LIFESTREAM

PURIFICATION SYSTEMS, LLC

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Australian Sponsor:
Emergo Australia
Level 20, Tower II
Darling Park
201 Sussex Street
Sydney NSW 2000

Installation Guide

LC-15-100-002.F (rev 01.01.20)

Angel of Water® CM-1 Series (120G5/240G7)
HyGIeaCare® Prep System (120G5/240G7)

Lifestream Purification Systems, LLC
7303 Burleson Rd., Suite 801
Austin, TX 78744 USA
TEL +1.512.707.8383
Toll Free U.S. 877.564.3185

lifestream.systems

ETL CLASSIFIED

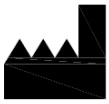
C ETL LISTED US

Intertek
4001754

CE 2797

Trademark Notice

Proprietary Statement



Lifestream

Purification Systems, LLC
7303 Burleson Rd., Suite 801
Austin, TX 78744 USA
Tel +1.512.707.8383 Fax +1.512.707.8484
www.angelofwater.com/info@angelofwater.com
lifestream.systems

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SAVE THESE INSTRUCTIONS

NOTE: Check ALL parts for shipping damage. If shipping damage is noted, **DO NOT USE**.

Contact carrier or manufacturer for further instructions.

NOTICE

The information contained in this document is subject to change without notice.

INTERNATIONAL SYMBOLS IN USE FOR LABELING

TYPE B APPLIED PART (for human use)

Rx ONLY

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician.

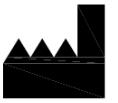
ATTENTION: Uniquement sur ordonnance.

Dangerous voltage

Warning: dangerous voltage

Caution

General warning sign



Manufacturer

YYYY

Date of manufacture

UV Light hazard symbol

Single use/Do not reuse

Instructions for use

Serial number

Sterilization using ethylene oxide

INTERNATIONAL SYMBOLS IN USE

Presence of phthalates (flex tube only). Any risk of leaching in this application is minimal as component is not used for fluid storage; however, residual risk has not been evaluated for children or for pregnant or nursing women.

Authorized representative
in the European Community

Lower limit
of temperature

Temperature limit

Upper limit
of temperature

Use by

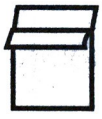
Batch code

Reference number

OTHER SYMBOLS IN USE

Open here - arrow peel pouch

Case



Pouch - peel open

Technical Information and Specifications

ELECTRICAL:
This System is a Class I, Type B Applied Part.
This ME equipment conforms to AAMI Std ES60601-1 & IEC Std 60601-1 and is certified to CSA Std C22.2 No. 60601-1.
This ME equipment is tested to IEC 60601-1-2:2014, Edition 4.0

ELECTRICAL RATINGS for Models 120G5 and 240G7
MODEL 120G5: 110-120 V~ 60 Hz unit is rated for 2A (U.S., Canada)
MODEL 240G7: 220-240 V~ 50/60 Hz unit is rated for 1A (EU, Asia)

POWER CORDS
This system comes with a ten-foot-long, hospital grade power cord manufactured by Volex or equivalent (UL, CSA Listed) for the 110-120 V~ 60 Hz unit.
This system comes with an eight-foot-long, hospital grade power cord manufactured by Volex or equivalent (UL, CSA Listed) for the 220-240 V~ 50/60 Hz unit.

FILTERS
Pre-Filter: Rated per filter manufacturer's instructions
UV Sediment: Rated at 16,000 gallons or 4 months

NORMAL USE
For this system in normal use, the patient is positioned on basin cabinet with nozzle inserted for duration of procedure (30-40 minutes). The operator is in the room monitoring patient. There is no change of setting of a control. The operator does not touch the patient while touching the viewing tube bulb holder or the UV harness assembly. In the event of a power outage to the system or any other performance change or change in the operating environment, the operator should have the patient slide off the rectal nozzle and stop the session. The procedure may resume once normal operating conditions have been restored.

APPLIED PARTS
Colon cleansing nozzle (rectal nozzle), backrest, basin cabinet

UV LIGHT
This system comes with a UV Light/Sediment Filter manufactured by Severn Trent Services. Germicidal 254 nanometers; rated for 7,500 hours of continuous use or 24 months of intermittent use.

LIGHT BULBS (only two varieties may be used with this device)
(Compact Fluorescent)
Viewing tube: Rated at 10,000 hours, 9W
Tower: Rated at 8,000 hours,14W
OR
(LED under 3000 K)
Viewing tube: Rated 10W or less
Tower: Rated 10W or less

TEMPERATURE SENSOR/CONTROLLER SOFTWARE
Accuracy at 25° C: ± 1° F + 1 digit

PLUMBING:

PRESSURE, FLOW RATE, AND WATER TEMPERATURE TO THE PATIENT
Gravity only - averages 1 p.s.i.; 1 liter or less per minute of flow
Temperature safe range 37°C / 99°F–39.8°C / 103°F

PRESSURE, FLOW RATE, AND WATER TEMPERATURE TO THE ME EQUIPMENT FROM MUNICIPAL WATER SOURCE
Pressure of incoming water not to exceed 100 p.s.i.
(NOTE: Municipal water pressures average 35 – 60 p.s.i..)
Temperature of water from incoming water source not to exceed 55°C / 131°F

DISPOSAL OF ME
Before disposing of applied parts (disposable accessories) and/or the entire ME system into the municipal waste stream at the end of its EXPECTED SERVICE LIFE, consult and follow local guidelines and procedures, including safe disposal of mercury-containing components.

UPON REQUEST
Manufacturer will provide diagrams, component part descriptions, calibration instructions, revision levels of software for temperature sensor/controller, or other information as necessary to assist service personnel to repair parts.

Warnings and Caution Statements/Avis

GENERAL WARNINGS/AVERTISSEMENTS GÉNÉRAUX

WARNING: GENERAL WARNING
DO NOT install or use this equipment without first reading and understanding these INSTRUCTIONS. If you are unable to understand these instructions, including all warnings and cautions, contact the manufacturer, a health care professional, or technical personnel before attempting to install or use this equipment. Otherwise, injury or damage may occur.

AVERTISSEMENT : MISE EN GARDE GÉNÉRALE
NE PAS installer ou utiliser cet équipement sans avoir préalablement lu et compris ces INSTRUCTIONS. Si vous ne comprenez pas ces instructions, y compris tous les avertissements et les mises en garde, contactez le fabricant, un professionnel de la santé ou technique avant d'essayer d'installer ou d'utiliser cet équipement. Dans le cas contraire, des blessures ou des dommages peuvent survenir.

WARNING: NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.
AVERTISSEMENT: Modification de l'appareil EM interdite.

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
AVERTISSEMENT: Pour éviter tout risque de choc électrique, cet appareil doit être raccordé uniquement à un réseau d'alimentation équipé d'une terre de protection.

WARNING: Connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety. Responsible organization is referred to the standard IEC 60601-1 for requirements applicable to ME systems.
AVERTISSEMENT: La connexion d'un appareil électrique au socle a prises multiples conduit effectivement à créer un système EM et que cela peut entraîner un niveau réduit de sécurité. Pour les exigences qui sont ap- plicable à un système EM, l'organisme responsable doit être renvoyé à la présente norme (IEC 60601-1).

CAUTIONS/MISES EN GARDE

CAUTION: If moving the system to another location, move by hand or padded piano dolly. To avoid cracking the fiberglass body, never move the system by metal-bladed forklift or dolly. Do NOT push or pull on equipment from its high side. When necessary push the equipment from a lower point near its base.
MISE EN GARDE: Pour déplacer l'appareil, utilisez un chariot ou un socle roulant rembourré. Pour éviter de fendre la membrane de fibre de verre, n'utilisez jamais un chariot élévateur à fourche ou un chariot dont les lames sont en métal. Évitez de pousser ou de tirer l'enceinte en empoignant le haut; s'il faut la déplacer, pous- sez sur la partie inférieure, près de la base.

CAUTION: Flush out rough plumbing lines before final connection to equipment.
MISE EN GARDE: Rincez les conduites de plomberie avant d'effectuer le raccord final à l'équipement.

COMPONENT WARNINGS/CAUTIONS
AVERTISSEMENTS/MISES EN GARDE CONCERNANT LES COMPOSANTS

UV LIGHT UNIT / UNITÉ UV

WARNING: Protect eyes and skin from direct UV radiation.
AVERTISSEMENT: Protéger les yeux et la peau contre le rayonnement UV direct.
DANGER: Ultraviolet light. Protect eyes and skin. May damage exposed tissue.
DANGER: Lampe à ultraviolets. Protéger les yeux et la peau. Peut endommager les tissus exposés.
DANGER: Electrical hazard. No user serviceable parts inside.
DANGER: Risque d'électrocution. Pas de pièce réparable par l'utilisateur à l'intérieur.
DANGER: High Voltage. Disconnect all power to unit before servicing.
DANGER: Tension élevée. Coupez l'alimentation électrique avant toute tâche de maintenance.

FILTER CANISTER / FILTRE RÉSERVOIR

WARNING: Do not use where water is microbiologically unsafe or with water of unknown quality without adequate disinfection before and after the unit.
AVERTISSEMENT: Ne pas utiliser lorsque l'eau est dangereuse d'un point de vue microbiologique ou avec de l'eau dont la qualité n'est pas connue sans une désinfection adéquate avant et après l'unité.
CAUTION: O-ring must be properly seated in the groove of the lower housing, or a water leak could occur. Protect filter from freezing!
MISE EN GARDE: Le joint torique doit être correctement positionné dans la rainure du boîtier inférieur, sinon une fuite d'eau peut se produire. Filtre de protection contre le gel!

WATER CYCLING DEVICE / DISPOSITIF DE CIRCULATION D'EAU

CAUTION: For longer and quieter performance keep housing filled with liquid.
MISE EN GARDE: Pour des performances plus longues et plus silencieuses, veillez à ce que le boîtier soit toujours rempli de liquide.

Electromagnetic Compatibility for Medical Electrical Equipment Warnings and Caution Statements /
Compatibilité Électromagnétique pour les Appareils Électromédicaux Avis
(IEC 60601-1-2 3rd Edition 2007-03)

 This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been designed to provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

 Cet appareil produit, utilise, et peut transmettre par rayonnement de l'énergie de fréquences radio. Un assemblage ou un usage non conformes aux instructions données dans ce manuel peuvent entraîner des perturbations électromagnétiques. Nos appareils sont conçus pour assurer une protection raisonnable contre les perturbations électromagnétiques, dans la mesure où on les fait fonctionner dans les conditions pertinentes décrites dans ce manuel.

 This equipment contains electronic and ferrous components whose operation can be affected by intense electromagnetic fields. Do not operate this system in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment. Electromagnetic interference could disrupt the operation of the system.

 Cet appareil contient des composants électroniques et ferreux dont le fonctionnement peut être compromis par la présence de puissants champs électromagnétiques. N'utilisez pas l'appareil dans un milieu où s'effectue de l'IRM ni près d'appareils de diathermie chirurgicale, de défibrillateurs, ou d'appareils de thérapie à ondes courtes. Les perturbations électromagnétiques pourraient nuire au bon fonctionnement du système.

 The following warning applies any time you operate or service the system: To avoid explosion, do not operate the system in the presence of flammable anesthetics or in an atmosphere of explosive gases. Operating the system in flammable or explosive atmospheres may result in fire or explosion.

 Les mises en garde qui suivent s'appliquent en tout temps pendant le fonctionnement ou l'entretien du système: Pour éviter les explosions, n'utilisez pas l'appareil lorsqu'un anesthésique inflammable ou un gaz explosif est présent. L'utilisation de l'appareil dans une atmosphère explosive ou inflammable peut entraîner un incendie ou une explosion.

See more electromagnetic compatibility warnings, precautions, and data tables in APPENDIX A.

Environmental Conditions / Les conditions environnementales

Environmental Conditions				
Temperature:				
Operating		+15°C/+59°F		+30°C/+86°F
Storage		+1°C/+33°F		+50°C/+120°F
Transport		-20°C/0°F		+50°C/+120°F
Relative Humidity:				
Operating		0-75% (non condensing)		
Storage		0-75% (non condensing)		
Transport		0-95% (non condensing)		
Atmospheric Pressure:				
Operating		700 hPa to 1060 hPa		
Storage		700 hPa to 1060 hPa		
Altitude: Operating		a ≤ 3000 m		

Les conditions environnementales				
Température:				
fonctionnement		+15°C/+59°F		+30°C/86°F
stockage		+1°C/+33°F		+50°C/+120°F
transport		-20°C/0°F		+50°C/+120°F
Humidité relative:				
fonctionnement		0-75% (sans condensation)		
stockage		0-75% (sans condensation)		
transport		0-95% (sans condensation)		
Pression atmosphérique:				
fonctionnement		700 hPa to 1060 hPa		
stockage		700 hPa to 1060 hPa		
Altitude: fonctionnement		a ≤ 3000 m		

Steps to Installation

All diagrams and images in this section are for illustrative purposes only.

Step 1. Electrical Outlet and Rough Plumbing Placement

1) An aerial view of the system appears in Figure 1.1 below. Both electrical outlet and rough plumbing (One 1/2–inch Hot; One 1/2-inch Cold Drain Connection) need to be placed in either Range A or B pictured. You may choose A or B depending upon procedure room constraints. The Exhaust Vent Opening (1 1/2" (3.8 cm) pipe, **See Step 11**) needs to be placed in the ceiling above or in the wall beside the tower cabinet depending upon procedure room constraints and building code requirements.

   Manufacturer's Recommendation: Bring 1-inch water lines to the procedure room for optimal water pressure. Connect the 1/2-inch fittings that go to the device to the 1-inch water lines from the wall.

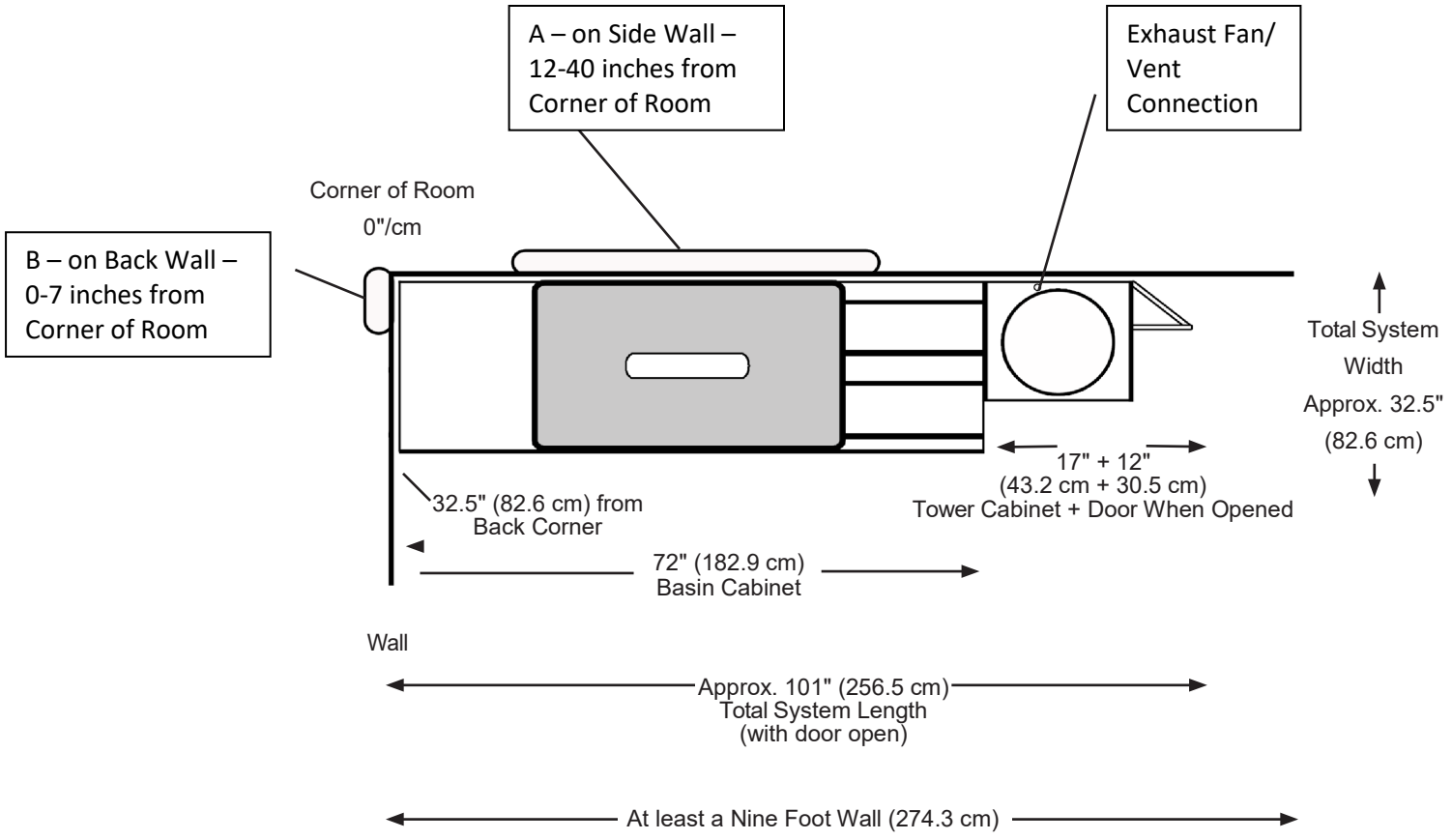
Figure 1.1

Aerial View of System

Placement Ranges A and B are for the

Electrical Outlet and Rough Plumbing Connections (Hot, Cold, Drain)

A-B = Access Points to Rough Plumbing



All diagrams and images are for illustrative purposes only.

Step 2. Electrical Outlet Installation

Install an outlet socket that conforms to national and/or local municipal electrical standards (110-120V~ for U.S. and Canada/220-240V~ for Europe and Asia) in the wall closest to the system. Lifestream recommends a hospital grade (green dot) duplex outlet or a GFCI outlet. For UK, Lifestream recommends an RCD (residual current device) protected socket outlet. CONSULT A LICENSED (QUALIFIED) ELECTRICIAN TO DETERMINE THE LOCAL CODE REQUIREMENTS FOR YOUR HEALTH CARE FACILITY.

1) **Side Wall Placement of Electrical Outlet** (must be within 18" (45 cm) of the floor). If side wall is used for outlet, make placement between 12 and 40 inches (30.5 – 101.6 cm) from the corner of the room **(RANGE A)** to avoid interfering with the supporting leg and sides of the system's basin cabinet.
2) **Back Wall Placement of Electrical Outlet** (must be within 18" (45 cm) of the floor). If back wall is used for outlet, make placement inside of 7 inches (0 - 17.8 cm) from the corner of the room **(RANGE B)** to avoid interfering with the supporting leg and sides of the system's basin cabinet.

Figure 2.1

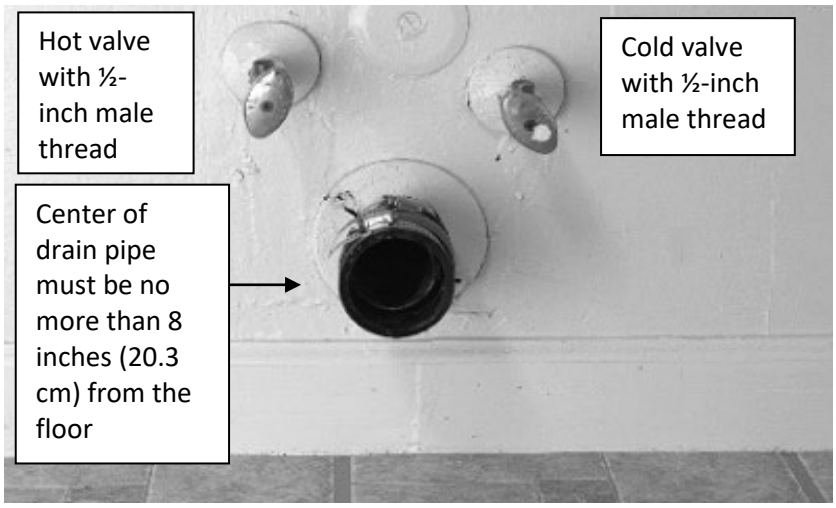
Standard U.S. GFCI Outlet

Step 3. Rough Plumbing (Supply Lines and Drain Connection) Installation

CONSULT A LICENSED (QUALIFIED) PLUMBER TO DETERMINE THE LOCAL CODE REQUIREMENTS FOR YOUR HEALTH CARE FACILITY.

1) The drain must be of 3-inch (7.6 cm) PVC pipe. Install the 3-inch drain pipe so that it is **8 inches (20.3 cm) from the center of the pipe off the floor or less, BUT NOT MORE THAN 8 INCHES HIGH.** See Figure 3.1 below. A wall-mounted drain pipe is shown. (A floor-placed drain is acceptable in either Range A or B next to the side or back wall. The center of 3-inch drain pipe should be at least 3 inches to finished side or back wall but no more than 4 inches to not interfere with basin cabinet placement later).

Figure 3.1



2) The system requires both one hot and one cold line—as suggested bring 1-inch water lines to the procedure room for optimal water pressure. To the 1-inch water lines, connect male-threaded ½-inch (1.3 cm) fittings that then can connect to the device. The hot and cold water supply lines coming from the wall should be within 18" (45 cm) of the floor and should be in the Side / Back corner of the room where system is to be placed. Rough plumbing supplies are not included with the system.

Manufacturer's Recommendation: Use 1/2-inch x 1/2-inch FIP braided polymer faucet connectors of the proper length to connect from the wall to the device. See figure below.

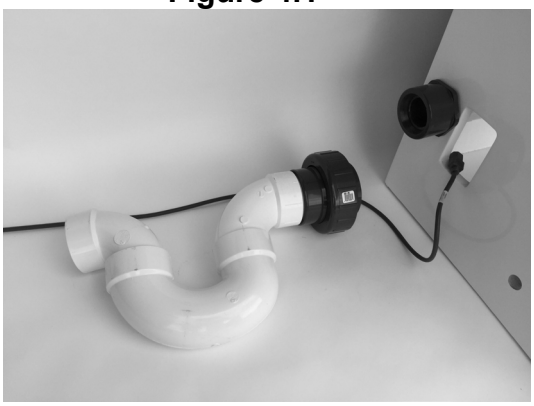
Figure 3.2

Step 4. Tower Cabinet Placement and Connections

1) Lay out the following items included with the system (see Figure 4.1):

    - 3-inch female union + P-trap

Figure 4.1



2) Position front of tower cabinet at exactly 74 inches (cm) from back finished wall and next to side wall. Attach female union + P-trap to tower male fitting and mock up any additional rough plumbing fittings and pipe lengths necessary before gluing. Confirm drain connection is correct for proper drainage. Then glue components into place.

3) Get Power Cord from Installation box. Plug male connection to wall electrical outlet and send other side through rectangular opening in front of tower cabinet as shown above in Figure 4.1. DO NOT plug female connection side of cord to Junction (Mains) Box yet.

Figure 4.2

Step 5. Basin Cabinet Placement to Tower Cabinet

1) Take basin cabinet and unroll the 2 electrical cords located to the right of the basin pipe connection (See Figure 5.1).

2) Slide basin cabinet into place in between back wall and front of tower cabinet just enough to send the 2 electrical cords into tower cabinet rectangular opening (to plug into each of their respective tower large junction box outlets later) (See Figure 5.2).

3) Align basin cabinet drain fitting to tower cabinet front opening and slide the two cabinets together until they are snug (See Figure 5.3), making sure that round male threads from basin drain go into round tower cabinet opening.

Figure 5.1

Figure 5.2

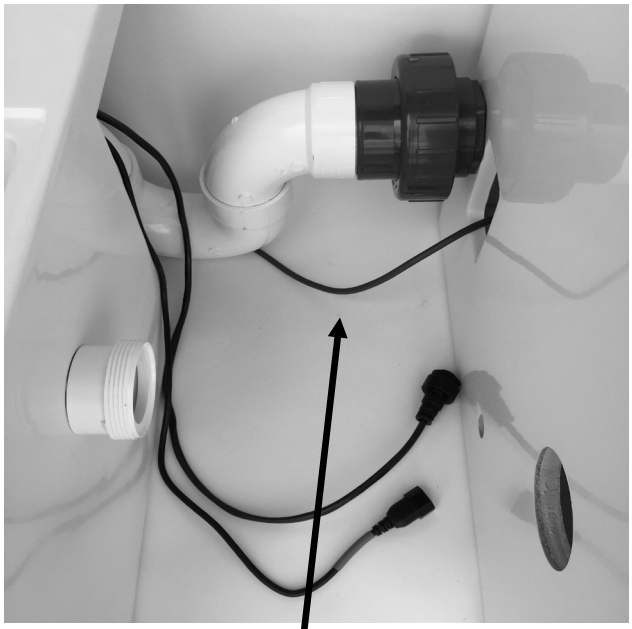
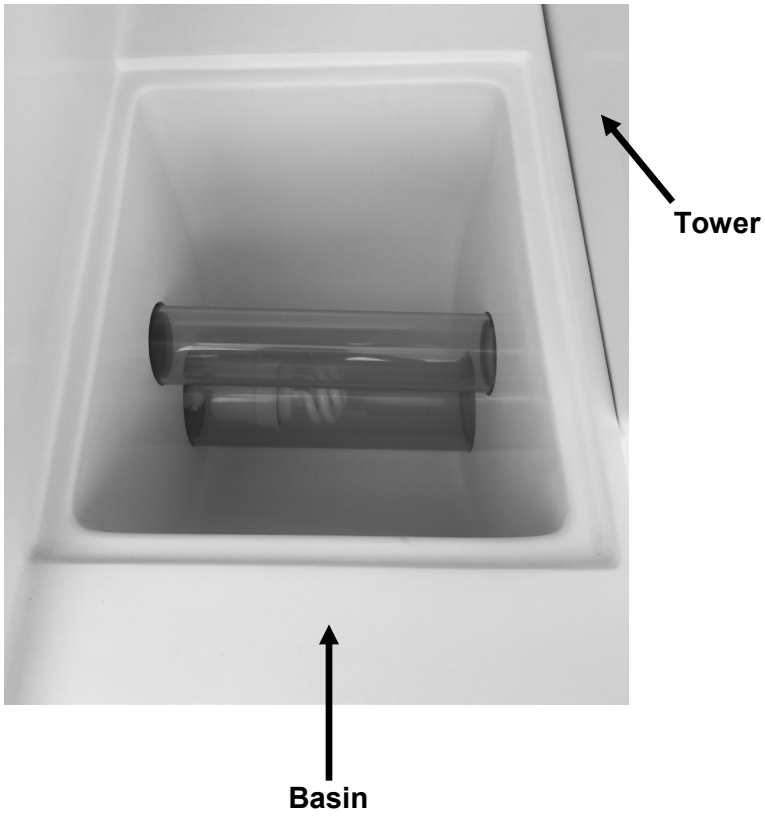


Figure 5.3

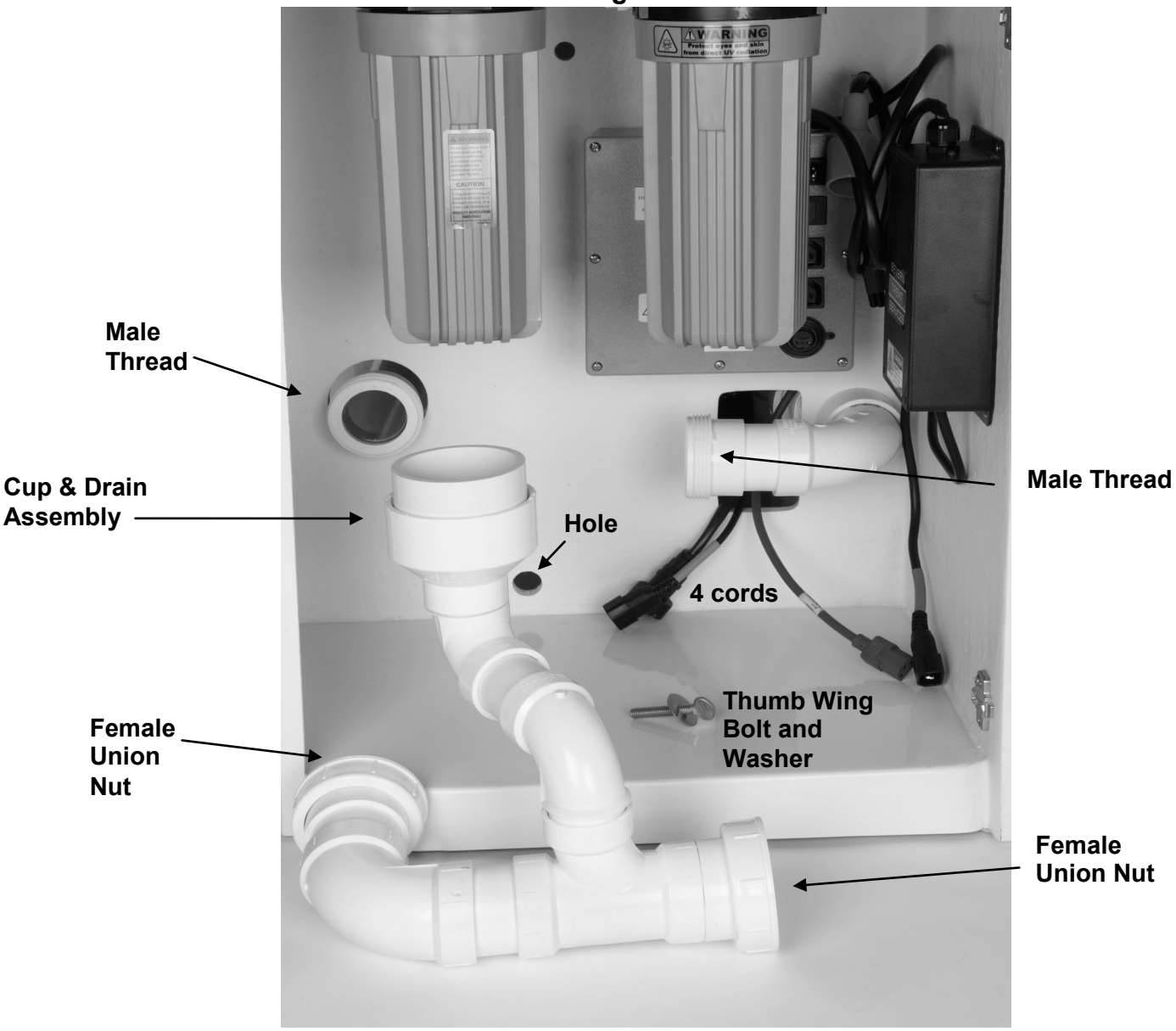


Step 6. Tower Drain Assembly Installation

1) Secure two cabinets together by screwing thumb wing bolt and washer supplied by Lifestream into hole on inside tower wall near bottom of cabinet (See Figure 6.1).

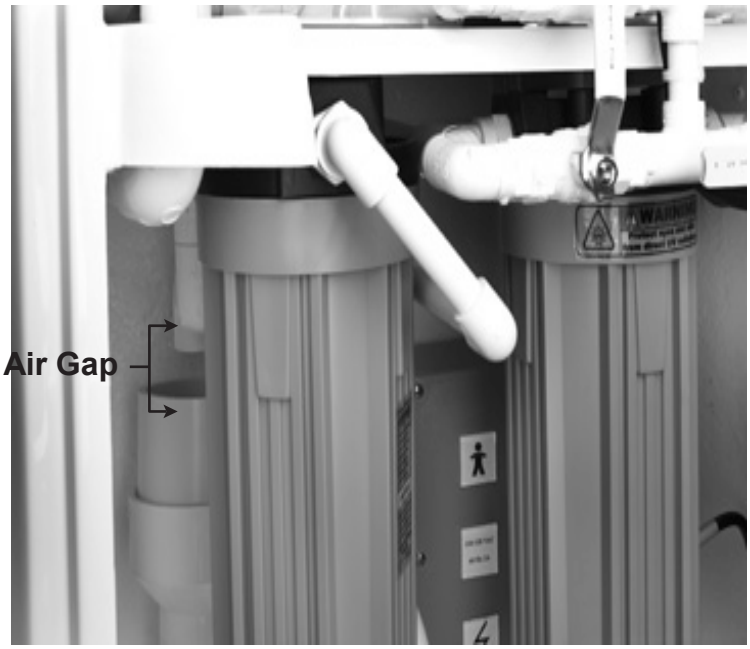
2) Now place Cup and Drain Assembly supplied by Lifestream on floor (See Figure 6.1). Slide into place and connect both female unions to male threads. Tighten completely.

Figure 6.1



3) Make sure Tank Exit is aligned over Cup and Drain Assembly. This is an **Air Gap** which keeps the tank above sanitary and the drain below separate (See Figure 6.2).

Figure 6.2

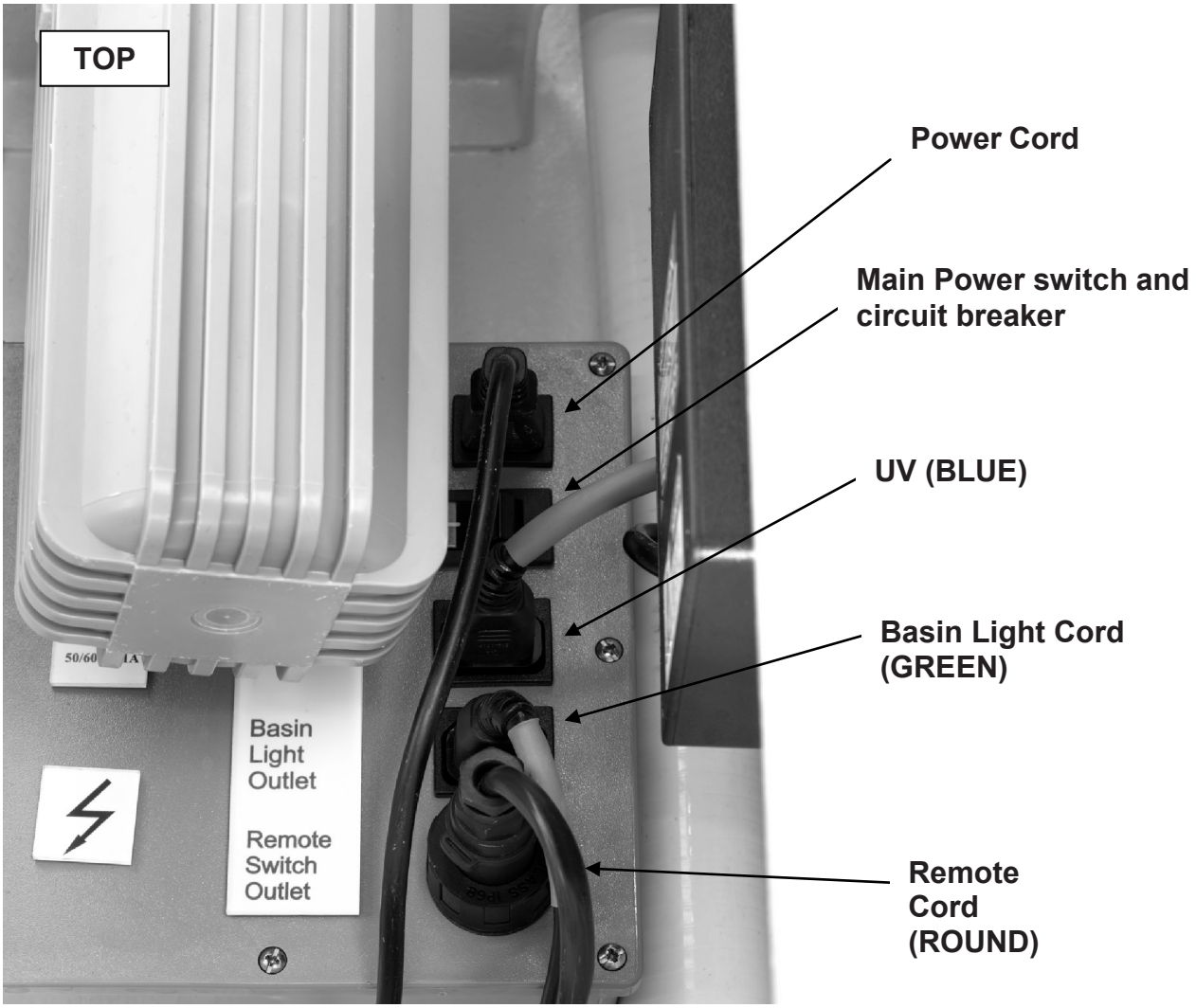


Step 7. Electrical Cord Connections

1) Plug each cord into its appropriate receptacle on the large Junction (Mains) Box. Double check to make sure this is done correctly or the corresponding function will not work. The cords are color matched. Although the female end of the power cord is shown in Figure 7.1 as plugged in to its inlet for placement, DO NOT plug in yet.

   The cord positions are as follows:

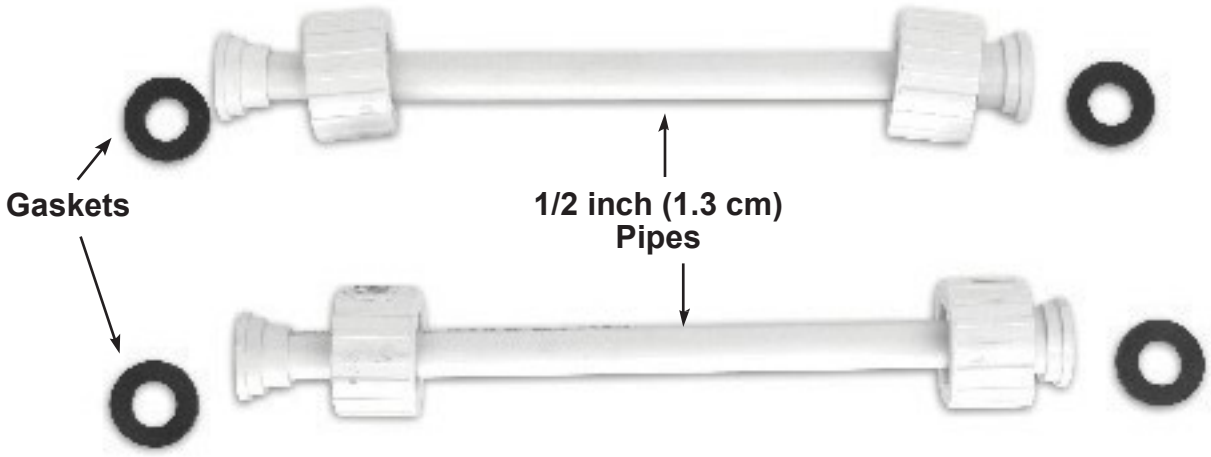
Figure 7.1



Step 8. Connecting Basin to Tower Connectors

1) Locate tower and basin 1/2-inch (1.3 cm) connecting pipes supplied by Lifestream with fittings as shown.

Figure 8.1



2) Connect those pipes and gaskets by hand-tightening them securely to front of basin and front of tower, as shown below.

Figure 8.2

Step 9. Final Hot and Cold Connections from Rough Plumbing to Basin Cabinet

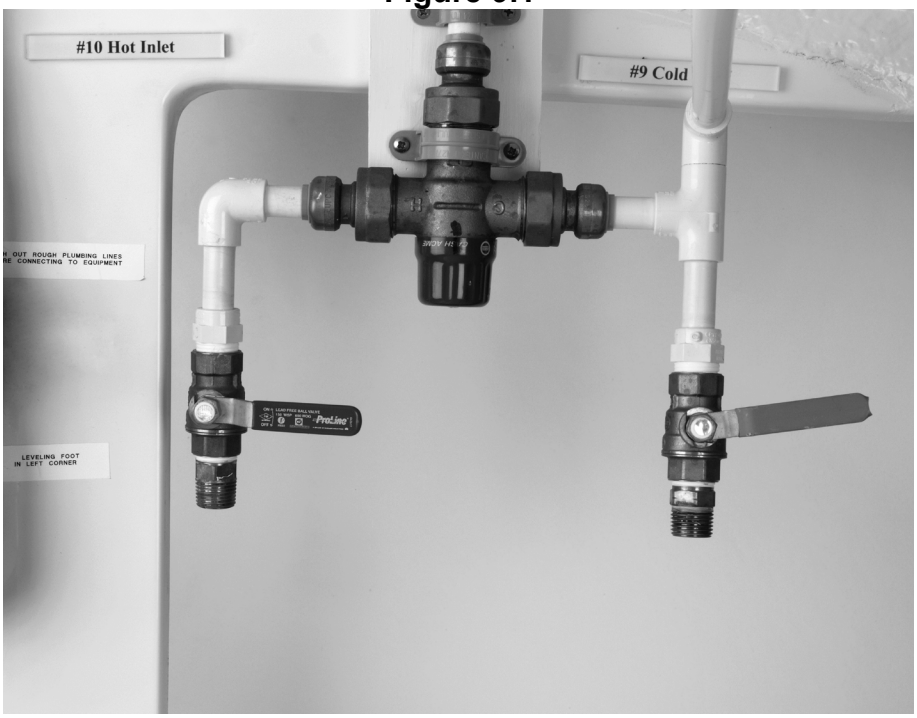
Flush out rough plumbing lines before final connection to equipment. Rincez les conduites de plomberie avant d'effectuer le raccord final à l'équipement.

1) Open large basin cabinet doors to connect hot and cold valves on the wall to system hot and cold connectors (1/2-inch male thread) (1.3 cm) shown below with the appropriate FIP hose connectors (not included). CONSULT YOUR LICENSED (QUALIFIED) PLUMBER.

NOTE: HOT Line is RED (left); COLD Line is BLUE (right). Temperature of hot water from hot water supply to equipment (#10 valve) should not exceed 131° F and 55° C.

DO NOT TURN ON HOT AND COLD VALVES FROM THE WALL TO YOUR SYSTEM YET.

Figure 9.1



Step 10. Final Installation Checklist

Your system should now have:

(1) Two cabinets tightly secured by screwing in the thumb wing bolt with washer from tower cabinet to the basin cabinet.

(2) Tower drain assembly installed inside tower cabinet.

(3) All electrical cord connectors between basin and tower cabinets plugged in.

(4) Both basin to tower connectors installed between cabinets.

(5) Complete connections to the external hot and cold water sources.

(6) Final drain pipe connection to the wall (or floor) drain.

Step 11. Connecting your Exhaust Fan

1) When all other final connections are made, connect the exhaust fan from its port on top of the tower cabinet to the rough plumbing. Connect a 1½-inch (3.8 cm) draft pipe (not included) to the exhaust port fitting at the top of the tower and vent either through side wall or through the ceiling to the outside.

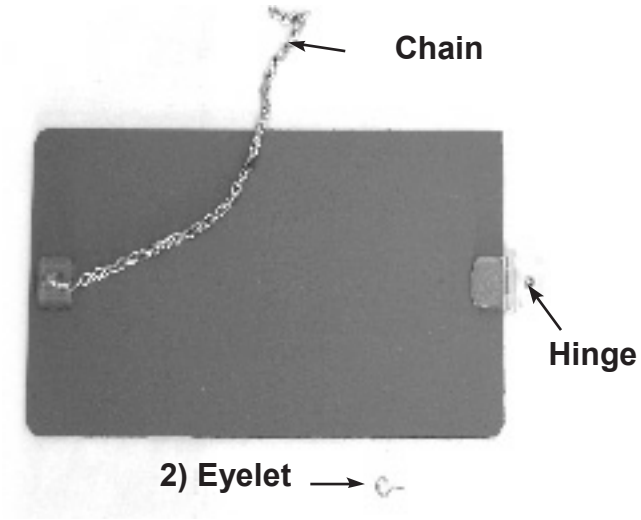
Manufacturer's Recommendation: How the fan is vented is TO BE DETERMINED BY LICENSED PLUMBER /HEALTH CARE SETTING REQUIREMENTS but should be a dedicated vent pipe to the outside of the building only.

Figure 11.1

Step 12. Mirror Installation

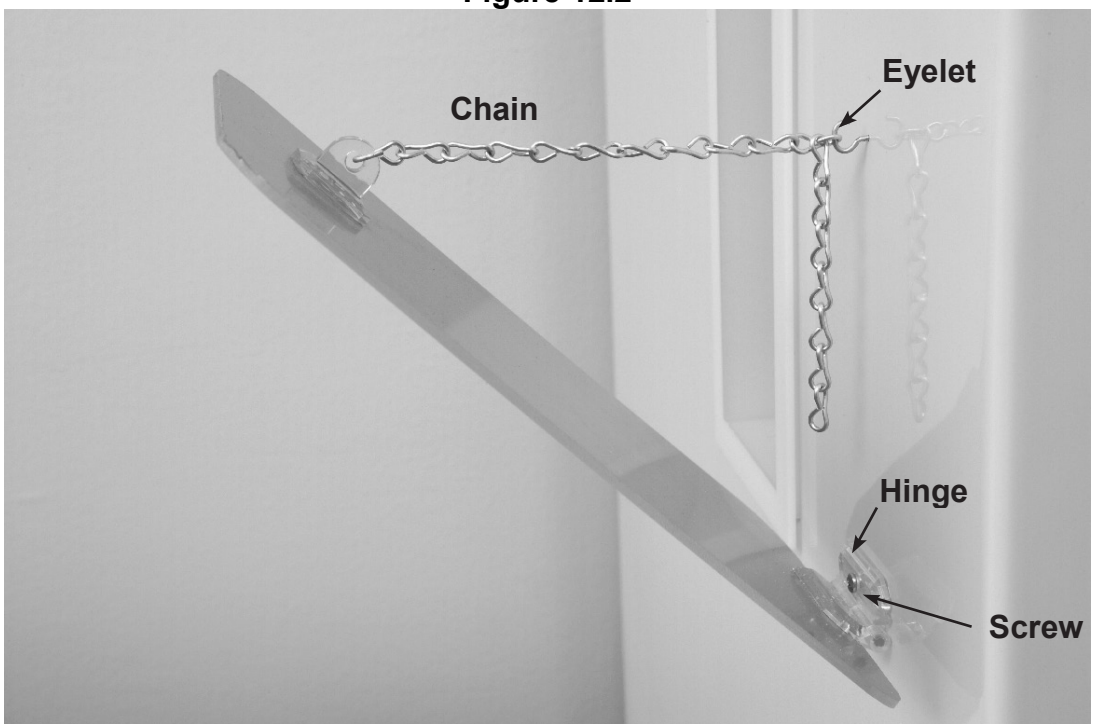
The mirror has a bottom hinge to attach to tower cabinet, an eyelet to hold the chain, and the chain itself. Install mirror on front of tower to right of viewing window in the pre-drilled holes.

Figure 12.1



1) Screw small eyelet provided into top pre-drilled hole.
2) Remove and then connect screw on lower hole on front of the tower cabinet to inside of hinge at the base of the mirror.
3) Connect chain as shown.
4) Adjust for correct angle of the viewing tube for the patient positioned on the system.

Figure 12.2



Step 13. Plugging Power Cord to Electrical Source

1) Plug the female end of the power cord into the Junction (Mains) Box inlet. Refer to Figure 7.1.

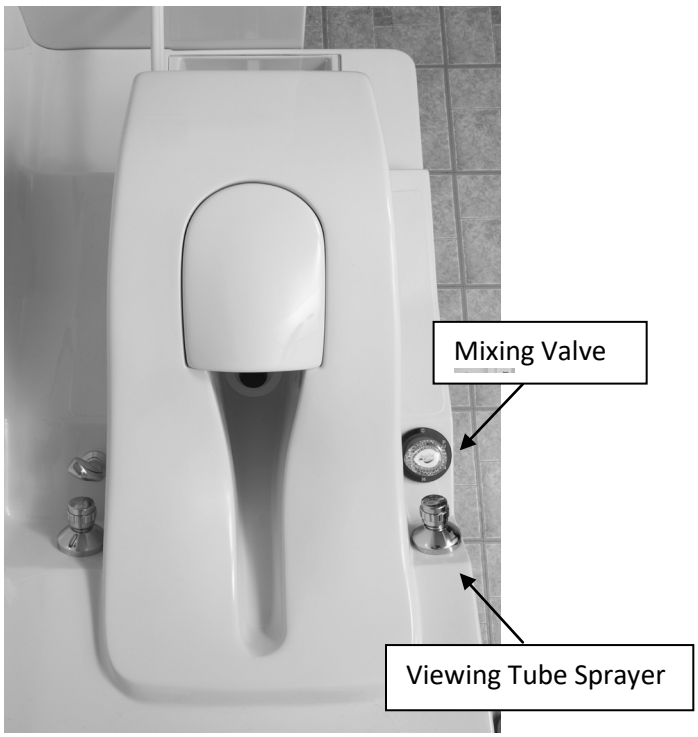
   NOTE: Lifestream supplies a 110-120 V~ or 220-240 V~ power cord that is country specific.

2) The system is now installed.

Step 14. Preparing System for Use

1) OPEN system basin cabinet large doors.
2) OPEN hot and cold valves at the wall.
3) OPEN Valves #9 and #10 (by reaching in to basin cabinet large doors).
4) OPEN Mixing Valve (by lifting the crystal handle).
5) OPEN Viewing Tube Sprayer handle.

Figure 14.1



6) **IF APPLICABLE**, SEAT the Spill-Resistant Vacuum Breakers (described on P. 15 of the User's Guide) by doing the following:

A) LOCATE the two shutoffs on each of the vacuum breakers:

--one below the main body of the valve (inlet) ;
--one above the main body of the valve (outlet)

B) OPEN the bottom inflow shutoff valve **QUICKLY**. You may hear a "popping" sound as the vacuum breaker seats.

C) **SLOWLY** OPEN the top outflow shutoff.

The vacuum breakers are now seated.

NOTE: It is normal for some water to spill out from the vacuum breaker when it seats.

Figure 14.2

Shutoffs CLOSED

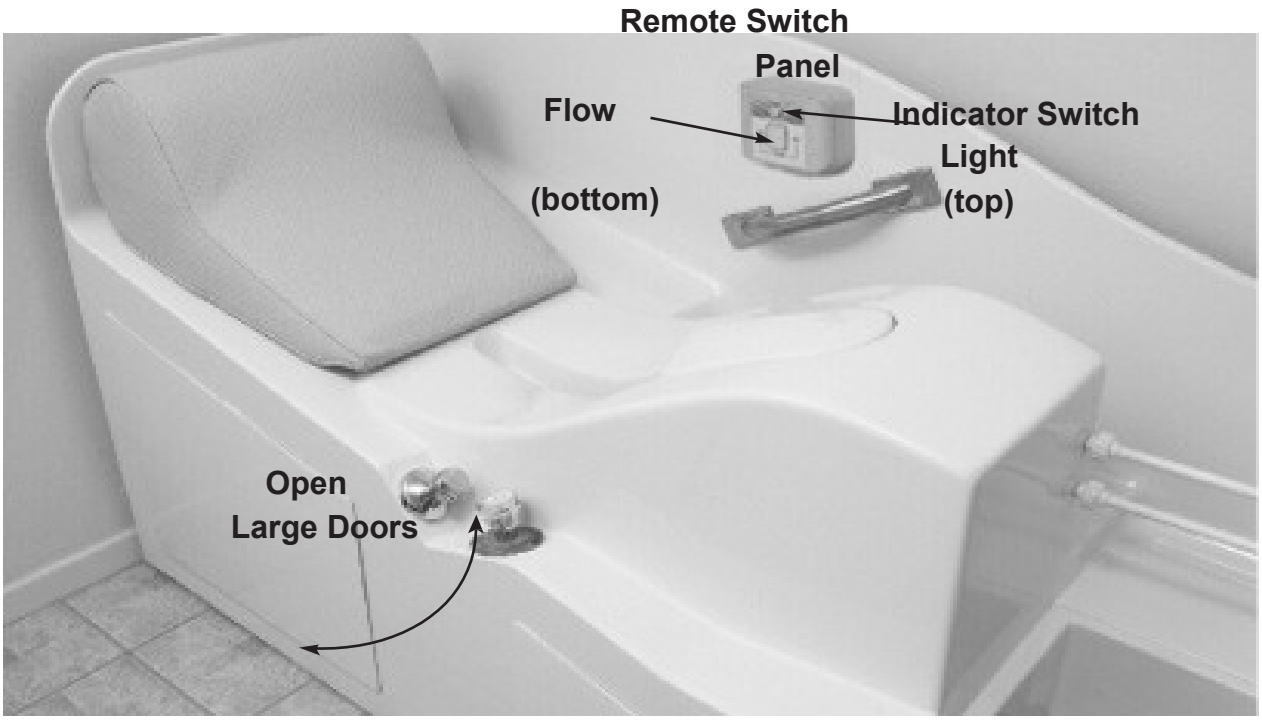
Shutoffs OPENED

7) CHECK that the Cup and Drain Assembly at the bottom of the tower is sufficiently tightened to prevent leaking while Viewing Tube Sprayer is ON. CLOSE sprayer.

8) OPEN volume control for Basin Sprayer and CHECK it by spraying water into the basin channel.

9) CLOSE a) Mixing Valve; b) Viewing Tube Sprayer; and c) Volume Control Valve.

Figure 14.3



10) CHECK that the Main Power Switch on the large Junction (Mains) Box in the tower is turned ON (refer to Figure 7.1). Turn on LIGHTS Switch on Tower Switch Panel to make sure that tower and basin lights come on.

Figure 14.4

Tower Switch Panel

Step 15. System Ready for Use

Figure 15.1

Once your system is installed according to the Installation Guide and sanitized according to the User's Guide, it is ready for use.

For questions regarding installation, please contact Lifestream:

Lifestream Purification Systems, LLC
7303 Burleson Rd., Suite 801 • Austin, TX 78744 USA
TEL +1.512.707.8383 • FAX +1.512.707.8484 • TOLL FREE U.S. 877.564.3185

APPENDIX A: Electromagnetic Compatibility Information and Data Tables

Electromagnetic Compatibility for Medical Electrical Equipment /

Compatibilité Électromagnétique pour les Appareils Électromédicaux

(IEC 60601-1-2 3rd Edition 2007-03)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Les Appareils Électromédicaux nécessitent des précautions spéciales vis-à-vis de la CEM et qu'ils do vent être installés et être mis en service selon les informations CEM fournies par le Guide d'utilisateur.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Les appareils de communications RF portatifs et mobiles peuvent affecter les Appareils Électromédicaux.

The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of this device as replacement parts for internal components, may result in increased Emissions or decreased Immunity of the system.

L'utilisation d'accessoires, de transducteurs, et de câbles autres que ceux spécifiés, à l'exception des transducteurs et des câbles vendus par le fabricant de l'appareil comme pièces de remplacement des composants internes, peut avoir comme conséquence une augmentation des Émissions ou une diminution de l'Immunité de l'appareil.

The system should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

L'appareil ne soit pas utilisé à côté d'autres appareils ou empilé avec ces derniers est nécessaire; s'il n'est pas possible de faire autrement, il convient que l'appareil soit surveillé pour en vérifier le fonctionnement normal dans la configuration dans laquelle il sera utilisé.

Guidance and manufacturer's declaration–electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The system 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.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration–electromagnetic immunity

The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system 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	±6 kV contact ±8 kV air	±6 kV contact ±8 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 ±1 kV for input/output lines	±2 kV for power supply lines N/A	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 line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A / m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration–electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 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 metres (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: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration–electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a]should be less than the compli- ance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment and the system			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
	$d = 1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23