, button status change to 

and tank depressurization is in progress.

Wait a few seconds during the chamber depressurization.

The door opens automatically.

REPLACE THE FLUID BAG.

You are free to disconnect the irrigation set. Reconnect it before placing the new bag inside the chamber.

Check to have correctly connected the fluid bag to the associated Rocamed tubing set before closing the Endoflow pressure chamber.

Extreme precaution must be taken when handling liquids around electrical equipment. DO NOT operate the ENDOFLOW® II if liquid has been spilled on the unit.

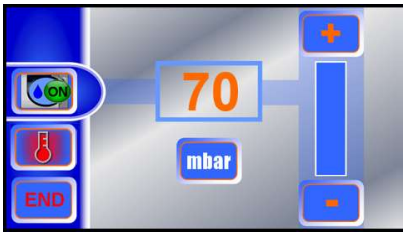
In case of accidental perforations, or fluid leaks from a defective fluid bag, or leaks due to improper handling, immediately turn off the device and ideally, disconnect the plug from the electrical outlet on the wall.

In the event the machine shuts off for safety reasons before the door can be automatically opened, after disconnecting the plug from the wall outlet, then use the hook located under the device to open the door.

Wipe up the fluid inside the machine as rapidly as possible and continue the operation with another machine or a gravity feed.

ROCAMED highly recommends that the user return the machine to ROCAMED for an inspection of the product.

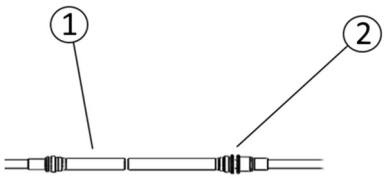
Close the door gently to the first click. Then the door locks automatically.



Chambers is pressurized.

Open the clamp of the irrigation set.

5.4.3. Suction

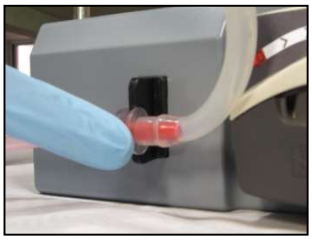


Connection part of ROCAMED Suction Tubing
① = Flexible part of the pipe
② = Keying system connector

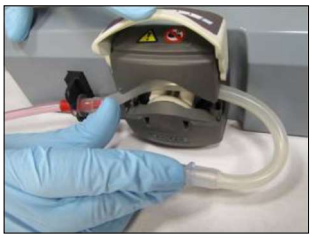
The ENDOFLOW® II is for use only with ROCAMED Disposable Sets. The device may not function as intended with the use of unapproved Disposable Sets.

All ROCAMED set are disposable products and **SHOULD NEVER BE REUSED OR RE-STERILIZED AFTER AN INTERVENTION** to reduce the risk of cross contamination.

Set-up:



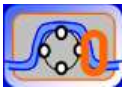
Clip the keying system connector (3) to its housing.



Place the flexible part of the pipe (2) in the pump head and close the cover.

Speed Selection:

Press the pump symbol on the top left of the touch screen.



Header speed selection appears.

Select the desired speed.

The pump starts at the selected speed.

5.5. Peripherals

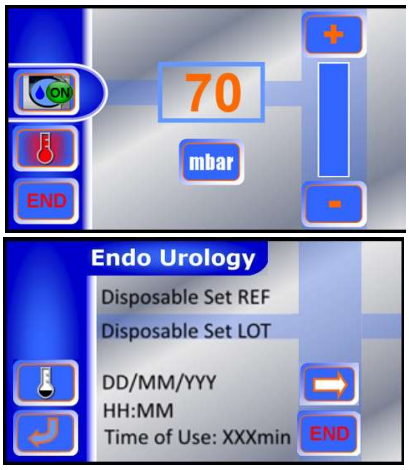
The foot switch connects to the connector on the rear panel.

- The yellow foot switch increases the irrigation for a given time (see Specifications).
- The red foot switch is used to control the suction speed (only with MEN02P).

Use of peripherals other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the ENDOFLOW® II

The ENDOFLOW® II is for use only with ROCAMED peripherals. The device may not function as intended with the use of unapproved peripherals.

5.6. After Use



Close all clamps;

Press the END button and wait for complete chamber depressurization.

END

Press the END button again to confirm the end of the procedure.

END

When door is/are opened, remove the fluid bag.
Disconnect the Disposable Set.

Turn Off the device.
Close the door.

5.7. Cleaning after Use

ENDOFLOW® II cannot be sterilized.

Cleaning is required after each use on a patient. There are no specific disinfecting agents to use. The device has been designed and the covers are resistant to all standard disinfectants.
ENDOFLOW®II chambers are designed in order to avoid any leakage on electronic or electrical parts.

Use an alcohol-free solution to clean the screen.
Spray the solution on a microfiber cloth. Pass the soaked cloth over the screen without pressing and wipe until the product has completely evaporated.
It is recommended not to spray the screen directly.

6. Troubleshooting

ERR n°	Description	Actions required
ERR06	Irrigation set connected to Left chamber is Expired	Use another Irrigation set
ERR08	Application on Left chambers Different	Check that the two pipes are for the same application
ERR11	Irrigation set already used on Left chamber	Use another Irrigation set
ERR17	Irrigation set connected to Right chamber is Expired	Use another Irrigation set
ERR19	Application on Right chambers Different	Check that the two pipes are for the same application
ERR21	Irrigation set already used on Right chamber	Use another Irrigation set
ERR30	Left Lock Door System	Call ROCAMED customer service
ERR31	Right Lock Door System	
ERR33	No signal on Left chamber Pressure sensor	
ERR34	No signal on Right chamber Pressure sensor	
ERR35	Left chamber Temperature sensor	
ERR36	Left bag Temperature sensor	
ERR40	Right chamber Temperature sensor	
ERR41	Right bag Temperature sensor	
ERR44	Left chamber Failure Pressure	
ERR45	Right chamber Failure Pressure	
ERR46	No Input Air	Check the air connection at the rear of the machine.
ERR47	Suction Pump Default	Verify that he Suction Set is correctly positioned.
ERR49	Left chamber pressurization failure	Call ROCAMED customer service
ERR50	Right chamber pressurization failure	
ERR51	Left chamber depressurization failure	
ERR52	Right chamber depressurization failure	

7. Limited Warranty

ROCAMED warrants to the Original Purchaser that ENDOFLOW® II shall be free from defects in materials and workmanship under normal use, if used in accordance with this Instruction for Use, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its discretion without charge (except for a minimal charge for postage and handling) any ENDOFLOW® II which is defective if a claim is made during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty:
This warranty extends only to the Original Purchaser of the ENDOFLOW® II. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases ENDOFLOW® II for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. Warranty Performance Procedure:
Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows:

Notice to the Manufacturer must include date of purchase, model, serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE ENDOFLOW® II. If authorized, the ENDOFLOW® II must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty:
The warranty is void if the ENDOFLOW® II Irrigation, Warming and Suction System has been:
- repaired by someone other than the Manufacturer or its authorized agent;
- altered so that its stability or reliability is affected;
- misused;
- damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Instruction for Use or use with non-approved accessories. Removal or damage to the ENDOFLOW® II serial numbers will invalidate this warranty.

D. Limitations and Exclusions:
Repair or replacement of the ENDOFLOW® II or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:
- No agent, representative, or unauthorized employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied;
- There is no warranty of merchantability or fitness or use of the ENDOFLOW® II for any particular purpose.
- The ENDOFLOW® II can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the ENDOFLOW® II for any particular medical treatment.
- All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the ENDOFLOW® II for any particular medical treatment or for any medical complications resulting from the use of the ENDOFLOW® II. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the ENDOFLOW® II.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

8. Service

Do not modify this equipment without authorization of the manufacturer.
All service must be performed by ROCAMED, or an authorized service representative. Service by any other person or organization voids the warranty and transfers liability for malfunctions of the device to the servicing organization.

8.1. Warranty Service

Units received for repair which have not been obviously abused or impact damaged and are still under warranty will be promptly repaired and returned at no charge. See the limited warranty section of this manual.

8.2. Non-Warranty Work

Units received which have suffered obvious abuse or impact damage and units no longer under warranty will be promptly inspected and a verbal estimate of repair cost will be supplied. A purchase order will be required from the hospital consistent with the verbal estimate. A written estimate will be provided upon request. Before returning your ENDOFLOW® II for service, contact ROCAMED for authorization of returned goods.

8.3. Expected Service Life

All components of the ENDOFLOW® II have an expected service life of 5 years.

8.4. Destruction

Destruction of the ENDOFLOW® II: Return the device to the distributor, who will send it to the manufacturer, which is the only entity authorized to dismantle and recycle the components of the ENDOFLOW® II (in accordance with WEEE Directive).

8.5. Service Contacts

ROCAMED SAM
Z.I. de Signes
40 Allée de Varsovie
83870 SIGNES
FRANCE
sav@rocamed.com
Tél : +33 6 08 60 30 81

9. Maintenance

9.1. Preventive Maintenance

ENDOFLOW® II has been designed with 2 sensors for the same measurand (pressure and temperature) for redundancy reason.
By design, we have made the choice to stop the function if the two sensors are not giving the same information.
For that reason, device do not require preventive maintenance.
For the same reason, no auto-test is needed.

9.2. Fuse Change

To replace the fuses, unplug the machine by removing the plug from the wall outlet, remove the fuse box door from the power supply plug on the back using a flat, straight tool, and replace the 2 used fuses with 2 new identical fuses.

9.3. Manual Door Opening

If the door have to be manually opened:

- device must be turn off;
- electrical power cord and air medical flexible must be disconnect form the device;
- then, pull the hook under the device to open the door manually.

9.4. Other

For other maintenance, please contact Service Department (see §8.5).

10. Specification

10.1. General

Classification according to Medical Device Directive 93/42/EEC	Class IIa

10.2. Dimensions and Weight

Product References	**MEN01**	**MEN02P**
Dimensions (mm)	L=400 x P=425 x H=240	L=520 x P=450 x H=240
Weight (kg)	13 kg	21 kg
Chamber capacity	Standards bags from 1L to 3L.	

10.3. Electrical & Pneumatic

Products References	**MEN01**	**MEN02P**
Input Voltage	220V-230V	220V-230V
Frequency	50/60Hz	50/60Hz
Puissance	500VA	1000VA
Safety fuse	F10AH250V	
Protection against electric shock	Class I	
Degree of electric shock protection	Type BF	
Input Air	3 to 7 bars	

10.4. Performance

10.4.1. Irrigation

The ENDOFLOW® II is provided with a pressure control system.

Pressure Range	Accuracy
0 – 350 mbar	±30%
350 – 1000 mbar	±10%

10.4.2. Temperature

The ENDOFLOW® II is provided with a regulated temperature system.

	Set point	Accuracy
Temperature	38°C	±2°C

10.4.3. Suction

Suction flow depends on the rotational speed of the pump:

	Flow (ml/min)
Speed 0	0 ml/min
Speed 1	51 ml/min
Speed 2	77 ml/min
Speed 3	102 ml/min
Speed M	290 ml/min

Flow rate tests were carried out using water at zero suction pressure and Bioprene tubing, with the pump head rotating clockwise. Actual flow rates achieved may vary because of changes in temperature, viscosity, inlet and discharge pressures, system configuration.

10.4.4. Boost (Irrigation)

This function is only available with the Foot Switch ROCAMED peripherals.
It increases temporarily the pressure according to the application.

Application	Increase of pressure	Duration
Laparoscopy	100 mbar	30s±5s
Arthroscopy	40 mbar	30s±5s
Hysteroscopy	20 mbar	30s±5s
EndoUrology	20 mbar	30s±5s

10.4.5. RFID

RF Type	Transmitter
Frequency	13.56MHz
Output power	Less than 200mW
Bandwidth	13M56K8XXN
Type of Modulation	ASK 10%

10.5. Normal Use

ENDOFLOW® II is designed to be used in operating room according standards in force in the country of use. Appropriate values of temperature and humidity are required for the proper functioning of the device. The working temperature of the device should be between 10°C and 30°C, while humidity should not exceed 65%.

10.6. Storage

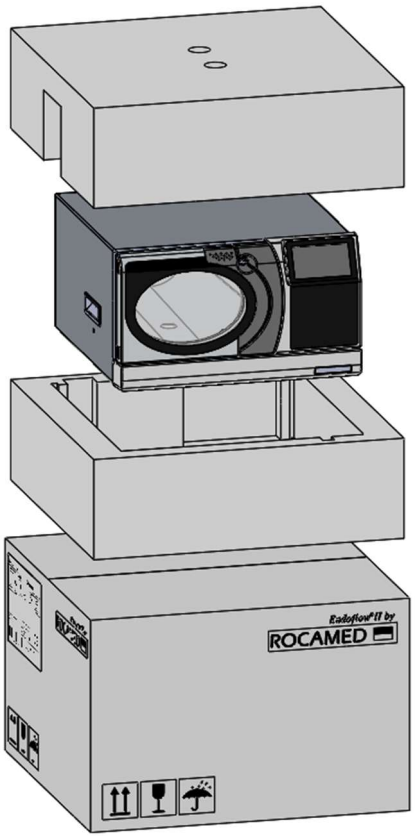
The ENDOFLOW® II should be stored in the following environmental conditions:

- Temperature: [6°C ; 70°C] / [43°F; 140°F]
- Humidity: [0% ; 90%]
- Pressure: [59.5kPa ; 101.3kPa]

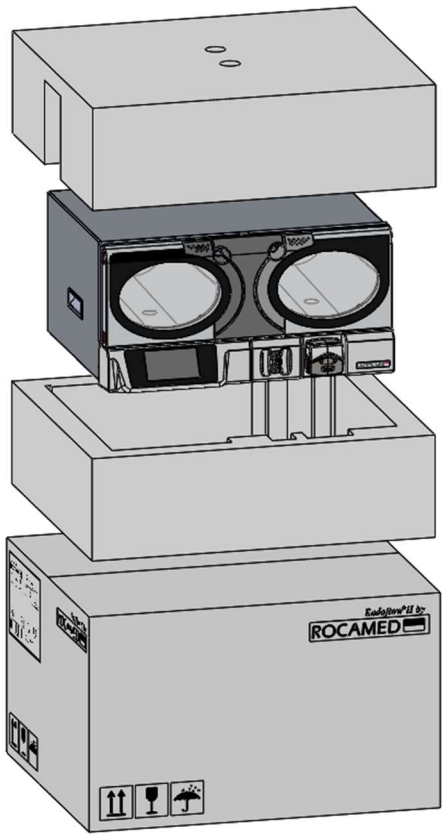
10.7. Shipping

Keep the original packaging for future shipping requirements of the device. ROCAMED disclaims any liability for damage to the ENDOFLOW® II if it is not shipped in its original packaging.

MEN01 & MEN01US



MEN02P & MEN02PUS



11. Electromagnetic Compatibility (EMC) Information

ENDOFLOW® II, is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

IEC 60601-1-2 ed.4.1 **Manufacturer's guidelines and statement - ELECTROMAGNETIC EMISSIONS**		
Emissions test	**Compliance**	**Electromagnetic environment - guidelines**
RF Emissions CISPR 11	Group 1	ENDOFLOW® II uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause interference with neighboring electronic devices.
RF Emissions CISPR 11	Class A	ENDOFLOW® II is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable	

IEC 60601-1-2 ed.4.1 **Manufactures guidelines and statement - ELECTROMAGNETIC IMMUNITY**			
IMMUNITY test	**Test level**	**Compliance**	**Electromagnetic environment - guidelines**
Electrostatic discharges (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Compliant	The flooring should be made of wood, concrete, or ceramic tile. If the floor is covered with synthetic materials, the relative humidity must be at least 30%.
Radiated RF EM field IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Compliant	Portable and mobile RF communications equipment should be used no closer to any part of ENDOFLOW® II, including cables.
IMMUNITY to proximity fields from RF wireless communications equipment, IEC 61000-4-3	Levels of table 9 below	Levels of table 9 below	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 80% AM at 1kHz 6 V in ISM radio bands between [0.15MHz-80MHz]	Compliant	
Electrostatic fast transient / burst IEC 61000-4-4	±2 kV for AC power lines ±1 kV for input/output lines	Compliant	Main power quality shall be that for a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Compliant	

Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	0% U_T for 0.5 cycles at: 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle 70% U_T for 25/30 cycles at 0°.	Compliant	
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz or 60Hz	Compliant	Power frequency magnetic fields should be at levels characteristic of a location in a typical commercial or hospital environment.
Radiated fields in close proximity IEC 61000-4-39	65 A/m (134.2 kHz) 7.5 A/m (7.5 kHz)	Compliant	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Modulation	Immunity test level (V/m)
385	Pulse modulation 18 Hz	27
450	FM, ± 5 kHz deviation 1 kHz sine	28
710	Pulse modulation 217 Hz	9
745		
780		
810	Pulse modulation 18 Hz	28
870		
930		
1720	Pulse modulation 217 Hz	28
1845		
1970		
2450	Pulse modulation 217 Hz	28
5240	Pulse modulation 217 Hz	9
5500		
5785		

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