

My Perfect Colon[®] *Pro*
Natural Hydro-Therapy at Home



EN

User guide

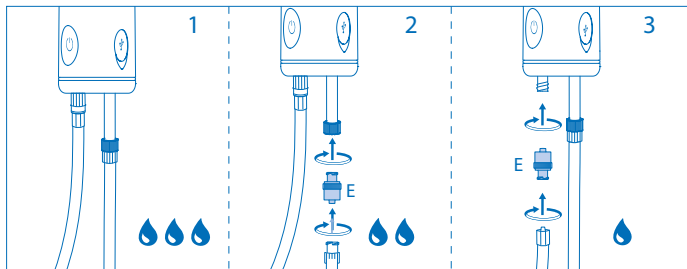
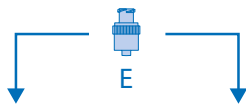
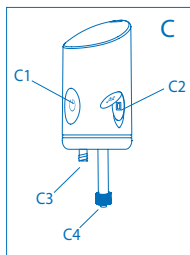
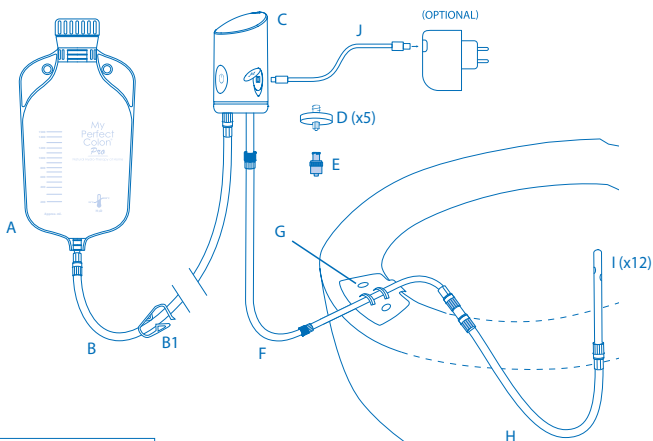
www.waterpowered.eu

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General Diagram



WARNING: Read the instruction manual carefully before use and keep it for future reference.

Use My Perfect Colon PRO according to the indications of your doctor and/or professional health worker. The indications received should prevail over these instructions.

WHAT IS MY PERFECT COLON PRO

My Perfect Colon PRO is an EC medical device for transanal irrigation.

PRODUCT STRUCTURE AND CONTENT:

- A. 2-litre bag with suction cups and liquid crystal thermometer
 - B. Suction tube (1.5 metres) with tube clamp (B1) and fittings
 - C. Grip with on/off button and light indicator (C1), Charging socket (C2), Water Inlet Fitting (C3), Water Outlet Fitting (C4)
 - D. 5 Micron Membrane Filter (x5)
 - E. Water supply reducer (x1)
 - F. Outlet tube (1 metre) with fittings
 - G. Support with suction cups
 - H. Modeling tube with fittings
 - I. Rectal Cannula (x12)
 - J. USB cable
- Case for My Perfect Colon PRO
 - Multilanguage Manual

GENERAL WARNINGS

When using electrical products, especially in the presence of children, it is necessary to follow basic safety precautions.

- To reduce the risk of electric shock when the device is charging, do not touch the plug with wet hands;
- Do not use while in the bath or when wet;
- Do not place it near or drop it in water or other liquids;
- Do not place or store the device where there is a risk that it may fall into the bath or sink;
- Check if the cable is damaged before using it;
- Do not use the device if it has a damaged cable or socket, if it does not work correctly, if it has fallen, is damaged or been dropped in water. In this case, contact Water Powered srl;
- Keep the cable away from heat sources;
- Do not connect the device to a voltage system other than the specified one or one that does not have a grounding line and lifesaver;
- Do not use the device during the recharging phase;
- The device does not produce electromagnetic interference.

WARNINGS AND PRECAUTIONS FOR USE

- Before using My Perfect Colon PRO, consult your doctor or a health professional specialized in transanal irrigation to check suitability to your personal situation;
- Transanal irrigation with My Perfect Colon Pro should always be carried out with caution;
- Carry out the first transanal irrigation under the supervision of a health worker;
- Consult your doctor for any kind of doubt about the use of the device;
- If you feel any particular discomfort during or after using My Perfect Colon Pro, stop using it and consult your doctor. Immediately request medical assistance if during or after the irrigation procedure you feel intense or continuous abdominal pain, back pain or rectal bleeding during or after the irrigation. Intestinal perforation is an extremely rare but very serious complication of transanal irrigation. Symptoms of intestinal perforation include intense and prolonged abdominal or back pain or rectal bleeding;
- Keep the device out of the reach of children. Supervise children if they are near the device to avoid the

risk of strangulation with tubes, suffocation with the bag or with small components that may detach from the product;

- For hygiene reasons, every My Perfect Colon PRO device must be used only by one user;
- The rectal cannula is disposable, and reuse is potentially harmful to the user;
- Use water between 36°C and 38°C;
- Use clean running water or, if you have any doubts about the quality, use My Perfect Colon water filters. Alternatively, use bottled water
- Turn off the device when the water in the bag finishes;
- Empty your bladder before irrigation;
- Make sure you are comfortably seated on the toilet to facilitate pelvic floor relaxation;
- In some cases, it is possible that the effect of the irrigation could be particularly effective and that the stimulus to evacuate could recur several times in the 2-3 hours after irrigation;
- The body has to get used to the treatment with transanal irrigation. In the absence of particular pathologies and if you follow a healthy lifestyle and a correct diet, the beneficial effects will be seen after a few sessions;
- The tubes must be installed as per instructions so as not to cause damage to the device.

CONTRAINDICATIONS

- Transanal irrigation with My Perfect Colon PRO must not be carried out in the following cases:
 - Acute diverticulitis;
 - Acute inflammatory bowel disease;
 - Colorectal carcinoma;
 - Known rectal or colorectal stenosis;
 - Within 4 months of colorectal or rectal surgery;
 - Within 5 weeks of endoscopic polypectomy;
 - Ischemic colitis;
 - Children under 3 years of age. For children it is always necessary to consult their doctor before use;
 - Women during pregnancy, planned pregnancy or breastfeeding.
- Special care should be taken if you suffer or have suffered from the following diseases in the past:
 - Faecal compress: in case of strong constipation, it is necessary to carry out an initial cleaning of the intestine before starting irrigation treatment;
 - Painful anorectal conditions, such as rhagades, fistulas, third or fourth-degree haemorrhoids;
 - Patients with a risk of autonomous dysreflexia should carry out irrigation under supervision;
 - Severe diverticulosis or diverticular abscess;
 - Irradiation therapy in the abdominal or pelvic region;
 - Previous rectal or colorectal surgery;
 - Previous major surgeries in the pelvic area;
 - Severe Autonomic Dysreflexion;
 - Variation in the consistency of faeces, such as diarrhoea (the cause of diarrhoea should be identified)
 - Increased risk of bleeding or ongoing anticoagulant therapy (excluding aspirin or clopidogrel);
 - Long-term corticosteroid therapy;
 - Rectal medication.
- The device is not suitable for use by children or persons with reduced physical, sensory or mental abilities unless they receive adequate assistance;
- Do not use the device for applications other than those indicated;
- Do not use accessories not recommended by the manufacturer;
- Do not drop or insert any foreign object into the openings of the device;

INSTRUCTIONS

Preparation of the device and Use sitting on W.C.

1. Connect the 1.5-metre suction tube (B) to the bag (A) using the threaded connection, turning clockwise until it stops;

2. Ensure the tube clamp (B1) on tube B is tight and fill the bag with warm water (between 36 ° and 38 ° - check the temperature highlighted in green/brown on the thermometer affixed to the bag. If no colored dot appears, the water temperature is higher or lower than the thermometer range. The value is indicative - tolerance +/- 10%);
3. Close the bag by screwing the cap well, fix it to the wall (smooth and clean surface) or a mirror thanks to the suction cups at the height of about 1m or place it on the floor or a stable surface; Position the bag near the toilet bowl so that the tube clamp (B1) can be reached by hand when seated;
4. Connect the other end of the suction tube (B) to the water inlet fitting (C3) located on the handle;
5. Connect the 1-metre tube (F) to the water outlet tube fitting (C4) located on the handle C;
6. Connect the other end of the tube F to the support (G) and apply the suction cups to the front of the toilet seat or the toilet itself;
7. Connect the tube fitting of the suction cup holder (G) to the modeling tube (H);
8. Connect the cannula (I) to the modeling tube (H);
9. Unlock the tube clamp (B1) to allow the passage of water and, placing the cannula (I) inside the toilet, press the power button C1; run the water through the tubes for a few seconds to check the correct connection and operation (it is possible that the air present in the empty tubes is initially sucked and expelled);
10. Switch off the device by pressing the C1 button, tighten the tube clamp (B1) and sit on the toilet, placing the tubes between the legs;
11. Gently insert the cannula into the rectum without forcing it. If you feel resistance to insertion, remove the cannula and ensure that the rectum is empty (manual evacuation may be necessary to facilitate emptying). Try using lubricating ointments to facilitate insertion. If resistance persists, do not force it, stop irrigation and ask for the support of a health professional;
12. Unlock the tube clamp (B1) and start irrigation by pressing the power button C1 (the indicator light will turn on - read the paragraph "Instructions for irrigation");
13. To stop water supply, press the C1 button. To be aware of the amount of water introduced during washing, every 30" the device turns off interrupting the supply; this security system prevents more water than desired to being inadvertently introduced. Press the power button again to continue the irrigation for another 30". **To check the amount of water that is dispensed according to the different configurations, see table 1 in the paragraph "Instructions for irrigation";**
14. After irrigation, turn off the device by pressing the C1 button and close the tube clamp (B1).

Use for bedridden people:

In case of use by bedridden people, therefore not on the toilet, the mounting of the tube with support and suction cups (G) and the modeling tube (H) are not necessary. Connect the cannula directly to the outlet tube (F).

Use in supine position

For an even more effective cleanse, it is recommended to carry out washing in the supine position. For this purpose, the My Perfect Colon board and the Comfort Wash Mat are available. Accessories available on www.myperfectcolon.com or www.waterpowered.eu. In case of use in the supine position, the tube with support and suction cups (G) and the modeling tube (H) are not necessary. Connect the cannula directly to the outlet tube (F).

Indications for irrigation

- The amount of water required for transanal irrigation is subjective. For adults, it can vary from 300 to 1,000 ml up to a maximum of 1,500 ml (according to the instructions of your doctor). For children, 10-20 ml for each kg of weight. The bag can contain a max. of 2 liters of water;
- Use water between 36°C and 38°C. If the water is too hot, it can damage the delicate lining of the intestine. If too cold, stomach cramps can occur. If you feel a temperature that is too hot or cold during use, turn off the device and replace the water in the bag with water at the correct temperature. Help yourself in regulating the water temperature with the thermometer placed on the bag;

- Make sure that the flow in the tubes is not blocked or slowed down by obstructions or kinks;
- During irrigation, position the bag at the height of about 1m, thanks to the suction cups supplied. Where the bag is placed on the ground, position it slightly on a slope so that the water is directed towards the outlet to avoid sucking in air;
- Emptying: after completing the insertion of water, the intestine will begin to empty. Especially during the first few uses, it may be necessary to wait a few minutes, even 15-30 minutes, before the colon begins to empty. Make sure to expel all the water. To facilitate emptying, try bending forward, coughing, and/or doing an abdominal massage;
- Evacuation times are subjective and may vary from session to session.
- Amount of water:
 - For every 30" session, about 475ml of water is dispensed (considering the position of the bag at about 1m of height);
 - If you prefer less water flow, connect the reducer between the connection of the outlet tube (C4) and the tube F (fig. 2): in this way there will be a reduction of about 30% of the flow rate compared to the normal one when the reducer is not mounted (fig. 1). If you prefer an even lower flow (approx. -70%), connect the reducer (E) between the suction tube (B) and the water inlet fitting (C3 - fig. 3). See the table below for the specification on the different flow rates;
 - Depending on the height at which the bag is positioned, the amount of water dispensed per minute may vary (the lower the bag is positioned, the lower the amount of water dispensed).

Table 1 - Amount of Water per Session according to the different Configurations - considering the device fully charged and the bag positioned at about 1m of height - (toler. +/-20%)

Time / Session of 30"	Without reducer and filter E (fig.1)	With Reducer (E) on Outlet tube (fig.2)	With Reducer (E) on Inlet tube (fig.3)	With Filter (D) on the outlet tube	With Filter (D) and Reducer (E) on the outlet tube
30 " / 1 Session	475ml approx.	325ml approx.	150ml approx.	375ml	275ml
60 " / 2 Sessions	950ml approx.	650ml approx.	300ml approx.	750ml	550ml
120 " / 3 Sessions	1425ml approx.	975ml approx.	450ml approx.	1125ml	825ml

- Quality of the Water and Filters My Perfect Colon:
 - Use clean running water or, if you have any doubts about the quality, use My Perfect Colon water filters. Alternatively, use bottled water;
 - Use of the filter D is optional. If you want to use it, fit between the C4 tube fitting and the F tube;
 - By mounting the filter, the quantity of water supplied is slightly reduced and in proportion to the quality of the water (the more impurities are present in suspension in the water, the more the flow tends to be reduced - see table 1 as a reference for the quantity of water supplied for each session under normal conditions);
 - Warning: Never use the filter for multiple irrigations. Replace the filter after each irrigation to ensure the purity of the water, an adequate flow, and avoid the proliferation of bacteria between one irrigation and the next. Replacement filters are available on the website www.myperfectcolon.com e www.waterpowered.eu.

RECHARGE MANAGEMENT

- The supplied cable has a USB socket. To recharge the device, connect the cable to the charging socket (C2) of the device and the other end to a common charger with a USB port (not supplied);

- It is advisable to carry out the first recharge of at least 1 hour;
- While charging is in progress, the indicator light (C1) will be red. When fully charged, the indicator light will turn off;
- Overload protection: charging will be automatically suspended when the battery is charged;
- With the device in operation, the indicator light will light up.

CLEANING AND MAINTENANCE

- Rectal Cannula: The cannula is for single use only. Do not reuse, wash, disinfect or sterilize. Reuse can lead to infections. After use, throw away the rectal cannula and dispose of it with normal household waste (Replacement cannulas are available on the website www.myperfectcolon.com and www.waterpowered.eu);
- Bag: after each use, empty it and let it dry, keeping the cap unscrewed and store it dry. The bag should preferably be changed after about 15 uses (Replacement bags are available on the website www.myperfectcolon.com and www.waterpowered.eu);
- After use, disconnect the tubes and drain the residual water (if necessary, blowing from one end);
- After drying all components with a delicate cloth, store them in a dry place at room temperature and away from direct sunlight. When storing the product, check that the tubes are not twisted and that they are not close to pointed / sharp objects;
- Store the product with the tubes detached from the bag and handle;
- To periodically clean the internal surface of the tubes and the bag, fill the bag with water and mild natural soap and start the device to let the water flow into the tubes, draining into the sink. Afterwards, repeat this procedure with at least 4 litres of clean running water to clean from any soap residue;
- At the end of use, detach the tubes and turn on the device for a few seconds shaking it with tubes hanging down to let the residual water run out;
- Leave the grip handle in a cool dry place, possibly vertically, until the transparent tube is completely dry.

RESOLVING EVENTUAL PROBLEMS

Problem	Possible Cause	Possible Solution
There is a leak between the tubes	Incorrect connection	Unscrew the fittings where the leak occurs and screw it back on
The device does not turn on	The pump does not start	Make sure the device is charged
Little / no water comes out of the cannula	Clogged tubes	Make sure there are no obstructions in the tubes or that they are not kinked
	Tightened tube clamp	Make sure the tube clamp (B1) is not tightened
	Bag positioned on the ground incorrectly	position the bag slightly inclined to direct the water towards the outlet and facilitate draft
	No water	Refill the bag with more water

In case of need, contact Water Powered srl to receive adequate instructions for solving the problems (customer@waterpowered.eu - www.myperfectcolon.com – www.waterpowered.eu).

TECHNICAL SPECIFICATIONS

Maximum water pressure: 80 PSI

Maximum water flow per minute: 1,2 L

Battery: Li-Ion 3.7V - 560mAh

Recommended Charger: 5V – 1A

Protection: IP21

Environmental Conditions of Use: Temperature from +18 to +35 °C; Humidity 30%-75% does not condense; Pressure 860÷1060 hPa;

Environmental conditions for transport and storage: Temperature -25÷70 °C, Humidity 25÷75%, Pressure 860÷1060 hPa.

SPARE PARTS AND ACCESSORIES

You can purchase the full range of My Perfect Colon products on the website www.myperfectcolon.com e www.waterpowered.eu.

WARRANTY

The warranty rules are valid only if the device is used according to the conditions of intended use.

With the exception of the maintenance operations described in the MAINTENANCE sect. and performed with the procedures indicated, any repair or modification made to the product by the user or by unauthorized companies will result in the forfeiture of the warranty.

The warranty does not extend to damage caused by inexperience or negligence in the use of the product or by poor or omitted maintenance.

The warranty is valid for a period of twelve (12) or twenty-four (24) months, depending on the type of buyer (legal or private).

The manufacturing company undertakes to replace the malfunctioning or incorrectly manufactured parts at its discretion, only after careful control and verification of faulty manufacture.

The transport and/or shipping costs in the event of incorrect use of the warranty terms are always charged to the buyer.

During the warranty period, the replaced components become the property of the manufacturer.

The warranty does not include damage resulting from excessive stress, such as the use of the product after finding a fault, the use of unsuitable operating methods, and failure to observe the instructions of use and maintenance.

The manufacturer assumes no responsibility for any difficulties that may arise in resale or use abroad due to the provisions in force in the country where the product was sold.

The defective product must be delivered to the manufacturer for replacement; otherwise, the replaced part will be charged to the buyer.

Authorized product assistance is performed directly by Water Powered s.r.l. or by a qualified technician appointed by the same.

DISPOSAL

The possibility of reusing some parts of the product is subject to the total responsibility of the user.



The symbol indicated in Legislative Decree 49 of 14 March 2014 transposes Directive 2012/19 / EU, indicating the need to dispose of the product in differentiated waste, specifically in electrical and electronic waste.

The product must not be disposed of with other domestic waste. Users must arrange for the disposal of the equipment to be scrapped by taking it to the collection point indicated for recycling electrical and electronic equipment.

DECLARATION OF CONFORMITY

Water Powered Srl declares that this device complies with the safety and performance requirements and the provisions of the MDR 2017/745 Regulation

The declaration of conformity can be downloaded from the website www.myperfectcolon.com. If it is not possible to download the documentation from the site, it is possible to request it directly from Water Powered Srl.

ACCIDENTS

Any serious incident in relation to the medical device we have supplied must be reported to the manufacturer and the competent authority of the Member State in which you are located.

ELECTROMAGNETIC COMPATIBILITY

Levels of conformity according to the EN 60601-1-2: 2015 standard

- ESD immunity 15kV in air 8kV on contact (EN 61000-4-2)
- 2kV / 100kHz burst immunity (EN 61000-4-4) power supply / 1kV signals
- Surge immunity (EN 61000-4-5): 1kV common / 2kV differential
- Magnetic field (EN 61000-4-8): 30A/m
- Immunity dips: 0% 0,5 cycles; 0% 1 cycle; 70% 25 cycles (50Hz) e 30 cycles (60Hz); Interruptions: 250 cycles (50Hz); 300 cycles (60Hz)
- Immunity to rf currents in the range 150kHz-80MHz (EN 61000-4-6) 3V modulation 80% 1kHz
- 6V modulation 80% 1kHz for the following frequency ranges:
 - 6,765 MHz ÷ 6,795 MHz
 - 13,553 MHz ÷ 13,567 MHz
 - 26,957 MHz ÷ 27,283 MHz
 - 40,66 MHz ÷ 40,70 MHz
- CISPR emissions 11 class A
- Harmonics EN 61000-3-2 class A
- Flicker pst, dt, dc

Immunity to magnetic field (EN 61000-4-3):

Field (V/m)	Frequency	Modulation
3	80MHz,2700MHz	1kHz AM 80%
27	380MHz,390MHz	18Hz PM 50%
28	430MHz,470MHz	18Hz PM 50%
9	704MHz,787MHz	217Hz PM 50%
28	800MHz,960MHz	18Hz PM 50%
28	1700MHz,1990MHz	217Hz PM 50%
28	2400MHz,2570MHz	217Hz PM 50%
9	5100MHz,5800MHz	217Hz PM 50%

Test level

Field	Form	Frequency
90V/m	AM 80% 1kHz	800MHz-960MHz
50 V/m	AM 80% 1kHz	1.4GHz-2GHz
35V/m	AM 80% 1kHz	2GHz-2.48GHz
28	2400MHz,2570MHz	217Hz PM 50%
9	5100MHz,5800MHz	217Hz PM 50%

Levels of conformity according to the EN 60118-13: 2011

Rated maximum output power of transmitter (W)	Distance (m) of separation according to the frequency of the transmitter		
	from 150kHz to 80MHz d = 1,2 vP	from 80MHz to 800MHz d = 1,2 vP	from 800MHz to 2.5GHz d = 2,3 vP
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

DISCLAIMER:

Although compliant with the EN 60601-1-2 standard, the My Perfect Colon PRO medical device can interfere with other devices in the vicinity. The device should not be used adjacent to or stacked with other equipment. Install the device away from other equipment that radiates high frequencies (short waves, microwaves, electrosurgical units, cell phones).

The use of this appliance near or placed on other appliances should be avoided, as this can lead to incorrect operation. In these cases, the device and other equipment must be kept under observation to verify their regular operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no less than 30 cm (12 inches) from any part of the My Perfect Colon PRO, including specified cables by Water Powered Srl. Otherwise, performance degradation of this equipment may occur."

The device is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The customer or the operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication devices (transmitters) and the medical device, as recommended below, in relation to the maximum output power of the radio communication devices.

For transmitters with a maximum rated output power not listed above, the recommended separation distance (d) in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the maximum rated output power of the transmitter in Watt (W) according to the transmitter manufacturer.

Note:

(1) At 80 MHz and 800 MHz, the higher frequency range applies.

(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



The company reserves the right to make partial or total changes to the product, which may differ from the manual's description.

The manufacturer, distributors and retailers decline all responsibility for any damage that may, directly or indirectly, arise to people or property due to failure to comply with all the requirements indicated in this user manual.

My Perfect Colon devices are not and do not replace the equipment used in colon hydrotherapy centres. Visit www.myperfectcolon.com or contact customer@waterpowered.eu for further information.

For any clarification or further information, visit the site www.myperfectcolon.com or contact customer care by email customer@waterpowered.eu.

Symbols

Meaning



Manufacturer



EC Brand The device respects the regulation MDR 2017/745.



Catalogue number



Lot number



Keep away from sunlight



Keep away from damp

SYMBOLS

Symbols

Meaning



Warning



Read the instructions before use.



Read the instruction manual



For disposal, the product must be delivered to an appropriate collection point to recycle electrical and electronic equipment (WEEE).



Medical device



Manufacturing date