ARJOHUNTLEIGH
GETINGE GROUP

AURA

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 or other possible entrapment areas.**
- **Electrical equipment may be hazardous if misused. There are no user-serviceable parts inside the pump. The pump 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.**
- **The cover of this product is vapour permeable but not air permeable and may present a suffocation risk.**
- **There is no transport mode on the Aura seat cushion.**
- **Only the pump and seat combination as indicated by ArjoHuntleigh should be used. The correct function of the product cannot be guaranteed if incorrect pump and mattress combinations are used.**

Precautions

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

- Placing extra layers between the patient and the seat potentially reduces the benefits provided by the seat and should be avoided or kept to a minimum. As part of sensible pressure area care, it is advisable to avoid wearing clothing which may cause areas of localised high pressure due to creases, seams, etc. Placing objects in pockets should be avoided for the same reason.
- Do not expose the system, especially the seat, to naked flames, such as cigarettes, etc.
- In the event of a fire, a leak in the seat or mattress could propagate the fire.
- 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.
- Never use sharp objects or electrically heated under blankets on or under the system.
- Store the pump and seat in the protective bags supplied.

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.

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.

Expected Service Life

The **Aura** 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 **Aura** system. Failure to observe this caution could result in injury, or in extreme cases, death.

Design Policy and Copyright

1. Introduction

About this Manual

This manual is your introduction to the **Aura®** 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 **Aura** system, contact your ArjoHuntleigh sales office, listed at the end of this manual.

Intended use

The intended use of this product is to prevent and/or manage pressure ulcers for patients up to 120 kg (264 lb).

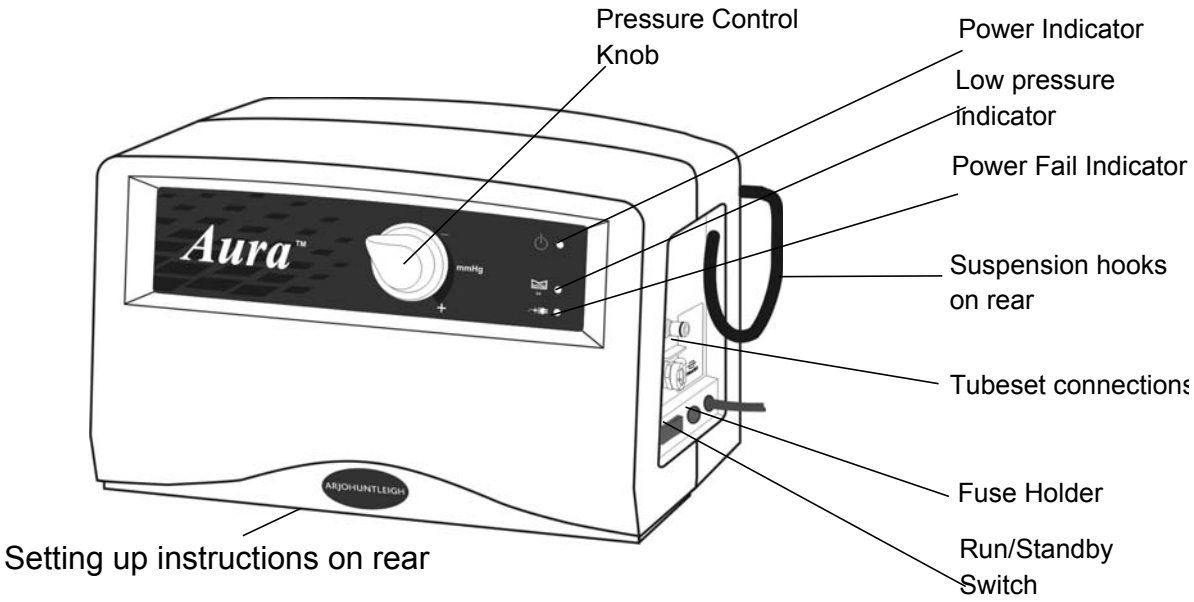
The **Aura** system should be used as part of a prescribed plan of care (refer to “Indications” on page 3).

About Aura

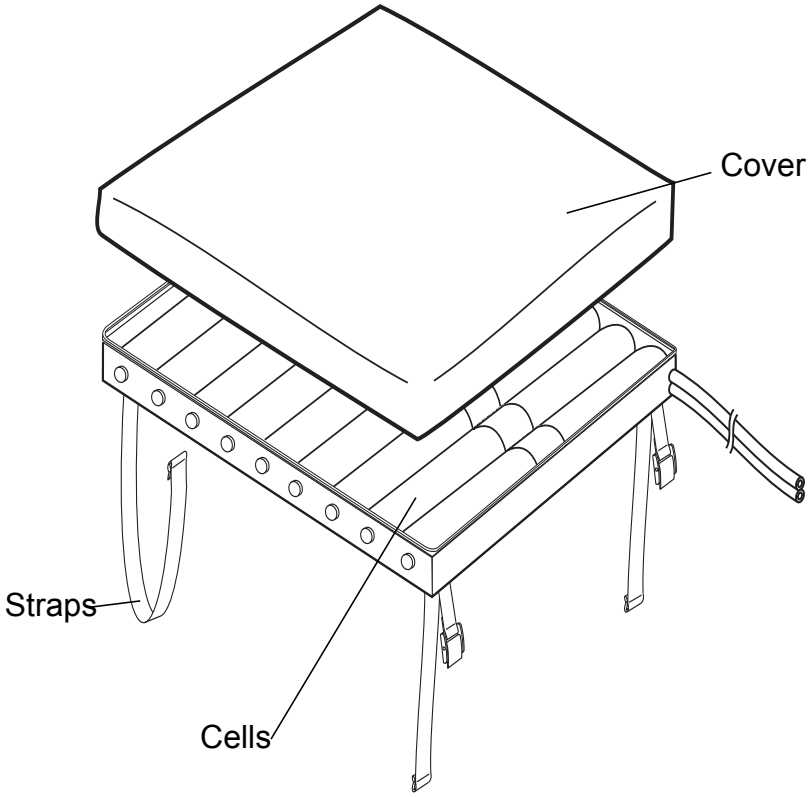
The **Aura** system consists of a pump and a seat cushion and can be used on standard hospital chairs.

A full technical description of the **Aura** system can be found in the Service Manual, part numbers SER0004 (pump) and SER0005 (seat cushion), available from your ArjoHuntleigh sales office.

Aura Pump



Aura Seat Cushion



2. Clinical Applications

Indications

The **Aura** systems are indicated for the prevention and/or management of all categories[1] of pressure ulcer, when combined with an individualised, comprehensive pressure ulcer protocol: for example, repositioning, nutritional support, skin care. Selection should be based upon a holistic assessment of the patient's individual care needs.

These systems represent one aspect of a pressure ulcer management protocol; all other aspects of care should be considered by the prescribing clinician.

If existing wounds do not improve or 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.

The **Aura** cushion is designed for patients weighing up to 120 kg (264 lb).

Contraindications

Do not use **Aura** systems for patients with unstable spinal fractures.

Cautions

If patients have other unstable fractures, or conditions which may be complicated by a soft or moving surface, advice should be sought from an appropriate clinician before use.

While the **Aura** systems have been designed to manage patients up to the weight limits indicated above, those approaching this upper limit are likely to have additional care and mobility needs and may be better suited to a specialist bariatric system.

Active therapy (alternating) cushions may be unsuitable for patients with poor sitting posture or pelvic deformity; advice from a seating specialist should be sought.

Care of the patient when sitting

Seated patients are at increased risk of pressure ulcers particularly if they are immobile or have wounds over the seating area. For optimal outcome, provide a pressure redistributing seat cushion in a chair which promotes a good sitting posture and has a level base seat to support the cushion, in addition to an individualised repositioning programme.

☞ *Mattress and cushion combinations may have different upper weight limits. Cushions should be used in combination with pressure-redistributing mattresses to provide 24-hour therapy.*

1. *NPUAP/EPUAP International Pressure Ulcer Guideline, 2009.*

3. Installation

The system is simple to set up and the following guidelines may assist you.

Preparing the Aura Cushion and Pump

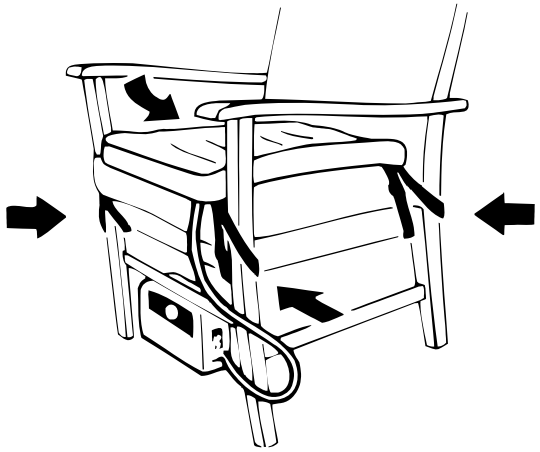
1. Remove the contents of the packaging. You should have the following items:
   - **Aura** pump with integral mains power cord and hanging bracket.
   - **Aura** seat cushion, with cover
2. Plug the pump power cable into wall socket. Do NOT switch the pump on.
3. The pump should be placed feet down on any convenient horizontal surface or alternatively suspended from the chair frame by means of the spring loaded hanging hooks.
4. Check that there are no sharp objects on the chair surface which may puncture the seat cushion.
5. Place the Aura cushion on top of the chair surface. From a standing position in front of the chair and facing it, ensure that:
   - the air feed tubes appear from the front right corner of the cushion
   - the cells are uppermost
   - the cells are in a horizontal position across the chair, NOT from front to back.

Cautions

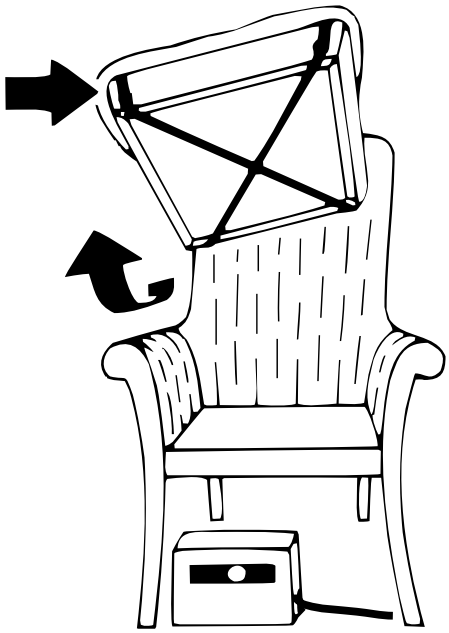
- **Do not use the Aura seat cushion without a foam cushion beneath it.**
- **Always use the Aura seat cushion with the protective top cover.**
- **Always use the Aura seat cushion in the correct orientation.**
- **Avoid trailing cables - ensure that cables and tubing are positioned beneath the chair to avoid causing a hazard.**

6. Secure the Aura cushion to the chair by using the fixing straps as shown in the following illustrations.

7. If the chair is of the open sided construction, then fix the cushion as shown below.



8. If the chair is of the closed side type with a removable seat cushion, fix the **Aura** cushion as shown below.

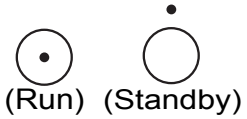


9. If the chair is of the closed side type with a non-removable seat cushion, then security will rely on the anti-slip pads on the base of the **Aura** cushion.
10. Place the protective cover over the cushion and zip up all round, taking care not to trap any material in the zip.
11. Connect the air feed tube connectors to the air outlet connectors on the pump unit, ensuring that the tubes are not “kinked” or twisted. Push the connectors in until they click.

4. Controls, Indicators and Alarms

Controls

Run/Standby Switch



This is situated on the side panel of the pump and is used to activate the unit and reset the alarm. Mains isolation should be performed by switching the pump to standby (◌̇) and then removing the mains plug from the socket.

Pressure Control

This is situated on the front panel and is adjusted by the user to provide extra comfort.

Indicators

Run/Standby

A light on the front panel indicates that the pump is running.

Low Pressure

In the event of low pressure in the seat cushion, the red Low Pressure alarm indicator starts flashing and an audible alarm sounds. The pitch of the alarm will increase at 60 second intervals.

Power Fail

In the event of mains failure, the red alarm indicator starts flashing and an audible alarm sounds. The pitch of the alarm will increase in time. If the power supply is returned the audible alarm stops, but the alarm light remains illuminated until the system is reset.

Alarms

Alarm Reset

When the cause of the alarm has been resolved, the pump must be reset. This can be achieved by switching the pump to Standby and back to Run using the Run/ Standby switch on the side panel.

Self Test

Every time the pump is switched on all indicator lights illuminate for approximately two seconds. During this period, the system self tests its circuits.

5. Operation

These instructions cover day-to-day operation of the system. Other operations, such as maintenance and repair, should only be carried out by suitably qualified personnel.

☞ *Refer to Section 4, Page 6 "Controls, Indicators and Alarms" for a comprehensive description of the controls and indicators on the pump.*

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

Installing the System

Before using the **Aura** system make sure that it has been installed correctly in accordance with Section 3, Page 4 "Installation".

WARNING

Do not place the patient on the seat cushion until it is fully inflated

Inflating the Seat Cushion

1. Connect the pump to the mains power supply using the supplied cable and set the pump power switch to its run (⊙) position.

☞ *It may take up to two minutes to inflate the cushion.*

2. When the seat cushion is inflated, the patient can sit on the seat cushion.

Pressure Control

Adjust the Pressure Control to the patient's requirements.

☞ *There is no transport mode on the **Aura** seat cushion.*

Shut Down

Power the pump off by switching the pump power switch to the standby (○) position. If the pump needs to be completely isolated from the mains power supply, remove the plug from the mains power socket.

Deflating the Seat Cushion

To deflate and store the seat cushion, do the following:

1. Switch off the pump, and disconnect the pump from the mains power supply.
2. Remove the tubeset from the pump.
3. Deflate the seat cushion.

☞ *Make sure the seat cushion is dry before rolling it up.*

6. 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 **Aura** system 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 cord 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. Do not boil or autoclave the cover.
Avoid immersing electrical parts in water during the cleaning process. Do not spray cleaning solutions directly onto the pump.

To clean

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

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

Chemical Disinfection

To protect the integrity of the cover 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 with a cloth moistened in 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.

	DO NOT WRING/MANGLE, AUTOCLAVE OR USE PHENOLIC BASED SOLUTIONS.
Thermal Disinfection	For information for the seat top cover, including laundering guidelines, refer to “Cleaning Symbols” on page 14.
Re-use with multiple patients	Professional hygiene maintenance is required before re-use of the system with a different patient.

7. Troubleshooting Guide

Problem	Possible Cause	Action
Seat cushion not inflating.	1. Tubes kinked. 2. Pump not switched on. 3. No pump output. 4. Punctured cell or leakage from T-connector 5. Tubes not correctly fitted.	Check Check Check Check. See Pump not operating below Check
Consistent **Low Pressure** Alarm.	1. Tubes not correctly fitted. 2. Leakage.	Check Check
The **Power Fail** indicators (audible and visual) are active.	1. A mains power failure has occurred. 2. The power cord has been removed from the wall socket.	Check Check
The **Power Fail** indicator remains constantly illuminated but there is no audible alarm.	There has been a mains power failure but power has been restored.	Check if electrical plug is correctly fitted, and if pump is running correctly.
Pump makes a lot of noise and/or is causing a lot of vibration.	System damaged or dirty.	Call Service Engineer for maintenance.
Pump not operating.	1. Pump Run switch not on. 2. Plug not inserted correctly. 3. Fuse blown. 4. Technical failure.	Switch on Check Call Service Engineer for maintenance. Call Service Engineer for maintenance.
All indicators remain illuminated on initial switch-on.	Internal fault.	Call Service Engineer for maintenance.

☞ *Ensure pump alarms are reset by operating the Run/Standby switch after the fault has been corrected.*

☞ *If the operation or performance of the pump is not restored by performing the troubleshooting procedures, stop using the system immediately and call the service engineer.*

8. Technical Description

PUMP		
Model:	Aura	
	UK	USA
Part Numbers:	ALS01	ALS03
Supply Voltage:	230 V	120 V
Supply Frequency:	50 Hz	60 Hz
Power Input:	14 VA	14 VA
Size:	248 x 160 x 116 mm (9.8 x 6.3 x 4.6 in.)	
Weight:	2.75 kg (6 lb)	
Case Material:	ABS Plastic	
Plug Fuse Rating:	5A to BS1362 (UK ONLY)	
Pump Fuse Rating:	F500 mA H 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:	10 minute Operating Cycle	
Pressure Range:	70 - 100 mmHg ± 5%	

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)	700hPa to 1060 hPa
Storage (Long Term)	+10°C to +40°C (+50°F to +104°F)	20% to 95% (non-condensing)	700 hPa to 1060 hPa
Storage (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 the "Operating" ranges, allow time for its temperature to stabilise to normal, before use.*

PUMP SYMBOLS					
	The operator must read this document (Instructions for Use) before use. Note: This symbol is blue on the product label.		Standby		Do not dispose of in domestic refuse
 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		Run		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).		Double Insulated		Manufacturer: This symbol is accompanied by the name and the address of the manufacturer.

SEAT	
Aura Seat Cushion	**403001**
Length:	455 mm (17.9 in.)
Width:	470 mm (18.5 in.)
Height:	50 mm (2.0 in.) minimum
Cell Material:	Polyurethane
Top Cover Material:	Polyurethane Knitted Fabric
Weight:	0.7 kg (1.5 lb)

COVER SPECIFICATION	
Feature	**Standard Cover (Dartex®)**
Removable Cover	Yes
Moisture Vapour Permeable	Yes
Air Permeable	No
Low Friction	Yes
Water Resistant / Repellent	Yes
Infection Control	Material coating is bacteriostatic, fungistatic, antimicrobial
Fire Retardant	BS 7175: 0,1 & 5
2-Way Stretch	Yes
Washing Conditions[a]	MAX 95°C (203°F) for 15 mins
Drying Conditions[b]	Tumble Dry up to 130°C (266°F) or Air Dry
Life Span	50 Wash Cycles (minimum)
Application Area	Acute and Homecare

a. The top cover may be washed. The temperature in the washing cycle may be up to 95°C (203°F); however it is recommended that you check your local policy to determine the time/ temperature ratio required to achieve thermal disinfection.
b. The top cover may be tumble dried or air dried. The temperature in the drying cycle may be up to 130°C (266°F); however it is recommended that you check your local policy to determine the time/temperature ratio required.

CLEANING SYMBOLS			
	Wash at 95°C (203°F) MAX		Tumble dry at 130°C
	Do not iron		Wipe surface with damp cloth
	Do Not Use Phenol-based cleaning Solutions		Use solution diluted to 1000 ppm of Available Chlorine

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	

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 Nimbus 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.*			

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 Nimbus pump 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 2.5GHz	3 V 3 V/m	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 $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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: *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 Nimbus pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorientating or relocating the Nimbus pump. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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GETINGE GROUP

GETINGE GROUP is a leading global provider of products and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. We operate under the three brands of **ArjoHuntleigh**, **GETINGE** and **MAQUET**. **ArjoHuntleigh** focuses on patient mobility and wound management solutions. **GETINGE** provides solutions for infection control within healthcare and contamination prevention within life sciences. **MAQUET** specializes in solutions, therapies and products for surgical interventions and intensive care.

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