



Quality Medical Supply

AQUA CLEANSE

Colon Irrigation System

OWNERS MANUAL

FOR PROFESSIONAL USE ONLY

Caution: Federal law restricts this device to sale by or on the
Order of a physician or licensed healthcare practitioner

Serial Number: _____

Original Purchase Date: _____

Quality Medical Supply, Inc.
1445 S. Table Mountain Rd
Chino Valley, AZ 86323
(877) 759-1277
Email: Info@QMSAZ.com

R_xonly

TABLE OF CONTENTS

Important Disclaimer	3
Safety Features	4 - 5
Indications for Use / Contraindications	6
Installation Guide	7 - 8
Device Design and Construction	9
Client Intake Form	10
Device Operation	11 – 13
Device Care	14
Routine Maintenance	15
Device Service Records	16
Troubleshooting	17 – 18
Warranty	19

IMPORTANT INFORMATION!

- ❖ At the end of each day be sure to **SHUT OFF THE WATER SUPPLY** to your colon therapy equipment! This is easily accomplished by turning the red and blue handles at the wall to the off position.

This simple procedure will prevent flooding of your facility if there should be a malfunction in your building's water supply or the device during your absence.

- ❖ Always use **SINGLE-USE ONLY** disposable speculum kits. These kits are designed for the utmost safety for your clients and your business.
NEVER RE-USE ANY SPECULUM OR TUBING!

- ❖ Quality Medical Supply, Inc assumes no responsibility for misinterpretation of the information contained herein. The treatment protocol in this manual is only to be used in conjunction with practical training through a certified organization recognized by regulatory authorities. The company expressly recommends that all contraindications (noted on page 6) be observed. Regulations governing colon hydrotherapy vary from state to state, please observe the regulations of your state.

SAFETY FEATURES

- Cross Contamination - Aqua Cleanse ensures protection from cross-contamination between individual clients through the use of anti-siphoning check valves. These valves will not allow water containing waste material to back up into the device. This feature, along with the use of single-use only disposable speculum kits, absolutely eliminates the possibility of transmitting any viruses from one person to another through the device.
- Mixing Valve – Aqua Cleanse incorporates the finest engineered thermostatic mixing valve available. This valve is an extremely accurate means of achieving and maintaining water temperatures. For added safety, these valves are also equipped with a scald guard feature; the hot water supply automatically shuts off when the cold water supply is lost.
- Flow Control - The Aqua Cleanse device offers precise flow control. By using an extremely sensitive stainless steel flow control valve. The finger touch sensitivity of the flow control knob allows for accurately administered treatments with less hand movements.
- Pressure Control - Each device comes equipped with an internal water pressure regulator. This valve is pre-set upon testing and is sealed with tamper proof tape. The function of the regulator valve is two-fold. First, if the flow control valve is inadvertently opened all the way, the regulator would only allow 3 pounds of pressure through the water outlet. This avoids any possibility of reaching pressure levels of the normal plumbing system (which can be as high as 80 pounds). Second, if for any reason the water outlet line to the client were to become pinched or obstructed, it would keep the accumulated back pressure from going any higher than 3 pounds of pressure.
- Pressure Gauge - A custom designed, color coded pressure gauge is installed in each Aqua Cleanse device. This tri-colored gauge allows the instrument operator an added measure of safety by providing a constant, easy-to-read reference to current water pressure.
- Internal Sanitizing System – Aqua Cleanse has a unique design preventing accidental client contact with the sanitizing solution. The sanitizing cycle has a

completely separate system; it is only engaged when the device is not being used for treatment. Therefore protecting client from accidental contact.

- Stainless Steel Cleaning Coupler – The Aqua Cleanse comes equipped with a lock-in cleaning system coupler. This enables the cleaning solution to be locked into the viewing tube for effective cleaning as required by 2016 FDA regulations.
- Traceability - Each Aqua Cleanse device is assigned an individual serial number and has an individual Device History File. This tracking system allows for complete traceability of the device's history. The serial number is comprised of numbers in the following sequence: chronological number sequence followed by the date of assembly (Example: the first machine, built on January 1, 2015 would be serial number 0001-01012015). The Device History File is kept in our warehouse for easy accessibility; the file contains:
 - all relevant testing information
 - the major components installed in the device (with lot numbers)
 - a traceability form
 - a checklist of all items shipped with that particular unit
- All Aqua Cleanse devices are manufactured under strict regulatory guidelines.

INDICATIONS FOR USE

Indications for Use:

This device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examination.

CONTRAINDICATIONS

Abdominal Hernia	Crohn's Disease	Lupus
Abdominal Pain	Colitis	Medication Concerns
Abdominal Surgery	Cirrhosis	Proctitis
Abnormal Distention	Diarrhea	Pregnancy
Acute Liver Failure	Dialysis Patients	Rectal Bleeding
Anemia	Diverticulitis	Rectal Pain
Aneurysm	Fissures/Fistulas	Rectal Surgery
Carcinoma	Hemorrhoidectomy	Renal Insufficiency
Cardiac Conditions	Intestinal Perforation	Uncontrolled Hypertension

PLEASE NOTE: Operator should be with the client at all times while the device is operational. Never leave the client alone during a session.

INSTALLATION GUIDANCE

Quality Medical Supply, Inc. does not provide installation of the Aqua Cleanse devices, however, plumbing and installation instructions are included with each device for your plumber's reference. It is the customer's responsibility to find a licensed reputable plumber to perform installation. See state and local requirements.

MOUNTING:

- The device should be mounted perfectly level on the wall. The center of the glass observation tube must be level with the surface of the therapy table. The center of the observation tube **should not** be more than 1/2" inch above the therapy table.
- The device can be mounted to the wall with bolts or screws depending on the wall material. Make sure they are strong enough to sustain the device's weight when full of water.

PLUMBING:

- Installation must be completed by a licensed plumber within the jurisdiction; according to the local city and state building code. All other installation procedures will void warranty.
- The building's water supply and the sewer drain must be located close to the floor to allow room for proper device height, as well as, the supply lines and drain trap on the bottom of the device.
- Flush pipes thoroughly before connecting the water supply lines to the device.
PLEASE NOTE: TANKLESS HOT WATER HEATERS ARE NOT COMPATIBLE WITH COLON THERAPY DEVICES.
- Quick disconnects are located on the bottom of the device for easy water supply connection. They are color coded for your convenience: **Blue – cold, Red – hot, Yellow – unfiltered, and Green - filtered.** Connect each hose to the color coordinated quick connection fitting.
- Connection of the device's waste system to the plumbing facility must be made before the drain trap.

- A premium 3-stage filtration system is included with this device and should be used at all times. Use only “Plug N Play” filters provided and be sure to replace as required by manufacturer. **NOTE: Follow the instructions below to purge all of the air from the system at initial set up and each time you change the filters. Allow ample time for the filters to completely fill with water during initial installation of filter cartridges.**

The following steps should be taken after all the water lines have been connected but before the instrument has been turned on for the first time. The procedure below is very easy to accomplish and should take about 20 minutes.

- Open the hot and cold shut-off valves at the source.
 - Make sure the “Temperature Control” valve is set at 100 degrees.
- Engage the pre-warm system by turning the Pre-warm valve to “Pre-warm” and the “Waste Control” valve to the “Empty/Pre-warm” position. Let the water flow until all of the air is purged from this cycle.
- Engage the cleaning system by turning the Cleaning system valve to “Sanitize”. Purge air from this cycle then turn the valve to “Treatment” and slowly open flow control to purge air from the remaining tubing inside the machine.
- When all 3 filters are full of water and air no longer can be heard passing through the instrument you are ready to begin using the device.

SANITIZING SYSTEM:

- Fill the Sanitizing Solution tank with a mixture of 30oz of water and 2oz Cetylcode II Disinfectant Solution (the tank is located on the top right-hand portion of the device). The sanitizing system is designed to mix the correct ratio of disinfectant solution with water inside the device.
- Attach the stainless steel cleaning system coupler tightly onto the coupler prior to using the sanitizing/cleaning cycle.

CAUTIONS:

- Do not remove the back panel or tamper with the device without prior authorization from the manufacturer.

DEVICE DESIGN AND CONSTRUCTION

- Aqua Cleanse devices are encased in a steel, rust resistant cabinet. It is painted with a polyester based paint with an easy to clean clear gloss overcoat for easy cleaning.
- All client-contact flow path fittings are manufactured of the highest quality stainless steel, which meets or exceeds all FDA standards for medical devices.
- All gauges and valves are of the highest quality materials and are pre-tested and calibrated upon assembly.
- Aqua Cleanse uses a custom manufactured stainless steel coupler which prevents leakage at the waste hose connection and locks in sanitizing solution during the sanitizing cycle.
- Quick disconnect fittings enable easy installation of all external hoses to the device and ensure leak-resistant connections.
- All internal connections are made by stainless steel fittings. There are absolutely no lead based soldered connections or components. There are no plastic fittings in the Aqua Cleanse.
- The device's electrical components run on a low voltage (12DC) power supply. This is the same wattage as a desktop calculator. The LED lighting is sealed in a waterproof casing and all electrical components are either covered or sealed with silicone. This completely eliminates any possibility of water leakage creating a short circuit of the device.
- A custom HD Resin view tube allows the client and operator the ability to observe outgoing waste material.

CLIENT INTAKE FORM

NAME _____ BIRTH DATE _____

ADDRESS _____

PHONE # _____ EMERGENCY CONTACT _____ PHONE # _____

DO YOU SUFFER FROM ANY OF THE FOLLOWING CONTRAINDICATIONS? (Please circle all that apply)

- | | | |
|---------------------|------------------------|---------------------------|
| Abdominal Hernia | Crohn's Disease | Lupus |
| Abdominal Pain | Colitis | Medication Concerns |
| Abdominal Surgery | Cirrhosis | Proctitis |
| Abnormal Distention | Diarrhea | Pregnancy |
| Acute Liver Failure | Dialysis Patients | Rectal Bleeding |
| Anemia | Diverticulitis | Rectal Pain |
| Aneurysm | Fissures/Fistulas | Rectal Surgery |
| Carcinoma | Hemorrhoidectomy | Renal Insufficiency |
| Cardiac Conditions | Intestinal Perforation | Uncontrolled Hypertension |

PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. DATE OF LAST BOWEL MOVEMENT? _____
2. HAVE YOU EVER EXPERIENCED COLONIC IRRIGATION? YES NO _____
3. WHAT MEDICATIONS ARE YOU CURRENTLY TAKING?
EXPLAIN: _____
4. HAVE YOU HAD ANY RECENT SURGERIES OR TRAUMA? YES NO
EXPLAIN: _____
5. IS THERE ANYTHING ELSE MEDICALLY THAT WE SHOULD KNOW ABOUT YOU?

I am not intentionally withholding any medical information which is important, and I understand the procedure of Colonic Irrigation as it has been explained to me. All of my questions have been answered and I agree to proceed with this session.

CLIENT SIGNATURE: _____ DATE: _____

DEVICE OPERATION



Notice: Only qualified personnel are to operate this device. Refer to state and local laws.

DAILY SET UP:

- Turn on the power to the LED light and timer. This is done by pushing the rocker switch on the side of the machine. The green light indicates the power is on.
- **Slowly** open the hot and cold water shut-off valves at the wall.
- Start the pre-warm feature. This is done by engaging the pre-warm valve and turning the waste control valve to empty.
- Adjust the mixing valve until the temperature gauge stabilizes at 100 degrees Fahrenheit.
- Slowly open the flow control valve until you achieve a consistent smooth flow of water.
- Pressure gauge should be steady at 2 PSI

BEGIN TREATMENT:

Note: This section is intended for reference only. This device must be operated by a trained professional ONLY!

The colon Hydrotherapy treatment should begin with a comprehensive CLIENT INTAKE FORM completed by your client (provided on page 10 of this manual.) The operator/therapist should review and discuss any possibility of contraindication with the client prior to beginning the treatment.

- Pre-warm the device. Set the mixing valve at the desired temperature (100F or 38C). Engage the pre-warm system by turning the valve to “Pre-warm” and the waste control valve to “Empty/Pre-warm”. Slowly open the flow control valve; let the water flow until desired temperature is obtained. Use the temperature gauge to ensure proper temperature setting.
- **When pre-warm is complete turn flow control knob off (closed).** Only then should you turn the treatment valve to “Treatment”. This will prevent any possibility of damage to the pressure gauge.
- Remove the waste hose, waterline, and disposable speculum from the kit. Lubricate both ends of the waste hose with sterile lubricant. Attach waste hose to the stainless steel coupler on the device. Attach small waterline to the water inlet barb located on the side of the device. Open disposable speculum bag, attach waterline to the hose barb on the side of the disposable speculum, then lubricate tip with sterile lubricant.
- Have client roll onto their left side; using gloves perform a digital rectal examination to assess for any abnormalities.
- Gently insert speculum into rectum. Remove obturator from speculum and gently connect corrugated waste hose to speculum. **Note: if discomfort or obstruction exists do not continue inserting the speculum.**
- Have the client roll over onto their back with knees slightly bent. To ensure client comfort make sure their gown is covering their entire lower body.
- Set the timer for 45 minutes.
- Set the valve to “Treatment” then open the flow control valve slowly while observing the pressure gauge, and allow pre-warmed water to flow at a rate of approximately .5 PSI. During this cycle the waste valve remains open.

- Begin the “Fill” cycle by turning the treatment valve to “Treatment” and the waste control valve to “Fill”. Then slowly turn the flow control valve to .5 PSI. Pressure will gradually rise until the pressure gauge reaches 1.5 - 2 PSI. When this happens begin the “Empty” cycle by turning the waste control valve to the “Empty” setting to evacuate water from the client. Continue this combination of steps for the duration of the treatment.
- The treatment is complete when the water in the observation tube runs clear. Close the flow control valve, leaving the waste control in the empty position. Make sure the client has finished draining, while continuing to lay on their back gently remove the speculum from the client. Raise the waste hose a few feet above the treatment table; draining all of the excess water from the tubing. Disconnect the hoses from the device and discard all components appropriately. **NEVER RE-USE ANY COMPONENT OF THE KIT!**

Assist your client off the table and ensure they make their way to the rest room to evacuate any residual water and waste material. They are ready to shed their gown and return to their clothing.

NOTE: Instructions to set the timer

1. Turn the power switch to the “on” position
2. Press the “up” or “down” button until you reach the desired time (once set it will remember your desired time)
3. Press the start button to start the timer. To pause the timer simply press the start button again. To resume press the start button again.
4. To reset the timer hold down the start button, this will bring back the original desired time setting.

DEVICE CARE

- **After each treatment** discard the kit components, use a sanitizing surface cleaner to clean the treatment table and all surfaces used during the treatment.
 - Sanitize the inside of the device using the integrated Sanitizing system. Mix 30oz of water with 2oz of Cetylde II Disinfectant Solution. Use gloves and protective eyewear for safety.
1. Ensure the stainless steel sanitizing coupler is attached tightly onto the coupler.
 2. Engage the Sanitizer by turning the lever from “off” to “Sanitize”. Let the solution mix for 30 seconds.
 3. Turn the waste control valve to “Fill”.
 4. Let the solution fill the viewing/observation tube then turn the sanitizer valve to the “off” position. Let the solution rest in the tube for 10 minutes.
 5. After a minimum of 10 minutes drain the viewing/observation tube by turning the waste control valve to “empty”.
 6. Turn the sanitizer valve to “Flush” and let the clean water flush out the sanitizer solution. Run until no bubbles or residue are visible.
 7. Swab the view tube and stainless steel coupler with a reusable 1” soft cleaning swab. Clean the swab with Cetylde II solution after use. Replacement swabs can be purchased from QMS when needed.
 8. Once the device is clean turn the sanitizing valve back to “flush” letting the clean water rinse the tube of any residue. If residue persists repeat this process until all residual residue is removed.
 9. During the cleaning process check the viewing/observation tube for cracks or fissures in the tube. Do not operate the device if the tube is damaged.

ROUTINE MAINTENANCE

1. Keep the device clean. Spray the entire device with disinfectant spray and wipe down after each session.
2. Follow the “Device Care” instructions after each use.
3. Use only Cetylcode II, as the sanitizing solution for inside of this device. This concentrated solution is meant to be mixed with water; the device is designed to inject a precise solution to water ration. If you spill any of the Cetylcode II be sure to clean it up immediately. This product can become corrosive to the paint on the device if left for a long period of time.
4. Change filters as recommended by the manufacturer. Change each filter by simply pushing the button above the filter and pull down. Discard the filter and replace by simply pushing the new filter into place.
 - Stage 1 Five micron sediment filter **(REPLACE EVERY 3 MONTHS)**
 - Stage 2 Heavy duty lead and Volatile Organic Compound (VOC) **(REPLACE EVERY 3 MONTHS)**
 - Stage 3 Hollow Fiber Technology using ultra filtration, **(REPLACE EVERY 6 MONTHS)**
5. If there is noticeable difference in the device’s pressure or performance it’s time to change the filters. You may have to change filters more often depending on your water supply.
6. If a leak should develop, contact QMS immediately at the 24-hour emergency phone (623) 512-9664. Serious damage to the instrument can be averted if these problems are addressed promptly after they are noticed and identified.
7. Troubleshooting a device problem without the assistance of one of our trained technicians can damage the device and will void the device warranty.
8. Remember... Turn off the shut-off valves at the end of the day!! Doing this will save wear and tear on the device and prevent any damage to your office if a problem occurs in your building’s water source!

DEVICE SERVICE RECORD

Service records for your device should be kept up-to-date at all times. QMS keeps records of all original parts as well as any replacement parts we have provided. It is up to you to keep track of your in-office maintenance records.

Below is a helpful way to keep track of services performed on your Aqua Cleanse device.

MAINTENANCE LOG

EQUIPMENT: Aqua Cleanse

MANUFACTURER: Quality Medical Supply, Inc.
13174 W. Foxfire Drive, Suite B-132
Surprise, AZ 85378

PURCHASE DATE: _____

SERIAL NUMBER: _____

SERVICE RECORD

DATE	SERVICE PERFORMED	PART REPLACED/LOT#

TROUBLESHOOTING

NO WATER FLOW

- Check water supply lines at the shut-off valves
- Lack of hot or cold water pressure will cause master mixing valve to shut down for scald protection.
- Filters may need to be replaced.

LOW WATER FLOW

- Filters need to be replaced
- Water supply lines are not completely open
- Your buildings water pressure is not sufficient

DOES NOT MAINTAIN TEMPERATURE

- Hot and cold supply lines may be reversed
- Master Valve may need service
- Water heater may be outdated and not able to maintain temperature

FLOW VALVE LEAKING

- Valve may need to be tightened
- Call QMS for service

WASTE WATER DOESN'T DRAIN PROPERLY

- Device is not installed at proper height or level
- Drain is too high
- Waste valve is not fully open
- Possible blockage in the drain

PRESSURE GAUGE CONSIDERATIONS

- Always have the waste control valve in the empty position when circulating water through the instrument, especially when using the pre-warm system.
- In the course of a colon hydrotherapy session, always set the pressure gauge reading to 0.5 PSI when setting the instrument waste control valve to the fill position.

- Never squeeze the waste evacuation hose in the course of the session when the device waste control valve is in the “fill” position.
- In the course of the session, when the instrument is in the “empty” position, never exceed 2 PSI reading on the pressure gauge.
- At the conclusion of the session, always make sure that the waste control valve is in the “empty” position when the flow control knob is being closed.
- Once the water delivery line (from the disposable speculum kit) is attached to the device, never allow it to fall below the height of the device. Doing so will cause back pressure on the gauge and may cause serious damage to the gauge.

By observing these few simple considerations, you will be able to eliminate the possibility of exerting increased back-pressure on the instruments pressure gauge and thus reduce the possibilities of damaging this component.

LIMITED WARRANTY

Quality Medical Supply, Inc. (of Surprise, AZ) the manufacturer of the Aqua Cleanse device, does hereby warrant to the purchaser of this device shall be free from defects of material and workmanship for a period of thirty-six (36) months from the date of delivery.

Manufacturer shall not be liable under this warranty if the product is repaired or altered by anyone who has not been approved by the manufacturer or if the product has been subject to misuse, negligence, abuse or accident. The warranty shall not apply to the product made by manufacturer, which shall not have been operated and maintained in accordance with manufacturer's printed operating instructions, included herewith. In case of work done during the warranted period of time, Quality Medical Supply, Inc. is not liable for time or money lost due to device downtime.

Failure of purchaser to use the product in accordance with the manufacturer's printed instructions shall operate as a waiver of the warranty and absolve manufacturer or independent distributor of any liability whatsoever.

User must purchase Quality Medical Supply associated kit during this warranty period. These kits have been specially designed to maximize the operation of the Aqua Cleanse Colon Irrigation System. Use of other speculum kits voids the warranty as we cannot guarantee the effectiveness of other products.