

# Standard Operating Procedures, Regulations & Guidelines

For

**I-ACT Recognized Schools  
&  
I-ACT Recognized Colon Hydrotherapy Establishments**

**OF THE**

**INTERNATIONAL ASSOCIATION  
COLON HYDROTHERAPY  
(I-ACT)**

These guidelines are a compilation of material gathered from experience and several colon hydrotherapy manuals to establish a mutual understanding. Thanks to all contributors.

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## **Purpose**

(1) These Business and Professional Regulations are promulgated in an effort to protect the health, safety and welfare of the public by ensuring that only those who are qualified by certification to administer colon hydrotherapy may do so.

(2) Prior to the administration of colon hydrotherapy, any person shall be required to present certification to the Board of successful completion of a course of study approved by I-ACT through an I-ACT approved colon hydrotherapy school or instructor and certified at the Foundation Level.

## **Scope of Practice**

Colon Hydrotherapy is the introduction of warm, filtered and temperature regulated water into the colon, the waste is softened and loosened, resulting in evacuation through natural peristalsis. This is repeated several times during the session.

## **Definitions**

(1) “Board” means the Board of Directors of the International Association for Colon Hydrotherapy (I-ACT).

(2) “Education Committee” is a group of dedicated members of I-ACT who volunteer their service to recommend educational guidelines to the Board.

(3) “Establishment” means an appropriate site or premises, or portion thereof, where a colon hydrotherapy session occurs

(4) “Colon Hydrotherapy” is the introduction of warm, filtered and temperature regulated water into the colon, the waste is softened and loosened, resulting in evacuation through natural peristalsis. This is repeated several times during the session.

(5) “Student” means a person studying colon hydrotherapy at any of the four Levels of training (i.e., Foundation Level, Intermediate Level, Advanced Level, or Instructor Level).

(6) “Instructor” means a certified colon hydrotherapist who plans to carry out the training and instruction of a student for a limited period of time. Instructors may train one to two students at a time.

(7) “Certification” means the procedure by which a colon hydrotherapist applies to the Board for approval documenting the student has successfully passed the I-ACT certification examination and fulfilled all requirements for each level of certification.

(8) “I-ACT recognized colon hydrotherapy school” means a facility which agrees to comply with the training and curriculum as recommended by I-ACT. Each school must be in compliance with the laws of their state. Schools may train as many students as they have room for.

(9) Equipment Classification  
Enema Kit

*From the code of federal regulations (CFR) 876.5210 Enema Kit. (*

*a) Identification. An enema kit is a device intended to instill water or other fluids into the colon through a nozzle inserted into the rectum to promote evacuation of the contents of the lower colon. The device consists of a container for fluid connected to the nozzle either directly or via tubing. This device does not include the colonic irrigation system (Sec. 876.5220).*

*(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 876.9. The device is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of Sec. 820.180 of this chapter, with respect to general requirements concerning records, and Sec. 820.198 of this chapter, with respect to complaint files. [48 FR 53023, Nov. 23, 1963, as amended at 65 FR 2317, Jan. 14, 2000]*

### **Colonic Irrigation System**

*From the code of federal regulations (CFR) Sec. 876.5220 Colonic irrigation system.*

*(a) Identification. A colonic irrigation system is a device intended to instill water into the colon through a nozzle inserted into the rectum to cleanse (evacuate) the contents of the lower colon. The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation. The device consists of a container for fluid connected to the nozzle via tubing and includes a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled. The device may include a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes. The device may use electrical power to heat the water. The device does not include the enema kit (Sec. 876.5210).*

*(b) Classification. (1) Class II (performance standards) when the device is intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations. (2) Class III (premarket approval) when the device is intended for other uses, including colon cleansing routinely for general well being.*

*(c) Date PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a colonic irrigation system described in paragraph (b)(2) of this section that was in commercial distribution before May 28, 1976. Any other colonic irrigation system shall have an approved PMA in effect before being placed in commercial distribution. [48 FR 53023, Nov. 23, 1983, as amended at 52 FR 17738, May 11, 1987; 61 FR 50707, Sept. 27, 1996]*

### **Qualifications for Individual Certification**

(1) Any person is qualified for certification as a colon hydrotherapist who:

(a) Has presented certification to the Board of successful completion of a course of study approved by I-ACT through an I-ACT recognized colon hydrotherapy school or instructor and certified at the Foundation Level; or, who has presented documentation they have been practicing in the field of colon hydrotherapy for more than one year and have performed more than 100 colonics in the past year and has passed a mandatory sixteen (16) hour course put on by an I-ACT instructor or school.

(b) Has taken the I-ACT written test and received a passing grade.

(c) Has completed the remaining requirements as directed by the I-ACT Board.

## **Examinations**

(1) A written examination for each level of certification shall be offered by I-ACT at least once yearly (at the annual convention), at I-ACT recognized schools or with an I-ACT Instructor. There is a fee of \$75.00 for each level of examination.

(a) The testing for Level 4 (Instructor Level) requires the completion of a 60 hour course put on by an I-ACT school or with and I-ACT Instructor. During that training, the individual will teach for a total of four instructor hours. Three {3} hours may be accomplished at an I-ACT recognized school, or with an I-ACT Instructor (it is desired that minimum of 8 individuals attend the instructor presentations). One hour must be completed at an I-ACT Convention (at a minimum, the presenting instructor should wear business casual attire). In addition, the prospective instructor must attend a mandatory two hour instructor workshop.

(2) Upon an applicant's passing the test and paying the initial certification fee and fulfilling all requirements for I-ACT Level 1, I-ACT shall then certify the individual at the Foundation Level. Completion of the requirements for Level 2, 3 or 4 will cause I-ACT to certify the individual at that level.

(3) All certification examinations must be proctored and an accurate record of each examination shall be made; and that record, together with all examination papers, shall be filed by I-ACT or the school certifying the examination and be kept indefinitely.

(4) Members testing at the convention will be allowed to take a test 2 times during the convention. If the member fails the exam 2 times they will be required to show additional training before they can retest. They may retest and pay \$75 for the test. If they fail this test they will be required to wait 6 months and show they have additional training. Before they can retest and pay an additional \$75 test fee. If the person does not pass this exam they will be required to retrain with A & P at a school, instructor or tutor and present a transcript.

(5) Maximum time allowed for Level 1 & 2 exam shall be 2 hours, and maximum time allowed for Level 3 exam shall be 3 hours. This time may be extended by the proctor as required for International students that English is not their first language or if the student has documented learning disabilities .

## **Posting of Certificates**

(1) All members shall post their I-ACT Certificate in their colonic establishment for easy viewing by the public.

## **Inactive Status**

(1) A member becomes inactive when an I-ACT member fails to renew their I-ACT membership, within 90 days of expiration of membership and pays an Inactive status fee of \$25.00 per year. The inactive status is good for a period of up to two years. Once a member goes inactive, they may reinstate their status by paying current years dues. However, any individual that allows their membership to I-ACT to be terminated automatically loses all levels of certification they had received. This individual must retest on each level before that level of certification may be reinstated.

### **I-ACT Recognized Colon Hydrotherapy School Criteria**

(1) The Board shall adopt reasonable standards, for I-ACT recognized schools.

(a) An I-ACT school must have at least one certified I-ACT Instructor on staff, and all training shall be conducted or supervised by an I-ACT Instructor.

(b) The school shall teach colon hydrotherapy utilizing the I-ACT Syllabus for the Foundation, Intermediate, Advanced, or Instructor Level as appropriate to the class.

(c) All training must be performed or supervised by the instructor.

(d) The school must provide I-ACT testing at the completion of each course of training.

(e) The school must comply with all guidelines of the I-ACT's Standard Operating Procedures, Regulations & Guidelines.

(2) Any person, firm, or corporation desiring to operate a colon hydrotherapy school shall submit to I-ACT, accompanied by any information requested by I-ACT, an application for recognition fee as directed by the I-ACT Board. Additionally the school must submit proof that they are in compliance with all state laws.

(3) I-ACT retains the right to visit any recognized school as it deems necessary.

### **I-ACT Zero Tolerance Policy**

Background: The International Association for Colon Hydrotherapy (I-ACT) recognizes the seriousness and extent of injury that any form of abuse may cause another and therefore supports Zero Tolerance of such abuse in any form: this includes any type of harassment, verbal, physical, emotional, financial or sexual, by an I-ACT member colon hydrotherapist.

I-ACT endeavors to provide protection of the public interest by addressing client-member, member-student and member-member abuse openly. I-ACT strives to provide an accessible and sensitive reporting process, and establishes deterrents through the administration of a disciplinary process reflecting the serious nature of the violation.

This policy has been created to advise our membership that I-ACT endorses the Principle of Zero Tolerance for abuse in any form and to ensure members understand that abuse in any form is unacceptable and will not be tolerated.

In defining abuse, it is important for the professional to be cognizant of the imbalance of power that exists in the professional colon hydrotherapy environment. Clients often seek professional services when they are vulnerable or in a state of pain. A member of this profession has the 'power' by virtue of their authority, knowledge, access to privileged information and the influence they potentially hold over the client, to exploit. It is expected, therefore, that the professional will address the client's needs in a sensitive and caring manner in accordance with the Standards of Practice and the Code of Ethics for the profession.

I-ACT is also aware that the most productive and satisfying environment is one in which instruction and growth is accomplished in a spirit of mutual trust and respect. Harassment is a form of discrimination that is offensive, impairs morale, undermines the integrity of Client/Member and Instructor/Student Member relationships and may cause serious harm to the productivity, efficiency and stability of our organization and industry.

I-ACT members will maintain confidentiality of client information, unless given written permission by the client or ordered by the courts. I-ACT members will clearly represent their educational qualifications and inform clients of the limits of their license or certification. I-ACT members should refer clients to an appropriate professional for services if the treatment is not within their scope of practice. I-ACT members will use precautions to do no harm to physical, mental and emotional health of clients and associates.

Abuse can be defined as:

### **Harassment**

Harassment on the basis of a person's gender, race, color, ancestry, ethnic or national origin, age, disability, arrest or conviction record, marital status, sexual preference, military or organizational membership will not be tolerated. Every individual has the right to receive colon hydrotherapy services, education and training in an environment which is free from discrimination, intimidation, and all forms of harassment.

### **Verbal - Non Verbal**

Verbal abuse may include but is not limited to, derogatory comments, sarcastic, demeaning or seductive remarks. It is also important to note that the tone of verbal communications may characterize how words are perceived. I-ACT members must be aware that a person's age; culture, socio-economic status and other particular sensitivities may affect how a client perceives communications with an I-ACT member.

Jokes, insults and innuendoes (based on race, sex, age, disability, etc.), and degrading sexual remarks, such as referring to someone as a stud, hunk or babe; whistling; cat calls; comments on a person's body or sex life, and/or pressures for sexual favors are examples of verbal abuse that is completely unacceptable.

Non-Verbal behaviors that are unacceptable could be gestures, staring, touching, hugging, patting, blocking a person's movement, standing too close, brushing against a person's body, any unsolicited touch or display of sexually suggestive or degrading pictures, racist or other derogatory cartoons, drawings or communications.

### **Physical**

Using unnecessary force in the course of providing treatment or training.

All therapist members will have an understanding regarding the Ethics of Touch.

All therapist members should follow the guidelines of the manufacturer for equipment use.

All therapist members will be aware of the I-ACT policy on insertion.

### **Emotional**

Where a member of the profession uses the position of power to intimidate or show insensitivity toward the client or a student. Emotional abuse demeans the client or student in such a way as to lower their sense of personal worth.

### **Financial**

The inappropriate use of a client's or student's funds, property or resources. May include such behaviors as:

- a. Attempting to, or actually persuading, deceiving, or threatening the client to part with their funds, property or possessions;
- b. Recommending excessive treatments/trainings with no \*\*clinical indication requiring the same;
- c. Use of a client's or student's money for purposes other than that intended by the client;
- d. Failure to provide the client or student a written refund policy and
- e. Failure to provide a refund for services if requested by client.

### **Sexual**

I-ACT defines sexual abuse to include:

- a. Sexual intercourse or other forms of physical sexual relations between the member and the client or student;
- b. Touching of a sexual nature, of the client or the student by a member;
- c. Behavior or remarks of a sexual nature by the member towards the client; Exception: "sexual nature" does not include touching, behavior or remarks of a clinical nature appropriate to the service provided.
- d. Touch should be therapeutic in nature providing a necessary action related to the treatment for a desired result.

### **Policy:**

I-ACT will investigate and act upon any complaints and information received dealing with allegations of abuse of a client in an effective, timely and sensitive manner.

In relation to those members found in violation of the Zero Tolerance Policy, I-ACT will uphold the sanctions mandated by the I-ACT Grievance Committee as approved by the Board. I-ACT is committed to imposing appropriate penalties to reflect the severity of the conduct of concern.

### **Disciplinary Guidelines**

#### **Grounds for Disciplinary Action**

(1) Attempting to procure a certificate to administer colon hydrotherapy by bribery or fraudulent misrepresentation.

(2) Practice or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the certified colon hydrotherapist knows or has reason to know that he/she is not competent nor authorized to perform.

(3) Refusing to permit I-ACT to visit the business premises of the certified colon hydrotherapist

on reasonable notice.

(4) Failing to keep the equipment and premises of the colon hydrotherapy establishment in a clean and sanitary condition on the inside and outside of the building.

(5) Conviction of felony after membership and certification.

(6) Behavior detrimental to the profession or goals of the association.

(7) Inappropriate advertising inconsistent with I-ACT guidelines.

(8) Three verifiable grievances that have gone through the grievance process and have been determined by the Board to have merit.

### **Disciplinary Action**

When the Board finds any person is acting in violation of any rules, it may enter an order imposing one or more of the following penalties:

(a) Refusal to certify any person, but that person can reapply within 90 days with a new application fee of \$75.00.

(b) Issuance of a reprimand or censure by promulgated, unanimous decision of the Board.

(c) Revocation of a certificate and suspension of the right to hold themselves out as an I-ACT certified colon hydrotherapist.

It is understood that any investigation, decertification, or censuring of a member, may cause I-ACT to expend funds for that investigation and may result in an expense or a cost. The person or member involved will be expected to pay this cost within 30 days. If the fee is not paid it will cause expulsion for the applicant.

### **Grievance Policy**

1) Grievances brought forth by the public will be considered for review by the grievance committee for issues involving the following criteria:

Those documents which define standards of behavior for I-ACT members, such as the Standard Operating Procedures, Code of Conduct, Zero Tolerance Policy, and By-Laws of I-ACT. (for example: complaints concerning scope of practice, ethics, advertising, facilities, cleanliness, and reuse of disposables. This is not an all inclusive list.)

A grievance must be in written form and signed.

2) Grievances brought forth by members of I-ACT against an Officer of the Board or Board Member, or fellow member:

Grievances considered will be those documents which define standards of behavior for I-ACT members, such as the Standard Operating Procedures, Code of Conduct, Zero Tolerance

Policy, and By-Laws of I-ACT.

A grievance must be in written form and signed.

3) Grievances regarding I-ACT recognized schools will only be accepted if they pertain to, education, testing, non-compliance with the syllabi, and the Standard Operating Procedures, Code of Conduct, Zero Tolerance Policy, and By-Laws of I-ACT.

A grievance must be in written form and signed.

4) Grievances regarding manufacturers or products are not within I-ACT authority or responsibility.

5). Prior to filing a grievance, both parties seek amicable resolution. The initial approach to settling any issue is open communication. If the concern(s) is /are not resolved in a timely fashion, a formal grievance should be filed according to I-ACT procedures. The grievance should be in writing and contain information about the grievance, submission date, name, address, telephone or cell phone number of grievant, location, date, contracts (if applicable) and description of the problem.

Disclaimer: I-ACT assumes no responsibility, legal or otherwise, for the outcome and/or resolution of any grievance.

### **Grievance Committee Guidelines**

These are the following steps that are followed by the I-ACT Grievance Committee (made up of I-ACT Board Members).

1. The office receives a grievance, logs it in and assigns a number. The office will then notify both the individual filing the grievance and the individual that the grievance was filed on that a grievance has been filed and they will be hearing from the Grievance Committee. The office then sends the grievance to the Grievance Committee for action.

2. A Committee member is assigned and notifies both parties who will be handling the grievance and will provide both individuals a projected time line.

3. When tasked for information, the School, Instructor or Therapist filed against has 10 days to acknowledge receipt and make contact with the grievance committee member handling the grievance.

4. The School, Instructor or Therapist has up to 30 more days to send paperwork to support their side of the grievance.

5. If additional paperwork is requested by the Committee member, the School, Instructor or Therapist has an additional 10 days to supply this new paperwork.

6. Failure to respond to item 3 or 4 above will cause the School, Instructor or Therapist to be

removed from the I-ACT referral list until the grievance has been resolved.

7. The Grievance Committee members makes a determination that:

a. there are no grounds or there is no basis for the grievance - in this case, both parties are notified and no action taken.

b. the grievance is valid. Both parties are notified and the grievance Committee member attempts to find a resolution between both individuals.

c. there is not enough information provided to definitely determine there were grounds for a grievance.

8. All grievances are reported to the Board (within 30-40 days). The Board will have the final authority to assign responsibility and take final action.

9. Both parties will be notified of resolution of the Board of Directors.

### **Whistle Blower Policy**

I-ACT has established a Whistle Blower policy to protect its members and employees that notify the Board or members of a policy or activity that may be in violation of the law. In part, It states:

I-ACT will not retaliate against a member or an employee who, in good faith, has made a protest or raised a complaint against some practice of I-ACT, or of another individual or entity with whom I-ACT had a business/membership relationship, on the basis of a reasonable belief that the practice is in violation of law or a clear mandate of public policy.

I-ACT will not retaliate against an employee who discloses or threatens to disclose to a supervisor or a public body any activity, policy, or practice of I-ACT that the employee reasonably believes is in violation of a law, or a rule, or regulation mandated pursuant to law or is in violation of a clear mandate or public policy concerning health, safety, welfare, or protection of the environment.

### **Standard Operating Protocols**

1. INDICATION FOR COLON HYDROTHERAPY: Must be in absolute compliance with the Code of Federal Regulations Title 21 for the Class of equipment in use. Use the indications approved by the FDA for your equipment (ie, constipation, etc.)

2. EFFECTS: Colon irrigation.

3. ROUTE: Administered rectally.

4. FREQUENCY: Based on the client's response and need as indicated by their physician or healthcare practitioner.
5. DURATION: Time required for administration is normally based upon the needs of the client however, in all cases the guidelines of the manufacturer should be followed.
6. RELEVANT HAZARDS: To ensure the highest level of safety for the consumer, always use FDA registered equipment.

There are reports of cross contamination due to improperly cleaned / disinfected equipment or table on equipment that was not registered with the FDA.

Always follow your manufacturer guidelines for cleansing your equipment to ensure there is no spread of disease, etc.

Improper use of the equipment by not following the guidelines of the manufacturer may cause injury (ie. alleged perforation of the colon).

Under no circumstances should single use devices be reused.

Under no circumstances should FDA registered equipment be modified or altered without the manufacturer's permission.

7. CONTRAINDICATIONS: Follow the guidelines of your manufacturer.
8. POSSIBLE SIDE EFFECTS: Weakness, nausea, vomiting, hunger, flatulence, fatigue, dizziness, abnormal energy, etc.
9. PRECAUTIONS: None. Follow the manufacturers guidelines for your equipment.

### **Referring Healthcare Provider**

1. All records should be made available to referring or consulting health care providers associated with the client and their therapies provided that a properly written release form is executed by the client beforehand.
2. Therapies for referral clients SHALL conform to the prescription or instructions of the referring health care giver. Client responses to indicated therapies and findings associated with all aspects of colon hydrotherapy care SHALL be reported to the referring health care giver on request.

Under no circumstances will the colon hydrotherapist prescribe or suggest other therapies, additional sessions, procedures, nutritional supplements, etc. to the client that were not originally prescribed or ordered by the referring physician or health care provider. The colon hydrotherapist may communicate to the referring health care professional an additional number of sessions to facilitate the prescription instructions

## The Session

1. Follow the instructions for the session as recommended by the prescription and consistent with the guidelines of the manufacturer of your equipment.
2. All techniques, methods, and procedures that are to be used during the colon hydrotherapy session must be completely and thoroughly explained to the client in advance. In no case should any additional technique be used without the permission of the client.
3. The client must be attended, or the therapist will be immediately available to the client, during the session at all times.
4. The Therapist must be professionally groomed and attired. The client SHALL be modestly draped with an acceptable gown or covering during all procedures. Techniques used in colon hydrotherapy procedures SHALL be adopted with the attempt to maximize the client's overall personal privacy and modesty, to maintain the client's dignity, state of comfort and ease.
5. The Therapist must ensure there is no action, language, or behavior that may be interpreted as a sexual advance.
6. The Therapist must ensure they stay in their scope of practice or areas that they are licensed by law to practice. Do not exceed the scope of practice for any license you may possess.
7. Even though gloves are used, hands and nails must be thoroughly washed with an antibacterial, antifungal soap before and after each client, and as necessary during the session.
8. When using Class 1 FDA registered equipment, the client must insert and remove the speculum/rectal nozzle; for Class 2 FDA registered equipment, the client must insert the rectal tube or speculum; or, follow the instruction of the referring physician; the guidelines of the manufacturer as approved by the FDA; or the directives from the authority of your city, county, state, or country ordinances.
9. To ensure the safety of the client, follow the manufacturer recommendations for procedures to be used during the session. In no case should the recommendation of the manufacturer be exceeded or ignored.
10. At the end of the session, clean, sanitize, and disinfect the equipment according to guidelines provided by the manufacturer of your equipment.

## Physical Premises

1. The design and physical layout of the premises, installation and maintenance of equipment, plumbing, electrical wiring, egress and ingress routes, parking and public access should conform to all local, county, and state zoning regulations. All facilities should have the proper occupancy permits and approvals by the local Board of Health, where required.
2. A separate client waiting area should be maintained.
3. Rest room facilities should be provided for and located at a convenient distance from the session room table. The rest room should have a toilet and a sink which should be used for hand washing after using the toilet. A pump-type soap dispenser is the desired method of dispensing soap and should be used for maximum sanitation.

## Advertising

1. The onus of responsibility should be on the colon hydrotherapist to maintain an absolutely factual and true representation of the colon hydrotherapy procedure and profession in all advertising medium, whether printed page or electronic media.
2. Advertising copy which states or implies that colon hydrotherapy can treat any disease, promise cure for any disease, or that makes unsubstantiated medical claims **SHALL NOT** be used.

“Advertising medium” means: any newspaper, airwave or computer transmission, telephone directory listing other than an in-column listing consisting only of a name, address, and telephone number, business card, handbill, flyer, sign other than a building directory listing all building tenants and their room or suite numbers, or other form of written advertising.”

## I-ACT Policy Statements

I-ACT requires the use of currently registered FDA equipment and only disposable speculums, rectal tubes, or rectal nozzles. However, should the Therapist use reusable speculums, these speculums should, at a minimum, be autoclaved for sanitation and cleanliness (30 minutes). Additionally, the autoclave unit must be tested and inspected by competent authority at least four times per year- maintain documentation. (Under NO conditions should a disposable speculum or rectal tube be reused). Individuals that use reusable speculums and/or are not using FDA registered devices will be removed from I-ACT membership on 12/31/2018.

I-ACT recognizes the FDA classifies equipment used to instill water into the colon through a nozzle inserted into the rectum to evacuate the contents of the colon into three distinct classes; Class I (Enema Kits), Class II and Class III are (Colon Irrigation Systems). Follow the guidelines of your manufacturer, as approved by the FDA for the type of equipment (devices) you are using. Make no claims as to the use of your device other than those approved by the FDA.

The main differences between Class I and Class II devices:

The code of federal regulations CFR 876.5210 & 876.5220 describe the differences between the Class I and the Class II devices. From that regulation, a Class I device is an enema system and does not include “colonic irrigation devices”. A “colon irrigation device” is a Class II device, which in part is described as: “The system is designed to allow evacuation of the contents of the colon during the administration of the colonic irrigation.

The Class I Device:

- The Class I device is defined as an enema system and may not have temperature control, temperature gauges or water purification as part of the device. Class I enema systems must be self-administered.
- Manufacturers of Class I devices are not required to have third party oversight as they need not comply with the good manufacturing practices and record keeping that are required of Class II manufacturers. Class I devices are not as heavily regulated and controlled by the FDA as Class II devices are.
- Owners of Class I devices may not market their service using the terms “colonics or colonic irrigation” in describing the scope of their practice of evacuating the contents of the lower bowel.

The Class II Device:

- The Class II Device is a “colonic irrigation device”.
- Manufacturers of Class II devices are required to have third party oversight and must comply with the good manufacturing practices and record keeping that are required by the FDA. Class II devices are heavily regulated and controlled by the FDA.
- The FDA requires Class II devices to be sold and used on or at the order of a physician or health care practitioner. This may be different in each state.

Although I-ACT is not aware of any laws that preclude you from assisting an individual with an enema, I-ACT does want you to consider upgrading your equipment to the equipment that provides the greatest safeguards to the public. In this profession, that would be equipment marketed as Class II devices.

Remember that I-ACT strongly recommends that all I-ACT members use FDA registered Class II devices or devices equivalent to Class II devices regulated by the appropriate agency in your country. Only individuals using FDA registered equipment will be placed on the I-ACT Web Site. As of 12/31/2018, only individuals that use FDA registered devices may be I-ACT members. Purchase equipment at your own risk. Ensure you are in compliance with your local, state, federal and country guidelines. Ensure that equipment you purchase is cleared for use in your country.

I-ACT recognizes there are two distinct types of colon irrigation systems; open and closed systems. However, it is I-ACT policy that the colon hydrotherapist / technician is always in attendance / or is immediately available to the client throughout the session. The degree of assistance is to be in compliance with the instructions of the manufacturer of the equipment as registered with the FDA, and/or as directed by a physician.

The policy on insertion is to require the client to insert the rectal tube or speculum; or, follow the instruction of the referring physician; the guidelines of the manufacturer as approved by the FDA; or the directives from the authority of your city, county, state, or country ordinances.

I-ACT recommends that you do not put the initials (CT) for colon hydrotherapist after your name, write it out in full. According to most state laws, putting initials after your name is not allowed unless you are licensed or have a degree from an accredited professional school.

Advertising copy which states or implies that colon hydrotherapy can treat any disease, promise cure for any disease, or that makes unsubstantiated medical claims SHALL NOT be used.

### **RECOMMENDED CHECK LIST** (TO BE KEPT UP TO DATE AT ALL TIMES)

1. Keep a list of all major contraindications to colon hydrotherapy from the manufacturer of your equipment readily available.
2. Keep a completed, detailed and **signed** Intake Questionnaire and a current and accurate history of all clients, being careful not to make any recommendations in print or verbal.
3. Keep the original of the doctor's prescription in your clients file.
4. Keep a checklist of equipment operation procedure which should include a record of settings used on each individual client.
5. DO NOT make any medical claims or have any literature making such claims.
6. Keep an emergency procedure checklist available in the event of any unforeseen circumstances.
7. Keep the manufacturer's operation manual in close proximity to your equipment.
8. Keep a maintenance record on your equipment and include any related repair orders.
9. Keep available the name, phone number, and address of any authorized repair company, usually the equipment manufacturer.
10. Use filtered water during session and keep a record of filter element life.
11. Use currently cleared FDA modern equipment. Have your currently cleared FDA equipment properly installed by a licensed plumber, making sure that the waste hose is correctly connected to the exiting sewer system, and ensure that it adheres to all local plumbing codes.
12. Keep your equipment clean, sanitized and in good operating condition, and never bypass or alter any safety features or any other features your manufacturer has installed without manufacturer permission.

13. Single use disposables are strongly recommended, NEVER reuse any part of the disposable kit, even if it were to be used on the same client on a return visit. IF Stainless Steel speculum are used, the speculum should be autoclaved for safety and sanitation. Additionally, the autoclave unit must be tested and inspected by competent authority at least four times per year (maintain documentation). This procedure must be in compliance with laws of your state for sterilization of stainless steel hospital equipment.
14. Always use sanitizing solution in concentrations recommended by the manufacturer.
15. Be aware that perceptions of cleanliness is of the utmost importance to members of any health department. This includes not only the appearance of your facility but your personal appearance as well.
16. Keep accurate bookkeeping and tax records.