

INSTRUCTIONS FOR USE

Flowtron Excel



WARNING

To avoid injury, always read this Instructions for Use and accompanied documents before using the product.



Mandatory to read the Instructions for Use

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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:

- EN60601-1:2006/A1:2013
- IEC60601-1:2005/A1:2012 and IEC60601-1-8:2012
- ANSI/AAMI ES60601-1(2005)+AMD(2012) and CAN/CSA-C22.2 No.60601-1(2008)+(2014)

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 gases.**
- **Only the pump and garment/insert combination as indicated by Arjo 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).**

WARNING - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 in) to any part of the *Flowtron* Excel (ACS550), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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.
- When the pump is in use the operator should remain in area in case the system alarms.
- If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

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 Arjo 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 Arjo.

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.

End of Life Disposal

- Garment material or any other textiles, polymers or plastic materials etc. should be sorted as combustible waste.
- Pump units have electrical and electronic components should be disassembled and recycled per Waste of Electrical and Electronic Equipment (WEEE) or in accordance with local or national regulation.

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 Arjo for information on correct disposal.

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 Arjo 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 patient use only. It is not for use in the home healthcare environment.

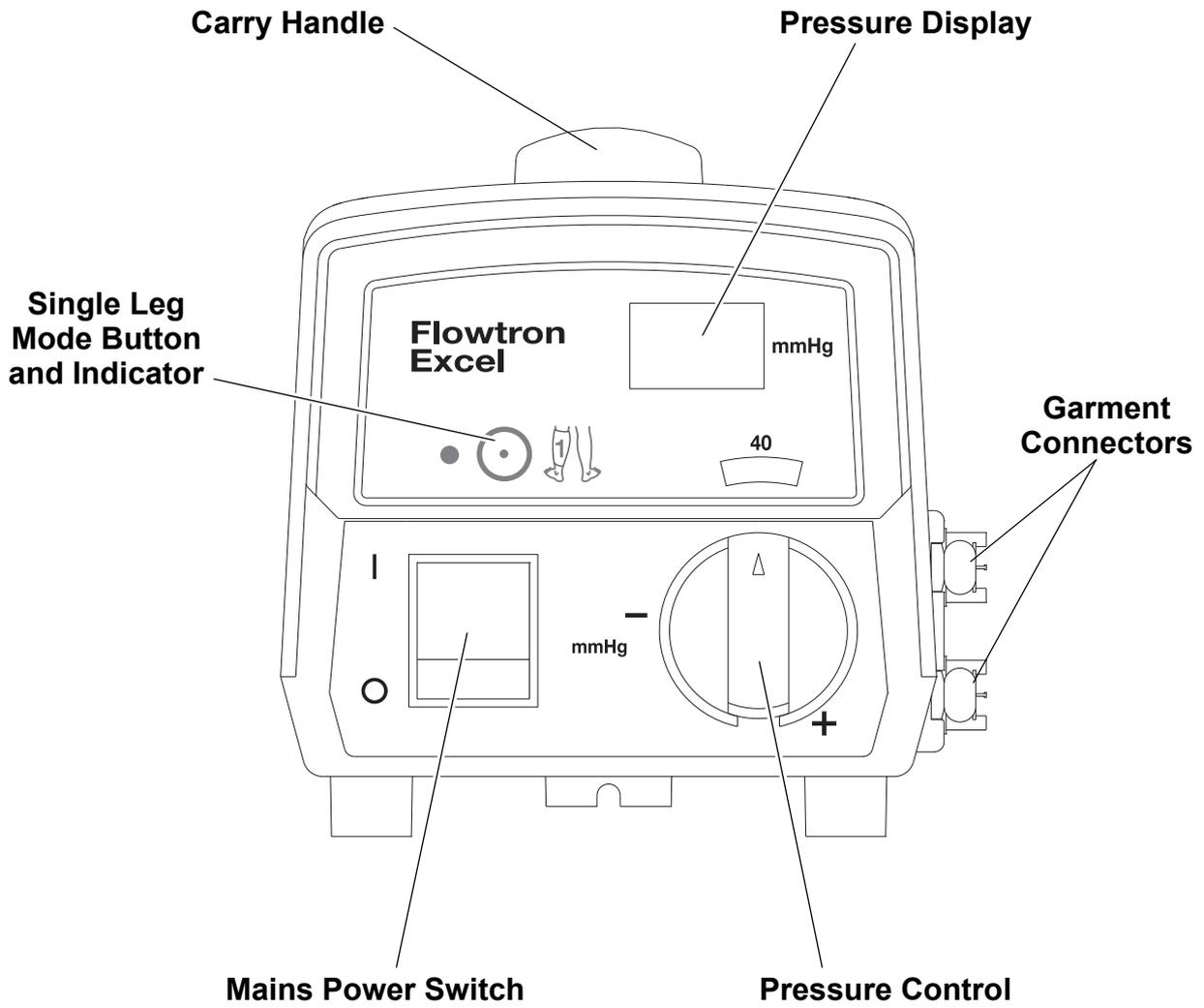
The *Flowtron* Excel system should be used as part of a prescribed plan of care (refer to “Indications” on page 3).

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 Arjo sales office.



Flowtron Excel Pump - Front View

2. Clinical Applications

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

This system 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.

NOTE

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.
- Arjo 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 when 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.

NOTE

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 hook and loop strap 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.

NOTE

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

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 yellow LED on the Front Panel illuminates.

NOTE

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.

NOTE

If the operation or performance of the pump changes during use, refer to “Troubleshooting - Alarm Condition” on page 11 of this IFU before calling a service engineer or contacting your local Arjo sales office.

NOTE

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.

NOTE

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.

NOTE

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.

NOTE

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

Service Period Arjo recommends that the *Flowtron Excel* pump is serviced every 12 months by an Arjo 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 - Alarm Condition

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. All the alarm conditions are low priority, in compliance with IEC60601-1-8.

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

Alarm Condition

Display	Problem	Corrective Action
Lo	<ol style="list-style-type: none"> Hose disconnected at garment. Garment leak. Low pressure. 	<ol style="list-style-type: none"> Check the hose connection at garment end. Check garment and replace if faulty. Call the service engineer.
HI	<ol style="list-style-type: none"> Hose kinked causing a blocked tube. Hose disconnected at pump. Single garment attached without pressing 'single leg' button. 	<ol style="list-style-type: none"> Check hoses for kinks or obstructions. Check the hose connection at pump outlet. Press 'single leg' button, if only one garment to be used.
F	Pump failure.	DO NOT USE PUMP. Call the service engineer.

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

- Switch the pump off, then on again.
- 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.

Troubleshooting

Display	Problem	Corrective Action
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.
Yellow LED on the top panel flashes (approximately 4 times per second)	Internal electronic fault	DO NOT USE PUMP. Call the service engineer.

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			
<i>Description</i>	<i>Garment Part No.</i>	<i>Size</i>	
Standard Calf Garment	DVT10	Circumference	up to 43cm (17")
Large Calf Garment	DVT20	Circumference	up to 58cm (23")
Standard Thigh Garment	DVT30	Circumference	up to 71cm (28")
Large Thigh Garment	DVT40	Circumference	up to 89cm (35")
Extra Large Calf Garment	DVT60L	Circumference	up to 81cm (32")
Calf Garment	L501-M	Circumference	up to 43cm (17")
Thigh Garment	L503-M	Circumference	up to 71cm (28")
Connector Tubing	L550 (SP057)	Length	150 cm (60")
Connector Tubing	L552 (SP061)	Length	300 cm (118")
Small Calf Garment	DVT5	Circumference	up to 36 cm (14")

11. Technical Specification

Table 1:

Pump	
Supply Voltage and Frequency:	230V / 50 Hz, 230V / 60 Hz, 220V / 60 Hz, 120V / 60 Hz, 100V / 50 Hz 100V / 60 Hz
Power Input:	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:	T1AL 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 (±10 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

Products should be well packaged and stored in a well-ventilated, dry and non-corrosive environment.

NOTE

If this pump unit is subjected to extreme cold during transit or storage, initial performance may be impaired. Connect to power supply and leave running for approx. 30 minutes 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
	With respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA-C22.2 No. 60601-1 (2008) + (2014) and ANSI/AAMI ES 60601-1 (2005) + AMD (2012) MEDICAL EQUIPMENT	I (On)	Power: Connects to the mains supply
	Refer to this document (Instructions for Use) for a description of the product classification (3rd Edition).	SN	Serial Number
	Refer to this document (Instructions for Use) for a description of the product classification (2nd Edition).	REF	Model number
	Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.		Type BF
	CE marking indicating conformity with European Community harmonised legislation Figures indicate Notified Body supervision.		Fuse
	Indicates the product is a Medical Device according to EU Medical Device Regulation 2017/745		Double Insulated
	Do not dispose of in domestic refuse		

12. Electromagnetic Compatibility (EMC)

Product has been tested for compliance with current regulatory standards regarding its capacity to block EMI (electromagnetic interference) from external sources.

Some procedures can help reduce electromagnetic interferences:

- Use only Arjo cables and spare parts to avoid increased emissions or decreased immunity which can compromise the correct functioning of the equipment.
- Ensure that other devices in patient-monitoring and/or life-support areas comply to accepted emissions standards.

WARNING

Wireless communications equipment such as wireless computer network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. can affect this equipment and should be kept at least 1.5m away from the equipment.

Intended Environment: Home Healthcare Environment and Professional Healthcare facility environment.

Exceptions: HF Surgical Equipment and the RF Shielded room of an ME SYSTEM for magnetic resonance imaging

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Guidance and manufacturer's declaration - electromagnetic emissions

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This equipment 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.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN 61000-4-2	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity level should be at least 30%
Conducted disturbances induced by RF fields EN 61000-4-6	3V in 0,15 MHz to 80 MHz 6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3V in 0,15 MHz to 80 MHz 6V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than 1.0m, if the transmitter's output power rating exceeds 1W ^a Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range ^b Interference may occur in the vicinity of equipment marked with this symbol: 
Radiated RF electromagnetic field EN 61000-4-3	Home Healthcare environment 10 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	Home Healthcare environment 10 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	
Electrical fast transient/burst EN 61000-4-4	±1kV SIP/SOP ports ±2kV AC port 100 kHz repetition frequency	±1kV SIP/SOP ports ±2kV AC port 100kHz repetition frequency	Mains power supply should be that of a typical commercial or hospital environment.
Power frequency Magnetic field EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity

Surge	$\pm 0,5\text{kV} \pm 1\text{kV}; \pm 2\text{ kV}$, AC Mains, Line to Ground	$\pm 0,5\text{kV} \pm 1\text{kV};$ $\pm 2\text{ kV}$, AC Mains, Line to Ground	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5	$\pm 0,5\text{kV} \pm 1\text{kV}$, AC Mains, Line to Line	$\pm 0,5\text{kV} \pm 1\text{kV}$, AC Mains, Line to Line	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery.

Note: *UT is the AC mains voltage prior to application of the test level.*

^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 product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

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AUSTRALIA

Arjo Australia
Building B, Level 3
11 Talavera Road
Macquarie Park, NSW, 2113,
Australia
Phone: 1800 072 040

BELGIQUE / BELGIË

Arjo Belgium
Evenbroekveld 16
9420 Erpe-Mere
Phone: +32 (0) 53 60 73 80
Fax: +32 (0) 53 60 73 81
E-mail: info.belgium@arjo.com

BRASIL

Arjo Brasil Equipamentos Médicos Ltda
Rua Marina Ciufuli Zanfelice, 329 PB02
Galpão - Lapa
São Paulo - SP - Brasil
CEP: 05040-000
Phone: 55-11-3588-5088
E-mail: vendas.latam@arjo.com
E-mail: servicios.latam@arjo.com

CANADA

Arjo Canada Inc.
90 Matheson Boulevard West
Suite 300
CA-MISSISSAUGA, ON, L5R 3R3
Tel/Tél: +1 905 238 7880
Free: +1 800 665 4831 Institutional
Free: +1 800 868 0441 Home Care
Fax: +1 905 238 7881
E-mail: info.canada@arjo.com

ČESKÁ REPUBLIKA

Arjo Czech Republic s.r.o.
Na Strži 1702/65
140 00 Praha
Czech Republic
Phone No: +420225092307
e-mail: info.cz@arjo.com

DANMARK

Arjo A/S
Vassingerødvej 52
DK-3540 LYNGE
Tel: +45 49 13 84 86
Fax: +45 49 13 84 87
E-mail:
dk_kundeservice@arjo.com

DEUTSCHLAND

Arjo GmbH
Peter-Sander-Strasse 10
DE-55252 MAINZ-KASTEL
Tel: +49 (0) 6134 186 0
Fax: +49 (0) 6134 186 160
E-mail: info-de@arjo.com

ESPAÑA

ARJO IBERIA S.L.
Poligono Can Salvatella
c/ Cabanyes 1-7
08210 Barberà del Valles
Barcelona - Spain
Telefono 1: +34 900 921 850
Telefono 2: +34 931 315 999

FRANCE

Arjo SAS
2 Avenue Alcide de Gasperi
CS 70133
FR-59436 RONCQ CEDEX
Tél: +33 (0) 3 20 28 13 13
Fax: +33 (0) 3 20 28 13 14
E-mail: info.france@arjo.com

HONG KONG

Arjo Hong Kong Limited
Room 411-414, 4/F, Manhattan Centre,
8 Kwai Cheong Road, Kwai Chung, N.T.,
HONG KONG
Tel: +852 2960 7600
Fax: +852 2960 1711

ITALIA

Arjo Italia S.p.A.
Via Giacomo Peroni 400-402
IT-00131 ROMA
Tel: +39 (0) 6 87426211
Fax: +39 (0) 6 87426222
E-mail: Italy.promo@arjo.com

MIDDLE EAST

Arjo Middle East FZ-LLC
Office 908, 9th Floor,
HQ Building, North Tower,
Dubai Science Park,
Al Barsha South
P.O Box 11488, Dubai,
United Arab Emirates
Direct +971 487 48053
Fax +971 487 48072
Email: Info.ME@arjo.com

NEDERLAND

Arjo Nederland BV
Biezenwei 21
4004 MB TIEL
Postbus 6116
4000 HC TIEL
Tel: +31 (0) 344 64 08 00
Fax: +31 (0) 344 64 08 85
E-mail: info.nl@arjo.com

NEW ZEALAND

Arjo Ltd
34 Vestey Drive
Mount Wellington
NZ-AUCKLAND 1060
Tel: +64 (0) 9 573 5344
Free Call: 0800 000 151
Fax: +64 (0) 9 573 5384
E-mail: nz.info@Arjo.com

NORGE

Arjo Norway AS
Olaf Helsets vei 5
N-0694 OSLO
Tel: +47 22 08 00 50
Faks: +47 22 08 00 51
E-mail: no.kundeservice@arjo.com

ÖSTERREICH

Arjo GmbH
Lemböckgasse 49 / Stiege A / 4.OG
A-1230 Wien
Tel: +43 1 8 66 56
Fax: +43 1 866 56 7000

POLSKA

Arjo Polska Sp. z o.o.
ul. Ks Piotra Wawrzyniaka 2
PL-62-052 KOMORNIKI (Poznań)
Tel: +48 61 662 15 50
Fax: +48 61 662 15 90
E-mail: arjo@arjo.com

PORTUGAL

Arjo em Portugal
MAQUET Portugal, Lda.
(Distribuidor Exclusivo)
Rua Poeta Bocage n.º 2 - 2G
PT-1600-233 Lisboa
Tel: +351 214 189 815
Fax: +351 214 177 413
E-mail: Portugal@arjo.com

SUISSE / SCHWEIZ

Arjo AG
Fabrikstrasse 8
Postfach
CH-4614 HÄGENDORF
Tél/Tel: +41 (0) 61 337 97 77
Fax: +41 (0) 61 311 97 42

SUOMI

Arjo Scandinavia AB
Riihitontuntie 7 C
02200 Espoo
Finland
Puh: +358 9 6824 1260
E-mail: Asiakaspalvelu.finland@arjo.com

SVERIGE

Arjo International HQ
Hans Michelsensgatan 10
SE-211 20 MALMÖ
Tel: +46 (0) 10 494 7760
Fax: +46 (0) 10 494 7761
E-mail: kundservice@arjo.com

UNITED KINGDOM

Arjo UK and Ireland
Houghton Hall Park
Houghton Regis
UK-DUNSTABLE LU5 5XF
Tel: +44 (0) 1582 745 700
Fax: +44 (0) 1582 745 745
E-mail: sales.admin@arjo.com

USA

Arjo Inc.
2349 W Lake Street Suite 250
US-Addison, IL 60101
Tel: +1 630 307 2756
Free: +1 800 323 1245 Institutional
Free: +1 800 868 0441 Home Care
Fax: +1 630 307 6195
E-mail: us.info@arjo.com

JAPAN

Arjo Japan K.K.
東京都港区虎ノ門三丁目7番8号
ランディック第2虎ノ門ビル9階
Tel: +81 (0)3-6435-6401
Fax: +81 (0)3-6435-6402
E-mail: info.japan@arjo.com

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ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö, Sweden
www.arjo.com

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