TRANSCENDENCIAS COMERCIALES S.L.

C.I.F. B-48833404

"HC – 2000 CLASSIC"

USER MANUAL

MD CE 0051

INDEX

Dear Customer:

Before you use the **HC-2000 Classic** machine for the first time, the manual must be read thoroughly with the specifications and directions for use, so that you know everything about the correct working and installation of the machine.

COLON HYDROTHERAPY MACHINE
MODEL "HC-2000 CLASSIC"

MANUFACTURER NAME:
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This equipment is designed and built with the following in mind:

1. Patient´s Safety

- System with full pressure & temperature regulation
- High-precision, highly reliable pressure gauge & thermostat
- The water supply will be cut off if the maximum pressure or the minimum or maximum temperature is exceeded, always ensuring that the therapy is carried out within the patient's safety parameters.

2. Easy Operation

- Easily visible & accessible controls
- Hermetic, odour-free drainage system

3. Economy

- Low maintenance
- Low consumption
- Easy installation
- Designed and built for long life

For spare parts or further information, consult:

Transcendencias Comerciales, S.L. (TRANSCOM)
Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
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For any spare parts requests, assistance, or additional information, always provide your unit's serial number. The serial number is write on the identification plate located on one side of the machine's casing, identified with the symbol:

SN

1. INDICATIONS FOR COLON CLEANING PROCEDURES

The HC-2000 Classic is a Colon cleaning device that is used for the introduction of water at different temperatures and pressures, always within the parameters of patient safety, in order to eliminate any waste found in the large intestine before a radiological or endoscopic examination.

2. CONTRAINDICATIONS FOR COLON CLEANING PROCEDURES

Severe Cardiac Disease, GI Haemorrhage/Perforation, Severe Haemorrhoids, Carcinoma of the Colon or Rectum, Fissures/Fistulas, Abdominal Hernia, Recent Colon or rectal Surgery, Renal Insufficiency, Abdominal Surgery, Intestinal perforations, Pregnancy, Abdominal Pain, Rectal bleeding and Abdominal distension

3. PRECAUTIONS

- Only use drinkable water
- Not for use on children or pregnant women.
- Only for use by Healthcare Professionals. This device is not intended for lay users.
- Do not modify this equipment without authorization of the manufacturer
- There is risk of reciprocal interferences if any diagnosis equipment is used in the same room during the treatment
- Follow the process manual instructions
- Diseases infection risk if disinfection after each session not done, with the disinfectant CIDEX OPA.
- The device is intended for use in professional settings (clinics, medical offices) only by qualified healthcare professionals
- This device is designed to be used with TRANSCOM disposable kits, the Hydrokit.
    - Risk of perforation if instructions are not followed.
    - Under no circumstances should any item of this kit be reused, as this could lead to blood borne and venereal diseases, or via contact with faeces.

Any serious incident related to the product must be reported to the manufacturer and the health authority.

4. INTENDED CLINICAL BENEFITS

- Colon cleansing through colonic irrigation to prepare it for colonoscopy or radiologic examination.
- Temperature and pressure control for patient safety and comfort.
- Electrical Safety Certificate guaranteeing that the user and patient are protected from electrical hazards.

- Electromagnetic Compatibility (EMC) Certificate guaranteeing that the device does not cause electromagnetic interference to other equipment, as well as ensuring that it continues to function when faced with disturbances caused by other systems in the vicinity.
- Validated device disinfection process to prevent patient infections.
- To ensure ease of handling, usability tests were carried out to evaluate and mitigate the risks associated with correct use and usage errors in normal use.
- It provides better water quality as the treatment water passes through a filter to remove sediment and then passes through a UVA lamp to treat any organic matter in the water.
- Functional tests carried out with all Hydrokit models to prevent dripping.
- Odor-free cleaning procedures, system closed hermetically, hygienic system, performed with Hydrokits, single-use and ergonomically designed to reduce possible discomfort during the procedure.
- Consistent quality throughout its shelf life.

5. SIDE EFFECTS

Minor side effects may occur related to the procedure, such as mild abdominal discomfort, rectal distension and mucosa irritation.

6. TARGET PATIENT POPULATION

Patients who require radiological or endoscopic examination.

7. INTENDED USERS

Only for use by Healthcare Professionals. This device is not intended for lay users.

8. CLINICAL SETTING

The device is intended for use in professional settings (clinics, medical offices) only by qualified healthcare professionals.

9. PATIENT POPULATION

The patient population would include both male and female adults.
Not to be used with children or pregnant women.

10. EQUIPMENT SHELF LIFE

This machine has a 7-year lifespan if the maintenance instructions are followed correctly. There is no risk associated with disposing of the machine at the end of its useful life because it is disinfected with each session. For electrical/electronic parts, dispose of them in accordance with local regulations.

11. SAFE DISPOSAL OF DEVICE, HYDROKITS AND FILTERS

HC-2000 Classic:

The device complies with directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment. It must be disinfected at the end of each session, as well as prior to its disposal.

This device cannot be thrown in the trash, it must be treated as waste electrical and electronic equipment (WEEE) and must therefore be selectively collected, as per local legislation. The waste management of this product is carried out in accordance with Directive 2012/19/EU.

Hydrokit:

After use, the components must be handled according to universal standard precautions, as they will be contaminated. Specific bags sufficiently resistant for the disposal of these wastes must be available, which must be in puncture and breakage-proof containers and shall be closed and managed as sanitary waste assimilable to urban waste.

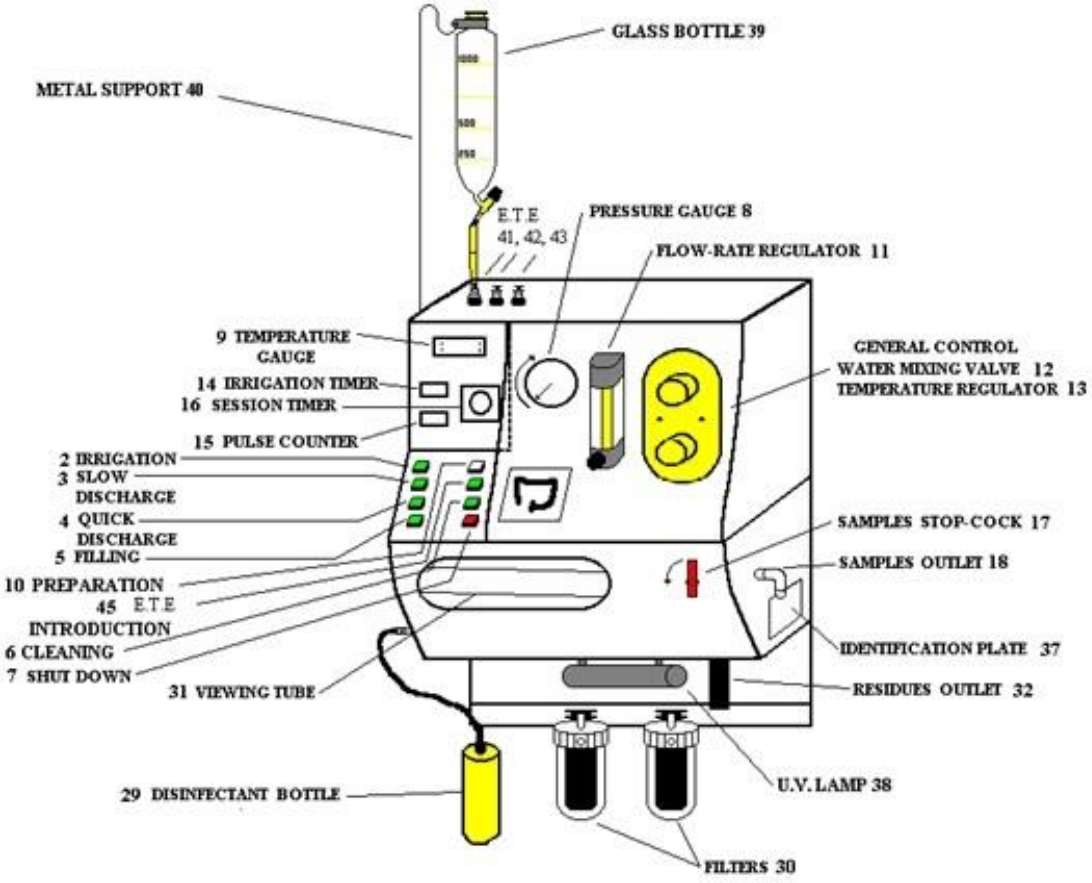
Water Filters:

TwinPure Filters are made of 100% polypropylene through which drinking water has passed, so they can be disposed of as urban waste.

12. RESPONSABILITY

The customer will be entirely responsible if these instructions and indications for use supplied by TRANSCOM SL are not followed.

13. DESING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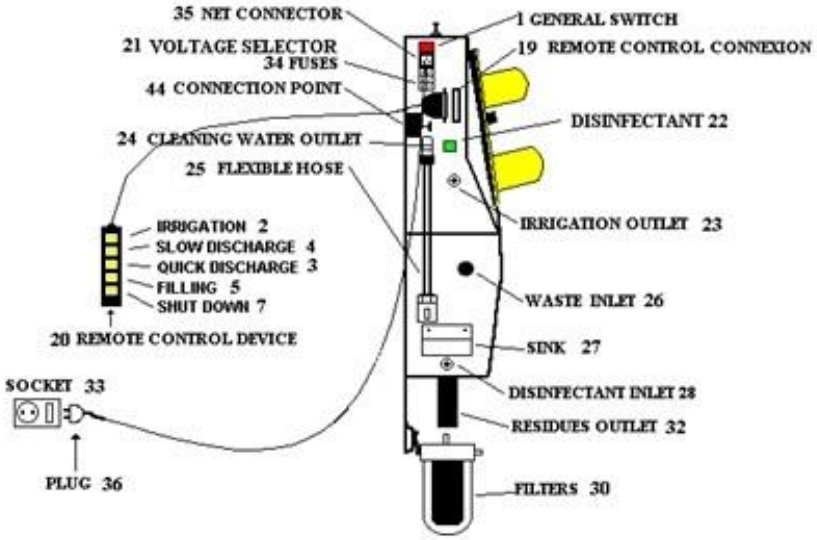
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14. CHARACTERISTICS OF HC-2000 CLASSIC

GENERAL SWITCH (1)

General switch. Set to (1) to switch on and (0) to switch off the machine.

VOLTAGE SELECTOR (21)

This selector allows to adapt the working of the device to the power of the net where it has been installed.

IRRIGATION (2)

Press this control when the Preparation button (10) is not connected. In this position a continuous inward and outward of water is produced. It will come in through the irrigation intake pipe and it will come out through the drainpipe outlet.

SLOW DISCHARGE (3)

This button has the same function as QUICK DISCHARGE, but the evacuation is carried out slowly so that the qualified staff can observe with accuracy the waste and assess it on the basis of consistency thickness, etc.

QUICK DISCHARGE (4)

Press this button at the request of the patient when the colon is full of water. In evacuation the waste is dragged along the outlet tube and can be observed in the glass display or screen.

FILLING (5)

In this position water passes through the water line (and through the rectal nozzle connected to it) to the large intestine until the colon is full, or the patient advises. If the intra-intestinal pressure exceeds 150 mbar or 2.17 PSI, the HC-2000 CLASSIC will stop automatically and will go to QUICK DISCHARGE position.

CLEANING (6)

When the session is finished, press this button to clean the drainpipe circuit of all waste and germs.

PREPARATION (10)

When turning on the machine the water circuit is closed by default.

Press PREPARATION button (10), the water will flow till reaching the temperature and flow rate wanted. Once reached the temperature and flow rate needed to do the qualified staff press again PREPARATION button (10) to stop the process and press IRRIGATION (2) to start with the session.

DISINFECTANT (22)

Press this button to do the suction of disinfectant during the disinfection process.

Once FILLING (5) button is pressed, press DISINFECTANT (22) button for a few seconds and fill the viewing tube as much as you want.

Finish the filling by pushing the CLEANING (6) button.

See the machine disinfecting instructions.

SHUT DOWN (7)

By pressing this button IRRIGATION function will be interrupted for safety reasons. The user, this is the qualified staff, can switch off the device as soon as he notices something wrong or when he is told to do it by the patient.

PRESSURE GAUGE (8)

This device displays the water pressure in irrigation. This manometer measures the pressure inside the patient's colon when the irrigation is being carried out. The pressure is set at 150 mbar (2.17 psi) during the session.

TEMPERATURE GAUGE (9)

Digital indicator showing the temperature programmed on the temperature regulator (13).

The internal memory of this device is set to the safety levels of 22º (71,6ºF) and 40ºC (104ºF). Irrigation will not be allowed by the security controls if the water temperature values are outside this security range.

ATTENTION: This display is NOT a temperature regulator. Avoid pressing the buttons without the indications of a Transcom representative.

FLOW RATE REGULATOR (11)

This is a system used to regulate water flow per hour (LITRES per hour), which allows the water quantity to be adjusted when it is introduced in the patient's large intestine. In the same way, it also controls the pressure flow rate.

At the bottom of the water flow regulator there is a round control knob. Turning the knob clockwise, less water come in, so lower pressure will be set. Turning the knob anticlockwise more water comes in, so higher pressurewill be set.

GENERAL CONTROL (12-13)

It consists of two elements:

1. MIXING VALVE (12). Allows the water inlet to be opened and closed, controlling the flow of water through the machine.

2. TEMPERATURE REGULATOR (13). Allows the water outlet temperature to be controlled, which can be increased or decreased at the discretion of qualified personnel. It features a numbered scale to facilitate temperature adjustment.

The bore that takes the temperature at the thermostatic valve is set at the outlet of this valve. On the temperature gauge you can see the temperature of the water that comes out from the thermostatic valve. Desired temperature needs to be adjusted in the temperature valve by making both the temperature and the verticalline drawn over the valve coincide.

We can correct the position of the control temperature of the Temperature Regulator (13) if there is any differencebetween the temperature of the Temperature Gauge (9) and what is being indicated by the temperature regulator. To readjust it, unscrew the cover of the control, turning it anticlockwise (holding the control so that it is only the cover that moves) and with a screwdriver unthread the fixing screw to the hub cap to the spindle. The spindle of thevalve has some grooves that fix perfectly with the grooves of the control. Pulling backwards on the control and turning it left or right at the same time and inserting them in the control of the spindle, you can readjust the temperatures and adjust to the one indicated by the thermostat control. Once the temperature has been adjusted,adjust the fixing screw of the hub cap and replace the cover of the control.

IRRIGATION TIMER (14)

Reset the counter to 0 before operating to know the length of time it has been used.

PULSE COUNTER (15)

By resetting the counter to 0 before starting the session the qualified staff can know how many liters have beenused in each session.

SESSION TIMER (16)

A time counter is included and can be programmed from 0 to 100 hours depending on the scale. The session timecould be arranged and whenever the period is completed the machine will stop.

IMPORTANT NOTE: Due to its characteristics, the pointer of this watch does not move when the programmedtime goes by. It is the green light that blinks more quickly until it stops, which indicates that the time for the sessionis over. To continue with a new session just turn off and on the machine.

SAMPLES STOPCOCK (17) AND SAMPLES OUTLET (18)

Separate faucet and residues outlet to take samples of the waste coming out for later analysis, at the request of thequalified staff.

REMOTE CONTROL CONNECTION (19) AND REMOTE CONTROL DEVICE (20)

This unit has a cable long enough to allow the colon cleaning session to be handled without touching the controlson the machine panel.

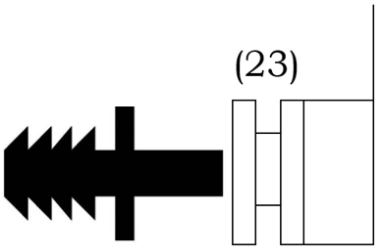
The remote control must always be connected, even if it is not used, otherwise the machine would not work.

The unit contains the following buttons: IRRIGATION (2); SLOW DISCHARGE (3); QUICK DISCHARGE (4); FILLING (5); and SHUT DOWN (7), and all of them can be used instead of the control panel, in which there is theDISINFECTION button (6).

IRRIGATION OUTLET (23)

This is a connection point on the machine. One black fitting must be fitted to this blue outlet in order to connect theHydrokit's water line to this point.

ATTENTION: Connect very carefully the black spigot connector fitting**,** the spiky side of the connector is connected to the irrigation tube. connect the straight end of the fitting to the blue irrigation outlet of the machine.



CLEANING WATER OUTLET (24) AND FLEXIBLE HOSE (25)

The flexible hose (25) is connected to the connection point (24) on the machine to clean it.
The water and the disinfectant that will be used in the disinfection process go through this flexible hose. Once the session is finished and the patient is not connected to any components, the flexible hose must beconnected to the waste inlet.

WASTE INLET (26)

This is a connection point on the machine which is used for the following operations:

- Waste removal: Fit the waste hose to carry out session.
- Disinfection the machine: Fit the flexible hose (25) after each session to disinfect the unit.

The residues inlet is a stainless steel connector (Peg shaped) to which the following components could beconnected:

- During the session, the waste hose
- During the disinfection, the flexible hose.

SINK (27)

The flexible hose (25) must be placed in this sink after disinfecting. This sink is just a place to lay the flex on. When the flex is laid on this little sink it has been previously disinfected because of the disinfection made before. This sink has been thought out to keep the little clean water drops that could come out from the flex. These drops can not cause contamination.

DISINFECTANT INLET (28), DISINFECTANT BOTTLE (29)

A plastic tube is connected from disinfectant inlet (28) on the machine to a disinfectant bottle (29), so that thesuction of disinfectant is done while doing the disinfection process.

FILTERS (30)

Two active filters are incorporated to filter the water before it enters the patient. It is important especially for the proper running of the apparatus as it avoids the build-up of elements present in the main water supply which coulddamage the components.

U.V. LAMP (38)

After flowing through the filters, the water is exposed to ultra-violet light.

VIEWING TUBE (31)

Transparent perspex tube for viewing the waste removed from the patient during the session. A light is built in tofacilitate observation.

RESIDUES OUTLET (32)

The drainage tube should be connected to this connection point on the machine.

SOCKET (33)

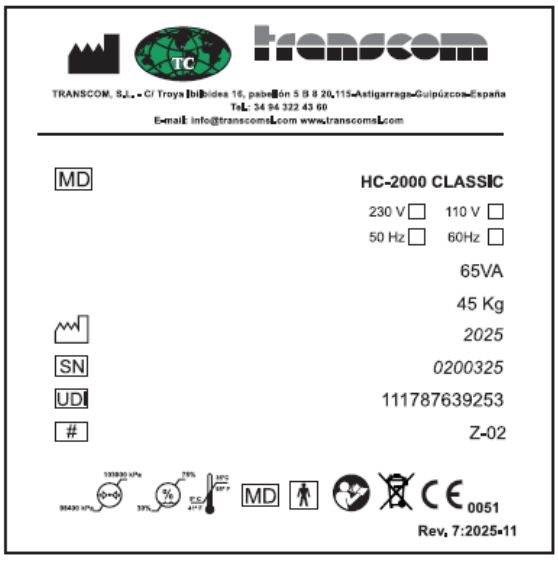
The mains socket should be at least 1 m from the machine on the left hand side.FUSES (34)
The machine is protected by four easily changeable fuses.

PLUG (36) AND NET CONNECTOR (35)

Connection point (35) on the machine, to connect the net connector and plug (36) supplied.

IDENTIFICATION PLATE (37)

All these machines carry an ID plate with the following data:



METAL SUPPORT AND GLASS BOTTLE DEVICE (39, 40, 44)

The connection (44) in machine is for the metal support (40) and the glass bottle (39).

INTRODUCTION ETE (41, 45)

There are connection points to the auxiliary input (41, 45).

15. STEP BY STEP DESCRIPTION OF A SESSION

Warning: The personnel must remain with the patient during the whole session.

1. Open the water stop-tap outside of the machine

2. Switch on the General Switch (1).

3. Wait 5 minutes before starting any procedure.

4. Set the session timer (16) to 1 hour. Check that the green lamp flashes. (One hour is the recommended time,but the qualified staff can vary it as desired).

5. Set the Water Mixing Valve (12) to maximum (large point).

6. Select the working temperature by dialing the Temperature Regulator (13) and verify on the TemperatureGauge (9) that this temperature has been attained.

7. Press “Preparation button” (10).

   NOTE: When the Preparation process is selected, this diverts the water directly to the drainage system, thusallowing the water to warm up for the preparation of the equipment prior to a session. This allows the water to directly by-pass the Residues Inlet and View Tube and 2-way solenoid valve and go directly into the drainage system; this way, any back flow of water or waste is prevented by a check valve. This position is used in the preparation of the equipment to allow the water temperature to raise or lower to the selected setting. Once all the steps have been completed and the temperature has arrived at the selected setting, press the “Preparation button” (10) to stop preparation process and start the irrigation.

8. Select the working flow rate at the Flow Rate Regulator (11) turning the black control knob set at the bottom of this regulator. Using the control knob set at the bottom of the Flow Rate Regulator select the working flow rate turning clockwise for decreasing the amount of water or turning counter-clockwise to increase the amount of water entering.

   The recommended rate is from 30 liters to 50 liters per hour, although it is possible to increase this amount without endangering the patient.

9. Reset the Irrigation timer (14) and the Pulse Counter (15) to zero.

10. Using the Water Hose (Inflow water line/hose) from the Hydrokit, connect one end of the hose to the Irrigation Outlet (23) and the other end of the hose to the Inlet port (Inflow water line/hose connection port) of the Speculum. Then connect the Waste Hose (Waste water line/hose) to the Waste Inlet (26). The other end of the Waste Hose is connected to the Waste water line/hose connection port of the Speculum after the Speculum is inserted into the patient and the obturator is removed, after Step 10.

11. Insert the Speculum into the patient and remove the obturator.

12. Connect the waste hose to the Speculum.

    Both the inflow Water Line/Hose and Waste Water Line/Hose must be connected to the Speculum manually. The inflow Water Line/Hose must be connected inserting the hose over the appendage that protrudes from the Rectal Nozzle. The other end is connected to the appendage that protrudes from the Irrigation Outlet (23). The Waste Water Line/Hose must be connected to the Residues Inlet (26) by inserting the hose over the metal appendage which is a tapered fitting, to insure a water tight fit. The other end of the Waste Water Line/Hose is connected to the Rectal Nozzle at the Waste Water Line/Hose connection port, which is also a tapered fitting, to insure a water tight fit

13. Once the machine reaches the wanted temperature press Preparation (10) again and after that press the irrigation button (2). In this position, water will enter and leave continuously.

    When you press Irrigation Button (2) this turns on the fresh water for the inflow Water Line. This allowsthe water to enter the inflow Water Line that is connected to the Speculum. The water enters the Speculum and leaves the Speculum through the Waste Hose without entering the colon, exiting through the Viewing Tube and leaving the device through the drain.

14. To direct water into the patient's colon, press "Filling Button" (5).

    When the Filling Button is pushed, the 2-way solenoid valve gets switched to the closed position. This stops the outward flow of water to the drainage system. The fresh water supply is a continuous flow of water during the colonic process. This water fills the View Tube and the Waster Water Line/Hose to the Speculum. Once filled, the fresh water then enters the colon. This process of filling ensures that no contamination from the View Tube or Waste Hose enters into the colon.

    When the Irrigation Button is pushed, the 2-way solenoid valve gets switched to the open position. This allows the water to pass into the Speculum, then down the Waste Water Line/Hose into the Residues Outlet and View Tube and through the 2-way solenoid valve and into the drainage system. During this process, the fresh water from the inflow Water Line/Hose is continuously running and helps wash the matter through Speculum and Waste Water Line and Residues Outlet and View Tube into the drainage system.

15. Once sufficient water has entered the patient´s colon, press the Quick Discharge Button (4) or the SlowDischarge Button (3).

    The increases or decreases of water pressure inside the patient's colon are displayed on the pressure gauge. More water implies higher pressure and less water implies lower pressure. The qualified staff will know when sufficient water is given by following.

    - **Patient's reponse**: The patient indicates to the qualified staff when they feel that the colon is full. The qualified staff can then press the Quick Discharge or Slow Discharge Button (The patient may remove the Rectal Nozzle by himself: it is not dangerous)

    - **Pressure Display**: On the pressure gauge, if the pressure is lower than 150 mbar or 2.17 psi the qualified staff can continue the session by manually pressing the Quick Discharge or Slow Discharge Buttons. If the pressure exceeds 150 mbar or 2.17 psi the device automatically switches off the irrigation process and activates the Quick Discharge.

16. Continue the session, alternating between "Filling" (5) and "Quick Discharge" (4) or "Slow Discharge" (3)

17. At the end of the session press "Quick Discharge" (4) and "Shut Down" (7) buttons and close the water supply to the machine by turning the control valve (12) to its closed position

    NOTE: The qualified staff must have completed the session. This means that neither water nor waste are inside the patient's colon. This is accomplished by the qualified staff verifying that the water and the waste have passed through the Waste (residue) Outlet (having seen the water and waste through the Viewing Tube).

18. Once the therapy session is over, the Hydrokit accessories will be removed. To do so, proceed as follows:

    a) Remove the Rectal Nozzle from the patient's sphincter by asking the patient to exhole while gently pulling the nozzle. Then continue with the following instructions.

    b) Disconnect the Water Line from the Irrigation Outlet (23) by a gentle pulling action.

    c) Disconnect the Waste Hose from the Waste Inlet (26) by a gentle pulling action.

    Note: Once all the above elements have been removed, they are not to be used again and must be discarded.

19. Disinfect the device.

16. SAMPLING

If suspect substances are detected and it is decided to take samples of the waste product from the user during thesession while in Irrigation (2), Slow Discharge (3) or Quick Discharge (4) modes, do as follows:

1. Press "Filling" (5)
2. Wait for the viewing tube (31) to fill.
3. Press Shut Down (7).
4. Place a container to collect the sample at the mouth of the Samples Outlet (18).
5. Open the sample stop-cock (17), collect the desired quantity and close it again.
6. Press Quick Discharge (4) again and continue the session.

17. INSTRUCTIONS FOR DISINFECTION

1. After the waste hose is removed the flexible hose (25) is connected to the Waste Inlet (26). The connectionmust be made in the following way:

a) At the end of the Flexible Hose which is not connected, there is a stainless steel appendage. This appendage must be placed into the Waste Inlet (26) pushing the stainless steel appendage until it is totally inside the Waste Inlet (26).

b) Once the Waste Inlet (26) is inside the stainless steel appendage, push the small lever of the appendage.

2. Check that the plastic tube (similar to the water line) is connected between the Disinfectant Inlet (28) and the Disinfectant Bottle (29). One end of the plastic tube must be placed into the Disinfectant Bottle (through the topof the bottle) and must be in contact with the disinfectant. The other end of the plastic tube must be connected to the Disinfectant Inlet (28). This Disinfection Inlet (28) must be pushed into the end of the plastic tube until the inlet is totally inside the tube.

3. Before disinfection of the equipment, thoroughly clean and rinse with water to remove any remaining debris left in the assembly by pressing the Cleaning Button. Then close the valve by pushing “Filling button” so that the disinfectant solution can be entered into the assembly. Once the valve is closed, press “Disinfection button” (22) for a few seconds to allow the suction of disinfectant which is mixed with water and introduced into the viewing tube. Finish the filling pushing the “Cleaning button” Avoid air bubbles. The total capacity of the assembly is 600 milliliters.

4. The disinfectant must remain in the assembly for a minimum of 10 minutes before removing. To remove the disinfectant, press the Quick Discharge Button.

5. Once the disinfection process has been completed, press the Disinfection Button to start the rinsing process. This process must be repeated 3 times. The rinsing process is as follows:

a) Press the Filling Button to close the valve. This allows the assembly to fill completely. The waterwill remain for a minimum of one minute inside the assembly.

b) Press the Quick Discharge Button to allow the water to flow to the waste drainage.

6. If there is no residual disinfectant, disconnect the Flexible Hose (25) lifting the little lever that was inserted when the Flexible Hose was connected. Then pull the Flexible Hose from the Waste Inlet (26) and place the Flexible Hose in the Sink (31).

Note: CIDEX OPA by ASP (Johnson & Johnson) must be used as disinfectant.

18. MAINTENANCE: CHANGING FILTER CARTRIDGES

These cartridges must be changed at least every 75 sessions,or either every six months.

1. Close the water faucets outside of the machine and put the control valve on preparation to reduce the pressure inside.

2. Twist to the left until the housing is completely free of its support.

3. Unscrew the used cartridge twisting it to the right.

4. Put a new cartridge screwing it to the left until it is completely adjusted.

5. Put the housing on again, screwing it to the left until it is completely adjusted.

IMPORTANT: Maintenance should not be performed while the equipment is being used on a patient.

IMPORTANT: Filters must be changed with new filters. Never reuse them.

19. TECHNICAL CHARACTERISTICS

The technical characteristics of the machine are:

- Rated working voltage: 220V/50Hz or 110V/60Hz
- Manual temperature control.
- Water flow adjustment
- Polypropylene Filters
- Automatic irrigation pressure safety at 150mbar (2,17 psi)
- Automatic irrigation temperature safety at 40ºC (104ºF)

TRANSCOM SL will make available on request circuit diagrams, calibration instructions, or other information that will assist Service personnel to repair those parts of HC-2000 CLASSIC that are designated by TRANSCOM SL as repairable by Service personnel

The applied part is the Hydrokit. The Hydrokit is connected to the machine in both irrigation and evacuationconnections

20. SESSION PARAMETERS

Therapy parameters will be within the following ranges

- 30 to 50 litre per hour.
- Adjustable flow controlPressure 0 - 150 mbar. (0-2,17 psi)
- Temperature 22 - 40°C. (71.6 – 104ºF)

21. SAFETY AND PERFORMANCE

High safety systems for pressure and temperature, due to the high sensitivity components that the machine isfitted with (such as the series connected pressure switches, which control the pressure variations in the mainsnetwork), are some of the principal characteristics of the HC-2000 CLASSIC.

As soon as temperature or pressure variables are exceeded (150 mbar. or 2.17 PSI / 40º C or 104º F), themachine automatically stops.

It is filled with a real litres-counter (counting the litres directly introduced into the patient) and a counter of the real irrigation time (separate from the session time)

Easy both to use and understand, even for the patient.

22. TROUBLE SHOOTING GUIDE

IRRIGATION

In case the Irrigation process does not work, this may be caused by the following situations:

1. Alarm temperature reached:

   Regulate the maximum or minimum temperature of the thermostatic gauge in Preparation

2. Pressure exceeded:
   a. Check that the rectal nozzle is correctly placed in the sphincter of the patient.
   b. Check that the circuit from the rectal nozzle to the wieving tube is not blocked.
   c. Check that the blue/black spigot is correctly inserted in the irrigation outlet

In case the problem is not caused by the former mentioned causes please contact TranscendenciasComerciales S.L.

3. Time Counter:
   a. In case the green lamp of the time counter does not light the lamp must be replaced. Please contact Transcendencias Comerciales S.L.
   b. If the green lamp is lighting without flashing, this means that the time is out. We should adjust the time in the time counter, then switch off the device and switch it on again.
4. Irrigation button without light:

   It might happen that although the Irrigation works, the lamp of the control panel does not light. If it happens we must replace the inside lamp. Please contact Transcendencias Comerciales S.L.

5. Other problems:

   If none of these situations happens, please contact Transcendencias Comerciales S.L., as the problem may be caused by a faulty relay, solenoid valve...

TEMPERATURE

1. If the temperature does not reach 100º F (38º C), check that the water heater works properly. If it does please contact Transcendencias Comerciales S.L., there may be a problem in the equipment.

2. If the thermostat shows an alarm sign, carry out as the workbook of the thermostat states.

PRESSURE

1. If during the session the pressure gauge does not show any rates this gauge must be replaced. Please contact Transcendencias Comerciales S.L.
2. In case the Quick Discharge does not get switched when the pressures exceed 2.17psi (150 mbar) the pressure gauge must be fitted. Please contact Transcendencias Comerciales S.L. Once the gauge is fitted if the problem still remains, the pressure gauge must be replaced. Please contact Transcendencias Comerciales S.L.

COUNTERS

In case the counters do not show any figures, the counters must be replaced. Please contact Transcendencias Comerciales S.L.

VIEWING TUBE

1. During the Filling the Viewing tube must be filled completely, if not or if it needs more than 2 minutes to be filled, the pressure regulator placed on the left side of the tube must be adjusted. Please contact Transcendencias Comerciales S.L.

2. If there is a leaking from the Samples Outlet, this outlet must be replaced. Please contact Transcendencias Comerciales S.L.

QUICK DISCHARGE, SLOW DISCHARGE, FILLING

If any of these functions do not work properly, the inside relays of the equipment must be replaced. Please contact Transcendencias Comerciales S.L. as soon as possible to solve this problem.

WATER LEAK

If you detect a leak anywhere in the equipment, proceed as follows:

1. Turn off the water supply on the inlet side of the unit.
2. Unplug the power cord.
3. Check the condition of the filter housings. Inspect both the housing and the housing covers. Make sure the O-rings are in place inside the lower housing filter.
4. Check the condition of the joints between tubes and connectors. Make sure all quick disconnects are connected; the best way is to disconnect and reconnect them, making sure they click into place.

If the leak persists, contact Transcendencias Comerciales S.L. as soon as possible.

23. WARNING LABELS

Please carefully follow these warnings to avoid misuse of the equipment:

- Before using the machine, read the instruction manual completely and thoroughly, strictly adhering to its specifications.
- To avoid the risk of electric shock, this equipment should only be connected to a grounded power source.
- This equipment should not be used in a flammable environment.
- Healthcare professionals must remain with the patient at all times.
- Tampering with or misuse of electrical components may result in electric shock.
- Tampering with settings or adjustments by unauthorized personnel may cause injury to the patient or user and will void any warranty or liability.
- Do not connect any other electrical appliance to the same power outlet or connect multiple power strips. For information regarding local wiring or building codes, it is recommended to consult with a local electrical contractor and plumber before operating this equipment.
- Do not tape any of the water lines, drain line, or electrical line to any other part of the colon cleansing machine or any combination thereof. Doing so will damage the equipment and impair its performance.
- Never leave the colon cleansing machine unattended while the water supply is on. Always turn off the water supply when the machine is unattended. We are not responsible for flooding of this equipment.
- The equipment must be attended at all times while the water supply is open to prevent flooding in case of a leak. The water supply may be cut off in the event of a leak if the equipment is unattended.
- Do not place the equipment in a location that may obstruct its operation with the device used to disconnect the equipment from the electrical network. This device is the power cord plug.
- **WARNING: Do not modify this equipment without authorization of the manufacturer**

- There is risk of reciprocal interferences if any diagnosis equipment is used in the same room during thetreatment

    - HC-2000 Classic needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS
    - Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT
    - HC-2000 Classic should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HC-2000 Classic should be observed to verify normal operation in the configuration in which it will be used.
    - HC-2000 Classic equipment is intended for use in a specific electromagnetic environment below specified.Customer must ensure to use in that environment.

Manufacturer's declaration – electromagnetic emissions:

<table>
<tr><td colspan="3">This device maintains basic safety and essential performance when used in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>This device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Complies</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Manufacturer's declaration – electromagnetic immunity:

This device maintains basic safety and essential performance when used in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV indirect contact ±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete orceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/bust IEC 61000-4-4	±2 kV for power supply lines	±2 kV for AC powersupply	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT for 0,5 at 8 ϕangles; 0 % 1 cycle; 70 % UT for 25cycles; 0 % for 5 sec	0 % UT for 0,5 at 8 ϕangles; 0 % 1 cycle; 70 % UT for 25cycles; 0 % for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz& 6 Vrms ISM frequency	3 Vrms 150 kHz to 80 MHz& 6 Vrms ISM frequency	Portable and mobile RF communications equipment should be used no closer to any part of This device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.7 GHz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey A, should be less than the compliance level in each frequency range B. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000- 4-3 & Immunity to proximity fields (EN 60601-1-2 table 9)	10 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 5.785 GHz FM Modulation & Pulse Modulation	10 V/m 80 MHz to 2.7 GHz AM Modulation & 9–28 V/m 385 MHz to 5.785 GHz FM & Pulse Modulation	

NOTE 1: UT is the AC mains voltage prior to application of the test level

NOTE 2: The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765–6.795 MHz; 13.553–13.567 MHz; 26.957–27.283 MHz and 40.66–40.70 MHz.

NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 4: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

24. SCHEDULED MAINTENANCE ITEMS

Our colon cleaning machine does not have any regular scheduled maintenance. Proper care, preventative maintenance, the section on cleaning methods and using the equipment as stated in the operation manual will lead to many years of life to the equipment.

Parts over the years will wear out from normal wear and tear on the equipment. When the first signs appear that there is a problem, or the equipment is not operating as usual, the equipment should not be used and the problem reported to Transcendencias Comerciales S.L. The equipment must be checked and inspected prior to using again.

All water lines and fittings should be checked for signs of wear and leaks, if so, replace as needed.

NOTE: Check all water line clamps for tightness and leaks, tighten as necessary. This should be done every two weeks or less on all clamps and fitting both colonic machine and the water filtration system.

If water filtration system is installed the water filters will have a regularly scheduled maintenance and replacement schedule. This is discussed in the section on water filtration systems. As stated, this will depend on your area water and the amount of treatments and time between filter cartridge replacements.

25. PACKING LIST AND DEVICE LABEL

A list of items below is provided with your colonic machine upon arrival. These items are to complete the installation and set-up for the operation of the colonic machine. Upon arrival you will have everything included for basic start up, all items are preassembled and are not in a kit form. They require simple connections to your water supply and drainage lines. Other accessories can be added as discussed in other sections of this manual.

Along with the machine, you should have received the following:

- Spigot connector tube 6mm — 4 units
- Polipropilene filter with housing — 2 units
- Fuse 2A — 2 units
- Fuse 1A — 2 units
- Poliurethane tube 10mm (1,5 m) — 2 units
- Net wire — 1 unit
- Control remote device — 1 unit
- Racor connecter 10mm - 1/2” — 2 units
- PVC pipe joint tube 32mm-1” — 1,5m
- Racor bend connector tube 10mm — 2 units
- Green led — 3 units
- Chrome bend connector for samples — 1 unit
- Process manual — 1 unit

Regarding equipment identification, each machine sold by Transcendencias Comerciales, S.L. is assigned a unique serial number. This number is indicated on the identification plate (37), previously described in section 14 of this manual, on equipment characteristics.

If you notice any deficiencies upon receiving the equipment and its additional components, please use and follow the instructions in the incident notification form found on the next page

TRANSCENDENCIAS COMERCIALES, S.L.
Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) ESPAÑA
Tel: +34 943 224 36 e-mail: info@transcomsl.com
www.transcomsl.com

Dear Customer:

Thank you for ordering the merchandise enclosed in this package. Before leaving our warehouse it was inspected by the Supervisor. Please inspect the contents thoroughly for damage or errors in fulfilling your order. If you find there is a problem, please send us the information requested below.

If merchandise was damaged in shipping, take the following steps:

If possible, note visible damage to cartons and the exent of damage before signing shiping documents. Save all original packing materials and containers for inspection by the carrier until the claim is settled. Contact our costumer service department directly for assistance.

DO NOT RETURN any merchandise without our prior a authorization. We will contact you inmediately upon receipt of this notice.

Product(s) ( )arrived damaged: ( )wrong order ( ) other:

Product(s) Involved - please specify cat. no., quantity, and description:

1. _____ 4. _____
2. _____ 5. _____
3. _____ 6. _____

DESCRIBE THE PROBLEM OR ERROR. If the item is damaged, indicate the exact damage or error and clearly the corrections desired:

_____

_____

_____

Invoice Nº or date of invoice: _____ Phone nº: _____

Customer name: _____

City: _____ State: _____ Zip: _____

Shipping Adress (If different from above): _____

26. WARRANTY INFORMATION

We the undersigned, guarantee all equipment to be free from defects in material and workmanship for a period of two years from the date of delivery, provided if the equipment is installed and operated according to the manufacturer's instructions.

Our obligation under this warranty is limited to the repair and/or replacement of any defective part or correcting any manufacturer's defects, without charge during the warranty period if the manufacturers/seller confirms the existence of such defects. The owner/owners obligation is to notify the seller/manufacturer via telephone, and follow up in writing of any problems thought to be the result of manufacturing error. Everyday wear and tear from use is not covered under this warranty. Owner/Owners of the colonic equipment will always have the right to free technical support for the life of the equipment and access to parts and accessories as long as the seller/manufacturer remains in business.

Our option to repair and/or replacement will be (F.O.B.) Free on Board to Transcendencias Comerciales S.L., Spain. Or if possible in certain locations where seller/manufacturer can fly into certain cities, at the seller discretion will fix or replace parts on the owner/owners premises. Therefore, there will be no compensation for transportation expenses unless the problem occurs during the two year unlimited warranty and the defect is manufacturer´s error. We shall pay one way shipping.

We will not be liable for any loss of business revenue, consequential damages or expenses occurring directly or indirectly from the use of the equipment covered under this warranty.

Cartridges are needed to be changed either every 75 sessions or every six months, if not Transcendencias Comerciales will not be responsible of the device.

Note: Obvious abuse, improper use and tampering with gauges, settings and etc., by unauthorized personnel, or without sellers/manufacturer supervision will void this warranty.

Note: All installation of the plumbing and electrical work to prepare for the arrival of the colonic machine and the Water Treatment System must be made by a licensed plumber and electrical contractor. Also they must meet the specifications set by Transcendencias Comerciales S.L.. This is to ensure 100% efficiency for the colonic equipment.

Customer's name	Type of equipment and Voltage	Serial Nº	Purchase date
	HC-2000 CLASSIC		

27. ASSISTANCE

GENERAL MANAGER

Tel: (34) 943 224 360

Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN

E-mail: admon@transcomsl.com web: www.transcomsl.com

SALES DEPARTMENT

Tel: (34) 943 224 360

Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN

E-mail: ventas@transcomsl.com web: www.transcomsl.com

TECHNICAL DEPARTMENT

Tel: (34) 943 224 360

Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN

E-mail: sat@transcomsl.com web: www.transcomsl.com

QUALITY DEPARTMENT

Tel: (34) 943 224 360

Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN

E-mail: info@transcomsl.com web: www.transcomsl.com

ACCOUNTING DEPARTMENT

Tel: (34) 943 224 360

Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN

E-mail: admon@transcomsl.com web: www.transcomsl.com

EXPORT DEPARTMENT

Tel: (34) 943 224 360

Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN

E-mail: exportacion@transcomsl.com web: www.transcomsl.com

28. SHIPPING

All shipping will be arranged between the customer and the manufacturer, which will best suit the needs of our clients. We use a wide variety of companies. Usually we ship by air.

The equipment is packed very carefully to avoid damage to the cabinet and the internal parts, sometimes caused by shipping. We use the best means of packing and take extra precautions to avoid shipping damage. The equipment is insured by the shipper and machine should be carefully checked after delivery for any infractions should be reported to the manufacturer immediately. So the damage can be reported to the shipping company.

Note: Due to being moved around and bumps in the shipping process, water leaks may occur, but are rare. Sometimes temperatures may play a factor in leaks, but would also be very rare and would have to go from one temperature extreme to the other. Please check water lines for leaks inside of the machine and re-tighten as necessary.

USING, STORING AND TRANSPORT

Environment pressure for using, transporting and storage must be between 984 and 1039 mbar.

Environment humidity for using, transporting and storage must be between 30% and 75%.

Environmental temperature for using, transporting and storage should be between 5ºC and 35ºC.

The machine is shipped packed in a cardboard box, on a sterilized pallet.

HC - 2000 CLASSIC: Quantity 1 (Non sterile)

Dimensions without filters:	720 x 280 x 770 mm
(lenght x width x height)	28,35 x 11,02 x 30,31 inches
Machine weight:	32 Kg.
	70,55 LBS.
Dimensions packaging:	1100 x 750 x 400 mm
(lenght x width x height)	28,35 x 11,02 x 30,31 inches
Packed machine weight:	52 Kg.
	70,55 LBS.

29. INSTALATION

The installation of the colonic machine, and the Water Treatment System must also be installed by a representative of Transcendencias Comerciales S.L. or a licensed plumber and must follow set installations/instructions. If this is not complied with and receipts keep, of the installation company and charges by that company. If these above items are not furnished, then this does void any and all warranties on the colonic machine and the Water Treatment System.

MANUFACTURER: **TRANSCENDENCIAS COMERCIALES, S.L.**

MODEL: **HC-2000 CLASSIC**

VOLTAGE: ☐ 110 V / 60 Hz

☐ 220 V / 50 Hz

DATE AND SIGNATURE SELLER: _____

DATE AND SIGNATURE BUYER: _____

30. SERVICE

To the Owner/Owners of the finest Colonic Irrigation equipment available on the market today: We want our customers to know how much we appreciate your business and trust in our corporation. We are dedicated to service, technical support and sales to our clients needs in the field of colonic irrigation. As we stated in the warranty section, you will always have the access to parts and technical support for the life of the equipment. We will do as much as possible to take care of your problems as they may arise and our reported. Please help us out by phone call and a follow up not explaining the equipment problem.

When you have a problem, here are some helpful hints before calling

- What seems to be the main malfunction?
- Have you checked the drainage system for blockage or leaks?
- If you have leaks, where exactly are they?
- Did you check your hot water heater and filtering system?
- Is the treatment table height correct?
- Is the water turned on and the connections properly together?
- Is the electrical plugged in?
- Did you trace the problem from the beginning to the problem?

These are some of the most asked questions that may help you and us to get to the source of malfunction. But whatever the problem maybe, little or big, please call us as soon as possible and have the machine running properly. See Trouble Shooting Guide Section for additional information.

SALES AND SERVICE TRANSCENDENCIAS COMERCIALES, S.L.
Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
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☎ Tel: +34 943 224 36 e-mail: info@transcomsl.com
www.transcomsl.com

31. ESSENTIAL TECHNICAL REQUIREMENTS FOR ASSEMBLY AND OPERATION OF THE HC-2000 CLASSIC APPLIANCE

TECHNICAL REQUIREMENTS

Pre-installation consists of:

- Cold water inlet via a 1/2" pipe, to which a 1/2" flexible hose shall be added.
- Shut-off valve on the cold water pipe, to be attached between the pipe and the flexible hose.
- Hot water inlet via a 1/2" pipe, to which a 1/2" flexible hose shall be added.
- Shut-off valve on the cold water pipe, to be attached between the pipe and the flexible hose.
- 32 mm. PVC pipe, to be connected to the foul water discharge pipe.
- Syphon for connection to the foul water drainage system. The syphon must be attached as low as possible. If this is not the case, the appliance cannot work properly.
- Two constant pressure adjustment devices tared to minimum 2 bar or 28,44 psi must be attached to the hot and cold water piping.
- An electric water heater, minimum 60 liters. The following cannot be fitted:
  - Low pressure accumulators
  - Low pressure instant heat devices
  - Low voltage instantaneous heaters
  - Bottled or mains gas water heaters, butane gas or town gas heaters.
- A power supply connection which, for safety reasons, must be placed at least 1 metre from the point where the appliance is to be fitted.

ELECTRICAL DATA TO BEAR IN MIND

Mains voltage must be 110V/60Hz ór 220V/50Hz.

Should your electrical connection be at a voltage other than that shown, inform Transcendencias Comerciales S.L. technical office so that the voltage may be adjusted.

DATA TO BEAR IN MIND REGARDING THE PRESSURE

The constant hot and cold water pressures must be equal. We recommend this pressure be not more than 2 bar or 28.44 psi, and also advise you to fit constant pressure adjustment devices for each hot and cold water inlet pipe.

If supply water has high amount of lime, a system for eliminate it should be installed. If not, there could be malfunctioning of device due to obstructions by lime.

SITING THE MACHINE

You may send us drawings of the place where you intend to put, and we will decide the ideal location.

DATA TO BEAR IN MIND REGARDING THE TEMPERATURE

- Adjustment of the appliance's temperature shall be carried out via the hot water supply using a pressure accumulator for greater accuracy of the required temperature.
- The temperature of the hot water shall be between 60ºC or 156ºF and 80ºC or 208F.
- The appliance requires an inlet temperature of 60ºC or 156ºF.

ABOUT STRETCHER TO BE USED:

- Never use stretchers higher than 70 cm.
- The stretcher must always be to the left of the machine.

RECOMMENDED HEIGHT FOR THE SYPHON

The siphon should be as low as possible to ensure that the machine will discharge for cleaning. At least 40 cm below the height of the stretcher. The drainage outlet must be at the right of the machine. Should not be this case, the outlet must be lowered a further 5 cm to ensure that the drainage tube (diameter 1´´) goes over the gap between the lower section of the filters and the metal sheet.

HOT AND COLD WATER INLETS

The distance between each inlet and its filter must be no more than 50 cm. It does not matter whether the inlets are situated to the right or left of the machine.

INT AT WHICH THE SOCKET IS TO BE PLACED

It is preferable that the socket is located at the left of the machine, and (at least) one metre from the incoming waste vertical.

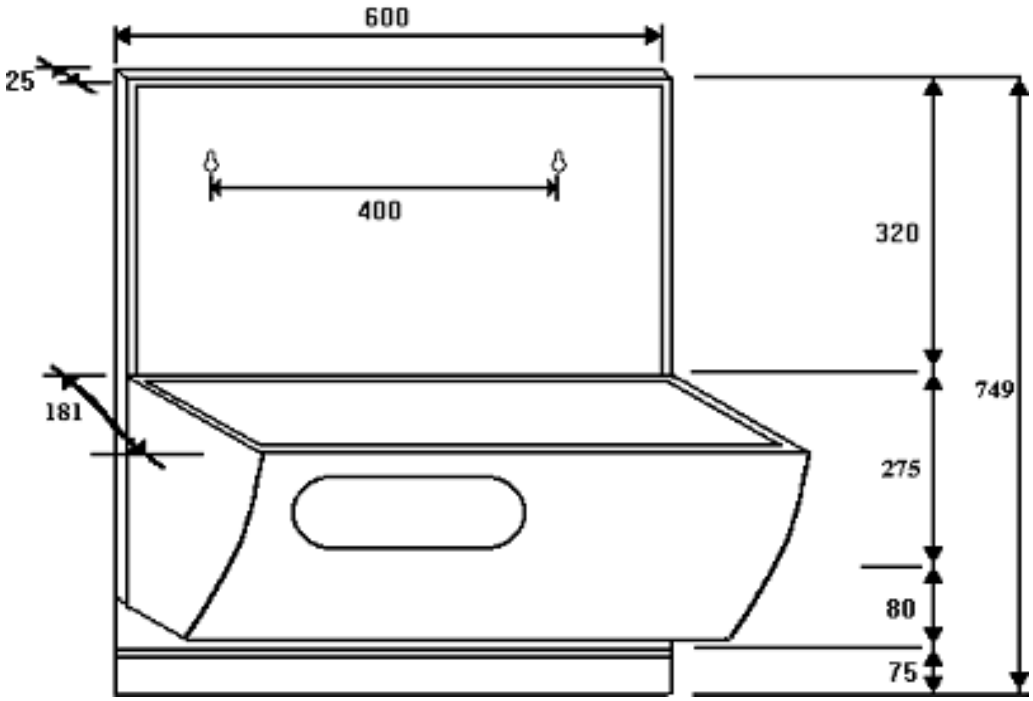
INSTALLATION SKETCH

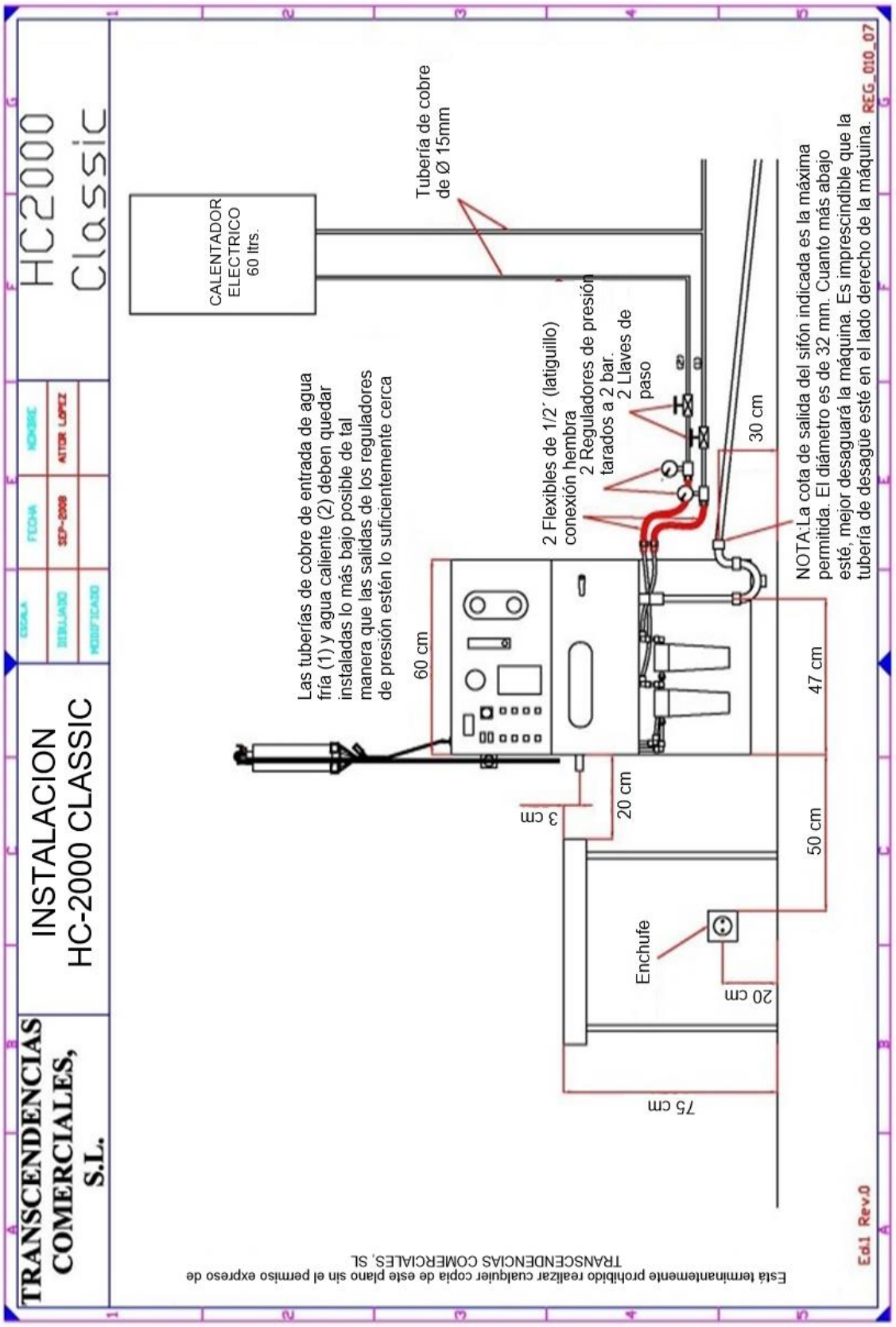
The drawings and sketches that follow on the next page are visual aids for proper machine installation.

If a bottle support be required, the entire vertical surface of the machine must be left free, at least 50 cm over the height shown below.

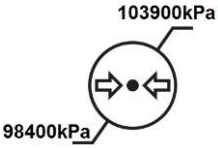
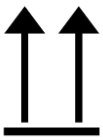
Note: Failure to comply with any of the aforementioned requirements will make it impossible to properly install and commission the machine.

MEASURES OF HC-2000 CLASSIC (mm)




HC2000
Classic
INSTALACION
HC-2000 CLASSIC
TRANSCENDENCIAS
COMERCIALES,
S.L.
CALENTADOR
ELECTRICO
60 ltrs.
Tubería de cobre
de Ø 15mm
2 Flexibles de 1/2" (latiguillo)
conexión hembra
2 Reguladores de presión
tarados a 2 bar.
2 Llaves de
paso
Las tuberías de cobre de entrada de agua
fría (1) y agua caliente (2) deben quedar
instaladas lo más bajo posible de tal
manera que las salidas de los reguladores
de presión estén lo suficientemente cerca
NOTA:La cota de salida del sifón indicada es la máxima
permitida. El diámetro es de 32 mm. Cuanto más abajo
esté, mejor desaguará la máquina. Es imprescindible que la
tubería de desagüe esté en el lado derecho de la máquina.
REG_010_07
60 cm
30 cm
47 cm
50 cm
20 cm
3 cm
Enchufe
20 cm
75 cm
Ed1 Rev.0
Está terminantemente prohibido realizar cualquier copia de este plano sin el permiso expreso de
TRANSCENDENCIAS COMERCIALES, SL

32. SYMBOLS USED

	Equipment clasification Type BF of the electromedical equipment depending on the leaking current. It corresponds also to the applicable part type BF.		Unique device identifier
	The instruction manual /booklet must be read		Medical Device
	Manufacture date		Atmospheric pressure limitation
	Manufacturer		Humidity limitation
	Protective earth connection		Temperature limitation
	Separate collection for WEEE-Waste of electrical and electronic equipment		Fragile, handle with care
	Serial number		This way up
	Model number		

33. OFFICIAL APPROVALS

The HC-2000 CLASSIC machine has been manufactured in strict compliance with applicable legal and technical regulations. Various verification tests have been carried out to ensure its safety and performance, after which the various approvals required for its commercialization and placement on the market have been obtained. These approvals are:

- RoSH Declaration of Conformity
- Electromagnetic Safety in accordance with ISO-60601
- European Union Declaration of Conformity.

These approvals are shown on the following pages of this instruction manual.

TRANSCENDENCIAS COMERCIALES S.L.
CIF: B-48.833.404

RoHS DECLARATION OF CONFORMITY (Directive 2011/65/EU)

1. **Name and Identification code**

Trade Name:	HC-2000 Classic
BASIC UDI-DI:	PP 12164 HC2000CZ02 38
UDI-DI:	111787639253
Device Type:	Medical device for colon cleaning
GMDN Code:	58181
Serial Number:	See identification plate

2. **Manufacturer Name and Address**

TRANSCENDENCIAS COMERCIALES, S.L.
Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) - Spain

3. **This declaration of conformity is issued under the sole responsibility of the manufacturer**

The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Signed for and on behalf of the manufacturer by:

Technical Manager
Patricia Romero

January 2026
Astigarraga, SPAIN

Rev.05
14/01/2026

DEKRA Testing and Certification, S.A.U.
Parque Tecnológico de Andalucía,
C/ Severo Ochoa nº 2 · 29590 Campanillas · Málaga · España
C.I.F. A29 507 456

DEKRA

Test report No:

NIE: 64365RSE.003

Partial Test report

Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.

(*) Identification of item tested	Colon cleansing medical device
(*) Trademark	TRANSCOM
(*) Model and /or type reference tested	HC-2000 Classic
(*) Derived model not tested	HC-1 Classic
Other identification of the product	S/N: 0200011
(*) Features	230/110 V ~; 50/60 Hz; 65 VA. Equipment with metallic enclosure. Protection against electric shock Class I. Type BF applied part.
Manufacturer	TRANSCENDENCIAS COMERCIALES, S.L. C/ Zubiberri, 31. Planta baja – local 1-20018 San Sebastián. Guipúzcoa. Spain.
Test method requested, standard	IEC 60601-1: 2005/A1:2012 + IEC 60601-1: 2005/A2:2020 EN 60601-1: 2006/A1:2013 UNE-EN 60601-1: 2006/A1:2013 POSE000_20 (General procedure of Safety Lab)
Summary	See Appendix A
Approved by (name / position & signature)	Rafael Gonzalez. SE Lab Manager Fecha: 2022.02.04 12:07:35 +01'00'
Date of issue	2022-02-04
Report template No	FSE571_00 + FSE463_08 (*) "Data provided by the client"

ilac-MRA ENAC ENSAYOS Nº 51/LE147

The tests marked with "#" are not covered by ENAC accreditation

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Test report No:
NIE: 70950REM.001

Partial Test report

EN 60601-1-2 (2015): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

(*) Identification of item tested	0200011
(*) Trademark	TRANSCOM
(*) Model and /or type reference	HC-2000 Classic
Other identification of the product	HW version: - SW version: -
(*) Features	230/110V; 50/60hZ - 65VA
Manufacturer	Transcendencias Comerciales, SL C/ Zubiberri 31 local 1- Bajo 20018 Donostia - GUIPÚZCOA - SPAIN
Test method requested, standard	Complementary tests to cover: - Radiated RF Electromagnetic field immunity test - Electrostatic discharge immunity test according to EN 60601-1-2 (2015)
Summary	IN COMPLIANCE
Approved by (name / position & signature)	Jose Manuel Gómez Industrial & Automotive EMC Lab. Manager
Date of issue	2022-01-27
Report template No	FDT08_23 (*) "Data provided by the client"

EU DECLARATION OF CONFORMITY
Regulation (EU) 2017/745 of Medical Devices

Product manufacturer: TRANSCENDENCIAS COMERCIALES, S.L

Single registration number (SRN): ES-MF-000006640

Adress: Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) – Spain

Declare under its responsibility that the products:

BASIC UDI-DI:		PP 12164 HC2000CZ02 38	
Model	**Trade Name**	**UDI-DI**	**Serial number**
Z-02	HC-2000 Classic	111787639253	

Device type: Medical device for colon cleaning

Intended Use:
The HC-2000 CLASSIC is a Colon cleaning medical device based on introducing water at different temperatures and pressures, always within patient safety parameters, in order to eliminate any waste found in the large intestine to cleanse the colon, such as before radiological or endoscopic examination.

GMDN Code: 58181

Classification (rule): Class IIA, rule 12 of Annex VIII

Waste management:
The waste management of this product is carried out in accordance with Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

Additional information:
This declaration of conformity is supported by the CE Certificate number 059/MDR of Conformity Assessment based on a Quality Management System in accordance with Chapter I of Annex IX of Regulation (EU) 2017/745 Medical Devices issued on the date of 22 of November of 2022 by IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ SPA, Notified Body number 0051.

Date: 15/01/2026

Patricia Romero
Technical Manager

Ramón Echevarría
General Manager

Rev: 06
15/01/2026

34. HYDROKIT

The images describe the steps to be carried out to connect the Hydrokit:

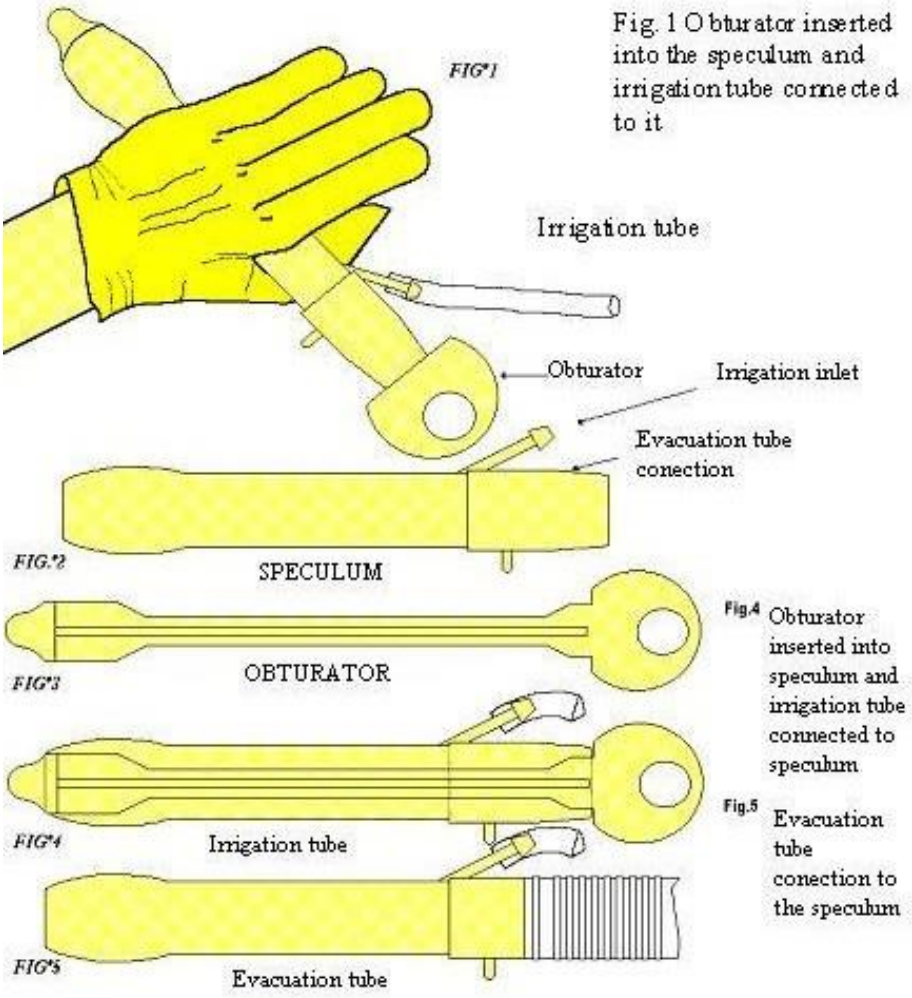


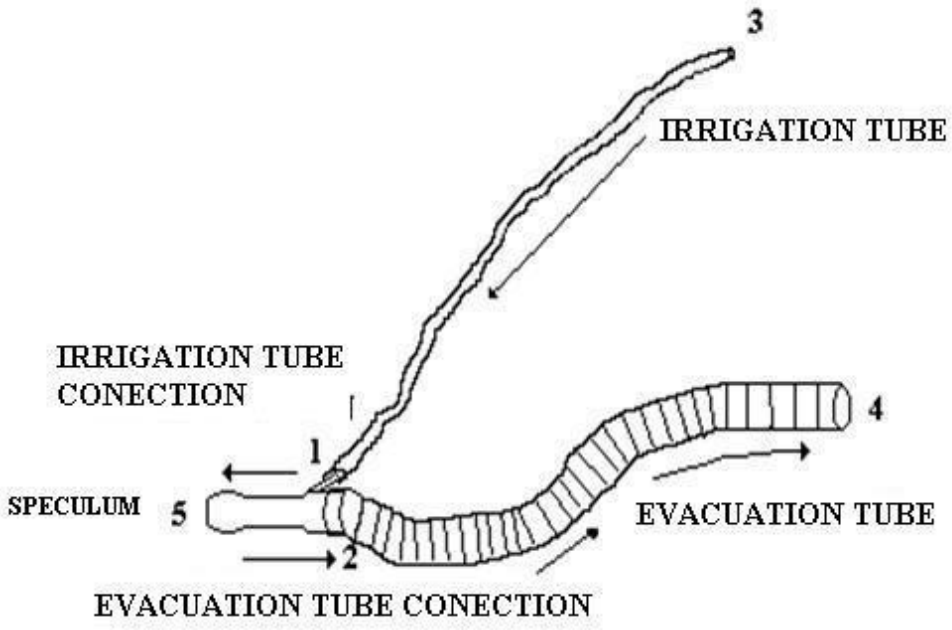
Fig. 1 Obturator inserted into the speculum and irrigation tube connected to it

Fig.4 Obturator inserted into speculum and irrigation tube connected to speculum

Fig.5 Evacuation tube conection to the speculum

The following image describes the connections of the Hydrokit with the Active Device and the patient

SPECULUM AND TUBES CONECTIONS



1. Connection of the irrigation tube with the speculum's water inlet spigot.
2. Connection of the evacuation tube with the water outlet connection of the speculum.
3. Connection of the irrigation tube with the irrigation outlet of the active device.
4. Connection of the evacuation tube with the waste inlet of the active device.
5. The tip of the speculum has a Curvi-Convex shape for easy insertion.