TRANSCENDENCIAS COMERCIALES S.L.

C.I.F. B-48833404

"HC – 1 CLASSIC"
PROCESS MANUAL

MD

CE 0051

INDEX

Dear Customer:

Before you use the **HC-1 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 – 1 CLASSIC"

MANUFACTURER NAME:
Transcendencias Comerciales, S.L. (TRANSCOM)

MANUFACTURER ADDRESS:
Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa)
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MANUFACTURER CONTACT:
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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
- Water supply will be cut off if the maximum pressure or minimum or maximum temperature is exceeded.

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
20115 Astigarraga (Guipúzcoa) - SPAIN

☎Tel: +34 943 224 360
www.transcomsl.com
e-mail: info@transcomsl.com

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-1 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.

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 PRODUCT

HC-1 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.

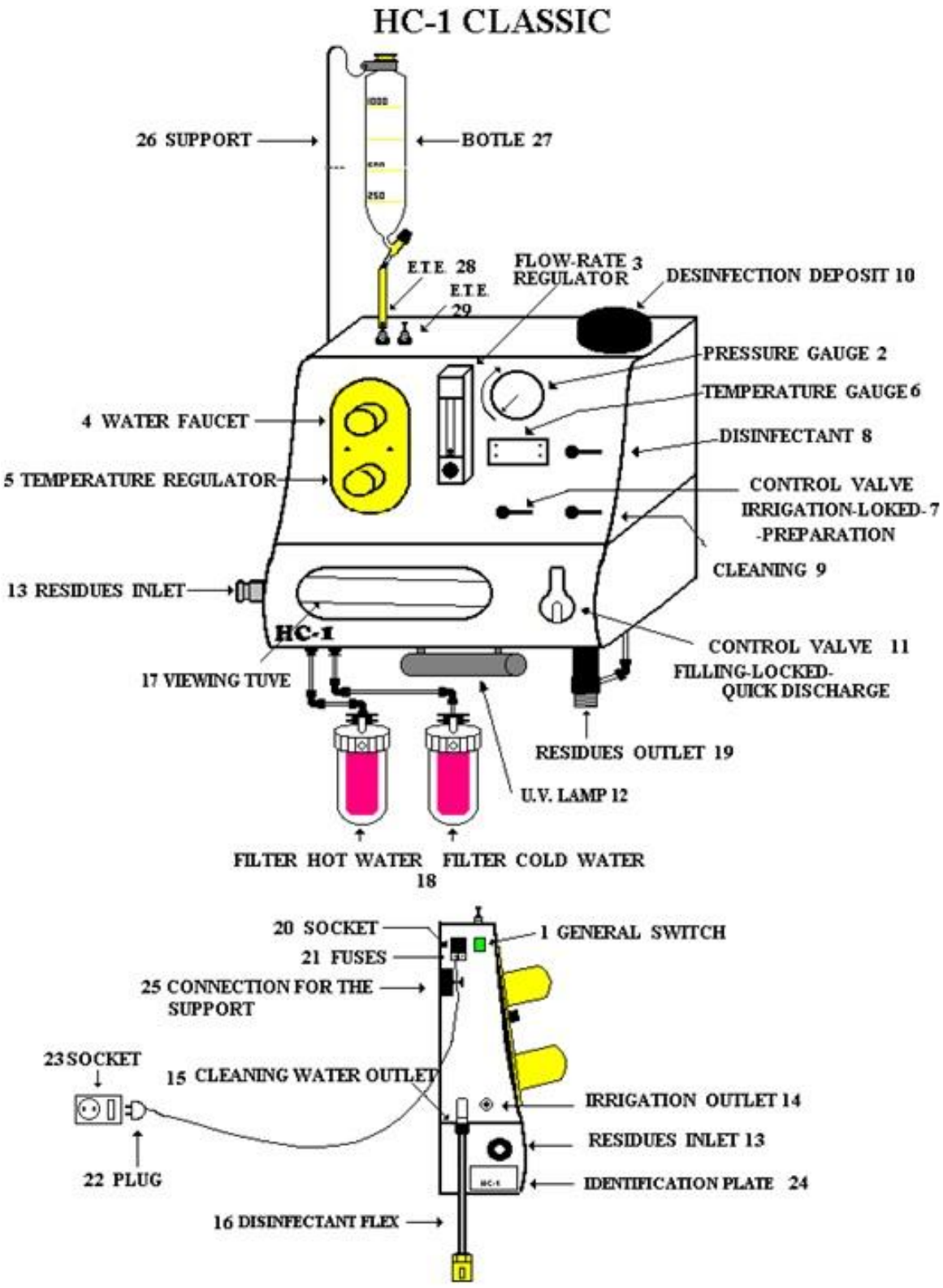
Hydrokit:
After use, the components must be handled according to universal standard precautions, as they will be contaminated. Specific bags sufficiently resistant for the disposal of these wastes must be available, which must be in puncture and breakage-proof containers and shall be closed and managed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


HC-1 CLASSIC
26 SUPPORT
BOTLE 27
ETE 28
ETE 29
FLOW-RATE REGULATOR 3
DESINFECTION DEPOSIT 10
PRESSURE GAUGE 2
TEMPERATURE GAUGE 6
4 WATER FAUCET
DISINFECTANT 8
5 TEMPERATURE REGULATOR
CONTROL VALVE IRRIGATION-LOKED- 7 -PREPARATION
CLEANING 9
13 RESIDUES INLET
HC-1
CONTROL VALVE 11 FILLING-LOCKED- QUICK DISCHARGE
17 VIEWING TUVE
RESIDUES OUTLET 19
U.V. LAMP 12
FILTER HOT WATER 18
FILTER COLD WATER
20 SOCKET
1 GENERAL SWITCH
21 FUSES
25 CONNECTION FOR THE SUPPORT
23 SOCKET
15 CLEANING WATER OUTLET
IRRIGATION OUTLET 14
RESIDUES INLET 13
22 PLUG
IDENTIFICATION PLATE 24
16 DISINFECTANT FLEX

14. CHARACTERISTICS OF HC-1 CLASSIC

GENERAL SWITCH (1)

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

PRESSURE GAUGE (2)

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.

FLOW RATE REGULATOR (3)

It controls the volume of water per hour and therefore regulates the quantity of water injected into the patient, and at what pressure.

At the bottom of the water flow regulator there is a round control. Turning this piece clockwise the water income diminish so lower pressure will be set. Turning this piece anti clockwise more water comes in so higher pressure will be set.

GENERAL CONTROL (4-5)

It consists of two elements:

1. Water Faucet (4): Allows the water inlet to be opened and closed, controlling the flow of water through the machine.

2. Temperature regulator (5): 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.

We can correct the position of the control temperature of the Thermostatic Valve (5) if there is any difference between the temperature of the Temperature Gauge (6) and the temperature indicated by the thermostatic valve. To readjust it, unscrew the cover of the control turning it anti clock wise (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 the valve has some grooves that fix perfectly with the grooves of the control. Pulling backwards of the control and turning it left or right at the same time and inserting them in the control of the spindle, you can read just the temperatures and adjust it to the one indicated by the Temperature Gauge (6). Once the temperature has been adjusted, adjust the fixing screw of the hub cap and replace the cover of the control.

TEMPERATURE GAUGE (6)

It is a digital indicator showing the temperature programmed on the Temperature Regulator (5). The maximum temperature is set at 40°C (104°F) and the minimum 22°C (71,6°F).

The internal memory of this device is set to the safety levels of 40°C and 22°C. If these temperatures are exceeded the system will cut in and the irrigation system will shut down for safety reasons.

NOTE: This display is not a temperature regulator. Avoid pressing buttons without instruction from a TRANSCOM representative.

CONTROL VALVE: PREPARATION - IRRIGATION - LOCKED (7)

Three way valve to prepare the machine and to control the water flow and the development of the session.

- PREPARATION: In this position water circulates until the selected temperature and flow rate are reached.
- IRRIGATION: Once the set levels are reached, move to this position to start session.
- LOCKED: This position stops the water flow.

DISINFECTANT VALVE (8)

This lets the disinfectant stored in the Disinfection Deposit (10) to clean the device.

See machine cleaning instructions.

CLEANING VALVE (9)

When the session is finished, turn this valve to clean the drainpipe circuit of all waste and germs. This cleans the inner circuits of the device.

See machine cleaning instructions.

DISINFECTION DEPOSIT (10)

This deposit holds the disinfectant used to clean the internal parts of the device thoroughly.

See machine cleaning instructions.

CONTROL VALVE (11): FILLING - DISCHARGE

It manually engages the Filling and Discharge functions.

- FILLING: In this position the control allows the water to enter into the colon through the water line and rectal nozzle, until the colon is filled with water. The Filling must be also stopped when the intra-intestinal pressure exceeds 150 mbar (2.17 psi) or because of the patient advice.

- DISCHARGE: Set the control at this position 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 viewing tube. In this position the control allows water and waste out of the colon through the Residues Outlet (19).

U.V. LAMP (12)

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

RESIDUES INLET (13)

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

- Waste removal: fit the removal tube to carry out session.

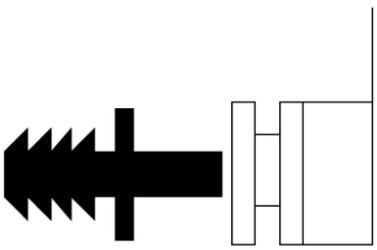
- Cleaning the machine: fit the Disinfectant Flex (16) after each session to clean the unit.

The residues inlet is a male connector to which the components mentioned before are fitted, the waste hose during the session and the flexible hose during the disinfection.

IRRIGATION OUTLET (14)

This is a connection point on the machine. One black fitting must be fitted to this blue outlet in order to connect the Hydrokit'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 (15)

The Disinfectant Flex (16) is connected to the Residues Inlet (13) on the machine to clean it. The water and the disinfectant 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 be reconnected to the waste inlet.

VIEWING TUBE (17)

Transparent PVC tube for viewing the waste removed from the patient during the session. A light is built in to facilitate observation.

FILTERS (18)

Two polypropylene filters are incorporated to filter the water before it is injected into the patient. This is important for the proper running of the machine as it avoids the build-up of elements present in the main water supply which could damage the components. These filters are connected to the hot and cold water pipes and to the machine.

RESIDUES OUTLET (19)

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

PLUG AND MAINS CABLE (20, 22)

Socket (20) on the machine is to connect the Plug (22) supplied.

The main socket should be at least 1 m from the machine on the left hand side.

FUSES (21)

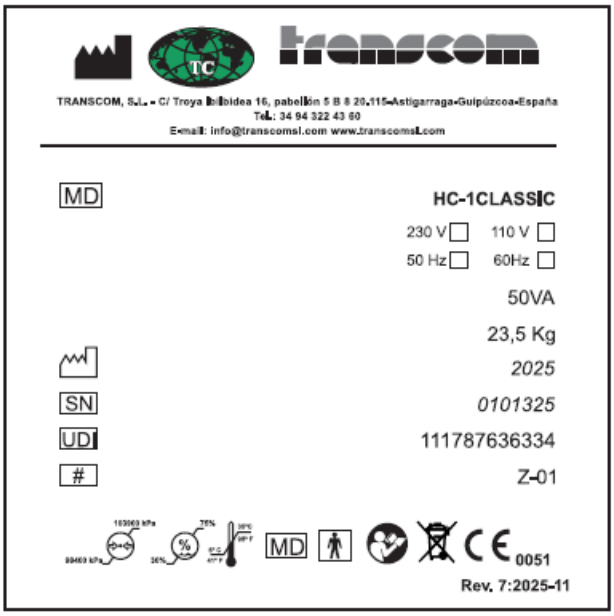
The machine is protected by four fuses very easy to change.

SOCKET (23)

The main socket should be at least 1 m from the machine on the left hand side.

IDENTIFICATION PLATE (24)

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



METAL SUPPORT AND GLASS BOTTLE (25, 26, 27)

The Connection of the support (25) in the machine is for the metal Support (26) and the Glass Bottle (27).

ETE (28, 29)

There are connection points to the auxiliary input (28, 29).

15. DESCRIPTION OF A SESSION

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

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

2. Switch on the general switch (1).

3. **Wait 5 minutes before starting any procedure.**

4. Set the Water Faucet (4) to maximum (large point - 12 o'clock- vertically).

5. Select the working temperature at the Temperature Regulator (5) turning it and check on the thermostat (6) that this temperature is reached.

6. Set the control valve (7) to "Preparation"

   NOTE: The control valve is a three-way valve (for Preparation, Locked and Irrigation). This valve controls the direction of the water to the Irrigation Outlet, if Irrigation position is chosen. When the Preparation position is selected, it diverts the water directly to the drainage system, thus allowing the water to warm up for the preparation of the equipment prior to a session. It allows the water to directly bypass the residues inlet and viewing tube and go directly into the drainage system. 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, the control valve is placed in the irrigation position. The third position is the closed position.

7. Select the working flow rate with the Flow Rate Regulator (3) turning the black control set at the bottom of this regulator.

   Using the control set at the bottom of the water flow regulator we can select the working flow rate by turning it. Turning clockwise to decrease the amount of water or turning anticlockwise to increase the amount of water entering. The recommended rate is from 30 to 50 litters per hour.

8. Using the inflow water line hose from the rectal nozzle kit, connect one end of the hose to the irrigation outlet (14) and the other end of the hose to the inlet port (inflow water line hose connection port) of the rectal nozzle. Then connect the waste hose to the waste hose is connected to the waste line hose connectionport of the rectal nozzle after the rectal nozzle is inserted into the patient and the obturator is removed, after step (8).

9. Insert the rectal nozzle into the patient and remove the obturator.

10. Connect the waste hose to the Speculum.

    Both the inflow water line hose and waste line hose must be connected to the speculum manually. The inflow water line hose must be connected by inserting the hose over the appendage that protrudes from the fitting we have connected to the Irrigation Outlet (14). The waste water line hose must be connected to the Residues Inlet (13) by inserting the hose over the 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.

11. Set the Control Valve (7) to "Irrigation". This three-way valve allows fresh water to enter the inflow water line that is connected to the rectal nozzle. The water enters the rectal nozzle and leaves the rectal nozzle through the viewing tube, the device through the drain.

12. Set the Control Valve (11) to “Filling” and monitor the Pressure Gauge (2) to ensure that the pressure does not exceed 150 mbar (2.17 psi).

    When “Filling” is selected water is directed into the patient´s colon. This position stops the outward flow of the water to the drainage system. The fresh water supply is a continuous flow of water during the colonic process. This water fills the viewing tube and the waste water line hose to the rectal nozzle. Once filled, then the fresh water enters the colon. This process of filling ensures no contamination from the viewing tube or waste hose into the colon.

    When “Irrigation” is selected the Control Valve (7) allows water to pass into the rectal nozzle, then down the waste water line hose into the residues outlet, view tube and drainage system. During this process the fresh water from the inflow water line hose is continuously running and helps to wash the stuff down the rectal nozzle and waste water line and residues inlet and view tube into the drainage system.

13. Once enough water has entered the patient’s colon, set the Control Valve (11) to “Discharge”.

    The increase or decrease of water pressure inside the patient´s colon is displayed on the Pressure Gauge (2). More water implies higher pressure and less water implies lower pressure. The personnel will know when sufficient water is given by the following:

    Patients response: The patient indicates to the personnel when they feel that the colon is full. The personnel can select “Discharge” (the patient may remove the rectal nozzle themselves. This option is not dangerous).

    Pressure Display: On the pressure gauge, if the pressure is lower than 150 mbar (2.17 psi) the session can continue by manually changing the valve to “Discharge”. If the pressure exceeds 150 mbar (2.17 psi) the therapist must decrease the flow rate.

14. Continue the session, alternating between "Filling" and "Discharge" (11)

15. At the end of the session set the Control Valve (7) to “Locked”.

16. Disconnect the water line from the machine and then from the patient, in that order.

17. Disconnect the waste hose from the patient and from the machine and dispose of the entire kit. The disconnection of this hose should be done in the following way:

    a) First of all the session must be finished. This means that neither water nor waste are inside the patient’s colon, so the water and the waste have passed through the waste (residue) inlet (having seen the water and waste through the viewing tube).

    b) Remove the rectal nozzle from the patient’s sphincter by gently pulling. Then continue with the following instructions.

c) Disconnect the water line from the Irrigation Outlet (14) by a gentle pulling action.

d) Disconnect the waste hose from the Residues Inlet (13) by a gentle pulling action.

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

18. Disinfect the device.

16. INSTRUCTIONS FOR DISINFECTION

1. After the waste hose is removed the Disinfectant Flex (16) is connected to the Residues Inlet (13). The connection must be made in the following way:

a) In the ending of the flexible hose which is not connected there is a metallic appendage. The waste inlet must be placed into this appendage (15) pushing it until the waste inlet is totally inside the appendage. Its flange must be pushed back to connect them.

b) Once the piece is connected, let the flange free to ensure the connection.

2. Before disinfection of the equipment, thoroughly clean, rinse with water to remove any remaining debris left inthe assembly, opening the Cleaning Valve (9) and setting the Control Valve (11) to “Discharge”. Then close the Cleaning Valve (9) and set the Control Valve (11) to “Filling”, open the Disinfection Valve (8) so the disinfectant solutioncan enter the assembly. The disinfection deposit has a total capacity of 600ml. If disinfectant does not come down open the Control Valve (11) a little bit, until 10 o’clock, and when disinfectant is down put the valve completely to“Filling” and return Disinfectant Valve (8) to “Closed”.

Disinfection must be done with a 33% dilution of the disinfectant, for which you must fill approximately one third of the Viewing Tube (17) with disinfectant and complete the assembly with water, opening the Cleaning Valve (9).

3. Open the Disinfectant Valve (8) till the Disinfection Deposit (10) empties, and then return it to its initial position.

NOTE: Do not open the Disinfectant (8) and Cleaning Valve (9) at the same time. The disinfectant and cleaning circuit are connected, so if during the disinfection operation you keep the Disinfectant (8) and Cleaning Valve (9) open simultaneously, due to pressure differences, the Disinfectant Deposit (10) will fill with water causing it to overflow.

4. The disinfectant must remain in the assembly for a minimum of 10 minutes before removing it. To remove it set the Control Valve (11) to “Discharge” and allow all the contents to come out.

5. Once the disinfection process has been completed open the Cleaning Valve (9) to start the rinsing process and remove any remaining disinfectant suds. This process must be repeated three times. The rinsing process is as follows:

a) Select “Filling” in the Control Valve (11). This allows the assembly to fill completely. The water will remain rinsing for a minimum of one minute inside the assembly.

b) Select “Discharge” to allow the water to flow to the waste drainage.

6. After the rinsing process has been completed a visual test needs to be done. So there is no residual disinfectant remaining in the device. This is done in a visual way. That means once the disinfectant is in the visor pipe the necessary time for disinfection the visor pipe will empty and the personnel should proceed to clear with water the visor pipe, then with a simple visual test is enough to assure that there is no residual disinfectant remaining in the device.

If there is no residual disinfectant, disconnect the Flexible hose (16) pulling back the ring around the flexible hose to disconnect it. Then pull the flex from the Residues Inlet (13).

The disinfectant to be used is CIDEX OPA by ASP (Johnson & Johnson)

17. MAINTENANCE: CHANGING FILTER CARTRIDGES

These cartridges must be changed at least every 75 sessions or either every six months. To change the cartridge, follow these instructions:

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 right 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 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: Cartridges must be changed with new Cartridges. Never reuse them.

18. TECHNICAL CHARACTERISTICS

- Rated working voltage: 230V/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 40°C (104°F)

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-1 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 evacuation connections

19. SESSION PARAMETERS

Therapy parameters will be within the following ranges:

- 30 to 50 litre per hour.
- Pressure 0 - 150 mbar (0 - 2,17 psi).
- Temperature 22 - 40°C (71,6 – 104°F).

20. SAFETY AND PERFORMANCE

Safety systems for temperature and pressure, which stop the irrigation process automatically when:

- The temperature is outside the safety range, established between 22ºC (71,6°F) and 40°C (104°F).
- Irrigation pressure reaches 150 mbar (2,17 psi).

21. TROUBLE SHOOTING GUIDE

IRRIGATION

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

1. Alarm temperature reached:
   Regulate the maximum or minimum temperature of the thermostatic gauge.

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 viewing tube is not blocked.
   c. In case the problem is not caused by the former mentioned causes please contact Transcom for service.

3. Other problems:
   If you experience irrigation problems other than those described above, please contact TRANSCOM, as the problem may be caused by an internal failure.

TEMPERATURE

1. If the temperature does not reach 100ºF (38ºC), check that water heater works properly.

2. If the thermostat shows an alarm sign, please contact Transcendencias Comerciales S.L. for service.

PRESSURE

1. If during the session the pressure gauge does not show any rates, it must be replaced.

2. In case the Irrigation does not switch off when the pressure exceeds 2.17 psi (150 mbar), the pressure gauge must be readjusted. Please contact Transcom SL.

VIEWING TUBE

During the filling mode 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 ajusted.

IF THERE IS A WATER LEAK

1. Shut off the water supply on the inlet side of the unit.

2. Disconnect power cord.

3. Check the status of the filter housings, inspect both the housing and the housing caps. Check to make sure the “O” rings are in the place within the bottom housing filter.

4. Check the status of the unions between pipes and connectors. Make sure all quick disconnects are put together; the best way is to disconnect and reconnect making sure they click into place.

DISINFECTION

1. If there is not disinfectant in the view tube when the valve is open.
   a. Check if the disinfectant deposit contains disinfectant.
   b. Check that every tubes are properly connected. Make sure that these tubes are without any fissures or cracks. If you notice any one the damage tube must be replaced.
   c. Once we have checked all the tubes and the two ways valve and they are all right, the anti-reflux valve has a problem and it must be changed.

2. If the viewing tube can not be filled with cleaning water:
   a. Check that every tubes are properly connected. Make sure that these tubes are without any fissures or cracks. If you notice any one the damage tube must be replaced.
   b. See viewing tube item, to solve the problem.

22. 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 the treatment:

    - HC-1 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-1 Classic should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the HC-1 should be observed to verify normal operation in the configuration in which it will be used.

    - HC-1 Classic equipment is intended for use in a specific electromagnetic environment below specified.

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 or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for AC power supply	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 ϕ angles; 0 % 1 cycle; 70 % UT for 25 cycles; 0 % for 5 sec	0 % UT for 0,5 at 8 ϕ angles; 0 % 1 cycle; 70 % UT for 25 cycles; 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.

23. SCHEDULED MAINTENANCE ITEMS

Our Colon Cleaning machine does not have any regular scheduled maintenance. But proper care and preventative maintenance and 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 you see the first signs of a problem or that the equipment is not operating as usual, you should stop using the equipment and report the problem to Transcendencias Comerciales S.L. for the device to be checked and inspected prior to a new use.

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 and 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.

24. 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 (1,5m)	2 units
• Net wire	1 unit
• Racor connecter 10mm - 1/2”	2 units
• Racor bend connector tube 10mm	2 units
• PVC pipe joint tube 32mm-1”	1,5 m
• 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, 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) SPAIN
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 extent of damage before signing shipping documents. Save all original packing materials and containers for inspection by the carrier until the claim is settled. Contact our customer service department directly for assistance.

DO NOT RETURN any merchandise without our prior an authorization. We will contact you immediately 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): _____

_____

25. 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, provide 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 manufacturers 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 years 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 seller's/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-1 CLASSIC		

26. ASSISTANCE

GENERAL MANAGER

Tel: (34) 943 224 360

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

Correo electrónico: 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

Correo electrónico: 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

Correo electrónico: 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

Correo electrónico: 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

Correo electrónico: 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

Correo electrónico: exportacion@transcomsl.com web: www.transcomsl.com

27. SHIPPING

All shipping will be arranged between the client and the manufacturer, which will best suit the needs of our customers. 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.

HC - 1 CLASSIC: Quantity 1 (Non sterile)

Dimensions without filters:	610 x 230 x 600 mm
(lenght x width x height)	24,02 x 9,06 x 23,62 inches
Machine weight:	23,5 KG.
	51,81 LBS.
Dimensions packaging:	750 x 700 x 410mm
(lenght x width x height)	29,53 x 27,56 x 16,14 inches
Packed machine weight:	28 Kg.
	61,7 LBS.

28. INSTALLATION

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-1 CLASSIC**

VOLTAGE: ☐ 110 V / 60 Hz

☐ 220 V / 50 Hz

DATE AND SIGNATURE SELLER: _____

DATE AND SIGNATURE BUYER: _____

29. 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 usout 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
TRASCENDENCIAS COMERCIALES SL
Calle Troya Ibilbidea 16, Pabellón 5A8-5B8
20115 Astigarraga (Guipúzcoa) SPAIN
Tel.:34 943 224360
Correo electrónico: ventas@transcomsl.com
web: www.transcomsl.com

30. ESSENTIAL TECHNICAL REQUIREMENTS FOR THE INSTALLATION AND CORRECT OPERATION OF THE HC-1 CLASSIC DEVICE

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.

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 60°C or 156°F and 80°C or 208°F.
- The appliance requires an inlet temperature of 60°C or 156°F.

ABOUT STRETCHER TO BE USED:

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

SITING THE MACHINE

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

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.

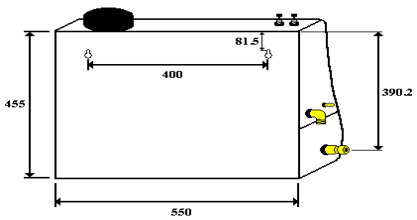
INT AT WHICH THE SOCKET IS TO BE PLACED

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

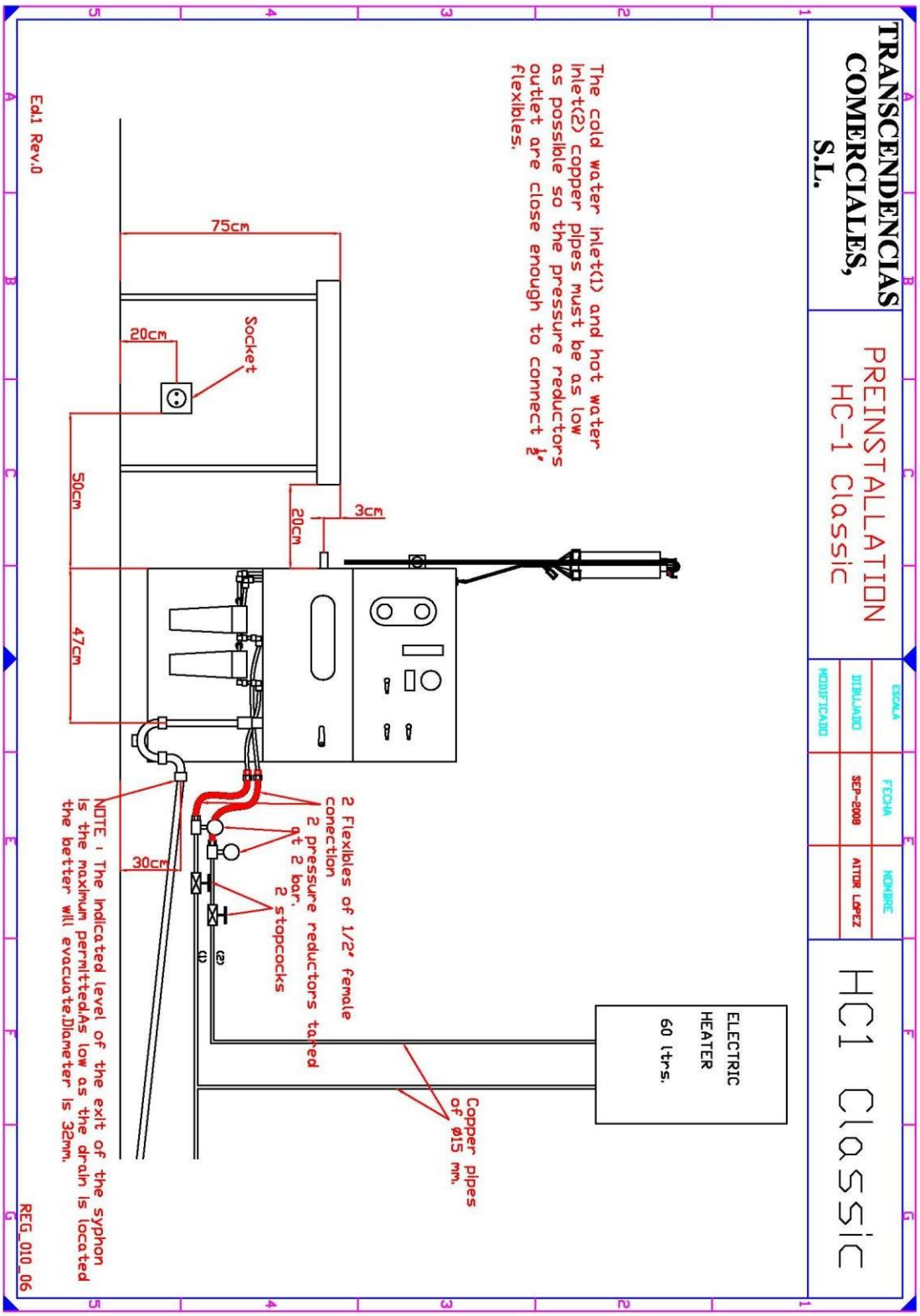
INSTALLATION SKETCH (MM)

The drawings and sketches that follow on the next page are visual aids for proper machine installation. If a bottle holder is required, the entire vertical surface of the machine must be kept clear (at least 50 cm above the height indicated below)

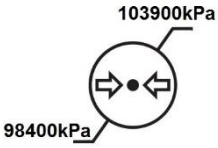
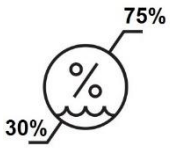
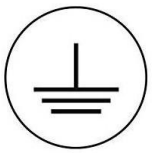
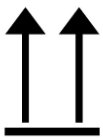
Failure to comply with any of the aforementioned requirements will make it impossible to properly install and commission the machine.



MEDIDAS EN mm.


TRANSCENDENCIAS COMERCIALES, S.L.
PREINSTALLATION HC-1 Classic
HC1 Classic
ESCALA
DIBUJADO
FECHA
SEP-2008
NOMBRE
AITOR LOPEZ
MODIFICADO
Ed.1 Rev.0
REG_010_06
The cold water inlet(1) and hot water inlet(2) copper pipes must be as low as possible so the pressure reductors outlet are close enough to connect ½" flexibles.
75cm
20cm
Socket
50cm
20cm
3cm
47cm
30cm
NOTE : The indicated level of the exit of the syphon is the maximum permitted.As low as the drain is located the better will evacuate.Diameter is 32mm.
2 Flexibles of 1/2" female conection
2 pressure reductors taxed at 2 bar.
2 stopcocks
ELECTRIC HEATER
60 ltrs.
Copper pipes of ø15 mm.

31. 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		

32. OFFICIAL APPROVALS

The HC - 1 Classic device 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-1 Classic
BASIC UDI-DI:	PP 12164 HC1CZ01 91
UDI-DI:	111787636334
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

ENAC ENSAYOS Nº 51/LE147

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

Test report No:

NIE: 64365RSE.001

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-1
(*) Derived model not tested	HC-1 Classic
Other identification of the product	S/N: 1100011
(*) Features	230/110 V ~; 50/60 Hz ; 40 VA . Equipment with insulating and 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 EN 60601-1: 2006/A1:2013 UNE-EN 60601-1: 2006/A1:2013 POSE000_16 (General procedure of Safety Lab)
Summary	See Appendix A
Approved by (name / position & signature)	Rafael Gonzalez. SE Lab Manager Firmado digitalmente por RAFAEL GONZÁLEZ LICERÁN Fecha: 2020.03.12 14:17:08 +01'00'
Date of issue	2020-03-12
Report template No	FSE571_00 + FSE463_08 (*) "Data provided by the client"

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

ilac-MRA ENAC ENSAYOS Nº 51/LE147

Test report No:
NIE: 61664REM.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	Colon cleansing medical device
(*) Trademark	TRANSCOM
(*) Model and /or type reference tested	HC-1
Other identification of the product	S/N: 1100011
(*) Features	230/110Vac. 50/60Hz. 40VA
Manufacturer	TRANSCENDENCIAS COMERCIALES, S.L. P. Empresarial Zuatzu. C/ Zubiberri, 31. Bajo 1. 20018. Donostia. Guipúzcoa. Spain.
Test method requested, standard	Complementary EMC tests to update to EN 60601-1-2 (2015) from previous version.
Approved by (name / position & signature)	Rafael López EMC Consumer & RF Lab. Manager RAFAEL LÓPEZ MARTÍN 2020.03.06 15:14:55 +01'00'
Date of issue	2020-03-06
Report template No	FDT08_22 (*) "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 product:

BASIC UDI-DI:		PP 12164 HC1CZ01 91	
Model	**Trade Name**	**UDI-DI**	**Serial number**
Z-01	HC-1 Classic	111787636334	

Device type: Medical device for colon cleaning

Intended Use:

The HC-1 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: 12/01/2026

Patricia Romero
Technical Manager

Ramón Echevarría
General Manager

Rev: 06
12/01/2026

33. HYDROKIT

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

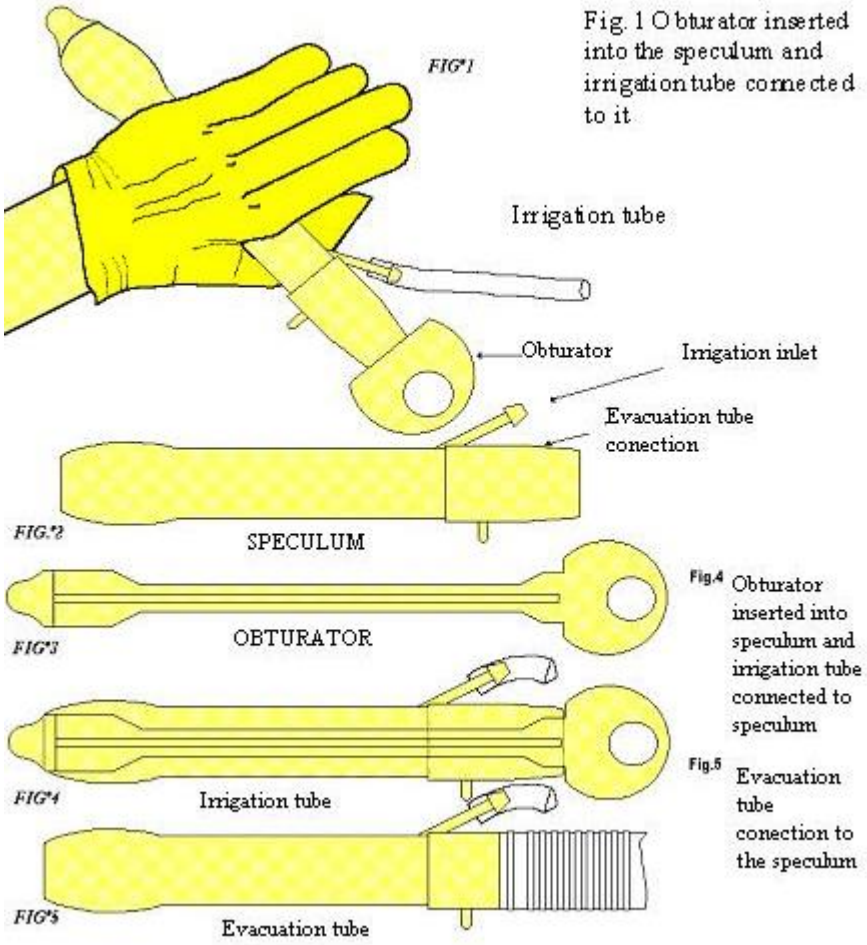
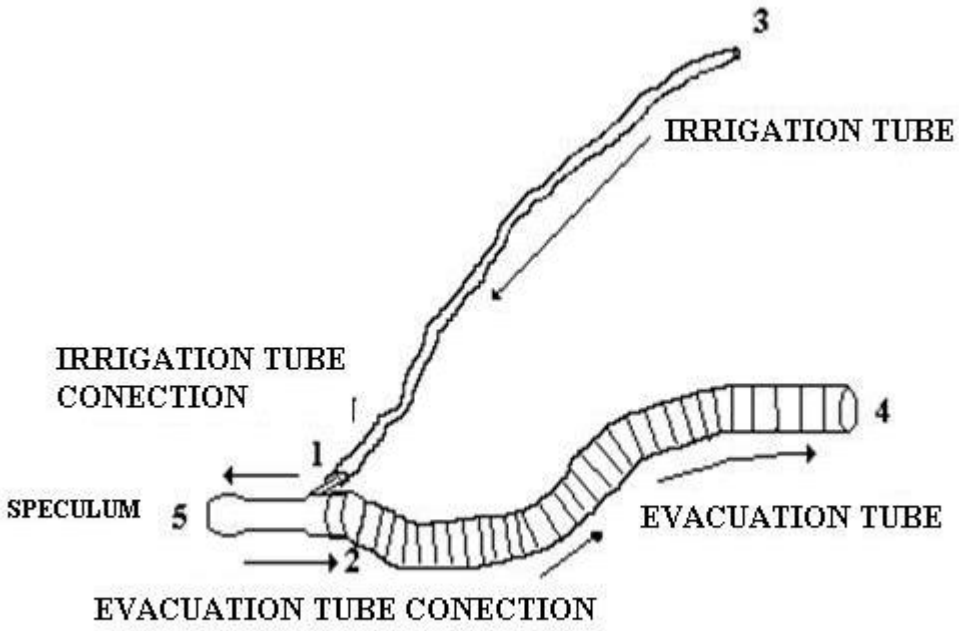


Fig. 1 Obturator inserted into the speculum and irrigation tube connected to it

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:



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.