

INSTRUCTIONS

ClearPath Controller



Caution:
Federal (USA) law restricts this device
to sale by or on order of a physician

CE
0470



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY. IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to medical techniques.

1. SAFETY PRECAUTIONS

1.1. Training

1.1.1. This equipment should only be used under the supervision of a trained physician in a medical facility. Do not use in any other location or for any purpose other than the intended application.

1.2. Installation

1.2.1. This equipment should never be installed or used in areas where the unit could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, which could adversely affect the equipment.

1.2.2. This equipment should never be installed or used in the presence of flammable or explosive gases or chemicals.

1.2.3. This equipment should never be installed, used or transported in an inclined position nor should it be subjected to impact or vibrations.

1.2.4. To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

1.2.5. Ensure that all power requirements are met and conform to those specified on the rating plate located on the rear panel.

1.2.6. Do not block the air intake vent for this equipment.

1.2.7. Do not allow the power cord to become twisted, crushed or pulled out.

1.2.8. Use only the power cord supplied with this product.

1.3. Prior to use

1.3.1. Confirm that this equipment functions properly and check the operation of all switches and indicators.

1.3.2. Prior to use verify that there are no sharp or unsmooth parts in the device that may come in contact with the patient.

1.3.3. To prevent electrical shock when used with endoscopes, this equipment is insulated type BF electro-medical equipment. Do not let it be grounded to other electrical devices being used on the patient. Rubber gloves should always be worn to prevent grounding through user.

1.3.4. Confirm that other devices used in conjunction with this equipment function properly and that these other devices will not adversely affect the operation or safety of this equipment. If any component of the endoscopic system is not properly functioning, the procedure should not be performed.

1.3.5. Check and confirm that all cords or cables are connected correctly and securely.

1.4. During use

1.4.1. Continually monitor this equipment and the patient for any signs of irregularity.

1.4.2. In the event that some type of irregularity is noted to the patient or this equipment, take the appropriate action to ensure patient safety. If the system does not function as it is supposed to abort the procedure, turn the ClearPath Controller off, disconnect it from the electricity and send for maintenance.

1.4.3. This equipment should only be used according to the instruction and operating conditions described in this manual. Failure to do so could result in compromised safety, equipment malfunctions or instrument damage.

1.4.4. This equipment should only be used in conjunction with approved medical devices, complying with IEC60601-1.

1.5. After use

1.5.1. Refer to the instruction in this manual for the right order which components should be turned off in.

1.5.2. Wipe all surfaces with gauze slightly dampened with alcohol.

1.5.3. Be sure that connector interfaces and ventilation ports are not allowed to become wet or splashed with liquids.

1.6. Storage

1.6.1. This equipment should never be stored in areas where the unit could get wet or be exposed to any environmental conditions such as high temperature, humidity, direct sunlight, dust, salt, which could adversely affect the equipment.

1.6.2. This equipment should never be installed or used in the presence of flammable or explosive gases or chemicals.

1.6.3. This equipment should never be installed, used or transported in an inclined position nor should it be subjected to impact or vibrations.

1.6.4. Cords and accessories should be cleaned and neatly stored.

1.6.5. This equipment should be maintained in a clean condition during storage and be ready for subsequent use.

1.6.6. The only way to disconnect the equipment from the supply mains is to disconnect the power cord, either from the inlet in the equipment or from the socket in the wall.

1.7. Service

1.7.1. Alterations/modifications to this equipment should never be made.

1.8. Maintenance

1.8.1. Periodically this equipment and any applicable accessory should be inspected for operation and safety.

1.9. Disposal

1.9.1. This equipment should be disposed of separately and should be sent to appropriate facilities for recovery and recycling.



2. SAFETY SIGNS



- General warning sign.



- Dangerous voltage.

3. INDICATIONS

The ClearPath Controller is intended to be used only with EasyGlide's ClearPath products. The Controller is intended to provide irrigating fluid and to control the evacuation flow during various endoscopic procedures as defined by the specific ClearPath product indications.

4. DEVICE DESCRIPTION

- 4.1. The ClearPath Controller comprises a peristaltic pump to enable irrigation of water and a pinch valve that allows control of the vacuum flow.
- 4.2. ClearPath Controller dimensions: 200X200X200 (excluding irrigation bottle support)
- 4.3. Cabinet weight: 7Kg.
- 4.4. Firmware version: 3.2.0
- 4.5. Hardware version: CC3100

5. CLASSIFICATION

- 5.1. The ClearPath Controller is classified as a class 2 FDA device.
- 5.2. The ClearPath Controller is classified as a class 2 CE device.

5.3. According to IEC 60601-1, the ClearPath Controller is classified as Class I medical electric equipment, continuous operation, with protection IP22; type BF applied parts without signal input output parts.

6. MAINTENANCE AND STORAGE

6.1. Clean the ClearPath Controller with gauze dampened with alcohol.

6.2. The ClearPath Controller is design to be carried by one person.

6.3. Environmental conditions:

6.3.1. Shipment and storage:

6.3.1.1. Ambient temperature: -25°C to $+55^{\circ}\text{C}$

6.3.1.2. Relative humidity: 20% to 95%

6.3.1.3. Atmospheric pressure: 800hPa to 1050hPa









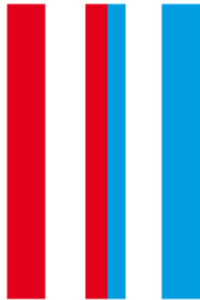




6.3.2. Operation:

6.3.2.1. Ambient temperature: $+15^{\circ}\text{C}$ to $+30^{\circ}\text{C}$








6.3.2.2. Relative humidity: 30% to 75%.










6.3.2.3. Atmospheric pressure: 800hPa to 1050hPa

7. MARKINGS

 <p>Manufacturing date</p>	 <p>Serial Number</p>	 <p>Batch code</p>
 <p>Catalogue number</p>	 <p>Dispose of separately</p>	 <p>Keep finger away from moving rotor</p>
<p>ClearPath Controller</p> <p>Product logo</p>	<p>Input: 100-240V ~ 50-60Hz, 2A IP22</p>   <p>Input ratings</p>	 <p>Colour coding for the pinch valve orifices</p>
 <p>Irrigation bottle</p>	<p>4A, 250V, T</p> <p>Pump drive fuse data</p>	<p>2*2A, 250V, T</p> <p>Main inlet fuse data</p>
 <p>Type BF applied part</p>	<p>CE 0470</p>	 <p>Do not reuse</p>
 <p>Do not use if package is damaged</p>		

8. LABELS

				
<div style="display: flex; justify-content: space-between; align-items: center;"> Ref CC3100A2 </div>				
<div style="border: 1px solid black; padding: 2px;">SN</div> EG0031	Contents: 1 unit		 2010-07	
<div style="border: 1px solid black; padding: 2px;">LOT</div> EG3100-10-02		Attention: this device is non-sterile See instruction for use.		
<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">EC</div> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;">REP</div> </div> MedNet GmbH, Eschstrasse 19, D-48167 Munster, Germany Tel: +49 2506 8644-0, Fax: +49 2506 8644-22 Email: info@medneteuropa.com				
 EasyGlide Ltd. 30 Haella St. Kfar Truman, Israel 73150 www.easy-glide.com				
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.				
DL-EG 025-01				

				
<div style="display: flex; justify-content: space-between; align-items: center;"> Ref CPA1100A </div>				
Contents: 1 unit	 2009-12	 2010-03		
<div style="border: 1px solid black; padding: 2px;">LOT</div> S 10 E 16 – 01 P	  	Attention: this device is non-sterile See instruction for use.		
Authorized representative: MedNet GmbH, Eschstrasse 19, D-48167 Munster, Germany Tel: +49 2506 8644-0, Fax: +49 2506 8644-22 Email: info@medneteuropa.com				
 EasyGlide Ltd. 30 Haella St. Kfar Truman, Israel 73150 www.easy-glide.com				
Caution: Federal (USA) law restricts this device to sale by or on order of a physician.				
DL-EG 009-04				

INSTRUCTIONS FOR USE

Figure 1

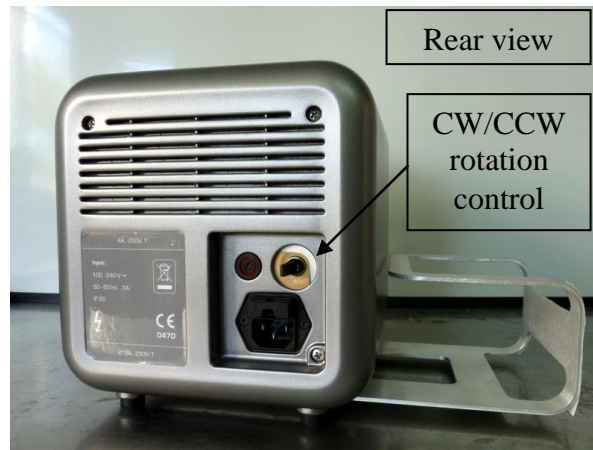
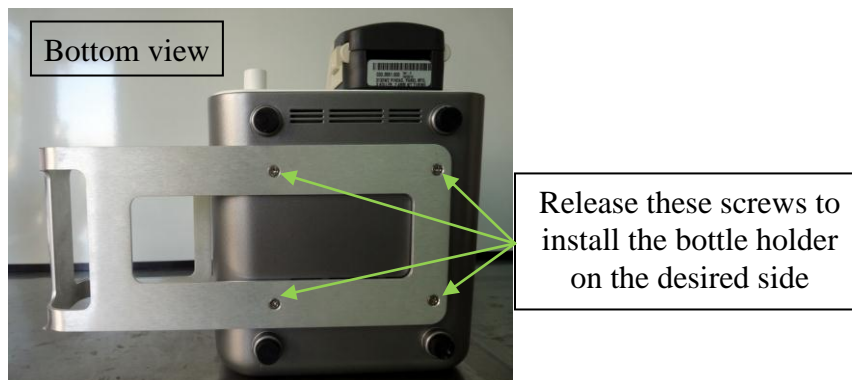


Figure 2



Figure 3



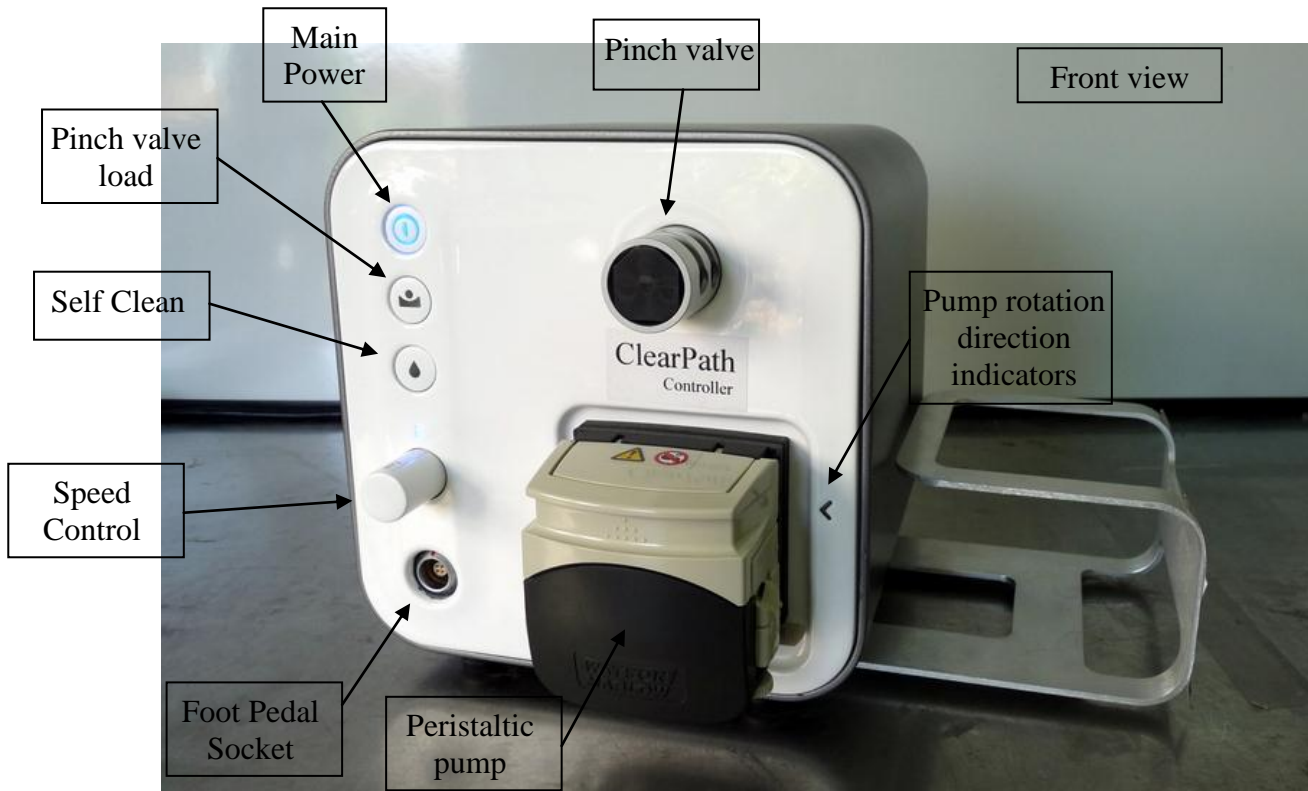
Installation:

For the medical staff's convenience this systems has two installation options. After placing the system in the location most convenient for you attach the bottle holder unit on the pump's right side/left side and set the pump's rotation to clock wise/counter clock wise rotation accordingly.

1. Use the CC/CCW rotation control switch on the rear of the unit to determine the rotation direction of the pump and set the bottle holder on the correct side, the BLUE arrows, on both sides of the pump head will indicate the chosen rotation direction of the pump (refer to figure 2).

- 1.1. For clock wise rotation (water bottle on the left) (refer to figures 2a, 3) – push the toggle switch (refer to figure 1) to the right.
- 1.2. For counter clock wise rotation (water bottle on the right) (refer to figure 2b, 3) – push the toggle switch (refer to figure 1) to the left.

Figure 4



Before the procedure:

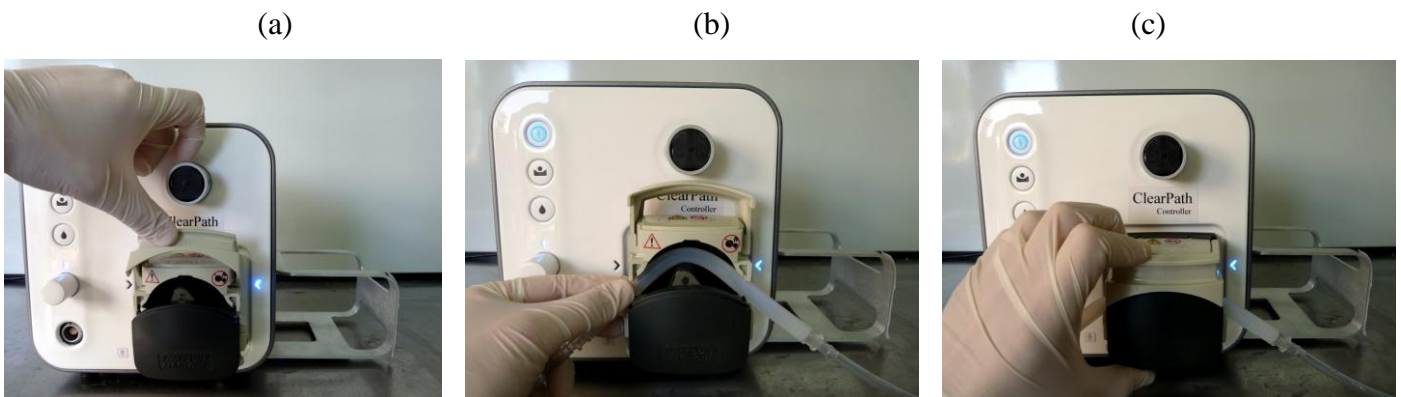
CAUTION: Use sterile water only.

1. Install the water bottle inside the bottle holder. If water bottle is not installed refer to figure 2 to determine on which side to place the water bottle according to the rotation direction indicators.
2. Install a CPT2100 24 hour irrigation tube: (refer to figure 5)
 - 2.1. Make sure that the support cabinet is turned OFF. Power switch located on front panel, all indicator lights should be off (see figure 4)
 - 2.2. Make sure that the pump drive is OFF; by inspection.
 - 2.3. Place the water supply tube inside the water bottle.

CAUTION: Make sure that the pump drive is off before installing the tubes.

- 2.4. Open the pump cover (5a), feed the irrigation tube around the peristaltic pump rollers (5b) and close the cover (5c); the section of tube that is designed to fit in the pump head is the thicker section of the tube ending on both ends with connections.

Figure 5

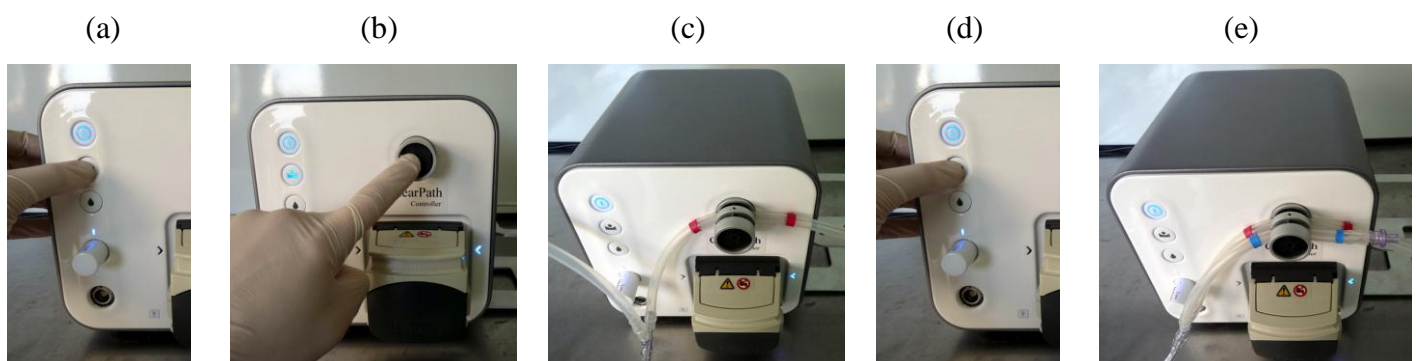


(Clause 3 - for procedures with ClearPath and ClearPath UGI only)

3. Install a suction tube: (refer to figure 6)

- 3.1. Attach the suction tube's arm, marked by two RED lines, to the suction tank.
- 3.2. Turn the support cabinet ON; a blue indicator light should light up in the switch.
- 3.3. Push the pinch valve load switch, a blue indicator light should light up on the switch. (6a).
- 3.4. Push the black button on the pinch valve's head (6b).
- 3.5. Install the short suction tube's arm, marked by two RED lines, in the pinch valve orifice closer to the cabinet's body, also marked by a RED line (6c). The section of tube that is designed to fit in the valve is the section between the two RED lines.
- 3.6. Push the pinch valve load switch, the blue indicator light should turn off (6d).
- 3.7. Install the short suction tube's arm, marked by two BLUE lines, in the pinch valve orifice more distant from the cabinet's body, also marked by a BLUE line (6e). The section of tube that is designed to fit in the valve is the section between the two BLUE lines.

Figure 6



4. Place the irrigation and suction pedals in a convenient place.

Figure 7



5. Set the speed control switch to the desired level: (refer to figure 7)

Notice: the following is a recommendation only; the three possible pump speeds can be used in conjunction with each of EasyGlide's products; a setting (high/medium/low) should be selected according to the situation and at the physician's discretion.

- 5.1. Use "LOW" when a soft wash is required.
 - 5.2. Use "MEDIUM" for ClearPath Lower GI and ClearPath Upper GI.
 - 5.3. Use "High" for ClearPath Irrigator.
6. Before starting the procedure, operate the pedals and verify, visually, that the system functions properly.

Notice: Install and connect the disposable unit according to the relevant IFU attached to it.

Notice: Priming - when operating the irrigation for the first time, a few seconds will be required for water to start flowing.

During the procedure:

7. Irrigation:

- 7.1. Operate the irrigation by stepping on the left pedal, marked by "irrigation".
- 7.2. Refrain from employing the irrigation repeatedly, on the same spot, unnecessarily.

8. Suction:

- 8.1. Operate the suction by stepping on the right pedal, marked by "suction".
- 8.2. Periodically monitor the amount of water used for irrigation and the amount of water evacuated through suction by visual inspection of the water and suction tanks.
- 8.3. For ClearPath and ClearPath UGI:
 - 8.3.1. Perform a complete cleaning of the tissue so as not to obstruct lesion detection.
 - 8.3.2. Evacuate all water remains as you advance in order to prevent local water accumulation.

After the procedure:

(Clauses 9, 10 - for procedures with ClearPath and ClearPath UGI only)

9. Push the "self clean" switch, a blue light will light up on the switch for the duration of the function's operation. (refer to figure 4) – This will clear the suction tube.
10. Disassemble the suction tube:
 - 10.1. Remove the short suction tube's arm marked by two BLUE lines from the valve.
 - 10.2. Push the pinch valve load switch, a blue indicator light will light up on the switch. (refer to figure 4)
 - 10.3. Remove the tube from the valve.
 - 10.4. Push the pinch valve load switch, the blue indicator light will turn off.

At the end of the day:

1. Disassemble the CPT2100 24 hour irrigation tube:

- 1.1. Turn the ClearPath Controller OFF; all indicator lights will turn off.
- 1.2. Make sure that the pump drive is OFF, by inspection.

CAUTION: Make sure that the pump drive is off before removing the tube.

- 1.3. Remove the water supply tube from the pump head.

Notice: Disconnecting the irrigation tube below the level of the fluid bottle may result in fluid siphoning from the bottle.

- 1.4. Dispose of the CPT2100 24 hour irrigation tube.

TROUBLESHOOTING

- Procedures should be performed only by qualified and trained physicians familiar with endoscopy techniques.
- Damaged unit: A damaged unit should be replaced with a new one.
- ClearPath Controller won't turn ON:
 - Make sure that the power supply cable is inserted all the way into the power supply socket.
- No irrigation:

Notice: Priming - when operating the irrigation for the first time, it is possible a few seconds will be required for water to start flowing.

- If the pump head is rotating:
 - Make sure that there is enough water in the tank.
 - Make sure that the irrigation tube is inserted correctly into the water tank and that the tube's tip is under water level.
 - Make sure that the irrigation tube's connectors along the way are well connected and do not leak water.
 - Make sure that there is nothing placed on the tube anywhere along the way, obstructing the water flow.
 - Try operating the foot pedal again for a few seconds.
- If the pump head is not turning:
 - If the support cabinet is turned ON:
 - Turn the support cabinet OFF.

CAUTION: Make sure that the pump drive is off before removing the tube.

- Open the pump head and make sure that the tube is placed correctly inside it and that it is not folded or kinked.
 - Close the pump head.
 - Turn the support cabinet ON.
 - Give the system a few seconds then try operating the foot pedal again for a few seconds.
 - If the support cabinet is OFF:
 - Make sure that the power switch is turned ON.
 - Make sure that the ClearPath Controller is properly connected to the electricity.
 - If there is still no irrigation but the pump drive is working: try replacing the disposable unit with a new one.
- No suction:

- Make sure that the suction source is operative.
- Make sure that the suction tank is connected to the suction source and that the white switch on the tank's handle is pointing to "ON".
- Make sure that suction tube is connected to the suction tank.
- Make sure that the support cabinet is turned ON.
- Make sure that both tubes are well placed inside the pinch valve, "BLUE" tube inside the "BLUE" orifice and "RED" tube inside the "RED" orifice.
- Make sure that the blue "pinch valve load" indicator is off. (refer to figure 3)
- Make sure that there is nothing placed on the tube anywhere along the way, obstructing the flow.
- Make sure that the suction tube's connectors along the way are well connected.
- If there is still no suction: try replacing the single use unit with a new one.



EasyGlide Ltd.

30 Haella St. Kfar Truman, Israel 73150

www.easy-glide.com



MedNet GmbH, Eschstrasse 19, D-48167 Munster, Germany

Tel: +49 2506 8644-0, Fax: +49 2506 8644-22 Email: info@medneteuropa.com