ROCAMED

# ENDOFLOW®II

Irrigation, Warming and Suction System



## Instruction For Use

NOTE-MEN-EN rev07 (16.01.2020)

CE
0459

ENDOFLOW® II Instruction for Use.
REF: MEN01, MEN01US, MEN02P, MEN02PUS
CE marked on: 20 September 2013

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 PROMEPLA SAM.

# Contents

## 1. About this Instruction For Use

This Instruction for Use describes the set-up and use of the ENDOFLOW® II Irrigation System.
The manual is intended for use by individuals trained in the healthcare and biomedical professions.

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 (230V, 50Hz)
- **MEN01US** ENDOFLOW® II single chamber (120V 60Hz, 100V 50/60Hz)
- **MEN02P** ENDOFLOW® II double chamber with aspiration pump (230V, 50Hz)
- **MEN02PUS** ENDOFLOW® II double chamber with aspiration pump (120V 60Hz, 100V 50/60Hz)

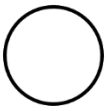
ENDOFLOW® II is provided with the following accessories:

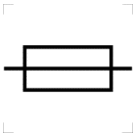
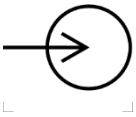
- MENCAIR AIR MEDICAL HOSE adapted to customers fittings;
- MENELEC POWER SUPPLY CORD adapted to customers plug, socket and voltage.

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 0459 | CE marking.<br>Conforms to the European Union Standards. |
| REF | Catalog number |
|  | Refer to instruction manual/booklet |
|  | OFF<br>Main electrical power off. |
|  | Alternating Current. |
|  | Equipotential Terminal |
| IP20 | Protection against ingress of fingers or similar objects |
|  | Foot Switch |
|  | Radio-Frequency (RF) energy (non-ionizing radiation) |
| RxOnly | U.S. federal law restricts this device to sale by or on the order of a physician |

| SYMBOL | DESCRIPTION |
|---|---|
|  | Manufacturer |
| SN | Serial number |
|  | Equipment Classification<br>Only tank for user and accessories for patient are considered as Type BF Applied Part. |
|  | ON<br>Main electrical power on. |
|  | Circuit breaker, fuse. |
|  | Input |
|  | DO NOT Allow Fingers to Contact Moving Parts |
|  | Manual cleaning |
| 2AFDC-MEN01US<br>2AFDC-MEN02PUS | This device complies with Part 15 of the FCC Rules and with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation |
| 20423-MEN01US<br>20423-MEN02PUS | Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement. |

Symbol used only on packaging:

| SYMBOL | DESCRIPTION |
|---|---|
|  | This way up |
|  | Fragile; handle with care |
|  | Keep away from rain |

| SYMBOL | DESCRIPTION |
|---|---|
|  | Temperature limit |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |

Symbol used only on single use devices packaging:

| SYMBOL | DESCRIPTION |
|---|---|
|  | Do not reuse |
|   | Sterilized using ethylene oxide |
|  | Use by |
|   | Batch code<br>LOT number |
|  | Do not use if package is damaged |
|   | This device is not made with natural rubber latex |

## 4. Indication for Use

The ENDOFLOW® II Irrigation, Warming and Suction System is indicated for use in medical facilities under direction of a trained physician during endo-urology, hysteroscopy and laparoscopy procedures in order to fill/wash the concerned working cavities.

## 5. Important Safety Information

WARNING

- **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**

Environmental

- The conditions of use, storage and transport must be respected;
- 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.

Electrical

- 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)
- ENDOFLOW® II requires caution with respect to Electromagnetic Compatibility (EMC) and must be operated according to EMC information in this document;
- ENDOFLOW® II can be affected by portable and mobile Radio Frequency (RF) devices;
- ENDOFLOW® II should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ENDOFLOW® II should be observed to verify normal operation in the configuration in which it will be used;
- Use of accessories and peripherals other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the ENDOFLOW® II;
- 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;
- 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.
- Do not position the ENDOFLOW® II so that it difficult to operate the disconnection of the device.

Disposable Sets, Accessories, Peripherals

- The ENDOFLOW® II is for use only with ROCAMED supplied or approved parts, accessories, peripherals and Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, peripherals or Disposable Sets;
- All ROCAMED set are disposable products. They are supplied double bagged, sterilized with ethylene oxide gas and **SHOULD NEVER BE REUSED OR RE-STERILIZED AFTER AN INTERVENTION** to reduce the risk of cross contamination;
- Use of other sets modifies the operation of the device. ROCAMED cannot be held responsible for the disturbance;
- Sets in which the integrity of the packaging does not guarantee the sterility should not be used.

Cleaning

- Do not use bleach or industrial detergents;
- ENDOFLOW® II cannot be sterilized.

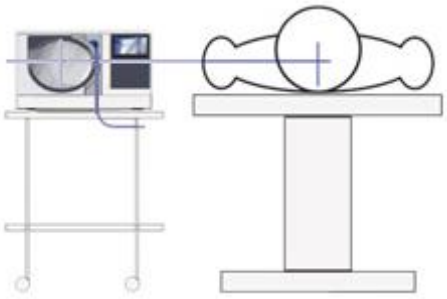
Service

- Do not modify this equipment without authorization of the manufacturer.

CAUTION

- Federal law (U.S.A.) restricts this device to be sale by or on the order of a physician.

- To ensure that the pressure displayed on the screen ENDOFLOW® II is the same as the pressure in the surgical cavity, the machine must be placed at the same height as the patient.

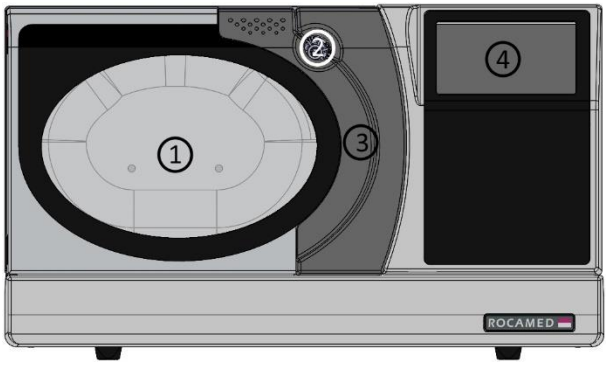


- In case of accidental perforations, or fluid leaks from a defective fluid bag, or leaks due to improper handling, immediately turn off the device (On/Off button on the rear panel) and ideally, disconnect the plug from the electrical outlet on the wall.
  In the event the machine shuts off for safety 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.

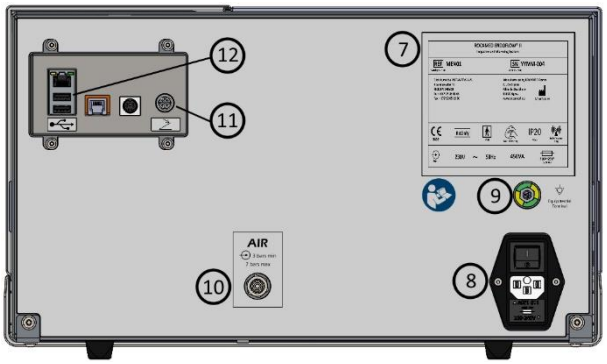
# 6. Operating Instruction

## 6.1. Device Description

### 6.1.1. MEN01 & MEN01US

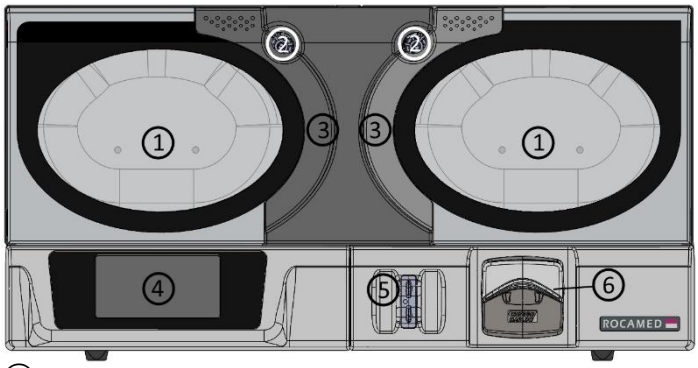



① = Pressurization and Warming chamber
② = Housing for the seal plug
③ = Automated opening door
④ = Touch screen control panel

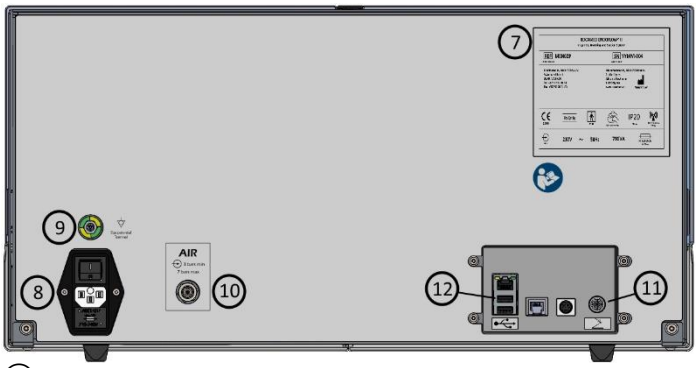



⑦ = Nameplate
⑧ = Electrical connection
⑨ = Equipotential connection
⑩ = Pneumatic connection
⑪ = ROCAMED footswitch connection
⑫ = USB connection for Software Update

### 6.1.2. MEN02P & MEN02PUS

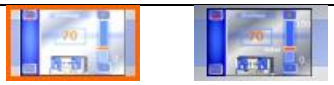
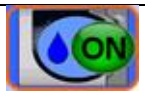
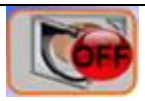
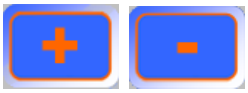
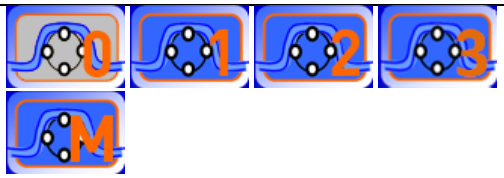



① = Pressurization and Warming chamber
② = Housing for the seal plug
③ = Automated opening door
④ = Touch screen control panel
⑤ = Suction pipe detection switch
⑥ = Peristaltic suction pump




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

### 6.2. Signification of Touch Screen Icons

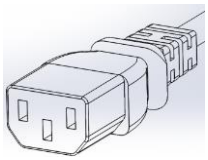
| SYMBOLS | FUNCTIONS | COMMENTS |
|---|---|---|
|  | Settings Menu | Provides access to the options menu of the machine |
|  | Sound | In the Settings menu:<br>Enable or disable the beep of the machine. |
|  | Brightness | In the Settings menu:<br>Adjusts the screen brightness (High or Low). |
|  | Date/Hour | In the Settings menu:<br>Sets the date and time of the machine. |
|  | Heater | RED HALO = ON<br>BLINK = Warming in progress |
|  | Door | Door closed<br>Chamber under pressure |
|  | | Door closed<br>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<br>(see Specifications) |
|  | Units | Allows you to change the units of pressure. |
|  | Suction speeds | Only with MEN02P & MEN02PUS<br>(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 |

## 6.3. Set-Up for Use

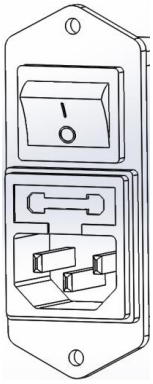
### 6.3.1. Electrical Connection

Connect the equipment used using the power cord to the wall socket.
Do not interrupt the protective earth and do not use in combination with an adapter or an extension.

Cable Connection



Device Connection



### 6.3.2. Pneumatic Connection

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

For MEN01 and MEN02P, do not try to screw. Push until the clic.

For MEN01US and MEN02PUS, screw the connector.

Cable Connection Device Connection

### 6.3.3. Turn ON

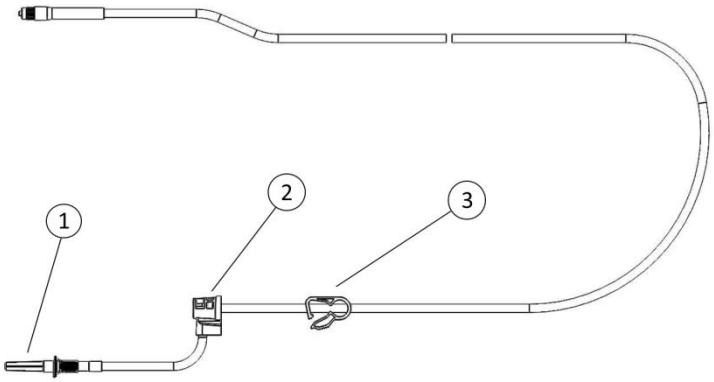
Turn on the switch on the rear panel.
A beep is heard. An orange light lights the chambers.
If no problem occurs during startup, the chambers are lit in blue and the touch screen is turn on.
The firmware version is displayed.

### 6.3.4. Warming

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

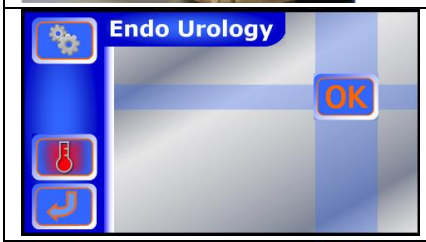
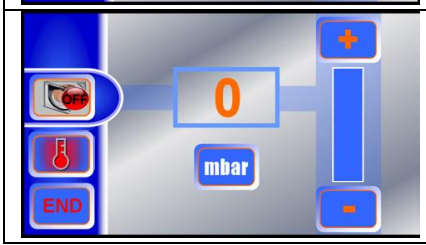
## 6.4. Using the ENDFLOW®II

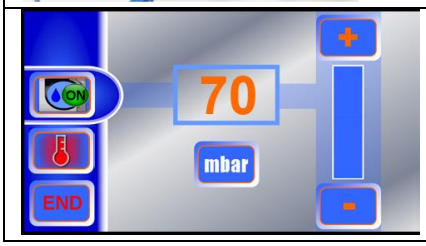
### 6.4.1. Irrigation




① = Spikes (pouches side)
② = Seal plugs
③ = Clamps

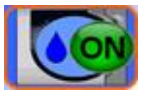
The assistant located in the sterile area should hold the end of the set used for irrigation (patient side) and give the opposite end (pouch side) to the assistant in charge of connecting it to the ENDOFLOW®II.

| | |
|---|---|
|   | 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;<br><br>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;<br>mbar mmHg $cmH_2O$ |

| | |
|---|---|
|  | Close the door gently to the first click. Then the door locks automatically; |
|  | The bag is pressurized; |
| | Open the clamp on the irrigation set. |

### 6.4.2. 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.

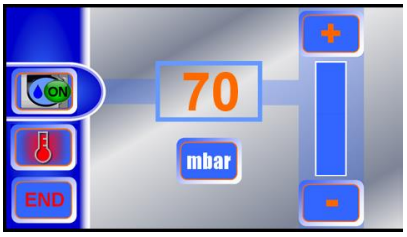
Wait a few seconds during the chamber depressurization;

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

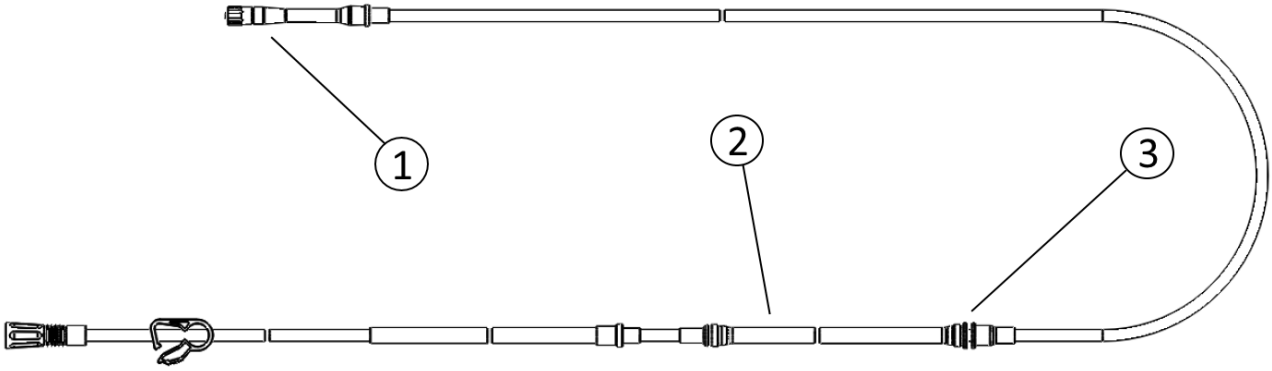

Close the door gently to the first click. Then the door locks automatically;




Chambers is pressurized;

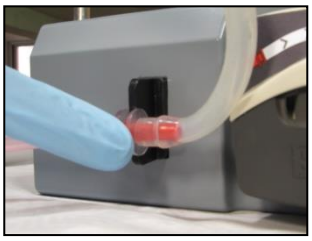
Open the clamp of the irrigation set.

### 6.4.3. Suction




① = Connection (patient side)
② = Flexible part of the pipe
③ = Keying system connector

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;

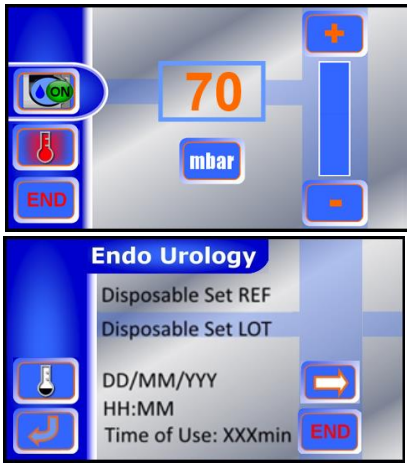
The pump starts at the selected speed.

## 6.5. 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).

## 6.6. After Use




Close all clamps;

Press the END button and wait for complete chamber depressurization;


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


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

Turn Off the device.
Close the door.

## 6.7. Cleaning after Use

Clean the external parts of the machine, the interior of the tank and the door in particular with disinfectants by using a single-use cloth or a disinfecting wipe.
The disinfectant used must be approved and authorized by the National laws and hospitals.

The tanks of the ENDOFLOW® are designed in order to avoid any leakage on electronic or electrical parts.

# 7. 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 | |

## 8. 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.

# 9. Service

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.

## 9.1. 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.

## 9.2. 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.

## 9.3. Expected Service Life

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

## 9.4. 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).

## 9.5. Service Contacts

Contact your ROCAMED After Sale-Service:

<u>USA & Rest of the World:</u>

ROCAMED SAM
9 Avenue Albert II
98000 Monaco
Monaco

Tel : +377 97 98 42 43
Fax : +377 92 05 61 50

<u>France:</u>

ROCAMED France
Z.I. de Signes
Allée de Stockholm
83870 Signes
France

Tél : 04 94 90 21 00
Fax : 04 94 98 60 55

# 10. Maintenance

## 10.1. 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.

## 10.2. 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.

## 10.3. Other

For other maintenance, please contact Service Department (see §9.5).

# 11. Specification

## 11.1. Dimensions and Weight

| Product References | **MEN01XX** | **MEN02PXX** |
|---|---|---|
| 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. | |

## 11.2. Electrical & Pneumatic

| Products References | **MEN01** | **MEN01US** | | **MEN02P** | **MEN02PUS** | |
|---|---|---|---|---|---|---|
| Input Voltage | 220V-230V | 120V | 100V | 220V-230V | 120V | 100V |
| Frequency | 50/60Hz | 60Hz | 50/60Hz | 50/60Hz | 60Hz | 50/60Hz |
| Puissance | 450VA | | | 790VA | | |
| Safety fuse | F10AH250V | | | | | |
| Input Air | 3 to 7 bars | | | | | |

## 11.3. Performance

### 11.3.1. Irrigation

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

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

### 11.3.2. Temperature

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

| | Set point | Accuracy |
|---|---|---|
| Temperature | 38°C | ±2°C |

#### 11.3.3. 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.

#### 11.3.4. Boost (Irrigation)

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

| Application | Increase of pressure | Duration |
|---|---|---|
| Laparoscopy | 100 mbar | 30s±5s |
| Hysteroscopy | 20 mbar | 30s±5s |
| EndoUrology | 20 mbar | 30s±5s |
| Arthroscopy (only on MEN01 & MEN02P) | 40 mbar | 30s±5s |

#### 11.3.5. RFID

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

### 11.4. 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%.

## 11.5. Cleaning

Clean the external parts of the machine, the interior of the tank and the door in particular with disinfectants by using a single-use cloth or a disinfecting wipe.
The disinfectant used must be approved and authorized by the National laws and hospitals.

The tanks of the ENDOFLOW® are designed in order to avoid any leakage on electronic or electrical parts.

## 11.6. Storage

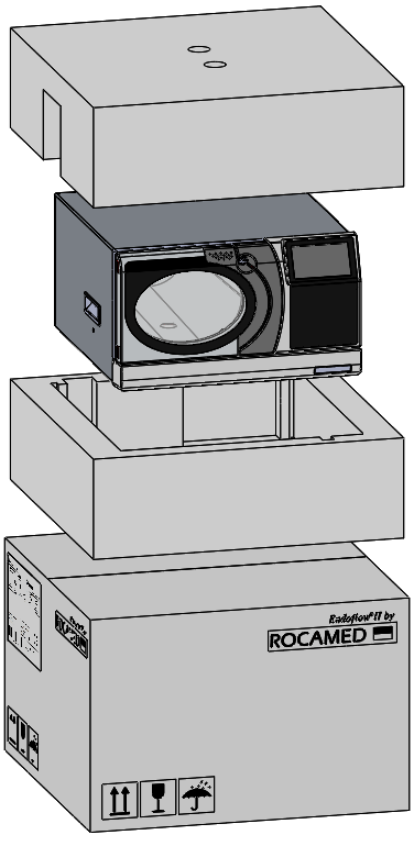
The ENDOFLOW® II should be stored in the following environmental conditions:

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

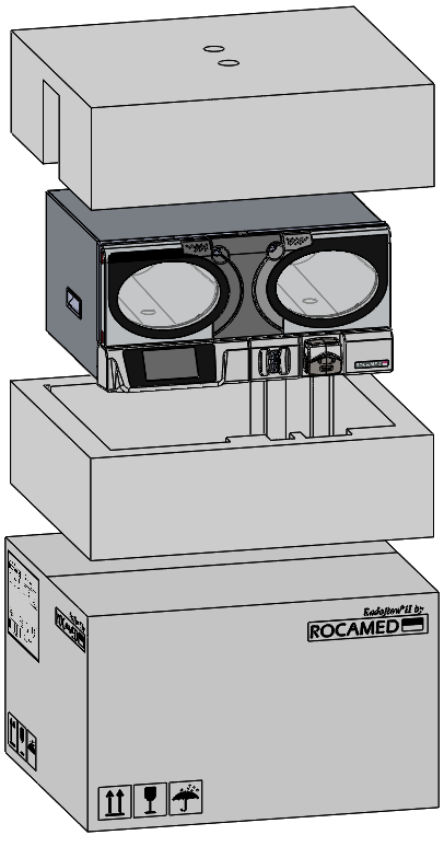
## 11.7. Shipping

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



## 12. Electromagnetic Compatibility (EMC) Information

**Table 1 - MANUFACTURER'S guidelines and statement – ELECTROMAGNETIC EMISSIONS – for all EM DEVICES and SYSTEMS**

<table>
<tr><th colspan="3">Manufacturer's guidelines and statement - electromagnetic emissions</th></tr>
<tr><td colspan="3">ENDOFLOW® II, a heating and sterile liquid irrigation system for endoscopic applications, was designed to be used in the electromagnetic environment described below. The client or user of ENDOFLOW® II must ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidelines</th></tr>
<tr><td>RF Emissions<br>CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF Emissions<br>CISPR 11</td><td>Class [A]</td><td rowspan="3">ENDOFLOW® II is designed for use in all locations including domestic locations and those directly connected to the public low voltage electrical power supply providing electricity to buildings for domestic use.</td></tr>
<tr><td>Harmonic emissions<br>IEC 61000-3-2</td><td>Class [A]</td></tr>
<tr><td>Voltage fluctuations and flicker<br>IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

**Table 2 - MANUFACTURER'S guidelines and statement – electromagnetic IMMUNITY – for all EM DEVICES and SYSTEMS**

| **Manufactures guidelines and statement - electromagnetic immunity** | | | |
|---|---|---|---|
| ENDOFLOW® II, a heating and sterile liquid irrigation system for endoscopic applications, was designed to be used in the electromagnetic environment described below.<br>The client or user of the ENDOFLOW® II must ensure that it is used in such an environment. | | | |
| **IMMUNITY test** | **Test level IEC 60601** | **Conformity level** | **Electromagnetic environment - guidelines** |
| Electrostatic discharges (ESD) IEC 61000-4-2 | ± 6 kV on contact<br>± 8 kV in the air | ± 6 kV on contact<br>± 8 kV in the air | 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%. |
| Electrical fast transient / burst IEC 61000-4-4 | ± 2 kV for electrical power lines<br>± 1 kV for input/output lines | ± 2 kV for electrical power lines<br>± 1 kV for input/output lines | The electrical power supply system must be suitable for a typical commercial or hospital environment. |
| Surge immunity test IEC 61000-4-5 | ± 1 kV between phases<br>± 2 kV between phase and ground | ± 1 kV between phases<br>± 2 kV between phase and ground | The electrical power supply system must be suitable for a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations immunity tests IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycles<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | <5 % $U_T$ (>95 % dip in $U_T$) for 0.5 cycles<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | The electrical power supply system must be suitable for a typical commercial or hospital environment. If the user of the ENDOFLOW® II requires continuous operation during electrical power outages, it is recommended to power the ENDOFLOW® II using an uninterruptible power source or a battery. |
| Power frequency magnetic field immunity test IEC 61000-4-8 | 3 A/m | 3 A/m | Magnetic fields at the frequency of the electrical system must be at levels characteristic of a representative area located in a typical commercial or hospital environment. |
| NOTE $U_T$ is the voltage of the alternative system before application of the test level. | | | |

**Table 4 - MANUFACTURER'S guidelines and statement – Electromagnetic IMMUNITY**

<table>
<tr><td colspan="4">Manufactures guidelines and statement - electromagnetic immunity</td></tr>
<tr><td colspan="4">ENDOFLOW® II, a heating and sterile liquid irrigation system for endoscopic applications, was designed to be used in the electromagnetic environment described below. The client or user of the ENDOFLOW® II must ensure that it is used in such an environment.</td></tr>
<tr><td>IMMUNITY test</td><td>TEST LEVEL ACCORDING TO IEC 60601</td><td>Conformity level</td><td>Electromagnetic environment - guidelines</td></tr>
<tr><td>Conducted RF Disturbances IEC 61000-4-6<br><br>Radiated RF Disturbances IEC 61000-4-3</td><td>3 $V_{eff}$ from 150kHz to 80MHz outside the ISM[a] bands.<br><br>3 V/m from 80 MHz to 2.5 GHz</td><td>1 $V_{eff}$<br><br>[3] V/m</td><td>Portable and mobile RF communication devices must not be used nearer to any part of the ENDOFLOW® II including the cables than the recommended separation distance, calculated using the equation applicable to the transmitter frequency.<br><br>Recommended separation distance:<br>$d = 1.2\sqrt{P}$<br>$d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ from 800 MHz to 2.5 GHz<br>where P is the maximum output power characteristic of the transmitter in watts (W), according to the manufacturer of the transmitter and d is the recommended separation distance in meters (m)[b].<br>The field intensities of fixed RF transmitters, determined by site electromagnetic inspection[c], must be lower than the compliance level, in each frequency range[d].<br>Interference may occur near the device marked with the following symbol:</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and at 800 MHz, the higher frequency range applies.<br>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people.</td></tr>
<tr><td colspan="4">a) The ISM bands (Industrial, Scientific, and Medical) between 150 kHz and 80 MHz are from 6.765 MHz to 6.795 MHz; from 13.553 MHz to 13.567 MHz; from 26.957 MHz to 27.283 MHz; and from 40.66 MHz to 40.70 MHz.<br>b) Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are designed to reduce the probability of interference that mobile/portable communication devices may cause, if they are inadvertently brought into the patient areas. For this reason, an additional factor of 10/3 was introduced into the formula used in calculating the recommended separation distance for transmitters in these frequency ranges.<br>c) The field intensities of fixed transmitters, such as base stations for radio telephones (cellular/wireless) and mobile terrestrial radios, amateur radio, AM and FM radio broadcasting, and TV broadcasting, cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic inspection should be considered. If the field intensity, measured at the location where [the EM DEVICE or SYSTEM] will be used, exceeds the applicable RF compliance level above, [the EM DEVICE or SYSTEM]should be observed to verify that it functions properly. If any abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the ENDOFLOW® II<br>d) In the 150 kHz to 80 MHz frequency range, field intensities must be lower than [V1] V/m.</td></tr>
</table>

**Table 6 – Recommended separation distances between portable and mobile RF communication devices and the EM DEVICE or SYSTEM**

| **Recommended separation distances between portable and mobile RF communication devices and the ENDOFLOW® II** | | | |
|---|---|---|---|
| ENDOFLOW® II is designed for use in an electromagnetic environment in which the radiated RF disturbances are controlled. The client or user of the ENDOFLOW® II may contribute to preventing electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters and the ENDOFLOW® II, such as is recommended below, depending upon the maximum transmission power of the communication device. | | | |
| **Maximum rated output power of the transmitter W** | **Separation distance depending upon the frequency of the transmitter m** | | |
| | **from 150 kHz to 80 MHz outside of the ISM bands** $d = 1.2\sqrt{P}$ | **from 80 MHz to 800 MHz** $d = 1.2\sqrt{P}$ | **from 800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |
| For transmitters which maximum rated output power is not given above, the recommended separation distance *d* in meters (m) may be determined by using the equation applicable to the frequency of the transmitter, where *P* is the characteristic of maximum transmission power of the transmitter in watts (W), according to its manufacturer.<br><br>NOTE 1 At 80 MHz and at 800 MHz, the separation distance for the higher frequency range applies.<br><br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects, and people. | | | |

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