BLACK & BLACK
SURGICAL

B89055 VITRUVIAN INFILTRATION PUMP OPERATING MANUAL

CONGRATULATIONS

Thank you for choosing Black & Black's **Vitruvian Infiltration Pump**. The Vitruvian Infiltration Pump is a peristaltic pump using three rollers to create pumping action to deliver tumescent fluid to the operative site.

This manual provides instructions for operation, maintenance, and troubleshooting assistance for the Black & Black Vitruvian Infiltration Pump. Users should be trained in its use and applicable medical procedures.

Please read this entire booklet before trying to use your pump.

CALL US

Our customer service department is staffed with friendly, knowledgeable people who are ready to help. Whether you need replacement disposables or assistance in troubleshooting an issue, they will help you or put you in touch with someone who can.

BLACK & BLACK
SURGICAL

FAX: 1-770-414-4879
EMAIL: Info@blackandblacksurgical.com

Caution: Federal (USA) Law restricts this device to use by or on the order of a physician.

CE 0297

EC REP

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Symbols

RxOnly — For Prescription Use Only

 CONSULT OPERATING MANUAL

 POWER ON

 POWER OFF

 TYPE B APPLIED PART

 Waste Electrical Products should not be disposed of in landfill. Please recycle where facilities exist. Check with your Local Authority for recycling advice.

IPX1 — Degree of protection against the ingress of water

CAUTION- NOT FOR INTRAVENOUS USE

Indications For Use

The Vitruvian Infiltration Pump is intended to be used for: Aesthetic Body Contouring

Intended User /Patient Population / Environment

Black & Black Surgical's Vitruvian Infiltration Pump should be handled and operated by healthcare professionals completely familiar with use of the device. RxOnly

The intended patient population for this device includes persons seeking surgical, plastic, or liposuction procedures for body contouring.

This device should be used in a hospital, clinical, surgical environment. **NOT INTENDED FOR HOME USE.**

Device should be operated outside of the sterile field and should therefore not come in contact with healthcare professional operating on patients.

Contraindications

This device is contraindicated for all the intended uses other than the ones claimed in this manual.

Warnings

All warnings and cautions should be familiar to, and reviewed by, all personnel prior to a procedure. These cautions and warnings are considered essential to the safety of personnel, patients, equipment, and property. If you have any questions, please contact Black & Black.

- This device will not, in and of itself, produce significant weight reduction.
- This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.
- The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.
- There should be NO direct patient contact by anyone touching this device at the same time, specifically, the Reverse Switch or other exposed metal objects on the device.
- Do not install tubing while pump is running; be sure pump is in off position before installing.
- Close pump head before turning the device on. Do not place body parts near moving parts

Precautions

- Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.
- Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- Results of this procedure may or may not be permanent.
- The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
- All reusable components used with the device must be sterilized and all disposable components replaced before using the device system on another patient.
- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- No user serviceable parts inside. Refer servicing to qualified personnel.
- Do not position device to make it difficult to unplug device.
- LED display of volume is secondary to using fluid bag to determine total volume infiltrated into patient.

Modifications

Modifications to any component of this device can create possible hazards and/or impair the safe use of this product during its use and will void the warranty.

Description of Components

FRONT VIEW

Flow Rate Adjusting Knob

In manual control mode, turn the Speed Adjusting Knob clockwise to increase the speed; Turn the Speed Adjusting Knob counter clockwise to decrease the speed.

Prime Key

In manual control mode press down the Prime Key to enter Prime status where the pump runs at full speed (525 mL/min) for quick filling or emptying of the tubing. Release the Prime Key so that the pump returns to its normal operating status.

Lever

This is a locking and releasing lever to hold the tubing in place

Reverse Switch

The reverse switch controls the direction of the pump rotor, so the operator can decide which direction they want to set up the fluid flow. Move switch right or left for desired direction.

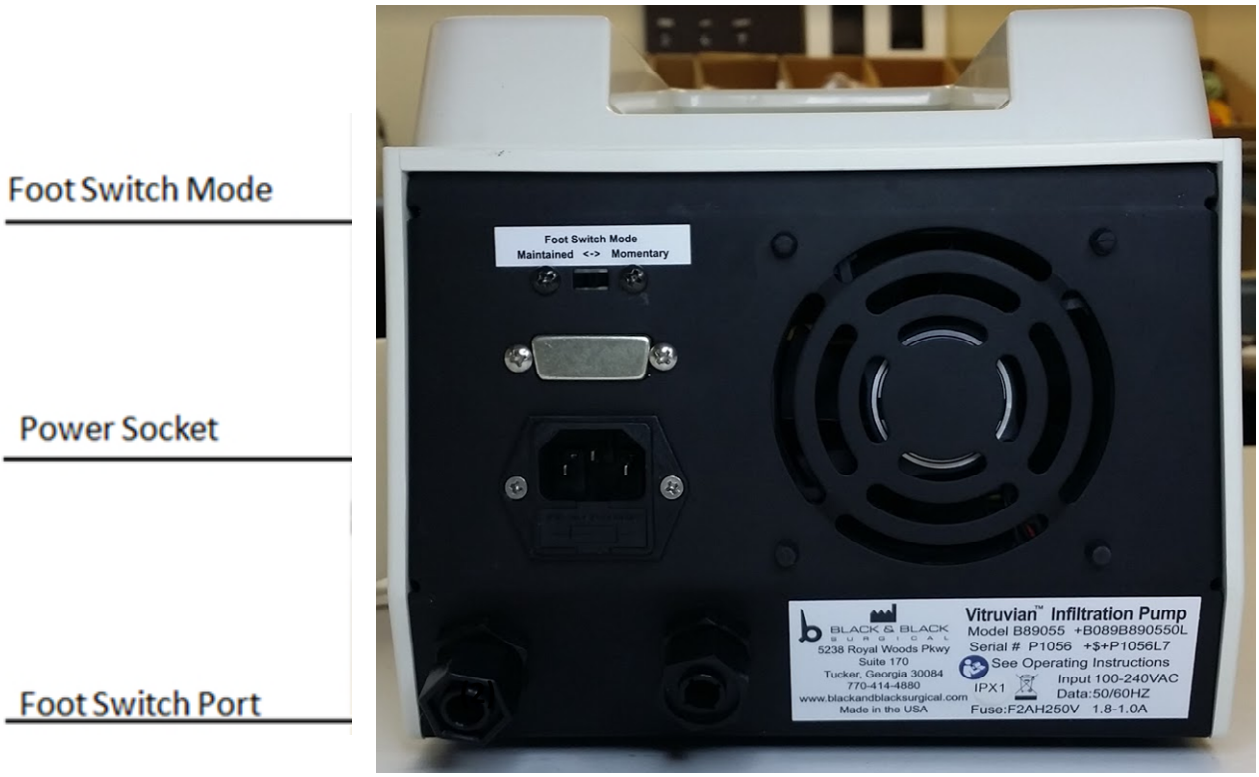
Power Switch

ON/OFF Switch.

Head

The rotor in the head with its three rollers, combined with the enclosed tubing, creates the pumping action which moves the fluid through the tubing.

Description of Components contd.



REAR VIEW

Food Switch Mode

Choose momentary or maintained mode.

- In the momentary mode, the pump will only run as long as the foot switch is pressed. Once pressure is removed, the pump stops. Factory settings are in momentary mode.
- In maintained mode, the pump turns on when the foot switch is pressed and runs until the foot switch is pressed again.

Power Socket

Insert any approved hospital-grade power cord with a C-14 connector.

Footswitch ports

These are the Pneumatic switches activated by the pneumatic foot pedals for easy safe operation.

Items included

The Vitruvian Infiltration Pump comes with:

- Hospital grade power cord
- (2) Foot pedals

Suggestions

Recommended Black & Black items:

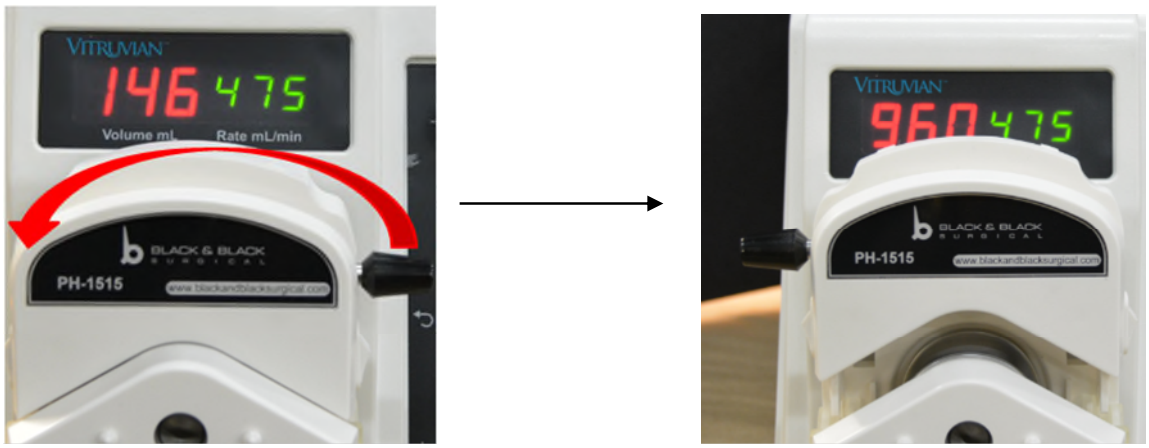
- B89213 - 13' SOFTOUCH PUMP TUBING SET-SINGLE SPIKE, BOX OF 10
- Some types of cannulas that may be purchased separately from Black & Black include:
    - B8TI-1215-LL - TUMESCENT INFILTRATION CANNULA; LUER LOCK, 12GAX15CM
    - B8TI-1426-LL - TUMESCENT INFILTRATION CANNULA; LUER LOCK 14GAX26CM
    - B8TI-1632-LL - TUMESCENT INFILTRATION CANNULA; LUER LOCK, 16GAX32CM

For more parts see catalog or visit www.blackandblacksurgical.com

Setup Instructions

1. The infiltration fluid, tubing set, and handle / cannula that are used with the Black & Black Vitruvian Infiltration Pump must be sterile. (Not supplied with this device)

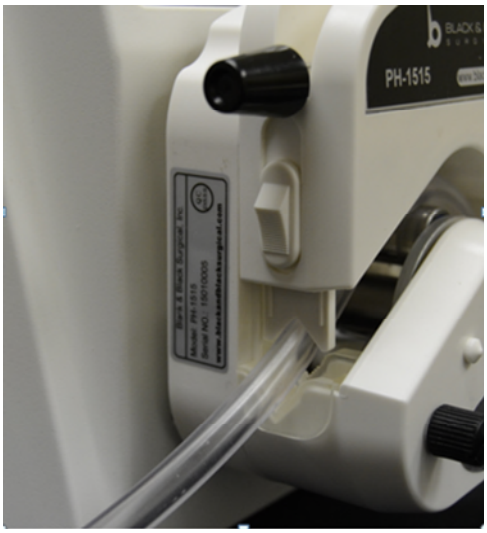
2. Open the pump head by lifting or raising the lever counter clockwise to the left 180°.



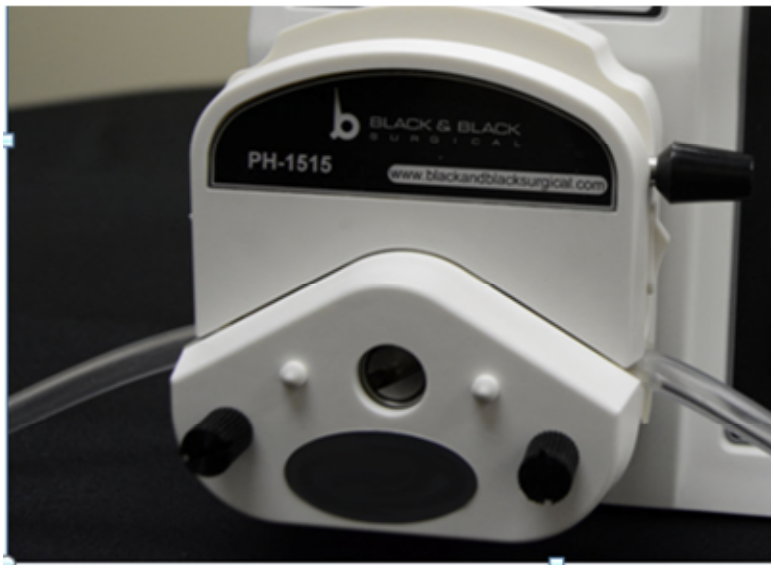
3. Tubing recommendations:
   Size: (7.5mm)Outer Diameter x (4.75mm) Inner Diameter
   Type: Soft

4. Place tubing on rollers by pulling up on spring loaded security latch and setting tubing in place as shown below:

5. Repeat step 4 with the other end of the tubing as shown below. Make sure there isn't excess tubing or slack inside pump head by gently pulling on both ends of the tubing.



6. Lower pump head by moving the lever clockwise 180° to the right to lock in place. Your unit will now look like this:



7. Connect pneumatic foot switch tubing to port located on the rear of the pump:

Turn connector clockwise to tighten onto port

→

Repeat this step for the second foot pedal.

Operating Procedures

1. Turn power to the Vitruvian Infiltration Pump ON (on front of unit) by flipping the switch to the "I" position.
2. Depress either footswitch to start the pump's operation. Release foot from footswitch to discontinue pump operation. Footswitches can be used interchangeably.
3. Press down the Prime Key to enter prime status when the pump runs at full speed (that is 525 mL/min) and the LED displays the maximum speed for emptying, filling and rinsing operation. Release the Prime Key so that the pump returns to its primary status.
4. To adjust flow rate, turn the Speed Adjusting Knob clockwise to increase the speed; Turn the Speed Adjusting Knob counter clockwise to decrease the speed.
5. The LED read out (+/- 15% accuracy) displays the volume infiltrated and the rate of dispensing. Refer to fluid bag for primary method of determining volume infiltrated.
6. To clear the LED read out, press and hold the speed adjusting knob for 2 seconds.
7. To shut down the unit, turn the power switch to the "O" position.

Unloading Tubing

1. Open pump head by turning lever counter clockwise to the left.
2. Lift up spring loaded security latch and remove tubing from one side then repeat on the other side

User Maintenance

1. NO PUMP MAINTENANCE IS REQUIRED. All components come lubricated. DO NOT lubricate.
2. Check condition of power cord and footswitch after each case. Replace if cracked or worn.

Cleaning the Pump Case

Always turn the pump off and unplug from wall before performing any of the following:

1. Dirt, stains, and dried material can be removed from the case by using any mild non-abrasive cleaner. Ground in or dried materials should be scrubbed with a soft non-metal bristle brush.
2. The surface should then be wiped clean with a damp cloth then dried with a soft dry cloth.
3. **DO NOT IMMERSE THE UNIT IN WATER OR ANY CLEANING SOLUTION.**
4. If any substance spills into head, remove head by loosening the tightening screws on the front of the pump head by turning them counter clockwise. Remove the pump head. Wipe away stains, etc.

5. To re-install pump head, insert the flat end of the pump head's shaft into the slot of drive's coupling. Make the positioning hole of the pump head match the positioning pin of the drive.

6. Tighten the screws connecting the pump head and the drive. Tighten the screws to the same degree. **Do not over tighten the screws to prevent damage to the housing.**

Troubleshooting Guide

Please contact Black & Black Surgical for assistance if the following solutions do not resolve the problem.

Problem	Possible Causes	Solution
Pump not operating	1. Power switch not on.	1. Turn power switch to “on”
	2. Power cord not plugged into wall outlet	2. Plug power cord into outlet
	3. Power cord not plugged into unit	3. Plug power cord into connector in rear or unit
	4. Foot switch not activated	4. Depress foot switch
Foot switch will not activate pump	1. Foot switch tubing not connected	1. Connect foot switch tube to connector in rear of unit
	2. Foot switch broken or leaking	2. Check for tear or broken tubing. Replace foot switch.
	3. Power switch not on.	3. Turn power switch to "ON"
Inadequate flow when foot pedal is pressed	1. Speed control set too low.	1. Turn speed adjusting knob clock-wise to increase speed.
	2. Wrong tubing in pump.	2. Check tubing
Pump head not rotating	1. Tubing is bunched up inside pump head	1. Straighten out tubing by pulling on both ends away from the pump head

Technical Specifications

Functions

Applicable Pump Head	PH-1515
Prime	Fast filling (525 mL/min)
Speed Control	Variable speed control
Display	Displays volume and rate (mL and mL/min)

Specifications

Speed	1 to 525 mL/min
Speed Precision	1 mL/min
Speed Adjusting	Continuous adjusting by rotary coded switch
Display Mode	Two LED displays reading mL and mL/min.
Applicable Power	100-240VAC, 50/60Hz, 1.8-1.0A
Power Consumption	< 48 W
Fuse	F2AH250B
Operating Conditions	Temperature 0 to 40 deg C (32 to 104 deg F) Relative humidity < 80% Atmospheric Pressure 50-106 kPa
Dimensions	(L x W x H) 285mm x 207mm x 180mm (11” x 8” x 7”)
IP Rating	IPX1
Unit Weight	3.2 kg (7.2 lbs)
IEC Classification	Class I Type B Applied Part

Damaged or Loss in Shipment

Examine shipment upon receipt for any external damage. If product package is damaged please contact Black & Black Surgical immediately.

If concealed loss or damage is discovered, retain all packaging materials, notify the transportation company immediately, and request an inspection. The agent will make an inspection and grant a concealed damage notation. A concealed damage report must be made within seven (7) days of shipment delivery. After seven (7) days, the transportation company reserves the right to refuse any claim for loss or damage.

Incorrect Items Shipped by Black & Black Surgical

Please check your shipment immediately for any shortage or incorrect items. If any discrepancies exist, notify Black & Black Surgical, (770) 414-4880, or info@blackandblacksurgical.com, at once. Your prompt attention will ensure credit or exchange.

ALL DISCREPANCIES BETWEEN THE PACKING LIST AND THE PRODUCTS RECEIVED MUST BE REPORTED WITHIN 48 HOURS OF RECEIPT OF THE PACKAGE TO QUALIFY FOR A CREDIT.

Returns

NO RETURNS OR EXCHANGES WILL BE ACCEPTED UNLESS YOU HAVE RECEIVED A RETURN OF MERCHANDISE AUTHORIZATION NUMBER (RMA) FROM BLACK & BLACK. THIS NUMBER MUST BE ON THE RETURN SHIPPING LABEL AND ALL WRITTEN COMMUNICATION.

Call Black & Black toll-free at 1-877-252-2517 to get a Return Merchandise Authorization (RMA) number for your order. You may also send an email to info@blackandblacksurgical.com to obtain your RMA.

ANY RETURN(S) WITHOUT RMA NUMBERS WILL NOT BE ACCEPTED AND WILL BE RETURNED TO THE SENDER.
RETURN AUTHORIZATIONS ARE VALID FOR 30 DAYS.

Full credit will be issued for any item returned in 30 days in the original packaging that is in undamaged and saleable condition.

A restocking charge of 25% will be charged to any product returned between 31-90 days. A credit memo, based on the dollar amount, will be issued to the account.

OPENED PACKAGES OR BOXES containing disposable items are not returnable for credit or exchange.

NO CREDIT WILL BE ISSUED ON ANY ITEM RETURNED AFTER 90 DAYS.

Return Shipping

Return shipping, insurance, and handling is the responsibility of the customer. Credits will not be issued until the product is received in acceptable condition. It is strongly recommended that the customer use a traceable freight shipping method.

Please ship products in their original packaging, including documentation with all tags attached. Failure to do so may result in a restocking fee to enable us to return the merchandise to a saleable condition.

Black & Black cannot be responsible for return shipping losses.

Each return must include the following information:

- Purchaser's name, telephone number and address
- B&B invoice number
- Invoice date
- RMA Number
- Purchaser purchase order number
- Quantity, catalog number and description of item
- Reason for return

Repair Program

If repairs are necessary due to damage other than that incurred during initial shipment (see section labeled DAMAGE OR LOSS IN SHIPMENT), contact Black & Black to return your unit. A Return of Goods Authorization number must be obtained from Black & Black's Customer Service Department prior to returning any merchandise. When requesting a Return Goods Authorization number, please follow the return policy as listed under the section labeled POLICY ON RETURNED GOODS. Then, please carefully repack and return it prepaid freight to:

Black & Black Surgical, Inc
Attn: repairs
RMA# _____
5175 South Royal Atlanta Dr.
Tucker, GA 30084
(770) 414-4880
(877) 252-2517

Repairs must be made by Black & Black Surgical or by an approved authorized agent. Attempting repair without prior authorization nullifies all warranties.

Service Life

Life span of device is determined by use and care. The service life of this product is 10 years from the date of purchase. At end of service life, dispose according to local ordinances.

Warranty

The warranty period for this product is one year. If repair or adjustment is necessary within the warranty period, the problem will be corrected at no charge if it is not due to misuse or abuse on the customer's part, as determined by the manufacturer. Repair costs outside the warranty period, or those resulting from product misuse or abuse, may be invoiced to you.

BLACK & BLACK
SURGICAL

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APPENDIX – A - Electromagnetic Compatibility Information

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

APPENDIX – A - Electromagnetic Compatibility Information, contd.

Guidance and manufacturer's declaration – electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 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.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EQUIPMENT. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

APPENDIX – A - Electromagnetic Compatibility Information, contd.

Recommended separation distances between portable and mobile RF communications equipment and the VITRUVIAN™ Infiltration Pump			
The VITRUVIAN™ Infiltration Pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VITRUVIAN™ Infiltration Pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VITRUVIAN™ Infiltration Pump 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.			

APPENDIX – A - Electromagnetic Compatibility Information, contd.

Guidance and manufacturer's declaration – electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT 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 ±1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	<5 % *UT* (>95 % dip in *UT*) for 0,5 cycle 40 % *UT* (60 % dip in *UT*) for 5 cycles 70 % *UT* (30 % dip in *UT*) for 25 cycles <5 % *UT* (>95 % dip in *UT*) for 5 sec	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			