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*CLEAN COLON
HYDROCOLONOTHERAPY*

HANDBOOK FOR USE



HYDROCOLONOTHERAPY DEVICE FOR PROFESSIONALS

004RA

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Thank you for choosing this device for hydrocolontherapy professional use, model 004RA

Before using this device we recommend to read carefully this handbook and keep it for possible future consultations

INDEX

	pag.
• Hydrocolontherapy device 004 RA for professionals.....	2
• Declaration of conformity.....	2
• CleanColon Italy Srl.....	2
• Signature of the Legal Representative.....	2
• Destination of use.....	3
• Maintenance and assistance.....	3
• Predisposition for the connection to the hydric and electric net.....	4
• Single use set nozzle description.....	5
• Filter for depuration of the water (optional).....	6
• Application and substitution of the filter.....	6
• Description of the device.....	7
• Instruction for the operator.....	9
○ The first time.....	9
○ Therapy phase.....	9
○ Cleaning phase.....	11
• Possible problems during therapy.....	12
• Technical features.....	13
• Suggestions on the room disposal.....	13
• Guarantee certificate.....	14

HYDROCOLON THERAPY DEVICE 004RA FRO PROFESSIONALS

DECLARATION OF CONFORMITY

The company Clean Colon with legal and operative seat in via Forze Armate 68 20147 Milano, states under its own responsibility that:

- The device 004RA with serial number has all the fundamental features required in the attachment 1 of the Directive 93/42/EEC on Medical Devices.
- The above mentioned device is in accordance with the rules CEI EN 60601-1 on the electric safety, and CEI EN 60601-1-2 on electromagnetic compatibility
- The above mentioned device fulfils the requirements of the rule UNI CEI EN ISO14971 on the risks management
- The above mentioned device is to be considered as belonging to the class 2b
- The above mentioned device is put on the market in NOT STERILE packaging
- The device is projected in accordance with the rules of the above mentioned directive
- The control procedure is carried on in accordance with the rules of the Quality System of the company and in accordance with the requirements indicated in the attachment VI points 3 and 4 of the Directive.

Clean Colon Italy
Signature of the Legal Representative

DESTINATION OF USE

The device 004RA is a device for hydrocolontherapy: this means an intestinal cleaning by means of cycles of warm and cold water reaching the patient through a flexible hose for single use to which extremity a single use nozzle is inserted. After having removed the intestinal impurities (fecalomas), the latter, pass through the flexible hose, reach the machine and are directed to the sewer system.

There is also the possibility to use a filter (optional) for the cleaning of the water before reaching the patient.

As the nozzle is an invasive instrument, the use of the 004RA is allowed only to specialized personnel having a qualification for the introduction and/or use of invasive instruments.

MAINTENANCE AND ASSISTANCE

004RA is an electro-hydraulic device whose maintenance/assistance must be executed only by CleanColon personnel or by persons authorized by CleanColon. The customer is not allowed to act on the machine as there is the risk to alter the calibration of some parts of the device and compromise the safety of the patient. In such case the guarantee will not be valid.

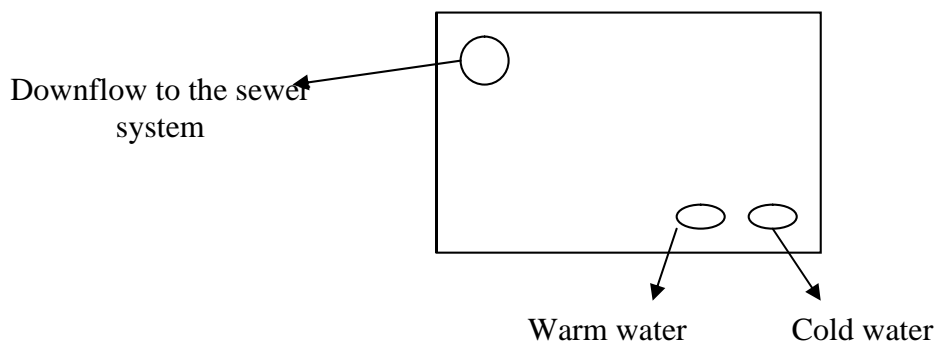
For any technical or functional necessities

Please contact exclusively the

Customer Service, tel. 039-2141078

PREDISPOSITION FOR THE CONNECTION TO THE HYDRIC AND ELECTRIC NET

Back side of the device 004RA



- Connect the outlets of cold water and warm water to respectively the cold and warm water connections of the hydric system. These connections should be provided with lock ball taps, female thread 3/8 GAS. The connections should be between 10 and 20 cm from the floor.
- Connect the outlet of the sewer system to the outlet of the hydric system, diameter 32 mm and between 10 and 20 cm from the floor.
- An electric plug of 10 A, 220 V should be at a maximal distance of 1,5 m from the device.

For advises on the room disposition where the therapy should take place, see the paragraph "Suggestions on the room disposition".

SINGLE USE SET NOZZLE

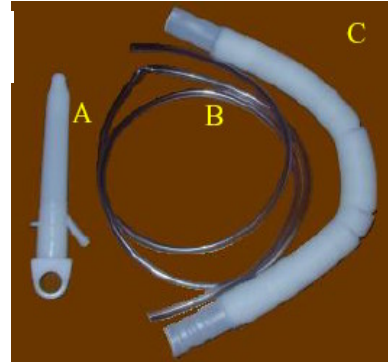
Together with the device 004RA we add a single use set nozzle free for the first treatment

DESCRIPTION

Single use set nozzle

- A. Ready for use nozzle
- B. Hose in PVC
- C. Knurled flexible and extensible hose

Fig. 1



Obturator

(remove after having inserted the nozzle in the patient's rectum)

- D. Ring for the obturator removal
- E. Rounded extremity to facilitate insertion

Fig. 2



Nozzle after insertion

- F. Connection to the knurled hose
- G. Connection to the PVC hose
- H. Water entrance to the patient

Fig. 3



Belt wit protection from sprinklings (Patent n° 01318041)

- I. Hole for the nozzle insertion

Fig. 4



FILTER FOR DEPURATION OF THE WATER (OPTIONAL)

If required, we can add a filter for the depuration of the water directed to the patient.

Fig. 5



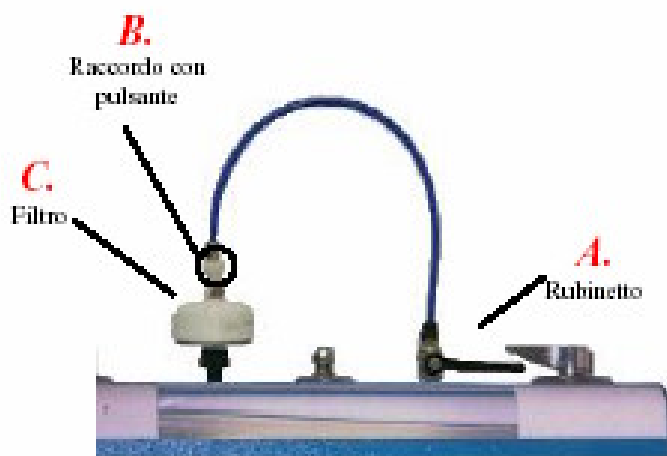
It is a filter for protection from bacteria, protozoa and particles, with EC certification belonging to the company PALL and suited for 96 hours of use, after which it must be substituted. During its use, the filter must not be removed because the possible penetration of air could reduce considerably the water flux.

Application and substitution of the filter

The filter must be absolutely removed and substituted after 140 therapies.

For the application and substitution of the filter, pay attention to the following indications:

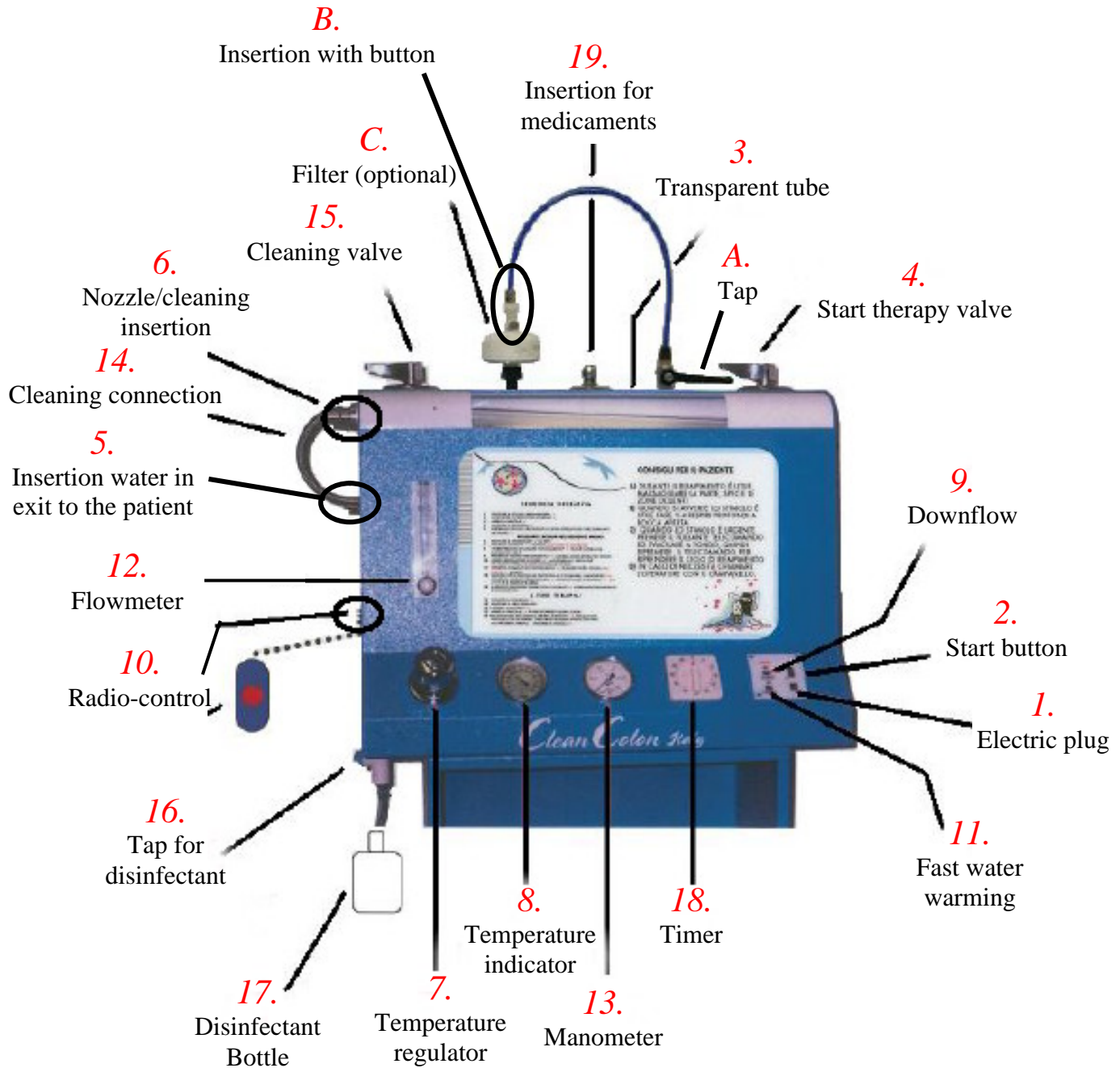
1. close the tap (A)
2. remove the connection (B) by pressing the apposite button.
3. Unscrew the filter (C) from its site (only in case of substitution).
4. Open the packaging of the new filter.
5. Screw the new filter in its site.
6. Put the connection (B) on the new filter.
7. Open the tap (A).



DESCRIPTION OF THE DEVICE

The device 004RA has two main working phases:

- Therapy phase: in which the hydrocolonotherapy on the patient is executed (buttons from 1 to 13)
- Cleaning phase: for the cleaning of the hoses where the faecal material has passed during the therapy phase (button from 4 to 6 and from 14 to 17)



1. *Electric plug for battery charge*

During the battery charging the device cannot work and therefore no therapies can be executed. The battery charge exhausts after 8 therapies (about 4 hours).

2. *Start button*

After pressing the start button two green lights appear in sequence. The fluorescent lamp in the *transparent tube (3)* enlightens and a short acoustic signal indicates that the device has been started correctly. Long acoustic sounds indicate an anomaly. In this case it is not possible to execute therapies and the customer service must be called.

3. *Transparent tube*

Water and fecalomas will pass through this tube.

4. *Start therapy valve*

5. *Water exit to the patient*

During the therapy phase the small PVC transparent tube must be inserted (picture 1, B) in this outlet. The other extremity of the tube will be inserted in the nozzle (picture 3, G).

6. *Nozzle/cleaning insertion*

Metal insertion with double function:

- During the therapy phase it is the insertion for the knurled flexible hose (picture 1, C) connected with the nozzle (picture 3, F)
- During the cleansing phase the free extremity of the *cleaning connection (14)* must be inserted here

7. *Temperature regulator*

8. *Temperature indicator*

9. *Downflow button*

It acts on the download valve (not indicated in the picture)

During the therapy phase, after pressing the downflow button, the downflow valve closes and a red light appears: from this moment the water flows to the patient's colon. When the light is green, the water and the fecalomas are directed to the sewer system.

10. *Downflow button on the radio-control*

It has the same function as the *downflow button (9)*. With the radio-control, the patient himself decides when he must start the downflow, when he has a defecation stimulus.

11. *Fast water warming*

This button brings the water temperature at the maximum level of 38°C in a short time.

12. *Flowmeter*

Its function is opening and regulating the water flow directed to the patient. For a correct use, set it on 0,5-0,7 l/min.

13. *Manometer*

It indicates the pressure of the water in entrance to the patient.

14. *Cleaning connection*

It is useful during the cleaning phase. Insert the free extremity in the *nozzle/cleaning insertion (6)*. During the therapy phase this connection (14) must be removed from the insertion (6) and the free extremity must be fixed on the back side of the device.

15. *Cleaning valve*

The cleaning phase is started when the cleaning valve is turned in position A (open).

16. *Tap for disinfectant*

Open it during the cleaning phase in order to permit the disinfectant to flow.

17. *Disinfectant bottle*

18. *Timer*

19. *Insertion for a possible addition of a medicament*

Through this insertion it is possible to add some medicaments to the water in entrance to the patient during the therapy phases.

20. *Filter* (optional) see picture 5

INSTRUCTIONS FOR THE OPERATOR

The first time

After the test, the device is completely emptied from water. The following operations are needed only before the first therapy:

- PRESS the *start button (2)*
- PRESS the *fast water warming (11)* for at least one minute.
- INSERT the small pvc hose (picture 1, B) in the *insertion water in exit to the patient (5)*. If there is a filter OPEN the *tap (A)* **slowly**.
- TURN the *flowmeter (12)* letting the water flow for at least one minute.
- STOP the water flow turning the *flowmeter (12)* in the opposite direction. If there is a filter, CLOSE the *tap (A)*.

Therapy phase

Let the patient wear single use drawers and proceed as here indicated:

Preparation to the therapy:

1. If the device is under charge, disconnect the battery charge device from the electric plug for battery charge (1).
2. PRESS the *Start button (2)*
3. CLOSE the *cleansing valve (15)* turning it on C.
4. OPEN the *Start therapy valve (4)* turning it on A
5. DISCONNECT the *Cleaning connection (14)* from the insertion (6) and fix it on the back side of the device.
6. OPEN the plastic sack of the nozzle.

7. INSERT the extremity of the small pvc tube (Fig. 1, B) in the nozzle insertion (Fig. 3, G) and the other extremity in the *insertion water in exit to the patient (5)* of the device.
8. INSERT the extremity of the knurled flexible and extensible tube (Fig. 1, C) in the *nozzle/cleaning insertion (6)* of the device.
9. LET the patient lie on the coach and ask him to lie on his left side with the left leg strained and the right leg bent.
10. INSERT the nozzle with the obturator (Fig. 1, A) in the patient's anus after having lubricated it with vaseline.
11. REMOVE the obturator pulling the ring (Fig. 2, D). In the patients anus there will be only the nozzle as in Fig. 3.
12. INSERT the nozzle in the sprinkling protection belt (Picture 4, I)
13. INSERT the free extremity of the knurled flexible and extensible hose (picture 1, C) in the insertion of the nozzle (Picture 3, F)
14. MAINTAIN the nozzle with the hand and let the patient turn in supine position.
15. FIX the sprinkling protection belt to the patient.

Therapy

16. SET the *Temperature regulator (7)* to 38°C. We recommend not to set higher temperatures and to keep temperature constantly under control through the *temperature indicator (8)*. The *temperature regulator (7)* is anyway provided with a mechanical block at 38°C. To overcome this value is possible pressing the red button and at the same time rotating it. This causes an acoustic signal that stops only when water temperature gets colder than 32°C
17. PRESS the *download button (9)* (or the *radio-control (10)*). A **red** light appears and for about 3 seconds water passes in the *transparent tube (3)*. If this does not happen, call the customer service.
18. PRESS the *fast water warming button (11)* till the temperature reaches the level decided (38°C). In this phase water will pass through the *transparent tube (3)* and will go directly to the sewer system.
19. PRESS the *download button (9)* (or the *radio-control (10)*). The light becomes **green**. In this moment possible air collected in the tubes is expelled.
20. If there is a filter, OPEN *the tap (A)* **slowly**.
21. Turn the *flowmeter (12)*. Water will begin to enter in the patient's rectum passing through the small hose in pvc (Picture 1, B). We remind that it is important to regulate the flowmeter on 0,5-0,7 l/min and that this regulation must be executed with the **green** light and with the *manometer (13)* in position "0". There are anyway three safety devices for the pressure control of the water in entrance to the patient.
 - 1 pressure reducer
 - 1 safety valve to the download
 - 1 pressure switch, which automatically controls the opening of the download valve.
22. PRESS the *download button (9)* (or the *radio-control (10)*). The light becomes **red**. In this moment the water will flow in the patient's colon and will begin its cleaning action. In this phase there is at the same time a cleaning of the hydric circuit as the water will pass for about three seconds also in the *transparent tube (3)* and then will be downloaded. If this does not happen in any step from **green** to **red** light, call the customer service

23. The patient can now PRESS the button on the *radio-control (10)* (the light will become **green**) every time he will feel the defecation stimulus. Normally this happens when the *manometer (13)* indicates 40-70 mbar. The fecalomas will pass through the knurled flexible hose (picture 1, C), to the *transparent tube (3)* and will go to the sewer system.
24. At the end of the phase, the patient will have to PRESS the button on the *radio-control (10)* once more (the light will become **red**) so that there will be another colon filling.
25. Tell the patient to REPEAT the phases 18 and 19 till the end of the therapy.
26. If there is a filter, CLOSE the *tap (A)*.
27. REMOVE the nozzle and throw it away.

Important:

During the therapy the patient will have to massage his stomach from the right to the left to facilitate the exit of water and fecal material.

After each therapy, put the device 004RA in charge inserting the battery charge in the *electric plug (1)* and execute the cleansing with a detergent as indicated here below.

Cleaning phase

At the end of each therapy it will be necessary to execute the following steps for cleaning and disinfection of the tubes which during the therapy phase have received the faecal material.

1. INSERT the free extremity of the *cleaning connection (14)* in the *nozzle/cleaning insertion (6)*
2. OPEN the *start therapy valve (4)* turning it on A.
3. CONTROL that the light is green, otherwise press the *download button (9)* (or the *radio-control (10)*).
4. OPEN the *cleaning valve (15)* turning it on A. Let the water flow in the transparent tube for about 10 seconds.
5. OPEN the *tap for disinfectant (16)*.
6. CLOSE the valve (4) turning it on C so that water with disinfectant will stay in the tube for a better cleaning action.
7. After some seconds Close the *tap for disinfectant (16)*.
8. CLOSE the *cleaning valve (15)* turning it in position C so that the passage of water in the cleaning circuit is blocked.

Possible problems during therapy

It is possible to have an insufficient defecation especially during the first therapy in patients older than 60 even with water pressure in the intestine between 60 and 70 mbar (see *manometer (13)*) indicating a stimulus by the patient. This means that there are obstructions and it will be necessary to let the water overcome the obstacle so that the pressure is reduced to 30-40mbar within 10-15 seconds. The procedure is following.

- MAINTAIN the water temperature at a temperature of 38°C.
- CLOSE the *flowmeter tap (12)* when the stimulus begins.
- Tell the patient to MASSAGE his stomach in the direction of water flow.
- Tell the patient to BREATHE deeply for more than one minute. The *manometer (13)* index will fall of 2 or more positions.
- OPEN the *flowmeter tap (12)* and reach 60-70 mbar (it will take from 30 to 60 seconds); if this happens it means that water is overcoming the obstacle and is filling the colon. Afterwards the stimulus will come.

Possible slight pains in one or more points of the stomach during the therapy have to be considered as normal. In case of spasms (which occur very rarely and are due to extremely big fecalomas or excessive presence of air) massage the stomach continuously. If necessary send the patient to the toilette and restart the therapy afterwards.

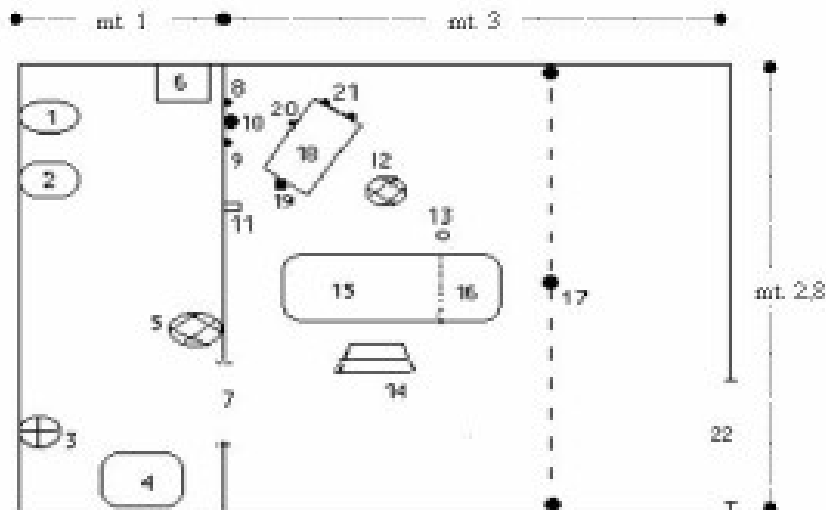
If at the end of the therapy the patient feels tired, this depends on the emuntor organs (liver, kidney) too much overloaded with toxins. In these cases recommend the patient to administrate potassium (e.g. eating a banana)

Technical features

Maximum pressure of the water to which the patient can be subjected	220 mBar
Maximum temperature of the water	38°C±2°C
Maximum flow of the water	0,5-1,5 l/min
Nozzle	Single use, not sterile
Alimentation	12 Vcc
Filter system (optional)	Filter with nylon membrane 6,6 with capacity of 0,2 µm

NOTE: the pressure indicated as maximum, in reality is never reached because the patient feels the defecation stimulus within 50 y 100 mBar.

Suggestions on the room disposition



1. WC	11. Electric plug 10 A, 220 V
2. Bidet	12. Doctor stool
3. Basket	13. Call ring
4. Washbasin	14. Two rung ladder
5. Stool	15. Patients couch
6. Clothes stand	16. Reclining headrest
7. Toilette door	17. Curtain
8. Warm water with ball tap female 3/8 (10 to 20 cm from the floor)	18. 004RA Device
9. Cold water with ball tap female 3/8 (10 to 20 cm from the floor)	19. Nozzle/cleaning insertion
10. Downflow to the sewer system 32 mm diameter and 10 to 20 cm from the floor	20. Downflow to the sewer system of the device
	21. Water entrance in the device
	22. Room door

Guarantee certificate
Validity 24 months

The hydrocolonotherapy device 004RA serial n° _____ sold on _____ to:
_____ is granted for a period of 24 months from the sale date: therefore during this period CleanColon Italy Srl is engaged to substitute free all the pieces needed for reparation, if the instructions and use modalities of the device have been respected.

In order to benefit from this guarantee, this document is needed and must be kept because it will not be substituted.

From the guarantee are excluded devices or accessories resulting defecting due to negligence or use carelessness, incorrect installation, faulty use or any use differentiating from the instructions indicated in the handbook, interventions by non specialized personnel, transport without due attention, natural events or any intentional or not intentional actions and in situations not depending on manufacture defects of the device.

From the guarantee are excluded services such as installation and/or hydric or electric connections.

The CleanColon Italy Srl declines any responsibility on possible direct or indirect damage to persons and/or things due to the not observance of the indications written in the handbook.

The device will be repaired in our customer centre. The transport costs and risks are at expense of the customer.

The execution of one or more reparations or substitutions during the guarantee period does not modify the validity date of the guarantee.

In case of reparation outside the guarantee, in addition to the manufacture costs, also the costs of the substituted parts will be debited to the customer.

The substitution of the device is excluded.