

User Manual

Medical Isolated Powersupply

Type IPs V3.2

Galvanic isolation of the power supply for
medical electrical devices and systems according to
EN 60601-1:2006/AC:2010/A1:2013 & EN 60601-1-2:2007/AC:2010
as well as EC Directive 93/42/EEC, MDD 2007



***Prior to commission / operation of the IPs
the user has to make himself familiar with
the functionality of the IPs by careful reading
this user manual!***

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1 General information

1.1 Important information

In terms of user and patient safety as well as the guarantee of the proper functioning of the IPs, the user has to obey the instructions of the user manual.

This document is part of the product and has to be retained accessible over the whole operating time of the IPs.

1.2 Warning notice



The symbol on the left is a safety warning. To avoid any risk of injury and dangerous situations, all safety instructions marked with this symbol must be followed.

1.3 Safety notice



DANGER

The IPs is intended exclusively for the purpose described in chapter 2.1 Purpose

- The housing of the IPs must not be opened!
- The IPs must not be changed!
- There are no repairs to be done on the IPs!
- Before cleaning and maintenance procedures, the IPs must be disconnected from the mains supply at all poles!
- The IPs must not be maintained during a patient is in contact with the medical system!
- The operation of the IPs is permitted under the ambient conditions listed in chapter 4.2 Technical data!
- To avoid the risk of an electric shock, the IPs may only be connected to a mains power supply with a protective conductor!

1.4 Device labels

The IPs has some labels. The following table supports you in understanding these labels:

Symbol	Description
	General warning against electric shock The IPs is an electrical device. To minimize the risk of an electric shock, follow all safety instructions in this manual.
	Follow the user manual To ensure that your IPs is always fully operational, we have added these user manual for you. Keep it always at hand and follow its instructions.
	Achtung! Vor dem Wiedereinschalten mind. 1 Minute warten! Wait at least 1 minute before restart!
	IPs On By pressing the power switch into this position, you turn on the IPs. Through this the output sockets will be powered.
	IPs Off By pressing the power switch into this position, you turn off the IPs. The output sockets will be powered off.
	Potential equalisation – POAG The metal pin marked in this way is used for a direct, electrically conductive connection of the IPs with the potential equalisation busbar of the electrical installation.
	Primary fuse (power input) Below this symbol combination the mains input socket is located. This contains also the holder for the primary fuses. For further information, refer to chapter 4.3.1 Primary fuses
	Secondary fuse (power output, galvanic isolated) The fuse holder for the secondary fuse is located above this symbol combination. For further information, refer to chapter 4.3.2 Secondary fuses.
	The IPs must not be disposed of with the household waste! If necessary, please contact us and inform your customers when reselling.
	AC (alternating current) The IPs is working with alternating current (50/60Hz).

Table 1.1: Device labels

2 General operating instructions

2.1 Purpose

The IP is a device to power medical electrical devices and systems with a galvanic isolated power supply. It provides the producer or user of medical electrical systems with a first fail-safe, floating power supply. The isolating transformer achieves a limitation of the leakage currents as well as a double or reinforced isolation to the grid. The realized isolation distances meet the requirements of the standard EN 60601-1:2006/AC:2010/A1:2013). In addition, a CB report for the power variants 330VA, 630VA, 1000 VA and 1400VA can be provided.

2.2 Product description

The IP is available in different power variants up to 1400VA. The isolating transformer is installed in a powder-coated metal housing, which is connected to the protective conductor and has a potential equalisation connector (POAG) in accordance with DIN 42801. This serves to avoid unacceptable potential differences and to minimize equalizing currents between the individual components of a medical electrical system.

The voltage input (primary side) of the IP is provided by a double fused IEC connector and can be all-pole disconnected by a power switch. Depending on the variant, the IP provides up to four or eight IEC sockets or two type F sockets as outputs (secondary side). For the available variants, refer to chapter 4.2 table 4.1 Technical Data.

The IP variants with IEC connectors avoid the accidental connection of improper devices with excessive power consumption or a risk to the general reliability of the medical electrical system.

A corresponding protection is achieved in the variants with type F sockets through a cover of the type F sockets, which can not be removed without tools.

Optionally, at the variants with IEC socket outputs, the power cords of the consumer devices can be secured by a strain relief against unintentional release from the IP. At the variant IP-330R3-4K also the input connector can be secured with a strain relief. Please refer to chapter 4.4 Accessory.

2.3 Personal qualification

2.3.1 Commissioning

NOTE

Hereby, the operator of the IP, who becomes the installer of a medical, electrical system by using it, is informed that connection and commissioning of the IP is only permitted to professionals or appropriately trained personnel.

The personnel qualification required for this purpose is determined by the Medical Device Directive. Thereafter, any use of medical devices is only permitted to persons with the required training, knowledge and experience (§2 MPBetreibV, Sect.2).

Please note that this user manual is not intended to illustrate the possible scenarios of using the IP. When installing a medical electrical system, improper connection of a component may result in a reduction of the electrical safety. For example, when connecting a PC system to a medical device, it is important to ensure that each peripheral device (monitor, printer, etc.) and electrically conductive connections to the computer (e.g. network cable) can bypass the IP safety function.

If you have further interfaces to your medical electrical system, for example parallel-, serial- or USB-interfaces, which you want to isolate, you are welcome to contact us (see chapter 5 Manufacturer / Contact).

2.3.2 Application

After commissioning, the IP can be switched on and off by pressing the switch on the front of the device. Apart from the prescribed safety inspection (see chapter 3.2 Safety inspection (STK)), the IP is maintenance-free. However should a malfunction occur, you will find a list of possible causes of faults in chapter 3.4 Failure reason as well as advice on how to resolve them.

Warning

A further elimination of causes of malfunction, as described in this manual, is not permitted to the user.

2.4 Connection and commissioning



DANGER

The connection of an electrical device to the IPs leads to the establishment of a medical electrical system and can result in a reduced level of safety!

The corresponding requirements can be found in the standard EN 60601-1.

NOTE

The assembly of medical electrical systems and their changes during their actual operating life make it necessary to check them for compliance with the requirements of the standard EN 60601-1.

Before connecting the electrical loads you have to loose the strain relief (if existing) with a crosstip screwdriver. Afterwards plug in the type F or IEC connector into the multiple socket of the IPs. Reinstall the strain relief.

NOTE

The maximum total power consumed by the loads connected to the IPs must not exceed the maximum output power indicated on the type plate of the IPs!

Overloading of the IPs results in the triggering of at least one fuse and thus to the failure of the IPs. For instructions on replacing the fuse, see chapter 4.3 Replacement of the fuses. Connect the IPs via the supplied power cord directly to a permanently installed power outlet. The socket must be protected with at least a type 16 B circuit breaker.

NOTE

Do not use extension cords, power strips or similar portable connection extensions to connect the IPs!

NOTE

To avoid impermissible potential differences and to minimize leakage currents between the components of a medical electrical system, the IPs has a potential equalization pin (in accordance with DIN 42801)

2.4.1 Positioning

The IPs is designed to operate on a solid flat surface (table, or similar). To secure him against unintentional movement, for example when installed in a trolley, it has two embedded M6 nuts in the housing base.

IMPORTANT: Use screws whose penetration depth into the housing is not more than 40mm.

The ambient temperature of the IPs in operation must not exceed 35°C (exception IPs-1400R3: 30°C). The IPs must not be operated while covered and a natural convection must be possible.

The remaining operating parameters can be found in table 4.1 Technical Data in chapter 4.

NOTE

The IPs is not protected against exposure to major mechanical forces and the ingress of liquids. In addition, it is not suitable for operation in atmospheres with combustible mixtures!

2.4.2 Interaction between ME-Devices

NOTE

The transformer of the IPs generates an electromagnetic field which can influence the function of other devices!

The corresponding requirements with regard to the electromagnetic requirements for medical devices can be found in the standard EN 60601-1-2.

If other components of the medical electrical system have special EMC requirements, these should be followed. If the use of the IPs nevertheless leads to an interference of other components, this can be reduced by creating a spatial distance to the IPs.

In rare cases, connecting high power switching power supplies with special power saving states may cause the IPs to a audibly humming, without affecting the IPs functionality or reliability.

2.5 Handling

The IP is provided with a switch in the front, which powers the IP in the position „I“. In this position the switch lights up green.

If this is not the case, please refer to chapter 3.4 Failure reason.



To stop the operation and disconnect the IP from the grid, set the switch to position „0“. The illumination of the switch goes out in this position

NOTE

Please note that turning off the IP will also cause the shutdown of all loads connected to it.

NOTE



Vor dem Wiedereinschalten mindestens 1 Minute warten!

Wait at least 1 minute before restarting!

If you want to interrupt the operation of the IP temporarily, please note that after switching off, there must be a break of at least 1 minute before switching the IP on again.

If you do not follow this instruction, the result may be an unintentional triggering of the home circuit breaker.

3 Maintenance

3.1 Cleaning and disinfection

In normal use, contact of the IP with the patient is not intended, therefore a disinfection of the IP is not specified. However, a cleaning of the housing is permitted.

NOTE

Switch off the IP before cleaning it and disconnect it from the grid. Make sure that no liquids get into the openings of the housings!

If necessary, clean the IP with a soft, lint-free, moistened cloth and mild cleaning additives such as those used at home. To remove tenacious dirt, the use of detergents and disinfectants based on n-propanol (<70% vol.) is also permitted.

Aggressive cleaners such as abrasives or alcohol are not permitted.

3.2 Safety inspection (STK)

NOTE

The IP must undergo a periodic safety check, which has to be performed at least every 2 years!

The required personnel qualification is defined by the Medical Device Directive (§6 MPBetreibV Sect.4). According to this, a STK has to be performed at least every 2 years according to the specifications of the manufacturer, as well as further criteria (§6 MPBetreibV, Sect.1).

In order to be able to guarantee the further safe use of the IP, the following steps have to be performed:

- Visual inspection for external damage and contamination (Housing, power connector, labels, etc.)
- Visual inspection of the fuses to the prescribed value.
- Ensuring availability and completeness of the documents.
- Control of the functionality in the context of the intended function of the IP based on its user manual.
- Testing of the electrical safety according to EN 60601-1 with measurement of protective conductor resistance, earth leakage and contact current (Section 8.6.4 a) and section 8.7, table 3 und 4).

3.3 Shutting-down and disposal

For decommissioning the IP, it must be switched off and its connected consumers must be disconnected directly at the IP connection.

NOTE

The electrical isolation of your electrical equipment according to EN 60601-1 and the EC Directive 43/42/EEC, MDD does not exist anymore after disconnecting from the IPs. Do not connect it to an unqualified supply if the above-mentioned protection should remain!



DeMeTec GmbH is aware of its responsibility towards the environment. Therefore, DeMeTec GmbH, according to WEEE since 13.8.2005, takes back all devices placed on the market for the purpose of proper disposal.

The IPs must not be disposed of with household waste!

If necessary, please contact us and inform your customers when reselling.

3.4 Failure reason

If the IPs does not work as intended, the following troubleshooting tips may be helpful.

Problem	Possible reason	Proposed solution
The main switch does not glow green.	IPs not powered	Power on the IPs with the main switch
	IPs is not connected to the grid	Connect the IPs with the provided power cord to the grid
	One or both primary fuses are broken	First disconnect the mains plug! Check both primary fuses. Replace defect fuses (see chapter 4.3.1).
The green light in the main switch is glowing, but the connected load does not work.	Load is not connected to the IPs	Connect load to the IPs
	Secondary fuse is broken	First disconnect the mains plug! Check the secondary fuse. Replace defect fuse (see chapter 4.3.2).
The problem can not be solved despite following the suggested solutions.	unclear	Contact your distributor or the manufacturer, refer to chapter 5 Manufacturer / Contact.

Table 3.1: Failure reasons & proposed solutions

3.5 What to do in case of a complaint?

If a problem with the IPs persists even after troubleshooting according to Chapter 3.4 Failure reason and after contacting us, you can send it in. If the IPs is outside the manufacturer's warranty of **2 years** from the date of purchase, you can also send it to us. We will gladly make you a repair offer.

Please note the following points:

- If available, please use the original packaging of the IPs for shipping, or at least equivalent packaging.
- If possible, please send the IPs with included individual parts (e.g. power cord). This may allow a faster fault diagnostics.
- Please ensure a sufficient franking of the shipment. Unpaid goods will not be accepted by DeMeTec GmbH
- Please note that the value of the shipment is not always insured by the carrier during transportation. In your interest choose an insured shipping method. For transport damages the DeMeTec GmbH assumes no liability.
- Please make sure that the housing of the IPs is in an acceptable condition. Unfortunately, we have to charge you for any contamination that cause aftertreatment in our house. For cleaning instructions, please refer to chapter 3.1 Cleaning and disinfection.

NOTE

Obvious damage to the IPs caused by handling of the IPs, which is excluded by this manual, as well as damage caused from the negligent handling of the IPs, are excluded from the manufacturer's warranty.

4 Technical specification

4.1 Type plate

Each IPs has a corresponding type plate. It contains among others the product name, information about the manufacturer, safety instructions, as well as a serial number, which also gives information about the year of manufacture. The first two digits of the number marked SN encode the year of manufacture. The first digit stands for the manufacturing decade (5 = 00, 6 = 10, 7 = 20), the second digit for the year. The number 68 thus stands for the year 2018. As an example, the type plate of an IPs-1000R3-8K is shown here. The information for the input and output parameters varies by type and can be found in table 4.1 Technical Data.

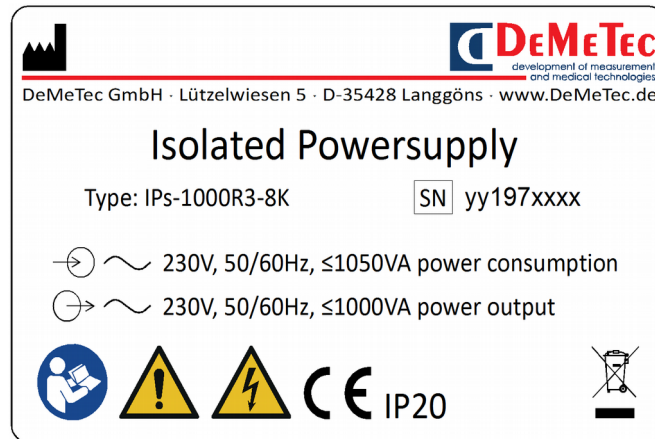


Figure 4.1: Type plate IPs-1000R3-8K

4.2 Technical data

	Model					
	IPs-330R3-4K	IPs-330R3-8K / 2S	IPs-630R3-8K / 2S	IPs-1000R3-8K / 2S	IPs-1000R3-8K-120V	IPs-1400R3-8K / 2S
Technical Data						
Power consumption max. [VA]	345	345	650	1050	1050	1450
Output power max. [VA]	330	330	630	1000	1000	1400
Mains voltage [V AC]	230	230	230	230	120	230
Output voltage [V AC]	230	230	230	230	120	230
Mains frequency [Hz]	50/60	50/60	50/60	50/60	50/60	50/60
Fuse 5 × 20 mm, 2 × In-/ 1 × Output [250V]	T 1,6 AH	T 1,6 AH	T 3,15 AH	T 5 AH	T 10 AH	T 6,3 AH
Number of IEC sockets or number of type F sockets	4 / -	8 / 2	8 / 2	8 / 2	8 / 2	8 / 2
Type F sockets protected against unauthorised access	-	yes	yes	yes	yes	yes
Power switch, green lighted	yes					
Potential equalisation according to <i>DIN 42801</i> (POAG)	yes					
Ambient temperature in operation	10 – 35°C					10 – 30°C
Ambient humidity in operation	25 – 95% relat.					
Ambient air pressure in operation	70 – 106kPa					
Housing	metal, 1.5mm height, incl. embedded screw nuts in the base (M6) for a permanent montage					
Surface finish	Powder coating, light grey, satin-finished					
Dimension (B×H×T) [mm]	170×95×200	212×135×280 (without feet H = 125)				
Weight [kg]	4,5	6	9	11	11	14
Scope of delivery						
Power cord	safety plug to IEC socket, 3m, black					
User manual	german, english on request					
Options						
Strain-relief IEC power outputs	yes					
Strain-relief IEC power inputs	yes	no				
Connections as <i>WAGO</i> -terminals possible (up to 4mm ²)	no	yes				
Classification						
Protection class	I					
Degree of protection of enclosure	IP20					
Operating mode	continuous operation					
Classification as defined by Annex IX, MDD	class I					
Sterilisation	no					
Operation in an oxygen-enriched atmosphere	not provided for					
Ambient temperature storage/transport	-20 – 50°C					
Ambient humidity storage/transport	15 – 95% relat.					
Ambient air pressure storage/transport	50 – 106kPa					

Table 4.1 Technical Data

4.3 Replacement of the fuses

If the analysis of a fault according to chapter 3.4 Failure reason leads to the conclusion that one of the three device fuses in the IPs has been triggered, then the procedure is as follows.

NOTE

Switch off the IPs with its main switch and disconnect the power cord if the IPs!



ATTENTION

The insertion of a wrong fuse can lead to a failure of the IPs or to the reduction of electrical safety due to unacceptable heating and as a result even to a fire of the IPs!

- Only fuses, which specifications correspond to table 4.1 Technical Data, may be used.
- The specification is also printed next to the fuse holders on the housing.
- Make sure that the fuse is legibly labeled with the appropriate values for your IPs model.

4.3.1 Primary fuses

The primary fuses of the IPs are located in the back of the device. The holder of the fuses can be opened by hand without tools. To do so, press with one finger from the top onto the snap lug of the fuse link, which then releases from the holder.

Pull the fuses out of the fuse link with your fingers and insert the new fuses. Put the fuse link back into the fuse holder so that it snaps into place with a hearable click.

Now you can reconnect the IPs to the grid and switch it on.

4.3.2 Secondary fuses

The secondary fuse of the IPs is located in the back of the device. The fuse holder can be opened with a flat-bladed screwdriver with a blade of max 8.5 × 1.8mm by turning it counterclockwise. Pull the fuse out of the fuse link with your fingers and insert the new fuse into it. Put the fuse link back into the fuse holder and tighten it clockwise again.

IMPORTANT: The outer edge of the fuse link must only be flush with the outer edge of the holder. The screwing with a greater force is not necessary!

You can now reconnect the IPs to the grid and switch it on.

4.4 Accessory

1. Power cord (IEC plug → IEC socket), 3m, black, item number: WR-117
2. Power cord (safety plug → IEC socket), 3m, black, item number: WR-104
3. Strain relief
 - For IPs -4K/-8K (secondary 4× IEC socket), item number: MBZ-004
 - For IPs -4K (primary 1× IEC plug), item number: MBZ-005

4.5 Spare parts

1. Power cord (safety plug → IEC socket), 3m, black, item number: WR-104
2. Fuses for:
 - IPs-330: T 1,6 AH, 250V, packing unit = 10 parts, item number: F-091
 - IPs-630: T 3,15 AH, 250V, packing unit = 10 parts, item number: F-088
 - IPs-1000: T 5 AH, 250V, packing unit = 10 parts, item number: F-102
 - IPs-1000 (Variant 120V): T 10 AH, 250V, packing unit = 10 parts., item number: F-103
 - IPs-1400: T 6,3 AH, 250V, packing unit = 10 parts., item number: F-089

5 Manufacturer / Contact

If you have any questions or problems, please contact your local dealer or the manufacturer:

Address: DeMeTec GmbH
Lützelwiesen 5
D-35428 Langgöns
Germany

Phone: +49 6403-7874-0
Fax: +49 6403-7874-30
E-Mail: EMail@DeMeTec.de
Home page: <http://www.DeMeTec.de>

6 Declaration of conformity

EC Declaration of Conformity for medical devices

(as defined by directive for medical devices 93/42/EEC, MDD 2007, Annex VII)



DeMeTec GmbH

Lützelwiesen 5, 35428 Langgöns (Germany)

We hereby declare, that the product

Isolated Power Supply – IPs Version 3.2

Type: IPs-330R3-2S, IPs-330R3-4K, IPs-330R3-8K, IPs-630R3-2S,
IPs-630R3-8K, IPs-1000R3-2S, IPs-1000R3-8K-120V,
IPs-1000R3-8K, IPs-1400R3-2S, IPs-1400R3-8K

was manufactured in harmony with the technical documentation as defined by Annex VII, section 3 of the medical device directive and that it corresponds to the requirements of the following directive:

Medical Device Directive 93/42/EEC

Meeting the following standards: **EN 60601-1:2006/AC:2010/A1:2013**
EN 60601-1-2:2007/AC:2010

As well the following guideline will be followed:

Directive 2011/65/EU (RoHS-II)

In compliance with the national Electrical and Electronic Equipment fabric Regulation



Langgöns, 2018-03-12



Manager
Head of Development Department



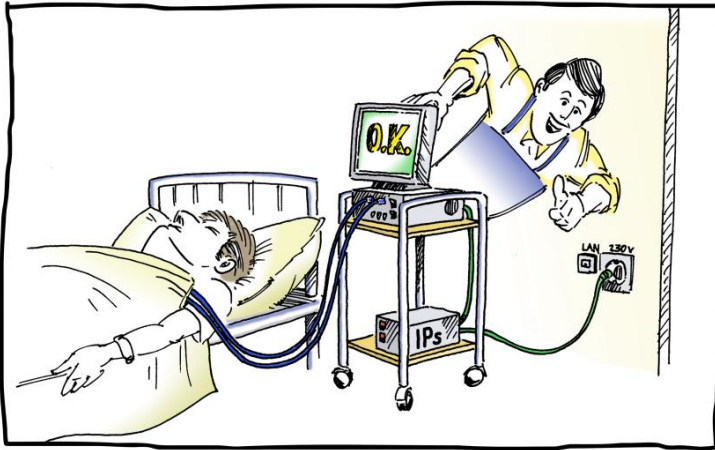
Quality Management Officer
Regulatory Affairs



Medical Network Isolation (NwI)



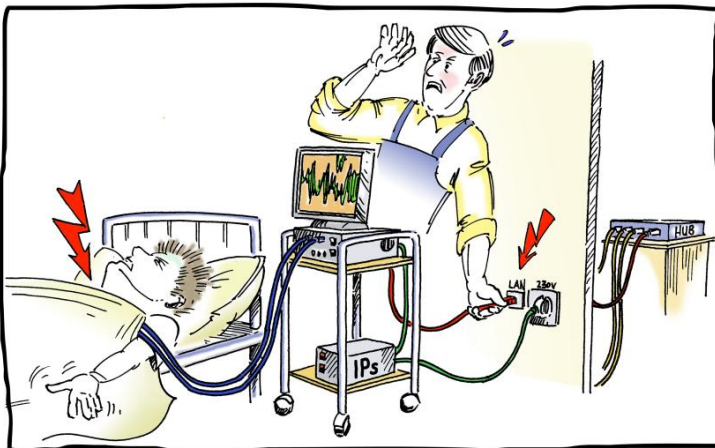
Mains Isolation...



So far so good...

Warranty of electrical security is realised by application of a mains isolating transformer for medical usage (Isolated Powersupply IPs). Available with a nominal Power output rated from 330 VA up to 1400 VA.

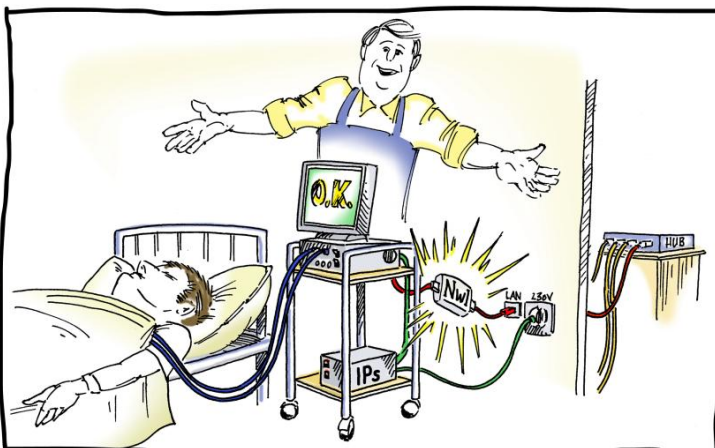
without network isolation?!



Danger!

By connecting the medical device or system (PC, measuring station, ...) to a Network (LAN) the electrical safety, accomplished by an isolating transformer, is deactivated.

Never again without Network Isolation (NwI)!



The Solution:

Pluggable network isolation for 10/100/1000 Base-T Nets with medical CE label (93/42/EEC, MDD 2007) and electrical safety according to EN 60601-1)
Connection: 2 RJ45 sockets
Proof voltage: 4kV
Dimensions: (90 × 50 × 25)mm³
Remaining cable length: min 80m for 1000Base-T