

Portable Intermittent Pneumatic Compression

Instructions for Use





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The Legacy IPC

Legacy IPC is a medically approved Intermittent Pneumatic Compression (IPC) device used to help prevent blood clots in the deep veins of the legs. The device uses cuffs that fill with air to squeeze the soleus and gastrocnemius muscles, simulating the effects of walking. This increases blood flow through the veins of the legs and helps to prevent the formation of blood clots and stasis.

Pump:-

- Silent.
- Rechargeable.
- Reusable.
- Compact.
- Simple to use.
- Continuous run time >24hrs.

Bladder:-

- Reusable.
- One size.
- Robust.

Comfort Sleeve:-

- Breathable.
- Biocompatible.
- Single-use.
- Comfortable.

PORTABLE- Measuring 106mm x 45mm x 17mm (4.17 x 1.77 x 0.67in) and weighing just 70g (0.154lbs), Legacy IPC is smaller and weighs less than a typical mobile phone.

SILENT- Legacy IPC uses state of the art pump technology, which provides silent operation for a comfortable and discrete treatment.

CONNECTED- Legacy IPC offers Bluetooth connectivity to allow for monitoring of a patient's device during their hospital stay and while recovering at home.



Patent: PCT/GB2022/052542

FEATURES AND BENEFITS

Portable



Silent



Connected via Bluetooth



Extended battery life, >24hrs on a single charge



Compression to 45mmHg



Alert System



Device Status monitoring



Easy cuff application



Simple Touch Button



Leak detection:

The Legacy IPC continuously monitors for a gross leak in the air system. If a gross leak is detected then the device will indicate this with a Red LED and an audio alert.

Blockage detection:

The Legacy IPC continuously monitors for a blockage in the air system. If a blockage is detected then the device will indicate this with a Red LED and an audio alert.



Indications for Use

The Legacy IPC is a prescription device intended for the prophylaxis of Deep Vein Thrombosis (DVT), stimulating venous and arterial circulation, aiding in the prevention of venous stasis ulcers, aiding in the healing of cutaneous ulcers, reducing acute/chronic edema and compartmental pressures. For use in home or hospital settings.

Intended Users

Legacy IPC is to be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time during hospital admission or home recovery.

Contraindications

Use of this device is contraindicated for patients with any of the following conditions:

- Infections in the limb, including cellulitis, without appropriate antibiotic coverage.
- The presence of lymphangiosarcoma.
- Suspicion or confirmation of the presence of Deep Vein Thrombosis (DVT).
- Inflammatory phlebitis or episodes of pulmonary embolism.
- Congestive Heart Failure (CHF).
- Pulmonary edema.
- Severe arteriosclerosis or other ischemic vascular disease.
- Any local condition of the extremity that would interfere with its application, including, but not limited to: dermatitis, immediately following vein ligature, gangrene, skin grafts, casts or splints, open wounds.

User Operation

These instructions are provided for users in a clinical or homecare setting; to gain an understanding of the safe operation of the complete Legacy IPC system.

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

Within the homecare setting, patients should have received a prescribed course of treatment and education on the proper use of the device.

Warnings and Cautions

The use of the device carries the following warnings:-

- The device is only to be used by the patient which has been prescribed for it's intended use.
- Medical Electrical Equipment can be affected by other medical devices, especially devices exhibiting strong electromagnetic waves like MRI.
- Do not immerse the Legacy Pump in any liquid or operate in a wet environment.
- Training on the use of this device is recommended.
- Do not repair or attempt to replace the battery.
- This equipment must only be used with the approved power supply 005-001 and USB Lead 006-001 which forms the Medical Equipment System and further information can be provided.
- Do not modify this equipment.
- There is a risk of strangulation if one gets entangled with the USB lead.
- Keep away from infants and children.
- Only parts supplied with the Legacy IPC system must be used to avoid any possible harm, degradation or invalidating of the Warranty.
- Use the device in a clean environment; that is free from dirt, dust, pets, hair etc.
- Do not use in direct sunlight.
- The device is not to be used with MRI investigations. It can safely be used with ionizing radiation investigations including X-ray, CT and nuclear medicine.
- To prevent extremity compartment syndrome, special attention should be given to patients who
 are positioned in the supine lithotomy position for extended lengths of time.
- Ensure that the power supply is positioned correctly, so that it is not difficult to disconnect from the supply mains to provide isolation.
- Do not use the product within an oxygen rich environment.

Precautions

- The Comfort Sleeve should be removed regularly to allow inspection of the skin. Any prolonged irritation, adverse skin condition, or insensitivity please consult your physician.
- Patients with vascular disease or diabetes require frequent skin assessment.
- Failure to use the pump within the Bladder holster and Comfort Sleeve could compromise the IP rating of the device.
- Periodically check the device while in use, assuring the Comfort Sleeve is fitted correctly.
- Keep the IPC device away from sources of liquids and do not immerse in water.
- Do not autoclave any parts of the system.
- Ensure the device is clean and dry prior to storage.
- For a non-surgical patient, the device should be applied as soon as the risk of DVT is identified.
- The device should be used continuously until the person is fully ambulatory. The device can also be used on ambulatory patients.
- None of the components used have been made with natural rubber Latex.

SYMBOLS GLOSSARY				
(2)	Read through manual before use			
((*))	Legacy needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document. Portable and mobile RF communications equipment can affect Legacy			
444	Manufacturer			
M	Date of Manufacture			
REF	Catalogue Number			
LOT	Manufacture Batch Code			
SN	Serial Number			
MD	Medical Device			
*	Type BF Applied Part – Legacy Comfort Sleeve (Part Nos. 003-010 and 003-020)			
**	Keep Dry/ Never immerse device in water directly, never apply water directly, and allow to dry thoroughly when cleaning			
<u> </u>	Warning: See Instructions for Use for warnings and precautions			
$R_{\!\!\scriptscriptstyle X}$	CAUTION: US Federal Law restricts this device for sale by or on the order of physicians			
IP ₂₂	Ingress Protection Marking. IP2X— Protected against solid objects over 12.5mm (e.g. finger) and IPX2— Protected against falling drops of water, if the cases are tilted at 15 degrees from vertical			
\triangle	Caution: See Instructions for Use for warnings and precautions			
2	The Legacy Pump is an electromechanical device that includes printed circuit boards and rechargeable battery. Do not discard in landfill. Consult local requirements for proper disposal instructions			
	Class II equipment/ Protection against electrical			
===	DC Current			
LI-POLYMER	Lithium Polymer battery included			
Батря	No components are made with natural rubber latex.			
45°C 113°F -20°C -4°F	Do not exceed storage conditions –20°C (-4°F) to 45°C (113°F)			
20%	Humidity Limits — Operating 20% to 80% (non-condensing) Storage 10% to 90% (non-condensing)			
(2)	Single Use — Do not reuse			
•	On/ Off Button			
®	Do not use if packaging is damaged			
[]i	Refer to operating manual			

BOX CONTENTS				
Legacy Pump 001-001	*Legacy	x2		
Legacy Bladder (LEFT) 002-010 Legacy Bladder (RIGHT) 002-020		x1		
Legacy Comfort Sleeve (LEFT) 003-010 Legacy Comfort Sleeve (RIGHT) 003-020	5 100	x1		
Legacy Power Supply 005-001		x1		
Legacy USB power lead 006-001		x1		
Legacy Instructions for Use	Ci000/001 v0	x1		

Re-ordering

For reordering, reporting a fault or requesting additional parts or information please contact IG Technology Ltd with the relevant part number and serial number: Replacement Comfort Sleeves can be ordered individually or in Packs of 10.

Comfort Sleeve Replacement Pack x10 Reordering Code : 003-110

CALF SLEEVE APPLICATION — QUICK GUIDE

Use the Bladder and Comfort sleeve to suit the correct leg. Unfold the Comfort Sleeve, insert the bladder and place the sleeve behind the patient's calf with the arrow pointing upwards. Secure the Comfort sleeve using the hook and loop patches. The steps are shown below:



1

Fold back the Comfort Sleeve pocket and insert the Holster through the slot, aligning the port with the lower hole



2

Pull back the pocket and fasten on the hook and loop, ensuring no creasing and that the Bladder is flat



3

From the front, insert the Pump under the strap and into the Holster.



4

Push the Bladder Port fully onto the black Pump connector



5

Position the Comfort Sleeve so that it is central to the calf, with the top approximately 2" (50mm) below the inside of the knee.



6

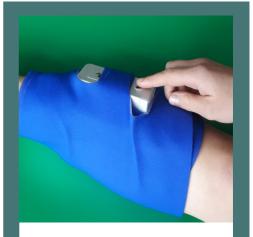
Pull the side with the Pump over the calf, and then secure tightly using the hook and loop straps, ensuring the pump is not obscured.

LEGACY OPERATING GUIDE



Step 1 - Charging

Connect the Power Supply (005-001) to the wall outlet so that the device can easily be connected and disconnected. Attach the USB lead (006-001) to the Legacy Pump (001-001) and connect it to the power supply provided. The green LED on the device will be continuously illuminated whilst charging and will extinguish when fully charged (approximately 3hrs). The device cannot be operated during charging.



Step 2 - Turning on/off



To turn ON, press and hold the button until the LED indicator flashes rapidly, then release within 2 seconds and a bleep will be heard. A green LED will be continuously illuminated to indicate that the device is ready. Device will automatically shutdown after 10mins if left idle.

To turn OFF, press and hold the button until the green LED flashes rapidly then remove you finger. A bleep is heard and no LED is present.

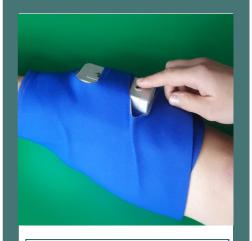
LEGACY OPERATING GUIDE



Step 3 - Start Treatment



Press and release the button twice (roughly half second between presses) to start treatment. The pump will bleep every time that it is pressed. A green LED will blink whilst the pump is active.



Step 4 - Stop Treatment



Press and release the button twice (roughly half second between presses) to stop treatment. The pump will bleep every time that it is pressed. A green LED will be continuously lit to indicate that the device is ready.

SYSTEM AND ERROR MESSAGES

SYSTEM AND ERROR MESSAGES

Pump Condition	LED	Audible Sound	Possible Cause	Action
OFF	Off	None	Unit switched off.	Turn device on by touching the button for 3 seconds until the LED flashes, then release the button (see page.8).
ON	Solid Green	Single bleep on power ON.	Unit on in idle mode and battery good (>5% to 100%).	Once the pump is connected to the Bladder, press the button twice in quick succession. A bleep is heard after each press.
LOW BATTERY	Solid Amber	None	Unit on in idle mode and battery low (<5% remaining).	Pump will continue to operate for a minimum of 30 minutes; though will need recharging.
FAULT	Solid Red	Continuous audible warning for 10 seconds.	Fault condition (Hardware fault, gross leak or blocked). Gross Leak is indicated if pressure is not reached in 30 seconds.	Try repeating the cycle by pressing the button twice; though if the fault persists check the connection to the bladder for any leakage or blockage.
OPERATING	Flashing Green	Single bleep at start of profile.	Profile running.	Bladder will inflate causing compression to the calf once a minute.

LEGACY APP GUIDE

Legacy IPC is designed to work with a mobile phone application (APP) which can be downloaded from the website **www.Legacy-IPC.com**. The application allows the user to monitor various parameters of the device using any smart mobile phone or tablet equipped with iOS or Android. The APP receives encrypted data, which is transmitted continuously from the device and requires a user account to allow access to the data. Once authenticated, the user is presented with a simple dashboard, from which they can monitor various parameters of the device. The following pages provide an overview of the key features of the APP.

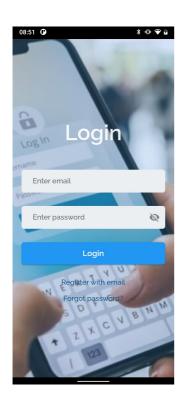


Login:

Press the "Login" button and enter user credentials to gain access to the APP. If a user account has not been created. then you must register.

Register:

Press the "Register" button and enter user details in order to create a user account. A valid email address and an internet connection is required.



Login:

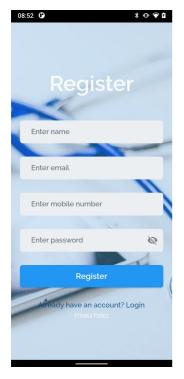
Enter user credentials and press the "Login" button to gain access to the APP.

Register:

Press the "Register with email" link to go to the registration page.

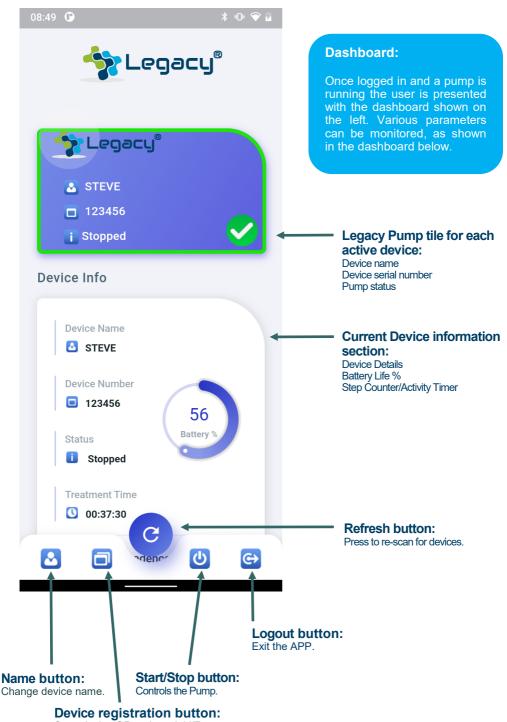
Forgot Password:

Press the "Forgot password?" link to go to the password request page.



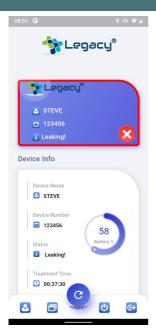
Register:

Enter user details and press "Register" to gain access to the APP. A valid email account and an internet connection is required.



Scan device QR code to Add/Remove it from user account.

LEGACY APP ALERTS





Leaking Pump Alert:

If the device detects a gross leak in the air system and the pump shows a fault, then the APP will show a "Leaking" alert. This will remain until the leak is resolved and the device is running correctly.

Blocked Pump Alert:

If the device detects a blockage in the air system then the APP will show a "Blocked" alert. This will remain until the blockage is resolved and the device is running correctly.

APP FEATURES:

- Leak alert.
- Blockage alert.
- Low battery alert.
- Step counter/Activity timer.
- Cycle counter.
- Battery monitor.

General Equipment Specification				
Dimensions	106 x 45 x 17 (mm) 4.17 x 1.77 x 0.67(in)			
Weight	70 (grams) 0.154 (lbs.)			
Power Supply	Class II, Input 100-240VAC, 50-60Hz; Output 5V@ 1.2A, 6W DC Max Model: EM1005AVRU Use only the 005-001 power supply and 006-001 USB Lead provided by IG Technology Ltd			
Mode of Operation	Continuous (Inflation = 15 seconds hours	Continuous (Inflation = 15 seconds, Rest = 45 seconds) for 24 hours		
Medical Equipment Classification	Class II when connected to power supply 005-001. During operation it is internally powered using the battery			
Pump	Max power Rating 0.7W			
Time between recharges	>24 hrs at 20°C			
Battery Type	Lithium Polymer 3.7V 1200mAh (rechargeable) Service Life : 500 discharge cycles typical			
Charging Time	approx. 3hrs - from depleted state			
Default Pressure (Tolerances)	45mmHg (±5mmHg)			
Operating Conditions	Temperature: +5°C to 40°C (41°F to 104°F) Atmospheric pressure: 70 kPa to 106 kPa	Relative humidity: 20% to 80% (non-condensing)		
Storage Conditions	Temperature: -20°C to 45°C (-4°F to 113°F)	Relative humidity: 10% to 90% (non-condensing). Keep dry and avoid from direct sunlight		
Wireless Connection	Bluetooth Low Energy (BLE)			
Noise	Typical 1-2 dBA above ambient (Silent)			
Lifetime	Legacy Pump = 1 year at 18 hours/ day Power Supply = 100,000 hours at 25 ⁰ C Comfort Sleeve = Single Use Bladder = Warranty Lifetime			

Troubleshooting

In the event of any changes in performance please try the following:-

Pump does not turn on:

- Check that the pump is charged, plug into charger (Amber Light) and recharge.
- If no light check the wall outlet and try alternative pump/charger.

Low pressure / Blockage Alarm:

- Check Pump to Bladder connection is secure and fully seated.
- Bladder leaking try the alternative bladder or pump.
- Bladder lose on the leg retighten the comfort sleeve.

Mobile APP not detecting the unit:

- Check that Bluetooth is enabled on the mobile device.
- Check that the mobile device supports BLE.
- Download the latest version of the APP.

Please contact **IG Technology** should problems persist with the serial and model number detail.

Cybersecurity Environment

The Mobile device running the Legacy IPC Application shall be kept up to date by ensuring that the latest Operating System (OS) updates are installed. OS and security updates are the responsibility of the platform developer (Android and IOS) and these help to reduce the risk of Cyber-attacks and Malware. The Legacy IPC Mobile Application should be kept up to date by checking for new versions periodically on the App store. If a new version is available then this should be installed and the previous version removed. Where possible, network connections should be made over a secure network and behind a suitable firewall.

In the event of a Cybersecurity breach please contact IG Technology Ltd who shall make every practical effort to restore/recover device configuration. Full details of the Cybersecurity Policy can be found at www.Legacy-IPC.com

User Maintenance

The Legacy IPC contains no serviceable parts. Any opening or tampering with the device will void the warranty. In the event the Legacy requires repairs please contact IG Technology Ltd Customer Service for assistance or possible replacement of any defective parts.

Do not handle the Legacy Bladder with any sharp objects. If punctured or you notice a leak do not attempt to repair. If the Legacy Pump will not be used for an extended period greater than 3 months, periodically charge the device and store in a dry, safe place.

Disposal



The Legacy IPC, including the pump, power supply and USB lead are an electromechanical device that includes printed circuit boards and a rechargeable battery. Do not discard in landfills and consult local environmental requirements for proper disposal instructions in your area. The Comfort Sleeve and Bladder should be disposed of according to waste disposal laws.

Cleaning and Disinfection



Warning: Device must be turned off and unplugged from the wall outlet before cleaning.



Warning: Do not immerse the Legacy Pump (001-001), Legacy Power Supply (005-001) or USB Lead (006-001) in any liquid for any reason. Do not use abrasive or volatile cleaners and do not place devices in a dryer.

To Clean

For excessive soiling or reuse of the Legacy Pump, Power supply or Bladder, cleaning and disinfection can be carried out using the following procedure. Clean all exposed surfaces using a soft cloth moistened with soapy water or mild detergent. Ensure that all surfaces are visibly clean and that the parts are stored dry. As an alternative isopropyl alcohol wipes (≥70% strength) can be used to clean surfaces.

Disinfection

For disinfection, wipe all exposed surfaces using alcohol based disinfectants (strength ≥70%), such as isopropyl alcohol wipes ensuring that all parts are wiped thoroughly.

Leave the device OFF and unplugged from the wall outlet for at least 30 minutes after cleaning or disinfecting to ensure the device is completely dry before using.

WARRANTY AND SERVICE

Warranty

IG Technology warrants its Legacy IPC device' to be free from defects in workmanship and materials for a one (1) year period from the date the device is delivered to the original purchaser ('Warranty Period'). This Limited Warranty is only for the original purchaser; is non-transferable, and does not cover any device that may have been damaged in transit, subject to misuse, neglect, accidents, or has been used in violation of IG Technology instructions. This includes, without limitation, the instructions contained in this Manual. IG Technology Ltd sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a device which is defective in either workmanship or materials. This is the sole remedy of the Purchaser.

Service

The Legacy IPC contains no user serviceable parts. Contact IG Technology Ltd Customer Service for assistance or replacement of any defective parts.

IG Technology Ltd

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Email: Customer@ig-technology.co.uk
Web: www.Legacy-IPC.com

EMC Safety Information

The use of the Legacy Pump requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this document.

Portable and mobile RF communications equipment can affect the Legacy Pump.

Technical Description

- Warning: The use of accessories, transducers and cables other than those specified and sold by IG Technology Ltd as replacement parts for internal components may result in increased emissions or decreased immunity of the Legacy device.
- Warning: The Legacy IPC should not be used adjacent to or stacked with other equipment.
- 3. Do not deviate from standard use.

IEC 61000-3-3

- 4. Warning: Wireless communications equipment could affect the Legacy IPC device.
- 5. Recommended separation distances between portable and mobile RF communications equipment and Legacy: The healthcare professional or the user of Legacy can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Legacy, according to the maximum output power of the communications equipment. Recommended separation distance d = I.2√P (80MHz to 800MHz) d = 2.3√P (800MHz to 2.7GHz) 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 meters (m).

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The Legacy Pump Intermittent Pneumatic Compression device is in compliance for each of the emissions test specified by the standard e.g. emissions class and group. It is the responsibility of the user to ensure that the Legacy is used in such an environment.

, ,		5 ,
Emissions	Compliance	Electromagnetic Environment—Guidance
RF Emissions CISPR 11	Group 1	The Legacy device uses RF energy only for it's internal function. Therefore, it's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Legacy device is suitable for use in all establishments, including domestic establishments and those directly connected
Harmonic Emissions	Not Applicable	to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctua- tions/flicker emissions	Not Applicable	

Test Specification for Enclosure Port Immunity to RF Wireless Communication Equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maxi- mum Power (W)	Distance (m)	Immunity Test Level (V/m)	Compli- ance Level
385	380-390	Tetra 400	Pulse Modu- lation 18Hz	1.8	0.3	27	27
450	430-470	GMRS 460 FRS 460	FM ^c ±5kHz Deviation 1kHz sine	2	0.3	28	28
710	704-787	LTE Band 13, 17	Pulse Modu- lation 217Hz	0.2	0.3	9	9
745		,					
780							
810	800-960	GSM 800/900,	Pulse Modu- lation 18Hz	2	0.3	28	28
870		TETRA 800, Iden 820, CDMA 850, LTE	TallOTT TOTAL				
930			820, CDMA				
1720	1990 C		Pulse Modu- lation 217Hz	2	0.3	28	28
1845							
1970		3,4,25, UMTS					
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n/, RFID 2450, LTE Band 7	Pulse Modu- lation 217Hz	2	0.3	28	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse Modu- lation 217Hz	0.2	0.2	9	9
5500							
5785							

NOTE A: For some services, only the uplink frequencies are included. NOTE B: The carrier shall be modulated using a 50% duty cycle square wave signal.

NOTE C: As an alternative to FM modulation, 50% pulse modulation at 18Hz may be used because while it does not represent actual modulation, it would be the worst case.

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The Legacy Pump Intermittent Pneumatic Compression device is in compliance for each of the immunity test specified by the standard e.g. emissions class and group. It is the responsibility of the user to ensure that the Legacy is used in such an environment.

	T		
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	
Electrostatic Discharge (ESD)	±8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF IEC 6100-4-3	10 V/m 80MHz—2.7GHz 80% AM at 1kHz	10 V/m 80MHz—2.7GHz 80% AM at 1kHz	
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100kHz repetition frequency	±2 kV 100kHz repetition frequency	
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ±1 kV and ±2kV line-to- ground	±0.5 kV, ±1 kV line-to-line ±0.5 kV, ±1 kV and ±2kV line- to-ground	
Conducted disturbances induced by RF IEC-4-6	3V 0.15MHz-80MHz 6V ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	3V 0.15MHz-80MHz 6V ISM and amateur radio bands between 0.15MHz and 80MHz 80% AM at 1kHz	
Power frequency magnetic field immunity IEC 61000-4-8	Not Applicable—the device does not contain any components which are sensitive to a magnetic field		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$0\%~U_{T};~0.5~cycle$ At $0^{\circ},45^{\circ},90^{\circ},135^{\circ},180^{\circ},225^{\circ},270^{\circ}$ and 315°	0% U_T : 0.5 cycle At $0^{\circ},45^{\circ},90^{\circ},135^{\circ},180^{\circ},225^{\circ},270^{\circ}$ and 315°	
	0% U _T : 1 cycle 70% U _T : 25/30 cycles Single phase: at 0 ⁰	$0\%~U_{T}$: 1 cycle 70% U_{T} : 25/30 cycles Single phase: at 0°	
	0% U _τ : 250/300 cycles	0% U _T : 250/300 cycles	

NOTE 1 U_T is the main voltage prior to application of the test level. E.g. 25/30 means 25 periods at 50Hz or 30 periods at 60Hz.

We hope you enjoy using the Legacy IPC system. If you require further information, spares or to report a problem please contact us using the details below:-



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