ARJOHUNTLEIGH
GETINGE GROUP

FLOWTRON EXCEL

Instructions for Use

CE
0086

...with people in mind

Contents

General Safety

Before you connect the system pump to a mains socket, read carefully all the installation instructions contained within this manual.

The system has been designed to comply with regulatory safety standards including:

- EN60601-1:1990/A13:1996 and IEC 60601-1:1988/A2:1995
- UL60601-1, UL2601-1 and CAN/CSA C22.2 No. 601.1-M90
- EN60601-1:2006 and IEC 60601-1:2005
- AAMI/ANSI ES60601-1:2006 and CAN/CSA C22.2 No.60601.1(2008)

Safety Warnings

- **It is the responsibility of the care giver to ensure that the user can use this product safely.**
- **Make sure that the mains power cable and tubeset or air hoses are positioned to avoid causing a trip or other hazard, and are clear of moving bed mechanisms or other possible entrapment areas.**
- **Electrical equipment may be hazardous if misused. There are no user-serviceable parts inside the pump. The pump's case must only be removed by authorised technical personnel. No modification of this equipment is allowed.**
- **The mains power socket/plug must be accessible at all times. To disconnect the pump completely from the electricity supply, remove the plug from the mains power socket.**
- **Disconnect the pump from the mains power socket before cleaning and inspecting.**
- **Keep the pump away from sources of liquids and do not immerse in water.**
- **Do not use the pump in the presence of uncontained flammable liquids or gasses.**
- **Only the pump and garment/insert combination as indicated by ArjoHuntleigh should be used. The correct function of the product cannot be guaranteed if incorrect pump and garment combinations are used.**
- **The Flowtron® Excel system is NOT intended for use in the Home Healthcare Environment (e.g. private dwellings or nursing homes).**

Caution (applicable to the USA market only)

- **US Federal law restricts this device to sale by or on the order of a physician.**

Precautions

For your own safety and the safety of the equipment, always take the following precautions:

- Do not expose the system to naked flames, such as cigarettes, etc.
- Do not store the system in direct sunlight.
- Do not use phenol-based solutions to clean the system.
- Make sure the system is clean and dry prior to use or storage.

Electromagnetic Compatibility (EMC)

This product complies with the requirements of applicable EMC Standards. Medical electrical equipment needs special precautions regarding EMC and needs to be installed in accordance with the following instructions:

- The use of accessories not specified by the manufacturer may result in increased emissions by, or decreased immunity of, the equipment, affecting its performance.
- Portable and mobile radio frequency (RF) communications equipment (e.g. mobile/cell phones) can affect medical electrical equipment.

- If this equipment needs to be used adjacent to other electrical equipment, normal operation must be checked before use.
- For detailed EMC information contact ArjoHuntleigh service personnel.

Expected Service Life

The **Flowtron Excel** pump has an expected service life of seven years. To maintain the condition of the pump have the pump serviced regularly according to the schedule recommended by ArjoHuntleigh.

Do NOT use unapproved accessories or attempt to modify, disassemble or otherwise misuse the **Flowtron Excel** system. Failure to observe this caution could result in injury, or in extreme cases, death.

Environmental Protection

Incorrect disposal of this equipment and its component parts, particularly batteries or other electrical components, may produce substances that are hazardous to the environment. To minimise these hazards, contact ArjoHuntleigh for information on correct disposal.

Design Policy and Copyright

1. Introduction

About this Manual

This manual is your introduction to the **Flowtron® Excel** system. You must read and fully understand this manual before using the system.

Use this manual to initially set-up the system, and keep it as a reference for day-to-day routines and as a guide to maintenance.

If you have any difficulties in setting-up or using the **Flowtron Excel** system, contact your local ArjoHuntleigh sales office, listed at the end of this manual.

Intended Use

The intended use of this product is to prevent Deep Vein Thrombosis (DVT). The garments are single use only. It is not for use in the home healthcare environment.

The **Flowtron Excel** system should be used as part of a prescribed plan of care (refer to “Indications” on page 3).

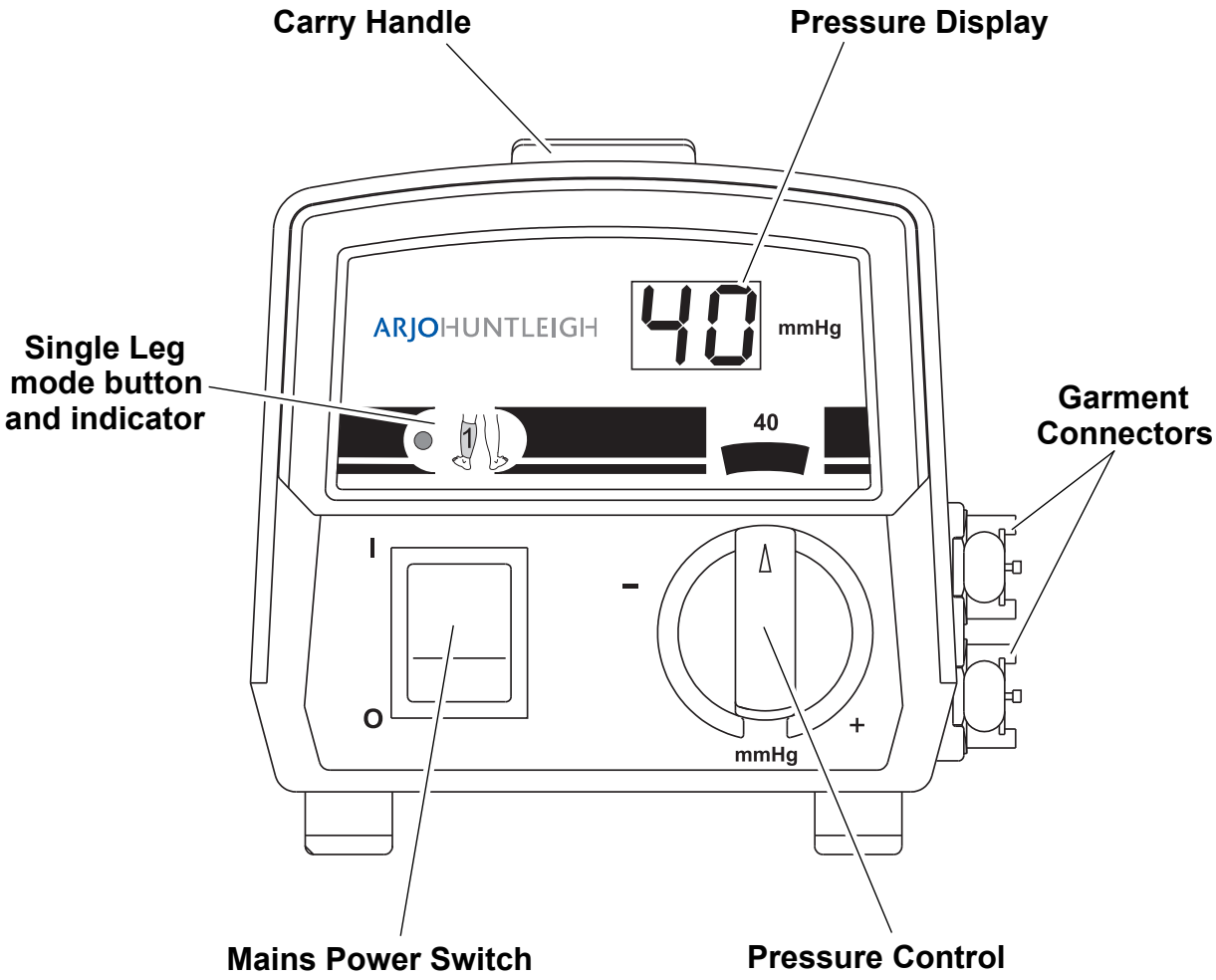
About Flowtron Excel

The **Flowtron Excel** pump operates on a 60-second automatically timed cycle consisting of approximately 12 seconds of inflation followed by approximately 48 seconds of deflation.

The **Flowtron Excel** system may be used on patients at risk of developing deep vein thrombosis and in conjunction with systemic interventions (e.g. anticoagulation drugs) for the high risk patient.

The Flowtron Excel is intended for use ONLY in Professional Healthcare Facilities (e.g. hospitals or physicians’ offices).

A full technical description of the **Flowtron Excel** system can be found in the Service Manual, part No. SER0019, available from your local ArjoHuntleigh sales office.



Flowtron Excel Pump - Front View

2. Clinical Applications

Indications

The primary application of the **Flowtron Excel** system is for the prevention of Deep Vein Thrombosis (DVT) when combined with an individualised monitoring programme.

These systems represent one aspect of a DVT strategy; if the patient's condition changes the overall therapy regimen should be reviewed by the prescribing clinician.

The above are guidelines only and should not replace clinical judgement.

Contraindications

The **Flowtron Excel** system should not be used in the following conditions:

1. Severe arteriosclerosis or other ischaemic vascular diseases.
2. Known or suspected acute Deep Vein Thrombosis (DVT) or phlebitis.
3. Severe congestive cardiac failure or any condition where an increase of fluid to the heart may be detrimental.
4. Pulmonary embolism.
5. Any local condition in which the garments would interfere, including gangrene, recent skin graft, dermatitis or untreated, infected leg wounds.

If you are unsure of any contraindications refer to the patient’s physician before using the device.

Cautions

1. Proper garment application and connection to the pump is essential.
2. Garments should be positioned in such a way that they do not create any potential for constant pressure points on the patient’s limb. Additional care should be taken when placing the garments on any deformed leg, or on legs with significant oedema.
3. When used for DVT prevention, continuous external pneumatic compression is recommended until the patient is fully ambulatory. Uninterrupted use of the **Flowtron Excel** system is encouraged.
4. Garments should be removed immediately if the patient experiences tingling, numbness or pain, and the physician notified.

5. The **Flowtron Excel** system should be **USED WITH CAUTION** on patients with:
   - Insensitive extremities.
   - Diabetes.
   - Impaired circulation.
   - Fragile or impaired skin.

☞ *These are guidelines only and should not replace clinical judgement and experience.*

Guidelines and Recommendations

General Recommendations

- While using the system, the patient's limbs should be checked during every shift, and more often if the patient has known circulatory or skin problems, or is diabetic.
- Clinical judgment should be used to determine if the patient's skin condition requires additional measures, or if the treatment should be discontinued and alternative modalities used.
- ArjoHuntleigh does not recommend the use of compression stockings with its system. If these are ordered by the physician, the clinician should ensure that the compression stockings are properly measured, applied and worn by the patient. Any compression stocking used should be routinely checked to ensure continued proper fit and application, in addition to assessing the condition of the skin.
- Where appropriate patients should be instructed in the proper use of the system, the purpose of therapy and that any problems should be reported to the nursing staff.

DVT Prophylaxis

- The **Flowtron Excel** system should be applied to the patient pre-operatively, prior to the induction of anaesthesia.
- The system should be used continuously for no less than 72 hours post-operatively or until the patient becomes fully ambulatory.
- If the garment cannot be applied to the operative limb during surgery, it may be applied to the limb once the patient reaches the recovery unit.

In the non-surgical patient, the system should be initiated immediately the risk of DVT formation is identified.

3. System Set Up

Installing the Pump

Attach the pump to the bed frame using the bed bracket, or place the pump on the floor under the bed.

Garment Application

1. Check that the mains power switch on the pump is in the off (O) position.
2. Remove the garments from the packaging and unfold.

☞ *Garments are for single patient use only. Do not use the garments on a different patient after treatment.*

3. Place the back of the patient's leg in the centre section of the garment with the connector tubing pointing downwards towards the foot.
4. Starting with the side of the garment that does not have the Velcro[1] tabs, wrap securely against the leg. While holding the garment against the leg, wrap the tabs over the top. Ensure that the garment is close-fitting and has no creases or folds. The connector tubing should be pointing towards the patient's heel.
5. Make sure the tubing assembly is connected to the garment connector on the pump.
6. Connect the garment connector to the tubing assembly. Ensure that a sharp 'click' is heard. Pull lightly to confirm proper connection.
7. Repeat steps 3 to 6 for the second garment, if used.

Garment Removal

1. To disconnect a garment, press on the tubing assembly snap-lock connector and pull the garment connector away from the tubing assembly.

To Use Only One Garment

To use only one garment, connect a single garment to either connector.

☞ *The snap-lock connectors on the pump are self-sealing and do not require unused garments to be attached.*

1. *Velcro® is a registered trademark of VELCRO USA Inc.*

4. Pre-Use Check

Before powering on the **Flowtron Excel** system, ensure that:

- The pressure control knob has been set to the mid position marked 40 mmHg  .
- Garments have been applied to the patient's legs correctly, close-fitting and without creases or folds.
- There are no kinks in the tubing.
- The pump is connected to the mains power supply but not switched on.
- All tubing connections are secure.
- The system has been arranged so that the power cable and garment tubing do not pose a trip or strangulation hazard.

5. Operation

Start Up

Connect the pump to the mains power supply using the power cable provided. Turn the mains power switch to the on (I) position and it will illuminate green. The pump performs a two-second self test cycle where the pressure display, LEDs and alarm are tested. The pump then proceeds directly to the inflation cycle.

The garments will inflate alternately. The first garment inflates for approximately 12 seconds and is deflated for approximately 48 seconds.

The second garment, if used, inflates 30 seconds after the first garment has deflated and follows the same inflation/deflation cycle.

If a single garment is attached, press the **Single Leg** button  to prevent the alarm system from indicating a fault. The system responds with a 'beep' and the red LED on the button illuminates.

☞ *If the* **Single Leg** *button*  *is pressed while two garments are connected, the system will automatically reset to two-garment operation after two single-garment inflation cycles.*

Verify that the pressure display is indicating the desired output pressure prescribed by the physician. Refer to section **"Pressure Adjustment" on page 8** for specific pressure setting instructions.

☞ *If the operation or performance of the pump changes during use, refer to "Troubleshooting" on page 11 of this IFU before calling a service engineer or contacting your local ArjoHuntleigh sales office.*

☞ *Loss of mains power will halt therapy.*

Shut Down

Turn the power switch to the off (O) position. Turning the power off will stop the patient therapy.

☞ *If it is required to completely isolate the pump from the mains power, remove the plug from the mains power socket.*

Disconnect and remove the garment(s) as required.

☞ *Garments are for single patient use only. Do not use the garments on a different patient after treatment.*

6. Pressure Adjustment

The pressure control mechanism is located on the front of the pump and ranges from 30-60mmHg. The pressure exerted by the garments on the leg can be adjusted by turning this knob. Turning the knob clockwise increases the pressure; counterclockwise decreases the pressure.

☞ *The recommended pressure setting is 40 mmHg. Alternatively, use the pressure prescribed by the treating physician.*

The **Flowtron Excel** pump pressure monitoring system is independent of the pressure control and delivery system, providing added reliability and safety. The digital display indicates the actual pressure that is delivered to the garments, and provides immediate and continuous feedback regarding pump performance.

The pressure display is used for the following functions:

Pressure Output Check

After turning the pump on, check that the pressure display is showing the desired output pressure when the garments are inflated. Visually recheck the display at regular intervals.

Adjusting the Output Pressure

If necessary, the pressure can be adjusted during the active inflation period, by rotating the pressure control knob until the desired pressure is displayed.

System Calibration Check

To confirm the calibration accuracy of the pressure control and display, perform the following check each time the pump is turned on:

During normal operation when the pressure display reads 40, the pointer on the pressure control knob should be located within the 40 mmHg arc on the front panel  .

If the display reads 40 but the control knob is not within the 40 mmHg arc, the pump should not be used and referred to service for recalibration.

7. Decontamination

The following processes are recommended, but should be adapted to comply with the local or national guidelines (Decontamination of Medical Devices) which may apply within the Healthcare Facility or the country of use. If you are uncertain, you should seek advice from your local Infection Control Specialist.

The **Flowtron Excel** pump should be routinely decontaminated between patients and at regular intervals while in use, as is good practice for all reusable medical devices.

WARNING

Remove the electrical supply to the pump by disconnecting the mains power cable from the mains power supply before cleaning.
Protective clothing should always be worn when carrying out decontamination procedures.

Caution

Do not use Phenol-based solutions or abrasive compounds or pads during the decontamination process as these will damage the surface coating. Avoid immersing electrical parts in water during the cleaning process. Do not spray cleaning solutions directly onto the pump. Do not immerse the tubeset in water.

To clean Clean all exposed surfaces and remove any organic debris by wiping with a cloth moistened with a simple (neutral) detergent and water.

Do not allow water or cleaning solutions to collect on the surface of the pump.

Chemical Disinfection We recommend a chlorine-releasing agent, such as sodium hypochlorite, at a strength of 1,000ppm available chlorine (this may vary from 250ppm to 10,000ppm depending on local policy and contamination status).

Wipe all cleaned surfaces with the solution, then wipe using a cloth moistened with water and dry thoroughly.

Alcohol based disinfectants (strength 70%) may be used as an alternative.

Ensure the product is dry before storage.

If an alternative disinfectant is selected from the wide variety available, we recommend that suitability for use is confirmed with the chemical supplier prior to use.

Caution

Garments are single patient use and hence cannot be cleaned or reused.

8. Routine Maintenance

Flowtron Excel System

Maintenance The equipment has been designed to be maintenance-free between service periods.

Servicing **ArjoHuntleigh** will make available on request service manuals, component parts lists and other information necessary for **ArjoHuntleigh** trained personnel to repair the system.

Service Period **ArjoHuntleigh** recommend that the **Flowtron Excel** pump is serviced every 12 months by an **ArjoHuntleigh** authorised service agent.

Flowtron Excel Pump

General Care, Maintenance and Inspection Check all electrical connections and power cable for signs of excessive wear.

Check the tubeset and connectors for any damage.

In the event of the pump being subjected to abnormal treatment, e.g. immersed in water or dropped, the unit must be returned to an authorised service centre.

Serial Labels The serial number for the pump is on the label on the back of the pump case. Quote this serial number when requesting service.

9. Troubleshooting

The **Flowtron Excel** system features an audible and visual alarm. If a problem occurs, the system will sense the fault and briefly flash a message on the front panel pressure display.

If the same fault continues for 10 successive inflations, the audible alarm will sound and a flashing message will remain on the pressure display until corrective action is completed.

The exception to this is an F fault which will alarm immediately.

Display	Problem	Corrective Action
Lo	1. Hose disconnected at garment. 2. Garment leak. 3. Low pressure.	1. Check the hose connection at garment end. 2. Check garment and replace if faulty. 3. Call the service engineer.
HI	1. Hose kinked causing a blocked tube. 2. Hose disconnected at pump. 3. Single garment attached without pressing 'single leg' button.	1. Check hoses for kinks or obstructions. 2. Check the hose connection at pump outlet. 3. Press 'single leg' button, if only one garment to be used.
F	Pump failure.	DO NOT USE PUMP. Call the service engineer.
No displays, no indications, no operation	1. Power failure. 2. Fuse blown.	1. Check mains power supply. Check power cable. 2. Call the service engineer.
Red LED on the Single Leg mode button flashes (approximately 4 times per second)	Internal electronic fault	DO NOT USE PUMP. Call the service engineer.

Alarm Cancel

After a fault has been corrected, the alarm can be cancelled by two methods:

1. Switch the pump off, then on again.
2. Allow the pump to run until it senses a normal inflation; it will then reset itself.

Continue to watch the display for approximately one minute after reset. If no flashing messages reappear, the fault has been cleared.

☞ *If the troubleshooting procedures do not return the system to normal performance, stop using the system immediately and call the service engineer.*

10. Accessories

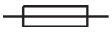
GARMENTS AND TUBING			
Description	*Garment Part No.*	*Size*	
Standard Calf Garment	DVT10	Circumference	up to 43cm (17″)
Calf Garment (Sterile)	DVT10S	Circumference	up to 43cm (17″)
Large Calf Garment	DVT20	Circumference	up to 58cm (23″)
Standard Thigh Garment	DVT30	Circumference	up to 71cm (28″)
Thigh Garment (Sterile)	DVT30S	Circumference	up to 71cm (28″)
Large Thigh Garment	DVT40	Circumference	up to 89cm (35″)
Extra Large Calf Garment	DVT60	Circumference	up to 71cm (28″)
Calf Garment	L501-M	Circumference	up to 43cm (17″)
Thigh Garment	L503-M	Circumference	up to 71cm (28″)
Connector Tubing	L550	Length	150cm (60″)
Connector Tubing	L552	Length	300cm (118″)

11. Technical Specification

Pump			
Model:	Flowtron Excel		
Part Numbers:	**UK/AUS**	**KSA**	**USA**
	247003 - UK 247003AU - AUS	247008	247001
Supply Voltage:	230 V	220 V	120 V
Supply Frequency:	50 Hz	60 Hz	60 Hz
Power Input:	35 VA MAX	35 VA MAX	35 VA MAX
Size:	133 x 152 x 275 mm		
Weight:	2.7 kg		
Case Material:	Fire Retardant ABS Plastic		
Plug Fuse Rating:	5A BS1362 (UK ONLY)		
Pump Fuse Rating:	F500 mAH 250 V		
Degree of protection against electric shock:	Class II, Double Insulated with Functional Earth Type BF		
Degree of protection against liquid ingress:	IPX0 - No protection		
Mode of operation:	Continuous		
Cycle or Therapy Modes:	60 seconds total		
	12 seconds inflation		
	48 seconds deflation		
Pressure Range:	30 - 60 mmHg (±4 mmHg)		

ENVIRONMENTAL INFORMATION			
Condition	**Temperature Range**	**Relative Humidity**	**Atmospheric Pressure**
Operating	+10 °C to +40 °C (+50 °F to +104 °F)	30% to 75% (non-condensing)	700 hPa to 1060 hPa
Storage and Transport (Long Term)	+10 °C to +40 °C (+50 °F to +104 °F)	20% to 95% (non-condensing)	700 hPa to 1060 hPa
Storage and Transport (Short Term)	-20 °C to +50 °C (-4 °F to +122 °F)	20% to 95% (non-condensing)	500 hPa to 1060 hPa

☞ *If the pump is stored in conditions outside of the "Operating" ranges, it should be allowed time to stabilise at normal operating conditions before use.*

Symbols					
	The operator must read this document (Instructions for Use) before use. Note: This symbol is blue on the product label.	**O** (Off)	Power: Disconnects from the mains supply		Do not dispose of in domestic refuse
CLASSIFIED C UL US 25EA CAN/CSA-C22.2 No 60601-1 (2008)	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601.1 (2008). MEDICAL EQUIPMENT	**I** (On)	Power: Connects to the mains supply		Type BF
	Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition).	**SN:**	Serial Number	**Ref:**	Model number
	Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition).		Fuse		Double Insulated
	Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.				

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

Guidance and manufacturer's declaration - electromagnetic immunity

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump 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 pump, including cables, that 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 V	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	$d = 2.3\sqrt{P}$ 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: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note: *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 pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorientating or relocating the pump.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the pump

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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	2.8	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 metres (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: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

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