

INSTRUCTIONS FOR USE

IndiGo

Intuitive drive assist



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Foreword

Thank you for choosing the IndiGo® Intuitive drive assist, it is available on the following bed frame systems:

- Citadel™ Bed Frame System
- Enterprise® 5000X Acute care hospital bed (excluding folded side rails)
- Enterprise® 8000X Acute care hospital bed
- Enterprise® 9000X Acute care hospital bed

Customer contact information

For questions regarding this product or other Arjo products and services, contact Arjo, an Arjo authorised representative or visit www.arjo.com.

Before using the product

The information in this Instructions For Use (IFU) is important for your safety. You must read and fully understand this IFU before using the product to help prevent potential injury. The information in this IFU is necessary for the proper and safe operation of the product.

Unauthorised modifications on any Arjo product can affect its safety and performance. Arjo will not be held responsible for any accidents or incidents resulting from such modifications to its products.

Service and support

It is necessary to perform routine maintenance to maintain the safety and reliability of the product. See the Care and preventive maintenance section for more information. Contact your local Arjo representative for spare parts.

Definitions in this IFU



WARNING

Warning means: Safety warning. Failure to understand and obey this warning may result in injury to you or others.

CAUTION

Caution means: Failure to follow these instructions may cause damage to all or parts of the system or product.

NOTE

Note means: This is important information for the correct use of this system or product.

Intended use

The IndiGo power assist is intended to provide powered assistance for medical beds during patient transfer. It should only be assembled onto compatible Arjo medical beds listed in the instructions for use.

The IndiGo power assist unit should only be used by appropriately trained personnel and for the purpose specified in the Instructions for Use. Any other use is prohibited.

Patient assessment

Refer to applicable bed IFU or power drive IFU for patient assessment.

Installation requirements

The product must be installed by appropriately trained personnel according to the Assembly and Installation Instructions which can only be superseded by local code.

Expected service life

The expected service life of IndiGo power assist is the maximum period of useful life. The expected service life of this equipment is ten (10) years, subject to preventive maintenance being carried out in accordance with the instructions for care and maintenance found in the Instructions for Use.

Safety instructions



WARNING

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



WARNING

To minimize the risk of serious injury, carefully read and follow all safety information and operating instructions before operating the product. Make sure all physician orders and facility protocols are followed.



WARNING

To prevent injury, activate the brake on the bed and call maintenance if unanticipated motion occurs.

CAUTION

Floor lifts and other care equipment that normally go under the bed must be handled with caution in order to not interfere with the intuitive drive assist.

CAUTION

Do not place any items on the intuitive drive assist cover during transport or storage.

CAUTION

Do not use on slopes greater than 6°. Do not use the intuitive drive assist to load a bed into van or truck.

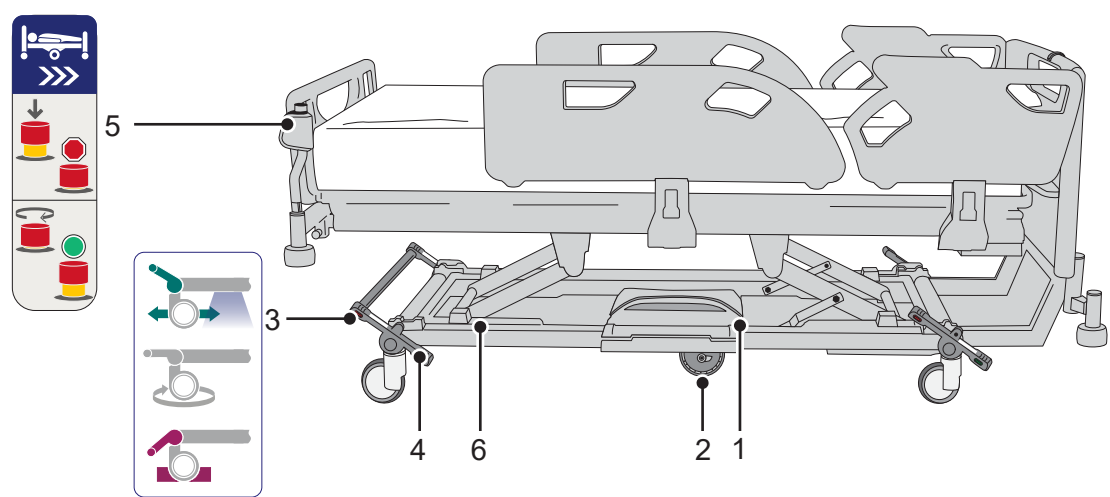
CAUTION

Low bed height will be reduced by approximately 17mm when using taller load cell screw covers.

CAUTION

When operating the intuitive drive assist, maintain contact with bed at all times.

Parts designation



1. Cover

2. Wheel

3. Activation / Deactivation and Brakes label (located on or near all pedal locations)

4. Pedal
5. Emergency stop switch (located at head and foot ends of bed)

6. Load cell screw cover (only used on Enterprise 9000X and Citadel Bed frame system beds)

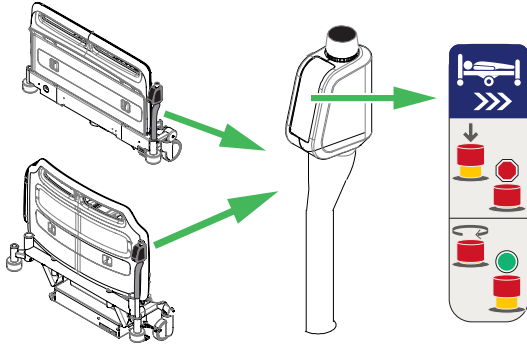
Light indications

Status	Light	Battery	Action
Full battery. During normal use, the battery will last for approximately 5000 m (3.10 miles).			
Low battery (1 flash / 1.6 seconds). During normal use, the battery will last for approximately 900 m (0.56 miles).		 20 % left	 Charge
Critical low battery (1 flash / 1 second). Drive wheel assist will be disabled in 20 seconds.		 6 % left	 Charge
Failure / Error (10 flashes / 1 second).			 Call Service

Refer to Troubleshooting on page 12 for more information.

Emergency stop switch

The intuitive drive assist comes equipped with emergency stop switches located at both the foot and head ends of the bed.



NOTE

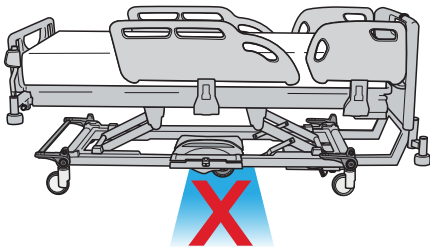
The emergency stop switch provides a gradual, slow stop rather than an immediate hard stop.

Activate emergency stop switch

1. Push down the emergency stop switch to activate it.



2. The electric brakes are applied to reduce momentum and slow the bed until stopped. The blue lights turn off and the drive wheel retracts up under the bed and off the floor.



The switch will stay down, with the intuitive drive assist deactivated, until the emergency stop switch is reset.

Reset emergency stop switch

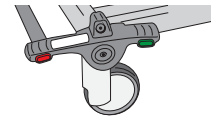
1. Twist the emergency stop switch clockwise.



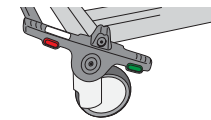
2. The switch will pop up and is now reset.



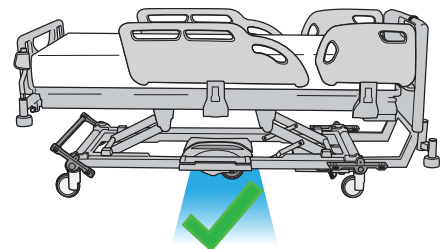
3. **To reset the drive wheel:** Cycle the brake pedal down to the free position.



Then back up to the activated position. The drive wheel is lowered to the floor.



4. The blue LED lights will turn on to indicate that the drive wheel is lowered to the floor and the intuitive drive assist is activated.



Use the intuitive drive assist

Before use

1. Identify that the bed is equipped with the intuitive drive assist by locating the emergency stop switch, the cover and/or the intuitive drive assist wheel.
2. Prepare for patient transport according to bed IFU and all applicable safety information and operating instructions.

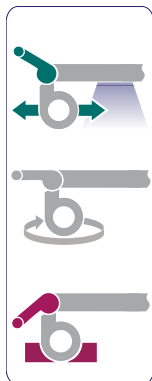
NOTE

The intuitive drive assist has the same safe working load as the bed to which it is fitted.

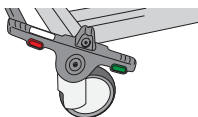
Activate, deactivate and brake

Activate, deactivate and brake the intuitive drive assist using the pedals located on each corner of the bed. Operate the pedals with your feet while wearing suitable shoes. Do not operate the pedals with your hands.

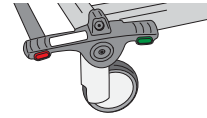
The pedals have three positions.



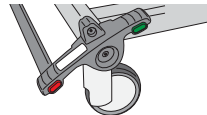
Activated: a centered drive wheel engages the floor when the intuitive drive assist is activated.



Free: all four casters are free to rotate and swivel and the intuitive drive assist wheel is deactivated.

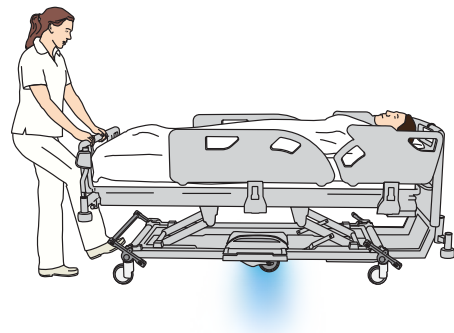


Brake: brakes are applied on all four casters and the intuitive drive assist wheel is deactivated.



To activate

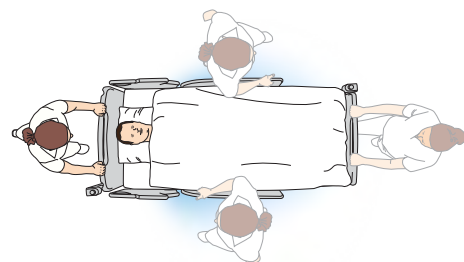
1. Place the pedal in the most upright position.
2. The wheel is lowered to the floor and blue lights illuminate to signify that the intuitive drive assist is active.



Move the bed

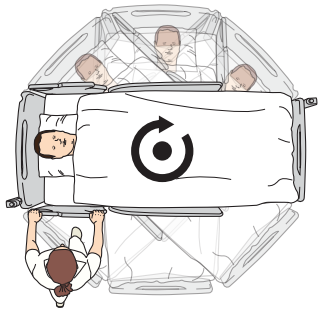
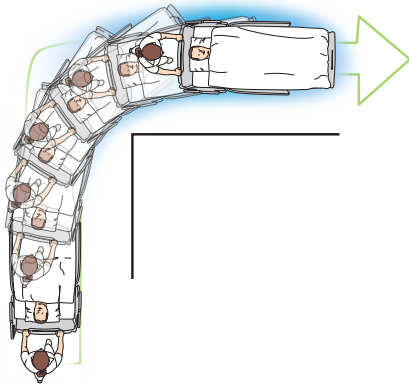
360 interface

Since the intuitive drive assist is built into the bed itself, there is no specific grip or handle. Push or pull the bed from the foot board, head board or the side rails as you normally would when moving the bed.



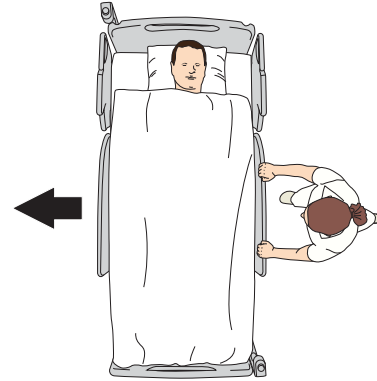
Maneuverability

The intuitive drive assist replaces the bed's ordinary steer lock function with a drive wheel centered under the bed, which improves the maneuverability and control. The drive wheel effectively minimizes the space needed when taking corners or full 360° turns.



In most cases, it is beneficial to keep the intuitive drive assist activated in confined spaces and crowded areas. Make sure there is space to operate before forward or reverse movement.

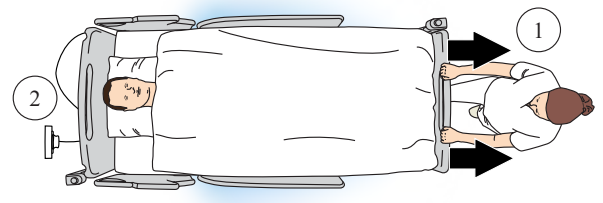
Deactivating the intuitive drive assist (pedal in free position), allows for small positioning adjustments and sideways movement.



Drive assistance

To fully benefit from the intuitive drive assist keep a constant pressure while moving on flat surfaces and up slopes.

1. To use the intuitive drive assist (1) activate it using the pedals on any corner of the bed.
2. Move bed slightly away from wall to access to the bed's power cord (2).



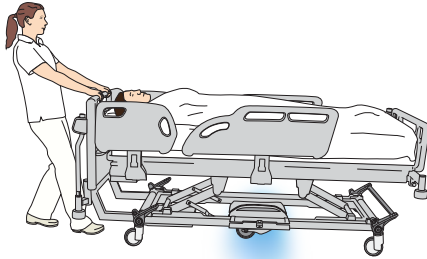
3. Unplug power cord from the wall.
4. Push or pull bed gently to begin drive assisted movement.

NOTE

The intuitive drive assist reacts to force applied by the user. The intuitive drive assist gives progressive assistance up to a maximum speed of 5 km/h (3 mph).

Continued on next page

- The intuitive drive assist may be kept activated in and out of elevators. Note that temporary deactivation allows for small positioning adjustments and sideways movement if required.
- Pull gently to decelerate and lean backwards to stop (brake assistance).



2. Charge the intuitive drive assist by connecting the bed's power cord to the wall outlet after every use.

- Control speed by a light constant pull while moving down slopes (brake assistance). The intuitive drive assist will provide brake assistance.

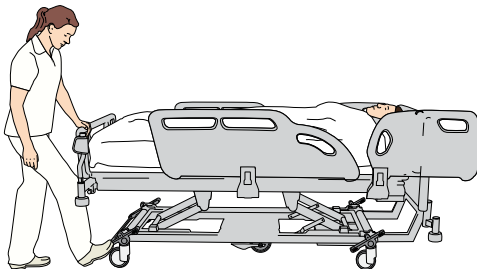
Sleep mode

When the intuitive drive assist is activated and the bed is not moved for approximately five minutes, it goes into sleep mode. The wheel lifts off the floor and the blue lights turn off.

To re-activate the intuitive drive assist, move the brake pedal to the free position and then back up to the activated position.

After use

1. Deactivate the intuitive drive assist and apply brakes by placing the pedal in the most downward position.



Care and preventive maintenance



WARNING

To prevent pinching of hand/fingers, the intuitive drive assist must be deactivated and bed brakes applied prior to removing obstructions, cleaning and/or servicing the intuitive drive assist wheel.

For cleaning and disinfection, please refer to cleaning and disinfection instructions in the bed IFU.

CAREGIVER / FACILITY OBLIGATIONS

Actions	Daily	Weekly
Check that the cover is undamaged.		•
Check that the intuitive drive assist is activated when pedal is in its most upward position.	•	
Check the emergency stop assemblies for signs of damage.	•	
Check that applicable labelling is present and legible.	•	

If the result of any of these tests is unsatisfactory, do not use the intuitive drive assist. Contact qualified service personnel.

Actions by qualified service personnel only



WARNING

To prevent injury and/or unsafe product, the maintenance activities must be carried out by qualified service personnel with documented training in maintenance of this product.

- Examine the intuitive drive assist for obvious signs of damage.
- Exercise the unit's operation, including the emergency stop switches. If any abnormalities are observed, refer to the Troubleshooting chapter.
- Examine the intuitive drive assist cables for cuts, abrasions, kinks or other deterioration. Contact Arjo if damage is observed.
- Examine the intuitive drive assist drive wheel and tire assembly for damage. If abnormalities are observed, replace the Drive wheel assembly. Refer to Drive wheel replacement procedures in the Service manual.
- Visually inspect the gas spring for excessive oil on shaft. Make sure the gas spring maintains downward force on the drive wheel when the intuitive drive assist is engaged. If excessive oil is present on the shaft or the gas spring does not maintain downward force when the intuitive drive assist is engaged, replace the gas spring. Refer to Gas spring replacement procedure in the Service Manual.
- Check all accessible nuts, bolts and other fasteners to make sure they are present and correctly tightened.
- Check that the intuitive drive assist does not interfere with the scale function through the bed's full range of motion.

Troubleshooting

SYMPTOM	POSSIBLE CAUSE	ACTION
Bed is difficult / heavy to maneuver	Brake pedal is in Free position or Brake position	Place brake pedals in the Activated position.
	Emergency stop switch(es) are pushed down	Make sure the switch(es) are not pushed down. Twist switch(es) clockwise to re-set.
	Brake bar sensor is not aligned with the intuitive drive assist sensor when pedal is in the Activated position	Make sure the pedal is in Activated position, then move the brake bar sensor to align it with the intuitive drive assist sensor. If needed, loosen the screw on the brake bar sensor to move, then tighten screw to secure in place.
Bed is difficult to maneuver sideways	Pedal is in the Activated position	Place pedal in Free position to deactivate the intuitive drive assist.
Bed moves in an unanticipated way	Failure / Error	Confirm that the intuitive drive assist is properly configured for the bed. Recalibrate the intuitive drive assist per testing chapter.
		Review LED error codes and implement corrections as necessary.
		Deactivate the intuitive drive assist by placing pedal in Brake position. Contact an Arjo - approved service agent.
Flashing blue light	Low battery	Complete patient transport / moving the bed and connect power cord to wall outlet.
	Critical low battery	
	Failure / Error	Complete patient transport/moving the bed or brake by placing pedal in Brake position. Contact an Arjo - approved service agent.
		Review LED error codes and implement corrections as necessary.
Emergency stop switch does not function properly	Failure / Error	Make sure the emergency stop switch assembly and cabling are intact and functional. Replace if damaged. If no damage is noted, troubleshoot PCBA.
Bed weigh scale reading error at low bed height	Cable routing interferes with bed articulation	Review cable routing to make sure proper amount of slack and/or service loop in applicable locations. Make sure taller load cell screw covers are installed.
All functions inoperative	Software and / or PCBA faulty	Replace PCBA.
	Cables defective	Check cables for cuts, abrasions, kinks or other deterioration and replace if needed.

SYMPTOM	POSSIBLE CAUSE	ACTION
Unanticipated noise	Failure / error	To complete patient transport/moving the bed, place the pedal in Free or Brake position to deactivate the intuitive drive assist. Contact an Arjo - approved service agent.
		Make sure drive wheel functions as intended. If noise continues, replace the intuitive drive assist unit.
No blue light	The intuitive drive assist is in sleep mode	Cycle foot pedal from Activated to Free position, wait 2 seconds, then cycle back to Activated to activate the intuitive drive assist.
	Pedal cycled too quickly	
	Brake pedal is in Free or Brake position	Place brake pedals in Activated position.
	Emergency stop switch(es) are pushed down	Cycle foot pedal from Activated to Free position, wait 2 seconds, then cycle back to Activated to activate the intuitive drive assist.
	Failure / Error	Complete patient transport/moving the bed or place the pedal in Brake position to brake. Contact an Arjo - approved service agent.
		Review LED error codes and implement corrections as necessary.
		Confirm charger status LED. - Red = Charging - Green = Fully charged, not charging or not connected to PCBA - No LED = Check AC cord connections or Replace charger
		Replace battery pack if charger is functioning properly.
	Low battery	Connect power cord to wall outlet. Contact an Arjo - approved service agent. Move the bed to reactivate the intuitive drive assist.
	Battery dead	Replace battery pack.
	Battery deeply discharged	Plug bed into AC outlet. Press battery wake up button located on the battery pack and charge for 8 hours.

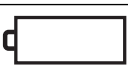
Technical specifications

GENERAL SPECIFICATIONS	
Li-Ion battery	25.2 V Nominal Voltage, 4.3 Amp Capacity Battery Charge Time From Empty: ~4 hours
Full battery achievable distance	5000 m (3.10 miles)
Low battery achievable distance	900 m (0.56 miles)
Critical battery time remaining	20 seconds
Maximum speed for full assistance	5 km/h (3 mph)
Intuitive drive assist wheel	Non-marking
Degree of liquid ingress protection	IPX4
Degree of protection against electric shock	Class 1
Allowed combination	Citadel Bed Frame System Enterprise 5000X Acute Care Hospital Bed (excluding folded side rails) Enterprise 8000X Acute Care Hospital Bed Enterprise 9000X Acute Care Hospital Bed
Watt - hour rating	108 Wh Nominal
Safe Working Load	The intuitive drive assist has the same Safe Working Load as the bed to which it is fitted.

OPERATING, TRANSPORT AND CONDITIONS	
Temperature (operating)	14 °C to 35 °C (57 °F to 95 °F)
Temperature (transport and storage)	-29 °C to 50 °C (-20 °F to 122 °F)
Relative humidity (operating)	20 %-80 %
Relative humidity (transport and storage)	20 % to 90 % at 30 °C (86 °F), non-condensing
Atmospheric pressure (operating)	700 hPa to 1060 hPa
Atmospheric pressure (transport and storage)	700 hPa to 1060 hPa

RECYCLING	
The device should be recycled according to local regulations.	
Battery	Lithium-ion. Not for disposal, only to be recycled.
Package	Wood and corrugated cardboard, recyclable.
Product	Electric, steel and plastic parts shall be separated and recycled according to marking on the unit.

Symbols used

SYMBOL EXPLANATION	
	Refer to instruction manual/ booklet - Instructions for use should be read.
	CE marking indicating conformity with European Community harmonised legislation.
	UL recognized marking indicating compliance with Canadian and U.S. safety standards
	Name and address of the manufacturer
	Manufacturing date
	Serial number
	Catalogue number
IPX4	X: The protection against ingress of solid foreign objects is not specified for this product. 4: Protected against splashing water.
	Lithium-Ion battery
	Atmospheric pressure limitations
	Relative humidity limitations
	Temperature limitations
	Separate electrical and electronic components for recycling in accordance with the European Directive 2012/19/EU (WEEE)

UNITED KINGDOM	
	UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended)
	UK Responsible Person & UK Importer: Arjo (UK) Ltd, ArjoHuntleigh House, Houghton Regis. LU5 5XF For Northern Ireland (NI) CE marking will still apply until further amendment to applicable regulations.

Electromagnetic compatibility

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:

Make sure that other devices in patient-monitoring and/or life-support areas comply to accepted emissions standards.

 WARNING

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

 WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

 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.

Intended Environment: Professional Healthcare Facility Environment.

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

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC EMISSIONS		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	This equipment uses RF energy only for its internal functions. 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	This 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.
NOTE: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Immunity test	EN 60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) EN 61000-4-2	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact	±2kV, ±4kV, ±8kV, ±15kV air ±8kV contact
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
Radiated RF electromagnetic field EN 61000-4-3	Professional Healthcare environment 3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	Professional Healthcare environment 3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment EN 61000-4-3	385 MHz - 27 V/m 450 MHz - 28 V/m 710, 745, 780 MHz - 9V/m 810, 870, 930 MHz - 28 V/m 1720, 1845, 1970, 2450 MHz – 28 V/m 5240,5500, 5785 MHz - 9V/m	385 MHz - 27 V/m 450 MHz - 28 V/m 710, 745, 780 MHz - 9V/m 810, 870, 930 MHz - 28 V/m 1720, 1845, 1970, 2450 MHz – 28 V/m 5240, 5500, 5785 MHz - 9V/m
Electrical fast transient/burst EN 61000-4-4	±2kV AC port 100kHz repetition frequency	±2kV AC port 100kHz repetition frequency
Power frequency Magnetic field EN 61000-4-8	30A/m 50 Hz or 60 Hz	30A/m 50 Hz
Surge EN 61000-4-5	±0,5kV ±1kV; ±2 kV, AC Mains, Line to Ground ±0,5kV ±1kV, AC Mains, Line to Line	±0,5kV ±1kV; ±2 kV, AC Mains, Line to Ground ±0,5kV ±1kV, AC Mains, Line to Line
Voltage dips, short interruptions and voltage variations on power supply input lines EN 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
Proximity magnetic fields EN 61000-4-39	134,2 kHz - 65 A/m 13,56 MHz - 7,5 A/m	134,2 kHz - 65 A/m 13,56 MHz - 7,5 A/m

NOTE

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

Compliance and requirements

FCC compliance statement:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy, and if it is not installed and used in accordance with the instruction manual, it may cause harmful interference to radio communications.

Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

Requirements for Canada:

This device complies with Industry Canada license exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

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