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INSTALLATION, OPERATIONS & MAINTENANCE MANUAL ARDYS

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NOTE: MD use must be done only after having read all sections of the current operation instructions.

- Please follow all warnings in these instructions for use in the enclosed MD's

Device intended for use by lay users, the profane user: the patient, uses only the push-buttons to switch on/off the lighting and for the nurse call and uses the electrical sockets to connect mobile phone to recharge or connect a radio set, in case of different use they should consult a healthcare professional.

1) DESCRIPTION

Wall mounted Bed head unit designed to meet the requirements of different hospitalization areas, for one bed, with possibly forming continuous lines for several beds

MODELS:

Ardys:	Single Bedhead unit equipped with electrical components, gas outlets +2 units lighting fittings
Ardys-S:	Single Bedhead unit equipped with electrical components, gas outlets +1 units lighting fittings
Ardys-D:	Double Bedhead unit equipped with electrical components, gas outlets +2 units lighting fittings
Ardys-DS:	Double Bedhead unit equipped with electrical components, gas outlets +1 units lighting fittings
Ardys-P:	Single Bedhead unit equipped with electrical components, gas outlets, without lighting
Ardys-PD:	Double Bedhead unit equipped with electrical components, gas outlets, without lighting



Representative image of model Ardys

2) INTENDED USE OF THE BED HEAD UNIT

Medical power supply units installed in hospital and medical environments, destined to medical gas distribution.

These medical supply units are medical devices designed to provide close access of direct and indirect lighting, electrical sockets, data sockets, nurse call, diagnostic signals and alarms and, specifically for authorized medical personnel, medical gas outlets, necessary for the care and treatment of patients by authorized medical personnel.

INTENDED USER PROFILE

The only form of direct contact between patient and device occurs during push the button on handle control panel for lights control and nurse call and/or switches and buttons for lighting control on device. the operator can be in contact to the aluminium structure, the polycarbonate covers and the push-button panels, to the switches, the electrical sockets, the buttons, the data sockets which are made of plastic material, then there are the gas sockets medical devices that are made of metal and equipotential sockets that can be metal or plastic and finally accessories made of plastic + metal.

It is strongly recommended that visitors consult healthcare personnel before performing any operation.

Installation and maintenance must be carried out exclusively by personnel specialized authorized by the manufacturer.

The medical device is used by:

- authorized medical personnel, in detail:

- Turn on / off the direct and indirect lighting
- Use electrical outlets
- Nurse call
- Diagnostic signals and alarms
- Distribution of medical gases

- people visiting the hospital rooms or by the patient himself "lay person" (not applicable for analysis laboratories): only non-medical functions, in detail:

- Turn on / off the direct and indirect lighting
- Use electrical outlets that are not currently being used by a medical device
- Nurse call

Authorized medical personnel:

The functions they perform are those of their position within the center hospitable. They are in charge of connecting the gas outlets present on the medical supply unit indicated for each patient and to connect the medical devices that will be powered by the medical supply unit.

To carry out these functions, the medical staff will have studies and basic knowledge in medicine and knowledge of electricity at the user level.



The medical personnel will have sufficient knowledge to read and understand the instructions for assembly that accompanies the headboard.

3) COMPONENTS

The ARDYS device can be delivered with a handset from which the user can control the lighting and send a warning signal to call for assistance. Minimal technical features:

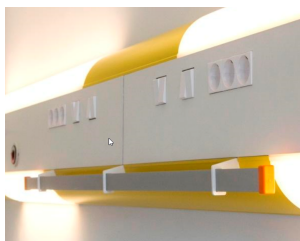
- Casing in self-extinguishing polycarbonate, no propagation of toxic fumes. Designed for housing the electrical control units with recessed seats to prevent the units from being switched on accidentally and unwanted calls due to pressure on the pushbutton units caused by movements of patient's body.
- Protection degree: IP43
- Safety plugs on fastening screws to prevent tampering by the patient.
- Silk-screened indications on control keys with symbols (designed for easy understanding (children, senior citizen, etc.)
- Flame-resistant white multi-wire cable

Components to be used with ARDYS:

Internal Code	Manufacturer	Photo	Description and Technical data	Material	Manufacturer references	Class according MDR
J10TH2xx	ELLEDUE		Handle push button control to nurse call and light turn off/on	Self-extinguishing polycarbonate, no propagation of toxic fumes	255703 260101 260102 260203 265104 TH2401 TH2406 TH2507 TH2551 TH2557 TH2577 NX0884	I
J10THNX0884 J10THNX0884-SC J10THNX0883 J10THNX0883-SC J10THNX0881 J10THNX0881-SC	IBERNEX		Handle push button control to nurse call and light turn off/on	Self-extinguishing polycarbonate, no propagation of toxic fumes	NX0884/SC NX0883 NX0883/SC NX0881 NX0881/SC	I

ACCOMPANYING COMPONENTS:

Components to be used with ARDYS:



Upon request the unit can be supplied with a medical rail placed on the upper, lower- part or on both on which various attachments can be mounted

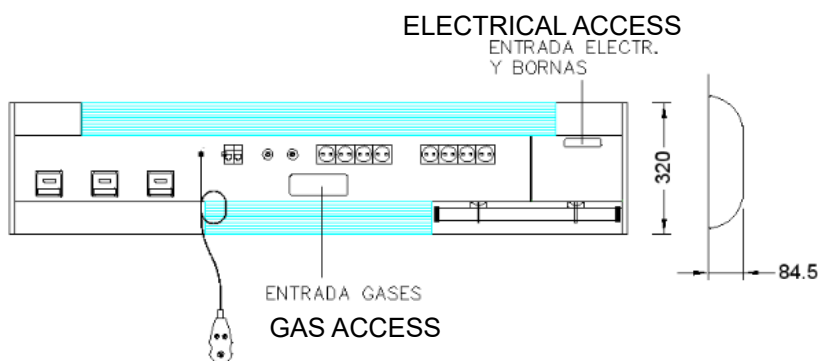
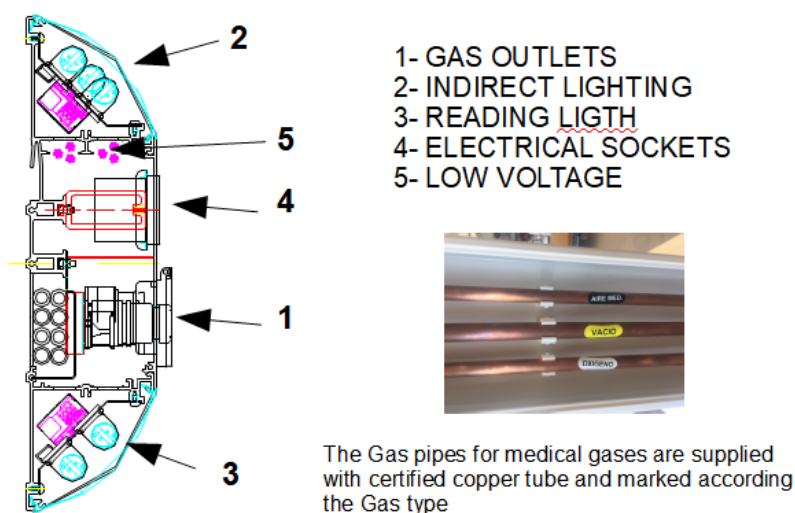
Support for Infusion bottles with 2 or 4 hooks are also available

Maximal load per meter for the medical rail: 10kg

Maximal load for Infusion bottles support: 4kg

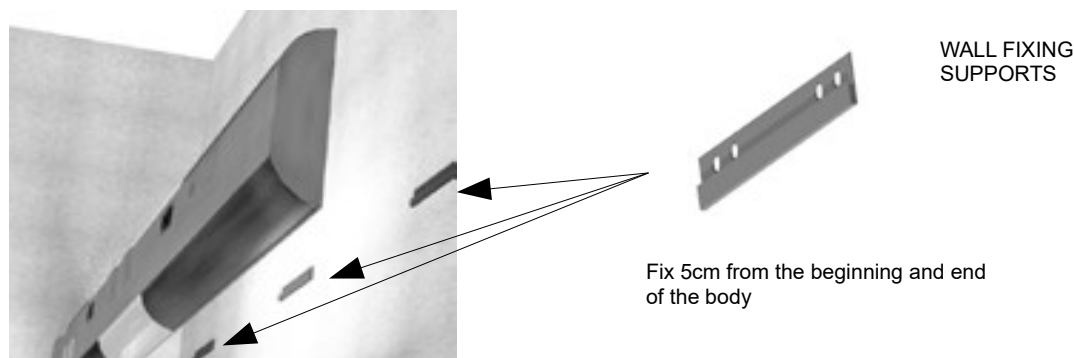
4) PARTS OF BEDHEAD UNIT

The Ardys unit has several separate compartments for electricity, for lighting and for medical gases, in accordance with international regulations and standards



5) INSTALLATION ON THE WALL

A) First we will proceed to define the fixing points on the wall. To do this, place the wall fixing supports in the desired position (ensuring that the parts remain horizontal) mark the centers of the hole to be made and make the holes. Insert the nylon plugs and screw the wall fixing support to them, use 5x50 screws or similar + nylon plugs



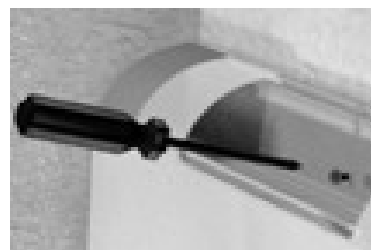
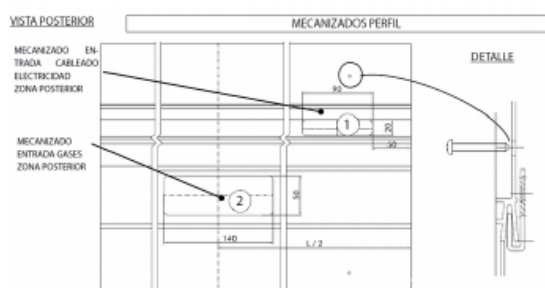
The medical supply units comes complete and tested, ready for installation on the wall.

It should be affixed at a height of 1.6 m from the floor and must be done by using steel plate, supplied with the device. The pieces to be used must be of the appropriate anchors for the type of wall and have a minimum resistance of 2.3 KN axial tensile stress.

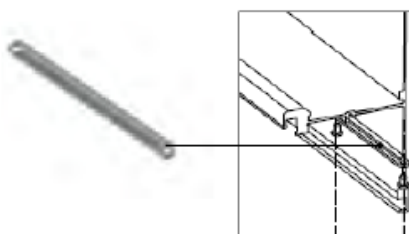
The distances between the fixing depend of the type of medical supply units and are shown directly on the drawings contained in the packaging. In the medical supply units there are 2 brackets for each bed with a distance of up to 1.600 mm. In the case of beds with increased center distance, more than 2 brackets will be used. Each bracket shall be fixed with 2 screws with the given characteristics. For some models, anchors (with the same center distance) are required in addition to the brackets.

- Use screws and plugs appropriate for fixing mounting brackets to the wall at the desired height (height 160 cm from the floor recommended)
- Place the medical supply units on the wall brackets
- Secure the medical supply units to the wall with screws and anchors using the rear holes

B) Place the BHU, and to prevent it can be removed in subsequent operations fix to the wall by screws on each side. Secure the junction by tightening the screws



C) Lines formed by several units will be joined by means of the included joining piece and fixed to the profile with DIN7981 3,9x6,5 screws



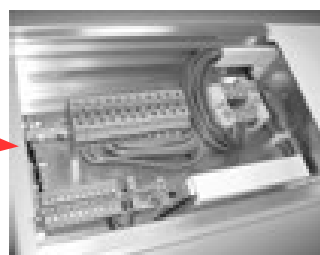
6) ELECTRICAL CONNECTIONS

Perform the electrical connection according to the wiring diagram placed inside the BHU



ELECTRICAL CONNECTIONS ARE TO BE CARRIED OUT BY COMPETENT PERSONS ONLY

Label indicating the wiring diagram are placed on the inner part of the plate who covers the electrical connections





RISK OF INJURY DUE TO ELECTRICAL SHOCK!

- Unit may contain electrical current.
- Please don't open system housing
- Before connecting to main power supply, pay attention to tension and frequency displayed on label
- Unit must be protected by circuit breaker differential switch
- To avoid electric shock danger, the unit must be wired with grounded connection
- Please don't exceed the electrical power medical unit as made for, which can be found on the labels applied on the device
- Please don't connect adapters between the device's electrical sockets and plugs

7) INSTALLATION OF MEDICAL GASES



GAS CONNECTION AND TESTING TO BE CARRIED OUT BY CERTIFIED GAS INSTALLER

The gas terminal units and pipeline system in the unit have been fully factory leak tested. After connection to the mains supply, the entire medical gas pipeline system is to be tested before being commissioned for use. Always respect the regulations associated with the installation of medical gases, all this checks has to be documented, according to the instructions for testing and verification of distribution networks

- Analysis of Fluid
- Proof crossings
- Proof of obstructions



Do not use oil or grease on any of the gas terminal units or pipe work for any reason as this could lead to a fire or an explosion. Use only approved oxygen compatible lubricants.



8) PROTECTION AGAINST FLAMMABLE MIXTURES

Not protected - RISK OF INJURY DUE TO EXPLOSION – Not suitable for installation in places where can produce a flammable anesthetic mixture with air, oxygen or nitrous oxide



9) RISK OF INJURY DUE TO UNAUTHORIZED USE!

- ARDYS Unit must not be tempered with or used differently from the intended use
- "ATTENTION": to avoid the risk of electrical shock, the bed head units must be connected to power with protective ground connection"
- do not connect the ground manifold of the bed head units to external equipment
- execute the fixing of equipment following the directions given on the layout and wiring diagram, using the appropriate anchors (brand Fischer, HILTI or similar)
- before connecting the device to main power have a particular attention to the plate reporting the voltage and frequency power

- don't exceed the electric power for which bed head units was built and labeled on the plate, don't connect adapters between the electrical sockets and plugs of device. the bed head units must be protected by appropriate differential switch.
- for the replacement of worn parts use components of same features
- when removing broken equipment, unpowered the equipment (using the switch on the general panel), and ask qualified personnel to replace the equipment
- the equipment must not be tampered or used for different purposes than providing issues
- the equipment unit must be installed and tested and used in accordance with the standards EN7396 by a qualified staff
- for the proper installation of gas outlets follow the instructions of manufacturer of gas outlet.
- equipment not sterilizable
- the user is not authorized to replace the components (such as transformers, relays, fuses, etc.), always use qualified personnel
- the bed head units requires special precautions regarding EMC (electromagnetic compatibility) and must be installed and put into service according to the information listed in the table 1 and 2, present in user manual, relative to the information on EMC (electromagnetic compatibility)
- the MD unit or MD system should not be used close to other equipment, if you were to use the MD system or the MD unit near or overlapping other equipment, it is necessary to keep checking the normal operation in the configuration in which it is used
- portable RF communications EQUIPMENT, including antennas, can effect medical electrical EQUIPMENT. The MD unit should be used no closer than 30cm (12 inches) to any part of portable RF communications EQUIPMENT, including antennas and cables specified by the manufacturer.
- other cables and accessories may negatively affect EMC performance.



10) RISK OF INJURY DUE TO SYSTEM PARTS FALLING DOWN

- Please don't overload medical supply unit's max load, listed on the related label.



11) RISK DUE TO UNQUALIFIED INSTALLATION!

- Medical supply unit installation must be done following indication listed on manufacturer installation manual.
- Electrical connection must be done following the manufacturer electrical scheme.
 Gas outlet distribution must be done by qualified personnel according to EN 7396-1 and EN 7396-2 regulations. Distribution medical gas system must be tested and prewired before delivery.



12) RISK DUE TO SPARE PARTS NOT AUTHORIZED BY THE MANUFACTURER!

- Please make sure to replace damaged parts with original parts only
- Please replace damaged screws with new ones with the same specification.

13) TECHNICAL SPECIFICATIONS

Regulation	The equipment should be considered class IIb
Classification according to the type of protection against electrical hazards	Class I device. The protection against electric shock is guaranteed by the metal parts of the ground protection
Classification by type of security against direct and indirect contact	The device is not equipped with applied parts
Classification according to the degree of protection against penetration of liquids and external agents	IP20
Classification according to the use and conditions	device for continuous operation
Noise level	Less than 35 dB
Testing in production for each single unit	For each unit the following tests are performed: -grounding impedance protection in accordance with 8.6 of standard CEI EN 60601-1 - standard measurement of leakage current and dielectric strength in accordance with 8.7 , 8.8, 16.6 of EN 60601-1 - Tests on medical gas and vacuum distribution in accordance with 12.3, 12.4, 12.5, 12.6 of EN ISO 7396-1 - Testing facilities on evacuation of anesthetic gases in accordance with 12.2, 12.3, 12.4 of EN ISO 7396-2 Tests carried out on end-of-line product form an integral part of this manual
Electromagnetic interference	The operation of other devices placed near the medical device (as portable equipment or furniture) can cause electromagnetic interference or other interference, always check with qualified personnel
Supply voltage	220-230 V 50/60z
Auxiliary voltage (usually)	12Vdc-12Vac, 24Vdc-24Vac
Power consumption - Lighting - Electrical socket	Max 150W Max 2000W for each socket
Replaceable components from technical support staff	All the electrical components present in the "Parts list"
Protection provided on external power circuit	Provides adequate protection with circuit breakers or fuses dimensioned according to the power indicated on the label
Reference standards	ISO 11197 CEI EN 60601-1 EN ISO 14971 EN ISO 15223-1 EN 20417 EN ISO 7396-1 EN ISO 7396-2 EN ISO 5359
Documentation available on request by the user	The manufacturer is committed to providing the circuit diagrams, component parts lists, calibration instructions or other information that the technical assistance needs to repair parts of replaceable component
Registered office of the manufacturer and production site	Parque tecnológico de Asturias P10, 33428 Llanera-Asturias-España
Unit of Measures	[mm]

14) REPLACEMENT PARTS OF LIGHTING SYSTEM

The ARDYS unit are equipped with high-efficiency Led modules with a useful life of 60,000 hours that guarantee operation without maintenance or replacements throughout the useful life of the medical device.

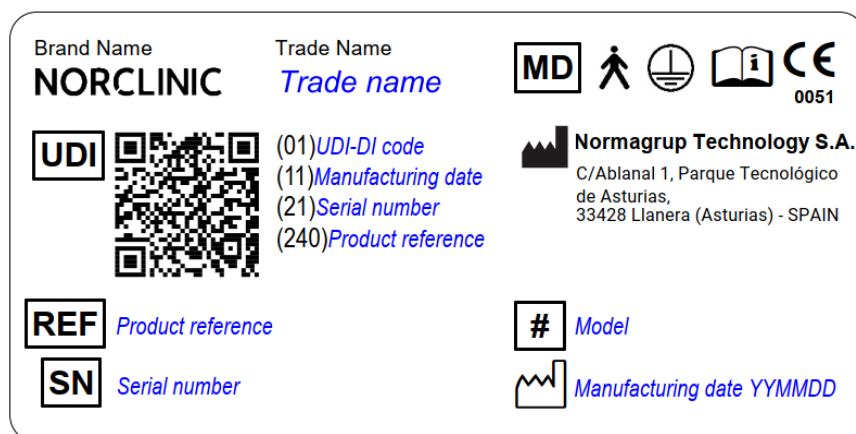
However if it is necessary to replace a module or power supply (ONLY BY PERSONNEL NORMAGRUP OR AUTHORIZED PERSONNEL BY NORMAGRUP) make sure that the external power supply is turned off, then remove the polycarbonate top. The reflector can be accessed as follows: the indirect and night light are found on top of this and the group of direct lights are found in the lower part. By unplugging the connector, you can remove the lighting group in order to replace the Led modules or electrical components (driver).

15) LABELLING

A label with the following information is placed on all ARDYS units at the top right of the profile



Below an example of label for model ARDYS:



Indicate the serial number



Indicate the date of production



Indicate the reference of the product



Please read instructions before installation



CE mark, the product complies with regulation (EU) 2017/745. Notified body: IMQ S.p.A. (0051)



Medical Device



Protected earth connection



Electrical safety type B



Manufacturer

THE USER AND/OR PATIENT NEED TO REPORT ANY SERIOUS INCIDENT IN RELATION TO THE DEVICE TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND /OR PATIENT IS ESTABLISHED

16) AMBIENT CONDITIONS DURING TRANSPORT AND STORAGE

Ambient Temperature: -10 - +50°C
 Relative humidity (non-condensing): 10-90%
 Atmospheric pressure: 70-110kPa

Do not overlap more than 8 devices and do not place them vertically. In case of irreparable damages or end-of-life equipment, the device must be disposed following the existing rules. If the user does not follow the rules above, he assumes full responsibility for creating potential effects to the environment and to human health

17) AMBIENT CONDITIONS DURING OPERATION

Ambient Temperature: +10 - +40°C
 Relative humidity (non-condensing): 10-90%
 Atmospheric pressure: 70-110kPa

18) RECOMMENDED MAINTENANCE

Regular inspections must be carried out according to the following specifications

Functionality test and visual inspection of the whole supply unit	Every 6 months by specialized service personnel
Symbol and labels are complete and legible	
Inspection of all cables, electrical sockets, gas outlets, accessories..	

If inside the power unit a flexible prepping for medical, anaesthetic and VAC gas are installed, you can find inspection points on the units and the suspension structure, in order to guarantee a proper inspection.

We recommend a regular inspection every 6 months. Flexible prepping replacement every 8 years is required. The new flexible prepping must be conform to standards laid down by EN ISO 5359.

After installation, tests must be perform in order to match standards laid down by EN ISO 7396-1 and EN ISO 7396-2.

19) CLEANING

The unit may be cleaned using a soft cloth with clean water mixed with mild non-abrasive detergent.

Do not use active solvents to clean the plastic parts.

Care should be taken not to expose the device excessively to fluids.

20) DISINFECTION OF APPLIED PART

The patient handset and cable may be cleaned and disinfected using a soft cloth with a surface disinfectant cleaner, we recommended for example Dismozon Plus manufacturer: Bode Chemie. with 1,6% Concentration. The application of this product showed good material compatibility and effectiveness.

21) GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

Following Laboratory EMC Test (Emissions and immunity) are performed in accordance with this standards: EN 60601-1-2 (2015)+A1(2021), EN 55015 (2013) / A11 (2020) & EN 61547 (2009).

Table 1. Electromagnetic emissions

The model ARDYS is intended for use in the electromagnetic environment especified below. The customer or the user of the ARDYS model should assure that it is used in such a environment		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR11	Group 1	The device ARDYS emit electromagnetic energy in order to perorm its intended function, for this its emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR11	Classe A	
Harmonic emissions IEC61000-3-2	Classe C	
Voltage fluctions/flicker emissions IEC61000-3-3	Comply	The device ARDYS 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

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

22) GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Following Laboratory EMC Test (Emissions and immunity) are performed in accordance with this standards: EN 60601-1-2 (2015)+A1(2021), EN 55015 (2013) / A11 (2020) & EN 61547 (2009).

Table 2. Electromagnetic immunity

The model ARDYS is intended for use in the electromagnetic environment specified below. The customer or the user of the ARDYS model should assure that it is used in such a environment		
IMMUNITY Test	test level and required electromagnetic environment	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC61000-4-2	Contact discharge: $\pm 8\text{ kV}$ Air discharge: $\pm 15\text{ kV}$	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the humidity should be at least 30%
Fast transient electrical disturbances (bursts)(IEC 61000-4-4)	Power cable: $\pm 2\text{ kV}$ Longer signal input lines/output lines: $\pm 1\text{ kV}$	Mains power quality should be that of a typical commercial or hospital environment
Impulse voltages (surges) (IEC 61000-4-5)	Voltage, external conductor – external conductor: $\pm 1\text{ kV}$ Voltage, external conductor – protective groundconductor: $\pm 2\text{ kV}$	Mains power quality should be that of a typical commercial or hospital environment
Magnetic fields at mains frequency(IEC 61000-4-8)	50 Hz: 30 A/m	Power frequency magnetic fields should be at levels charateristic of a location in a typical commercial or hospital environment
Voltage dips and short interruptions in the supplyvoltage (IEC 61000-4-11)	Voltage dips 100% and 30%, with 10ms, 20ms and 5s,different phase angles	Mains power quality should be that of a typical commercial or hospital environment
Radiated high-frequency disturbances(IEC 61000-4-3)	80 MHz to 2.7 GHz: 3 V/m	Mains power quality should be that of a typical commercial or hospital environment
Conducted high-frequency disturbances(IEC 61000-4-6)	150 kHz to 80 MHz: 3 V, ISM bands: 6 V	Mains power quality should be that of a typical commercial or hospital environment
Electromagnetic fields in the vicinity of wireless communication devices	Various frequencies from 385 MHz to 5785 MHz:9 V/m to 28 V/m	Mains power quality should be that of a typical commercial or hospital environment